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# Chapter 1: Executive Summary

## Market Outlook



#### **MARKET SIZE**

The global market for medical devices was valued at \$739.6 billion in 2023 and is projected to reach nearly \$1.3 trillion by the end of 2029.



### **MARKET GROWTH**

The global market is expected to grow at a CAGR of 9.8% from 2024 through the end of 2029.



#### MARKET DRIVERS / OPPORTUNITIES

- Increasing prevalence of chronic diseases and an aging population.
- Rising numbers of surgical procedures.
- Advances in technology.
- Increasing healthcare expenditures.



### MARKET RESTRAINTS / CHALLENGES

- Stringent regulatory scenario.
- Cybersecurity risks in medical devices.



#### **EMERGING TECHNOLOGIES**

- Blockchain for data security.
- Nanotechnology.
- Smart/innovative implants.





#### LEADING COMPANIES

- Medtronic.
- Abbott.
- Johnson & Johnson.
- Siemens Healthineers AG.
- F. Hoffmann-La Roche Ltd.

Source: BCC Research

# Scope of Report

This research report provides an in-depth analysis of the global medical device market and its competitive landscape through 2023. The report covers key players, competitive intelligence, advanced technologies and company profiles. The analysis includes recent developments and product portfolios of major players, as well as market share analysis and ranking. The analysis of the regulatory landscape focuses on recent regulations in regions such as the U.S., Europe and Japan. BCC Research estimates market size data for 2023 (base year) and forecasts values for 2024 through the end of 2029. This report also examines growth trends, drivers, restraints and opportunities in the global medical device market.

# Market Summary

The global market for medical devices was estimated at \$739.6 billion in 2023 and is expected to grow at a compound annual growth rate (CAGR) of 9.8% to reach \$1.3 trillion by the end of 2029. The medical devices industry encompasses many products, from simple bandages to complex surgical instruments and diagnostic machines. The industry increasingly uses digital health solutions, such as telemedicine and wearable devices, to monitor and manage health conditions more effectively.

Summary Table:
Global Market for Medical Devices, by Region, Through 2029
(\$ Billions)

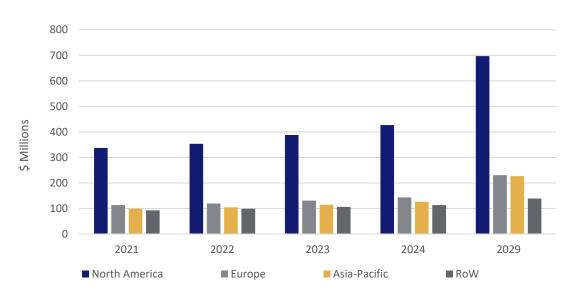
Region	2021	2022	2023	2024	2029	CAGR% 2024–2029
North America	337.0	353.7	387.6	426.6	697.3	10.3
Europe	113.3	119.6	130.9	143.6	230.7	9.9
Asia-Pacific	98.7	104.2	114.6	126.6	226.9	12.4
RoW	92.7	98.7	106.5	113.5	139.0	4.1
Total*	641.7	676.1	739.6	810.4	1,293.8	9.8

\*Note: Totals in this report's tables and figures may not match exactly because of rounding.

Source: BCC Research



Summary Figure:
Global Market for Medical Devices, by Region, 2021–2029
(\$ Billions)



Source: BCC Research



# Chapter 2: Market Overview

## Overview

The global medical device industry encompasses a broad range of products and technologies used for diagnosis, monitoring and treatment of medical conditions. These devices vary significantly in terms of complexity, from simple tools like bandages and thermometers to sophisticated equipment such as magnetic resonance imaging (MRI) machines, pacemakers and robotic surgical systems. The increasing prevalence of chronic diseases, an increasingly elderly population, advancing medical technology and rising healthcare expenditures are driving the growth of the global market for medical devices.

Medical devices can be classified into six categories: diagnostic devices, therapeutic devices, surgical instruments, durable medical equipment, implantable devices and wearable medical devices. Diagnostic devices include imaging systems, such as X-rays, MRI and computed tomography (CT) scans, and in vitro diagnostics (IVD) such as blood glucose monitors and pregnancy tests. Therapeutic devices, such as insulin pumps, dialysis machines and radiation therapy equipment, treat or manage specific health issues. Surgical instruments include such as scalpels, forceps and specialized robotic systems.

Durable medical equipment include wheelchairs, hospital beds and oxygen therapy equipment. Implantable devices, which include pacemakers, artificial joints and stents, enable the management of cardiovascular diseases, orthopedic conditions and other health issues. Wearable medical devices, such as smartwatches with health monitoring features, are becoming increasingly popular, contributing to the shift toward personalized healthcare and remote patient monitoring.

Medical devices are strictly regulated because they directly impact patient safety and health. In the U.S., the Food and Drug Administration (FDA) classifies medical devices as Class I, II or III, based on the risk associated with their use. Class I devices (e.g., bandages) are considered low-risk, while Class III (e.g., heart valves) are high-risk and require rigorous testing before approval. Similarly, the EU has its regulatory framework governed by the European Medicines Agency (EMA) and other regulatory bodies that oversee the safety and efficacy of medical devices.

Advances in AI, 3D printing, nanotechnology, and the Internet of Medical Things (IoMT) are transforming the medical device landscape. Diagnostic tools and robotic surgery systems are incorporating AI to improve precision and effectiveness. 3D printing is revolutionizing the production of custom prosthetics, implants, and even bio-printed tissues. The IoMT links medical devices to the internet, allowing for real-time data gathering and analysis, improving patient monitoring and response times.

Dominant companies in the highly competitive global medical device market include Medtronic, Johnson & Johnson, Siemens Healthineers and Abbott Laboratories. However, smaller, specialized firms that focus on niche areas such as wearable health tech products or biocompatible materials also contribute to the industry. The market is particularly robust in North America, Europe and parts of Asia, with the U.S. being a key player due to its advanced healthcare infrastructure and medical innovation.

The increasing demand for medical devices will continue during the forecast period, driven by longer life expectancy and improved healthcare access in developing regions.



### **Medical Device Codes**

More than 500,000 medical technologies are registered. As determined by the Global Medical Devices Nomenclature (GMDN) Agency, these fall within 16 product categories.

Table 1
Medical Device Codes

Code	Classification	Example
01	Active implantable technology	Cardiac pacemakers, neurostimulators
O2	Anesthetic and respiratory technology	Oxygen masks, gas delivery units, anesthesia breathing circuits
03	Dental technology	Dentistry tools, alloys, resins, floss, brushes
04	Electromechanical medical technology	X-ray machines, MRI and CT scanners
05	Hospital hardware	Hospital beds
O6	In vitro diagnostic technology	Pregnancy tests, genetic tests, glucose strips
07	Non-active implantable technology	Hip or knee joint replacements, cardiac stents
O8	Ophthalmic and optical technology	Spectacles, contact lenses, intraocular lenses, ophthalmoscopes
09	Reusable instruments	Surgical instruments, rigid endoscopes, blood pressure cuffs, stethoscopes, skin electrodes
O10	Single use technology	Syringes, needles, latex gloves, balloon catheters
011	Technical aids for the disabled	Wheelchairs, walking frames, hearing aids
012	Diagnostic and therapeutic radiation technology	Radiotherapy units
O13	Complementary therapy devices	Acupuncture needles/devices, bio-energy mapping systems/software, magnets, moxibustion devices, suction cups
014	Biologically derived devices	Biological heart valves
015	Healthcare facility products and adaptations	Gas delivery systems
016	Laboratory equipment	Most IVD that are not reagents

Source: Global Medical Devices Nomenclature (GMDN) Agency

## **Imaging Systems**

Imaging systems are extensively used for clinical applications. The term diagnostic (or medical) imaging encompasses the methods used to create images of the body or its segments.

Developed countries mainly use medical imaging, but emerging markets such as China, India, and Brazil are quickly adopting this technology to improve healthcare services. These areas are projected to become key growth markets due to higher government healthcare investments, modernization initiatives, and the growth of hospitals and healthcare centers. The rising disease prevalence, particularly with the growing burden of lifestyle-related conditions, has led to increasing demand for improved healthcare in these nations.



Medical imaging techniques include X-ray, MRI, ultrasound, endoscopy, elastography, tactile imaging, thermography and medical photography. The images and data generated through these techniques help clinicians make informed diagnoses. Medical imaging is vital in early detection and diagnosis of lifethreatening conditions. Safe and efficient imaging technologies save millions of lives annually by facilitating early detection, often reducing the need for invasive procedures. Patients who avoid invasive procedures typically experience faster recovery times, shorter hospital stays and more cost-effective healthcare. Advances in surgical imaging displays include integrating computer processing, digital data collection, 4K ultra-high definition (UHD) technology, and touchscreen capabilities. These innovations provide clinicians with enhanced imaging during examinations, leading to more accurate diagnoses.

## In Vitro Diagnostics

In vitro diagnostics (IVD) tests detect diseases by analyzing blood, urine and tissue from the body. Some tests are conducted in labs or other professional settings; others are designed for home use. The U.S. represents the largest market for such consumer-based tests. Companies looking to expand into consumer-oriented areas, notably the diabetes glucose-testing market, prioritize fast-growing regions like India and China.

The world's aging global population and the rising prevalence of lifestyle-related diseases are driving the rising demand for IVD. Healthcare systems seeking to lower costs increasingly adopt evidence-based diagnostic testing to improve accuracy and outcomes. Molecular diagnostics offers a significant opportunity for healthcare providers, hospitals, and pharmaceutical and biotech companies in the IVD sector. Consumers are increasingly choosing the cost-effective alternatives of self-care and personalized medicine to maintain their health.

#### Cardiovascular Disease Procedures

The global prevalence of heart disease continues to rise, primarily due to unhealthy lifestyle choices and habits. Each year, some 17.9 million deaths globally are attributed to cardiovascular diseases (CVDs), a number projected to increase to over 23.6 million by 2030 (World Health Organization, 2023). Interventional cardiology and minimally invasive surgery (MIS) have recently seen significant advances. For instance, drug-eluting stents, bioabsorbable stents, and transcatheter heart valves (such as TAVR for aortic valve replacement) have expanded treatment options. Pacemakers are now miniaturized, longer-lasting and can adjust pacing automatically based on the patient's physical activity, a feature known as rate responsiveness. Some are even leadless and can be implanted directly in the heart, reducing complications associated with traditional lead wires.

## **Orthopedic and Spinal Procedures**

Spinal surgery is witnessing an increase in MIS, typically involving incisions as small as one to two inches instead of the 10-inch incisions often associated with open surgical procedures. MIS techniques such as laparoscopy and robotic surgery can result in faster recovery times, less postoperative pain and shorter hospital stays than open surgeries. Innovations such as artificial disc replacements and mobile implants have further improved outcomes, reducing complications and enabling patients to return and maintain more active lifestyles. Commonly treated conditions associated with MIS include degenerative cervical and lumbar disc disease, lumbar and cervical stenosis, herniated discs, spinal instability, spine trauma and osteoporotic compression fractures.



Real-time radiography enables precise placement of spinal implants in MIS procedures. Surgeons employ techniques such as kyphoplasty for osteoporotic fractures, Axialif and eXLIF for lumbar fusions and percutaneous spinal fixation guided by radiographic imaging. Combining these technological innovations and a deeper understanding of anatomy has shortened recovery times. These methods now account for nearly 50% of total sales in the spinal surgery market. Real-time radiography is also used in dental, urological and renal applications, surgical instruments and drug delivery systems.

## Innovations in Medical Devices

According to the Organisation for Economic Co-operation and Development (OECD), innovation is viewed as both a process and an outcome. The two main principles of innovation are:

- A degree of novelty (patent) (whether an innovation is new to a firm, a market or an industry.
- Type of innovation (processor, product, service or system innovation).

This report analyzes the innovation process for medical devices. According to the WHO, a medical device is "any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes(s) of:

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury.
- Investigation, replacement, modification, or support of the anatomy or a physiological process.
- Supporting or sustaining life.
- Control of conception.
- Disinfection of medical devices.
- Providing information employed in vitro examination of specimens derived from the human body and that does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means. (EU's In Vitro Diagnostic Medical Devices Regulation)

## Stakeholders Involved in the Innovation Process

While medical professionals are central to adopting innovative clinical practices, patients, health economists, government officials, managers, insurers and regulators are also increasingly influential in the process. Their roles are growing in importance as they help shape the demand for new technologies, determine which services will be integrated into standard care and influence how these services are used, distributed, funded, evaluated and monitored.

As a result, the clinical evidence and decisions traditionally made by physicians, researchers and scientists are now weighed alongside cost efficiency considerations and sociopolitical factors, such as equitable access and involving non-clinical stakeholders in decision-making.

One key factor in the innovation process is the payment structure for medical services, which varies by region. In Germany, where insurance companies function as third-party payers, patients and healthcare providers have historically been shielded from the financial consequences of their decisions. However, this dynamic has changed over the past decade, with patients increasingly bearing part of the cost through co-payments and a reduction in the services covered by compulsory healthcare plans.



## PESTEL Analysis

A PESTEL analysis of the medical devices industry examines the political, economic, social, technological, environmental and legal factors influencing the industry.

#### **Political**

- Regulatory compliance: Government bodies like the U.S. FDA and Europe's CE heavily regulate
  the medical device industry. Approval processes, safety standards and regular audits affect
  product launches and profitability.
- **Healthcare policies:** Government policies around healthcare funding, insurance and patient care standards influence the demand for medical devices, particularly in public healthcare systems.
- **Trade tariffs and international relations**: Tariffs, trade wars or restrictions on exports, especially for specialized equipment, can disrupt global supply chains in the medical device industry.

#### **Economic**

- **Healthcare spending:** Countries with a high gross domestic product (GDP) and robust healthcare systems tend to spend more on advanced medical technologies, driving industry growth.
- **Cost of innovation:** Medical device companies need to invest in R&D. Technological innovation comes at a price, which can lead to increased product pricing and limited demand.
- **Economic stability:** Economic downturns can reduce healthcare spending and delay medical facility upgrades, while growth periods boost demand for advanced devices.

#### Social

- Aging population: An increasing global elderly population is driving demand for medical devices
  due to the higher incidence of chronic diseases, surgeries and the need for long-term wound
  care. In developed countries, demand has increased significantly for medical devices like
  diagnostic machines, prosthetics and mobility aids.
- Health awareness: Growing awareness of preventive healthcare and advances in medical treatments are increasing the use of diagnostic and therapeutic devices.
- **Chronic diseases:** The rising incidence of lifestyle diseases, such as diabetes and CVDs, requires continuous monitoring devices.

#### **Technological**

- Innovation and R&D: Advances in 3D printing, robotics, Al and wearable technology are transforming the medical devices landscape.
- **Digital health:** The increasing use of connected medical devices, telemedicine and data analytics is increasing demand for intelligent healthcare solutions.
- **Automation in manufacturing:** Technological improvements in manufacturing processes, like automation and AI, lead to more efficient and cost-effective production.



#### **Environmental**

- **Sustainability:** Companies are under pressure to reduce waste and energy consumption during the manufacturing process and use eco-friendly materials in devices.
- **Disposal of medical waste:** Disposal of medical devices and electronic waste poses environmental challenges, leading to regulatory scrutiny and greener disposal methods.
- **Climate change:** Disruptions caused by extreme weather events can affect global supply chains, particularly for sourcing raw materials or transporting devices.

#### Legal

- **Compliance with standards:** Medical devices must comply with various international, regional and national standards, making legal adherence complex and costly.
- Intellectual property rights: Companies must navigate patent laws and defend their IP from competitors.
- **Product liability:** Medical device manufacturers are subject to lawsuits if their products malfunction or cause harm, making legal risk mitigation a key priority.

# Porter's Five Forces Analysis

Porter's Five Forces is a classic model that organizations can use to make better strategic business decisions for their long-term success. The framework, developed by Harvard Business School professor Michael E. Porter in 1979, consists of the five forces or factors, that influence every industry. Although the five forces sometimes go by different names, in this report they are the bargaining power of buyers, bargaining power of suppliers; potential for new entrants to the market; competition in the industry; and the threat of substitutes.

#### **Bargaining Power of Buyers**

In the medical device industry, the bargaining power of buyers is high. Buyers, which include large hospitals, healthcare systems and governments with significant purchasing power, can negotiate for lower prices, especially with bulk purchases. Medical devices, especially for public healthcare systems, are often purchased based on strict budgets, making cost a critical factor.

#### **Bargaining Power of Suppliers**

Suppliers' bargaining power is low to moderate. Many medical devices rely on specialized materials, but multiple suppliers often provide these inputs, reducing supplier bargaining power. Companies in the medical device industry can source components from global suppliers, increasing competition among suppliers and reducing their bargaining power.

#### **Potential for New Entrants**

The potential for new entrants to the market is moderate. The medical device industry is heavily regulated, requiring significant capital investment in R&D and compliance with safety standards (e.g., FDA, CE certification). This creates a moderate to high barrier for new companies. Established companies hold numerous patents and have technological expertise, making it difficult for new entrants to compete on innovation.



#### **Threat of Substitutes**

The threat of substitutes is moderate. In a few cases, medical devices may be replaced by alternative treatments such as pharmaceuticals, less invasive procedures, or digital health solutions (e.g., telemedicine). Technological advances, such as wearable devices, Al and robotic surgery, can introduce substitutes for traditional medical devices, but it can be expensive to switch to these alternatives.

### **Industry Competition**

The medical device market is highly competitive. The medical device market also is fragmented, with leading companies like Medtronic, Johnson & Johnson and Siemens competing with numerous smaller firms. Large players often have the advantage due to economies of scale, but niche companies can compete through innovation. Companies compete not just on price but also on innovation. Continuous investment in R&D to develop more effective, user-friendly and safer devices drives competition.

## Supply Chain Analysis

Figure 1
Supply Chain of the Medical Device Industry



Source: BCC Research

## **Raw Materials Sourcing**

 Medical devices use various materials, including metals (stainless steel, titanium), polymers (silicone, polyethylene), ceramics and specialized biocompatible materials. Advanced devices also rely on electronic components like semiconductors.



- Raw material suppliers include companies like Royal DSM (for biocompatible materials) and Dow Corning (for medical-grade silicone). These companies often have long-term contracts with medical device manufacturers.
- Sourcing raw materials that meet stringent quality and regulatory standards is critical.
   Companies also face fluctuating raw material prices and global supply chain disruptions.

## Manufacturing

- Many companies rely on original equipment manufacturers (OEMs) to produce specialized parts
  or components for their medical devices. These components may include plastic molded parts,
  electronic circuits or precision metal.
- Increasingly, devices incorporate complex electronics, such as sensors and microchips, for advanced functionalities (e.g., IoT-enabled monitoring devices). Companies like Flex and Jabil provide electronic manufacturing services.
- Component manufacturing must adhere to strict quality control measures, as defects can affect patient safety. The ISO 13485 standard outlines requirements for a quality management system for medical device production.
- Many large medical device companies, like Medtronic or Johnson & Johnson, perform the final
  assembly in-house to maintain control over quality. However, smaller firms or specific product
  lines may outsource assembly to specialized contract manufacturers.

## Packaging and Sterilization

- Medical device packaging must meet strict standards to ensure sterility and protection during transport. Packaging materials should be durable, tamper-resistant and compliant with healthcare regulations.
- Devices implanted or used in sterile environments must undergo sterilization before shipment.
   Methods include ethylene oxide (EtO) gas, gamma irradiation and steam sterilization. STERIS and Medline are critical players in this stage.
- There is growing pressure to reduce environmental impact by using eco-friendly materials and sustainable packaging solutions without compromising regulatory compliance.

## **Regulatory Approval**

 Before reaching the market, medical devices must be approved by regulatory bodies such as the FDA in the U.S., CE marking in the EU and PMDA in Japan. These entities evaluate devices based on clinical trials, safety tests and manufacturing processes.



• Regulatory approvals can be lengthy and costly, especially for high-risk, Class III devices like pacemakers. Delays in approvals can affect the supply chain and product launch timelines.

### Distribution

- Large companies sell directly to hospitals, clinics and other healthcare providers through their in-house sales force. This direct relationship helps them maintain control over pricing and customer support.
- Smaller companies or those focusing on multiple markets may rely on third-party distributors like Cardinal Health, McKesson, or Henry Schein. Distributors have extensive networks and manage the logistics of delivering products to healthcare facilities.
- Medical devices often require specialized handling and storage, especially if they are temperature-sensitive or require sterilized conditions. DHL and UPS Healthcare provide specialized logistics services for medical device companies.

## **Aftermarket Services and Support**

- Many devices, especially capital equipment like imaging machines (MRI, CT scans) or robotic surgery systems, require regular maintenance, repair and software updates. GE Healthcare and Siemens Healthineers offer ongoing service contracts.
- Manufacturers often train healthcare professionals to ensure proper device usage. For example, Intuitive Surgical offers specialized training for surgeons using their da Vinci robotic systems.
- Manufacturers of connected devices may offer data monitoring services, analyzing device performance and providing insights for users and clinicians.

## Disposal

- Companies are responsible for managing and ensuring proper disposal or recycling.
- Medical devices, especially those with hazardous materials, must be disposed of under local and international waste management regulations, for example, the WEEE Directive in Europe.
- Increasingly, companies are being held accountable for reducing e-waste and adopting environmentally sustainable end-of-life management practices by incorporating circular economy models by recycling or refurbishing devices.



# Chapter 3: Market Dynamics

# **Market Dynamics**

The global medical device market is driven by demographic shifts, technological advances and healthcare needs. The increasing aging population is at the forefront of these changes, particularly in developed regions, where the elderly population is significantly growing. This demographic shift has heightened the demand for medical devices for managing age-related conditions such as CVDs, diabetes and orthopedic issues. Simultaneously the rise in the prevalence of chronic diseases across all age groups, has increased the need for sophisticated diagnostic and therapeutic devices. Furthermore, the trend towards preventive healthcare and early disease detection has spurred demand for medical equipment capable of providing timely and accurate diagnoses. Also, growing awareness of health and wellness is compelling consumers to seek regular health monitoring and management solutions, further fueling the demand for home-use medical devices such as wearable sensors and portable diagnostics.

Technological innovation is reshaping the medical device market. Integrating AI, machine learning, robotics and 3D printing has led to the development of more precise and less invasive medical solutions. For example, AI-powered diagnostic tools can analyze medical data faster and more reliably. Robotics in surgery has made procedures more precise, reducing recovery times. Advances in 3D printing enable medical device customization, allowing personalized treatments and solutions for individual patients.

Regulatory frameworks and government initiatives are also pivotal in shaping market dynamics. Governments across the globe are implementing policies that streamline the approval process for new medical devices, encouraging innovation while ensuring patient safety. This regulatory support and increased healthcare spending, especially in emerging markets, creates fertile ground for growth in the global medical device industry.



Figure 2
Market Dynamics of Medical Device Industry



Source: BCC Research

# Market Drivers

## **Technological Advances**

Technological innovations are transforming the global medical device industry. Advances in AI, robotics, 3D printing and minimally invasive procedures are reshaping how medical devices are developed, utilized and integrated into patient care. These advances are not only enhancing the precision, efficacy and accessibility of medical treatments but also are increasing demand for new and improved devices.

Al, which has emerged as a transformative force in the medical device industry, encompasses a range of technologies, including machine learning, deep learning and natural language processing, which are



being integrated into medical devices to enhance their capabilities. Al-driven systems are revolutionizing diagnostic imaging, data analysis and patient management, leading to more accurate diagnoses and personalized treatments.

Al has improved the accuracy of diagnostic imaging by enabling the analysis of complex medical images with high precision. Traditional diagnostic imaging methods, such as X-rays, CT scans and MRIs, often require expert radiologists to interpret the results. Al algorithms rapidly analyze these images, spotting patterns and anomalies humans might overlook. For example, Al systems have detected early signs of conditions such as cancer, stroke and neurological disorders. In oncology, Al algorithms can analyze mammograms or MRI scans to detect tumors at an earlier stage than traditional methods.

Al is also enhancing predictive analytics in healthcare. ML algorithms can analyze vast amounts of patient data, including electronic health records (EHRs), genetic information and lifestyle factors, to identify risk patterns and predict potential health issues. This enables healthcare providers to implement preventive measures and specific treatment plans based on individual risk profiles. For instance, Aldriven predictive models can forecast the likelihood of a patient developing conditions such as diabetes or cardiovascular disease, allowing for early intervention and lifestyle modifications to mitigate these risks.

3D printing technology, also known as additive manufacturing, makes it possible to quickly create custom-made medical devices, implants, and prosthetics, to each patient's needs, which leads to better treatment results. The production of custom implants and prosthetics are notable applications of 3D printing in medicine. Traditional manufacturing methods often involve standardized sizes and shapes, which may not fit all patients perfectly. With 3D printing, patient-specific implants and prosthetics can match each person's unique body shape. For example, 3D-printed orthopedic implants can be designed to match a patient's bone structure, resulting in a better fit. Similarly, 3D-printed prosthetics can be customized to accommodate users' specific needs and preferences, enhancing comfort and usability.

3D printing also creates anatomical models for surgical planning and simulation. Surgeons can use 3D-printed models of a patient's anatomy to practice and plan complex procedures before performing them in real life. These models provide a tangible representation of the patient's anatomy, allowing surgeons to rehearse surgical techniques and identify potential challenges. By improving pre-surgical planning and visualization, 3D printing enhances the precision and effectiveness of surgeries, reducing the risk of complications and improving patient outcomes.

Minimally invasive procedures have become a cornerstone of modern medicine, offering numerous benefits over traditional surgical techniques. These procedures involve smaller incisions, reduced tissue damage and quicker recovery times, improving patient outcomes and enhancing surgical efficiency.

Endoscopic procedures utilize specialized instruments and cameras to access internal organs and tissues through small incisions or natural body openings. Endoscopes have high-definition cameras and light sources, allowing surgeons to visualize and operate on internal structures with minimal disruption. Standard endoscopic procedures include laparoscopic surgery, gastrointestinal endoscopy and bronchoscopy. These techniques offer reduced pain, shorter hospital stays and faster recovery than traditional open surgeries. Additionally, endoscopic procedures are associated with a lower risk of infection and fewer postoperative complications.

These technologies enhance diagnostic accuracy, surgical precision and personalized treatment options, improving patient care and outcomes. As the medical device industry continues to evolve, the integration of emerging technologies and trends will shape the future of healthcare, offering new



possibilities for diagnosis, treatment and patient management. The continued advance of medical technology promises to make healthcare more efficient, practical and accessible for patients worldwide.

## Rising Healthcare Expenditures

Factors like population growth, medical advances, the growing prevalence of chronic diseases, and expanding healthcare services have dramatically increased global healthcare expenditures. Spending increases significantly impact different healthcare industry segments, including the medical device and pharmaceutical sectors. A comprehensive analysis of cost drivers and their impact on the medical device market is crucial for understanding the connection between rising healthcare expenses and the industry.

Healthcare expenditure is the total expenditure on healthcare, including public and private expenditures. It covers various applications, including medical services, hospital treatments, polyclinical services, medical supplies and medical equipment. Rapid advances in medical technology, including diagnostic tools, surgical techniques and treatment options, have provided sophisticated and often affordable healthcare services. New technologies, such as robotic-assisted surgery and advanced imaging techniques, also increase healthcare costs while improving patient outcomes.

The expansion of healthcare, especially in developing economies, has led to higher healthcare expenditures. Projects aimed at improving healthcare, improving universal healthcare, and improving healthcare contribute to increased overall spending. Like many other industries, the healthcare industry is impacted by rising prices and medical equipment/devices, pharmaceuticals, and personnel costs. As health services and the cost of goods increase, so does overall spending.

Table 2
Global Health Expenditures, by Country, 2022
(\$/Per Capita)

Country	Healthcare Expenditure, 2022 (\$/Per Capita)
U.S.	12,555
Switzerland	8,049
Germany	8,011
Austria	7,275
Sweden	6,438
Australia	6,372
Canada	6,319
Netherlands	6,729
U.K.	5,493
Japan	5,251
France	6,630
Belgium	6,600
Italy	4,291
Slovenia	4,114
Denmark	6,280
Ireland	6,047
Poland	2,973
Greece	3,015



Country	Healthcare Expenditure, 2022 (\$/Per Capita)
Mexico	1,181

Source: healthsystemtracker.org

In 2022, per capital health spending increased in nearly all peer nations. In the U.S., per capita health spending increased by 2.9%, which, while higher than in Australia (2.4%), Canada (0.7%) and the UK (0.5%), was still relatively modest compared to other nations. Belgium experienced the highest per capita health spending increase, with a 9.6% rise (Peterson-KFF Health System Tracker, 2022).

Healthcare spending is also heavily influenced by government policies and initiatives, particularly in the adoption of advanced medical devices. Many governments have implemented policies encouraging innovative medical technologies. These policies often include funding for R&D, tax incentives for medical device manufacturers and streamlined regulatory pathways for faster approval of new devices. Such initiatives support the growth of the medical device market and ensure that healthcare providers can access the latest tools to improve patient care.

Rising healthcare expenditures globally enable the adoption of advanced medical devices by providing the financial resources necessary for healthcare systems to invest in new technologies. This increased spending is driven by factors such as the growing burden of chronic diseases, aging populations, and supportive government policies. As a result, healthcare providers can offer patients more effective, efficient, and innovative care.

## **Growing Numbers of Surgical Procedures**

The rising number of surgical procedures across specialties, particularly in orthopedics, cardiology and cosmetic surgery, is a significant driver of demand in the medical device market. This growth in surgical volume is influencing the development and deployment of a wide range of medical devices designed to improve patient outcomes, enhance surgical precision and streamline operational efficiency.

A rising number of procedures characterizes orthopedic surgery due to an expanding aging population, increasing prevalence of musculoskeletal disorders and advances in surgical techniques. The demand for orthopedic surgical procedures is pushing demand for specialized medical devices. As the global population ages, the incidence of age-related musculoskeletal disorders such as osteoarthritis, osteoporosis and spinal degenerative diseases increases. These conditions often require surgical intervention to restore function and alleviate pain. Orthopedic surgeries, including joint replacements such as hip and knee arthroplasties, spinal fusions and fracture repairs, are becoming more common. The rise in these procedures drives demand for orthopedic implants, prosthetics and fixation devices designed to address various musculoskeletal issues.

Every year in the U.S., about 790,000 total knee replacements and 544,000 hip replacements are performed, and the number continues to increase due to an aging population. Total joint replacement is considered one of the safest and most dependable treatments available in medicine. Both hip and knee replacements can last for 20 years or longer, offering a long-term solution for arthritis of the hip or knee for most patients. (American College of Rheumatology, 2023).

Cardiology is another specialty experiencing a significant increase in surgical procedures, thanks to the rising prevalence of CVDs, advances in cardiac technology, and a growing elderly population. This growth



in cardiology procedures is driving demand for a wide range of medical devices designed to diagnose, treat and manage heart conditions. Heart disease remains the leading cause of death for men and women in the U.S., with about 500,000 open heart surgeries conducted annually. (Lifespan Health System, The Warren Alpert Medical School Brown University, 2023). CVDs, including coronary artery disease, heart failure and arrhythmias, are major health concerns. The increasing prevalence of these conditions, particularly among aging populations, has yielded a growing volume of cardiac procedures such as angioplasty, stenting and cardiac surgeries. These procedures require advanced medical devices, including coronary stents, balloon catheters and pacemakers.

Cosmetic surgery procedures are also rapidly growing, driven by societal trends, technological advances and increasing consumer demand for aesthetic enhances. The rise in cosmetic procedures influences the development and adoption of medical devices that support aesthetic and reconstructive goals. Societal attitudes toward beauty and appearance have increased demand for cosmetic procedures such as breast augmentation, liposuction and facial rejuvenation. This growing demand necessitates developing and refining medical devices used in cosmetic procedures, including implants, injectables and laser technologies.

The increasing volume of surgeries in specialties such as orthopedics, cardiology, and cosmetic surgery underscores a growing demand for advanced medical devices. As more patients undergo procedures like joint replacements, cardiac interventions, and aesthetic enhancements, the need for specialized implants, surgical tools, and supportive technologies rises.

## Increasing Prevalence of Chronic Diseases and Aging Population

Chronic diseases and the rise in the elderly population are two factors driving the global medical device market. Chronic diseases are conditions that are generally incurable but can be managed with medication interventions and lifestyle changes. These include CVD, diabetes, and respiratory diseases.

Table 3
Global Incidence of All Cancers, by WHO Region, 2022–2050
(Thousands)

Region	2022	2025	2030	2035	2040	2045	2050
Northern America	2,673	2,851	3,146	3,417	3,646	3,829	3,979
Asia	9,827	10,560	11,975	13,436	14,851	16,163	17,374
Europe	4,471	4,572	4,861	5,117	5,325	5,476	5,569
Latin America and the Caribbean	1,551	1,630	1,864	2,113	2,369	2,624	2,871
Africa	1,174	1,289	1,518	1,783	2,086	2,429	2,811
Oceania	269	293	328	362	396	428	459

Source: GLOBOCAN (2024)

The prevalence of chronic diseases continues to rise worldwide, driven by lifestyle changes, environmental factors and an expanding aging population. Cardiovascular diseases (CVDs), including cardiovascular disease, stroke and hypertension, are among the leading causes of morbidity and mortality.



worldwide. CVD is responsible for about 19.8 million deaths worldwide (American College of Cardiology, 2022). Poor diet, lack of physical activity, smoking and obesity all contribute to higher rates of heart disease. The growing prevalence of CVD is driving the need for corresponding medical interventions, including surgery, monitoring and long-term management, which require dressings and instrumentation.

Diabetes, especially type 2 diabetes, has increased dramatically due to increased rates of obesity, sedentary lifestyles and diet. In 2023, more than half a billion people globally were living with diabetes, impacting individuals of all ages in every country. This number is projected to reach 1.3 billion in the next 30 years. Current estimates place the global diabetes prevalence rate at 6.1%, making it one of the top 10 causes of death and disability worldwide. The highest regional prevalence is found in North Africa and the Middle East, where rates stand at 9.3% and are expected to rise to 16.8% by 2050. The Institute for Health Metrics and Evaluation projects that rates in Latin America and the Caribbean will rise to 11.3%. Managing diabetes often requires frequent blood glucose checks, insulin delivery, and patient health monitoring. Specialized glucose dressings, insulin pumps and wound dressings are used for diabetic wounds.

Smoking, air pollution and respiratory diseases are contributing to a rise in chronic respiratory illnesses such as COPD and asthma. The WHO reports that respiratory diseases cause a global mortality rate of about 7%.

Cancer incidence rates are rising due to factors such as aging, lifestyle changes and environmental exposure. Cancer treatment generally involves surgery. Medical treatments are required, including radiation therapy, wound dressings, proper wound management, safe dressing and transportation.

The global population is aging at an unprecedented rate. By 2050, 80% of older people will live in low- and middle-income countries (WHO, 2022). Increasing life expectancy and falling birth rates drive this demographic shift. Older people are more susceptible to chronic diseases and age-related health conditions, such as arthritis, osteoporosis and cognitive problems. Older people require ongoing medical care, including routine care, managing chronic conditions and treating acute health issues. This requires more medical supplies, including dressings, surgical equipment, and rehabilitation tools.

Orthopedic conditions, including arthritis, osteoporosis and joint degeneration, are also prevalent in the aging population. Elderly individuals often require interventional surgery for health conditions such as joint replacements, cardiac surgery and cancer surgery. The complexity of surgical and postoperative care increases as one ages. As a result, demand is growing for medical dressings. The increasing number of elderly patients drives demand for advanced medical devices to address their unique healthcare needs. Joint replacements, orthopedic implants and mobility aids are crucial in managing these conditions. For instance, knee and hip replacement surgeries, which involve the use of prosthetic joints, are common among older adults experiencing severe arthritis or joint damage. These orthopedic devices help restore function and reduce discomfort, enabling many individuals to maintain an active lifestyle.



Table 4
Elderly Population, by Country, 2021 and 2022
(% of Total)

Country	2021	2022
Argentina	11.686	11.853
Australia	16.793	17.075
Austria	19.360	19.503
Belgium	19.469	19.673
Brazil	10.153	10.491
Bulgaria	21.709	22.561
Canada	18.527	18.830
Chile	12.494	12.914
China (People's Republic of)	13.150	13.722
Colombia	9.524	9.743
Costa Rica	9.234	9.613
Croatia	22.357	22.631
Cyprus	16.482	16.565
Czechia	20.568	20.409
Denmark	20.301	20.398
Estonia	20.391	20.336
European Union (27 countries)	20.984	21.208
Finland	22.875	23.160
France	20.813	21.110
G20	12.119	12.411
Germany	22.061	22.134
Greece	22.618	22.797
Hungary	20.428	20.583
Iceland	14.861	15.009
India	6.802	6.896
Indonesia	7.003	7.266
Ireland	14.812	15.076
Israel	12.222	12.373
Italy	23.669	23.947
Japan	28.855	29.001
Korea	16.565	17.468
Latvia	20.836	20.925
Lithuania	19.950	19.973
Luxembourg	14.681	14.808
Malta	19.044	19.370
Mexico	7.858	8.091
Netherlands	19.914	20.128
New Zealand	15.993	16.396
Norway	18.076	18.333
OECD - Total	17.694	17.964
Poland	18.802	19.179
Portugal	23.415	23.791



Country	2021	2022
Romania	19.389	19.598
Russia	15.941	16.159
Saudi Arabia	3.488	2.679
Singapore	16.028	16.648
Slovak Republic	17.219	17.619
Slovenia	20.914	21.317
South Africa	6.129	6.193
Spain	19.950	20.204
Sweden	20.195	20.339
Switzerland	18.904	19.105
Türkiye	9.625	9.824
U.K.	18.705	18.920
U.S.	16.935	17.341
World	9.625	9.818

Source: Elderly population, Organisation for Economic Co-operation and Development (OECD)

The increasing prevalence of diabetes is driving demand for specialized medical fibers used in glucose monitoring devices and insulin pumps. These fibers are designed to meet specific requirements such as water resistance and long-term adhesion, to ensure that the devices stay securely attached and function effectively over extended periods. Pressure sores, or bedsores, are a common concern for patients in nursing homes. Older people often require complex surgical procedures such as joint replacements and cardiovascular interventions. Consequently, the demand for postoperative dressings has increased. Medical dressings for surgical sutures and wound support areas are critical for postoperative wound management and optimal recovery for elderly patients.

## Market Restraints

## **Stringent Regulatory Concerns**

The medical device industry is highly regulated to ensure the safety, efficacy and quality of devices used in clinical settings to treat patients. Strict regulatory frameworks, enforced by agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), are established to ensure medical devices' safety, efficacy and reliability before they are introduced to the market. These regulations, while necessary for safeguarding public health, often serve as a significant restraint on the growth and agility of medical device companies. They create an environment where bringing a new device to market is lengthy, complex and expensive. In particular, the rigorous nature of pre-market approvals, clinical trials and ongoing compliance requirements introduces substantial barriers that can delay product launches and elevate innovation costs.

For a medical device to gain approval in key markets such as the U.S. or the EU, manufacturers must first navigate complex regulatory pathways that vary in strictness depending on the type of device and its associated risks. In the U.S., the FDA classifies devices into three categories based on their potential to harm patients—Class I for low-risk devices, Class II for moderate-risk devices and Class III for high-risk devices, which include products like pacemakers and artificial heart valves. Devices that fall into the higher-risk categories, particularly those that are life-sustaining or life-supporting, must undergo the Pre-Market Approval (PMA) process, the most stringent type of FDA device marketing application. The PMA



process involves providing extensive clinical data and safety assessments, often requiring manufacturers to conduct lengthy and expensive clinical trials. These trials evaluate the device's safety and effectiveness under real-world conditions, ensuring that patients will not be exposed to unnecessary risks. However, for many companies, particularly smaller manufacturers and startups, the costs associated with these trials can be prohibitive.

The time required for regulatory approvals, especially for high-risk devices, can be considerable. It is not uncommon for the process to take years from the initial submission of a device to its eventual approval. For example, the development and approval of an implantable cardiac device, such as a defibrillator or pacemaker, may take up to a decade, factoring in not only the clinical trial phase but also the back-and-forth between the manufacturer and the FDA regarding safety data, testing protocols and design modifications. During this time, market needs may shift, or technological advances may outpace the development of the device, creating additional pressure on companies to remain competitive while waiting for regulatory approval. This delay can have far-reaching consequences, particularly in fast-moving fields like digital health or biotechnology, where the ability to quickly bring a product to market is key to gaining market share. Therefore, the extended timelines associated with regulatory approvals act as a restraint, particularly for companies developing cutting-edge technologies that must navigate these lengthy approval processes before they can be made available to patients.

Stringent regulatory approvals impose a substantial financial burden on companies, presenting a major challenge. The cost of bringing a new medical device to market can be staggering, particularly for highrisk devices that require extensive clinical trials and lengthy approval processes. Estimates suggest that the average cost of developing a Class III device like an implantable defibrillator can exceed \$100 million, with a substantial portion devoted to regulatory compliance. This financial burden is exacerbated by regulatory bodies often requiring companies to provide ongoing data on the device's performance, both before and after it enters the market. For smaller companies and startups, these costs can be insurmountable, creating a significant barrier to entry into the medical device market. Even for large, established companies, regulatory compliance's financial and resource-intensive nature can constrain the number of products they can develop and bring to market, thereby limiting innovation and the availability of new devices to healthcare providers.

The complexity of regulatory approval processes is a restraint on the global expansion of medical device makers. Every country has its own regulatory framework and obtaining approval to market a device in multiple regions requires navigating each country's requirements. Despite efforts to harmonize regulatory standards through organizations such as the International Medical Device Regulators Forum (IMDRF), differences remain. For example, a device approved by the FDA in the U.S. may require separate approval in the EU, Japan or China, each of which has its specific documentation requirements, clinical trial standards and post-market surveillance obligations. The need to comply with multiple regulatory frameworks increases the time and cost of bringing a device to global markets, restraining the international expansion of medical device companies. The lack of regulatory harmonization also means that companies must modify their products to meet the specific requirements of each market, adding to the complexity of the approval process and further delaying market entry.

The post-market surveillance requirements imposed by regulatory agencies also contribute to the restraints medical device manufacturers face. Once a device has been approved and brought to market, companies must conduct ongoing monitoring of its performance, including tracking and reporting adverse events to regulatory authorities. These requirements ensure the long-term safety and effectiveness of medical devices, but they also add to the financial burden faced by manufacturers. Companies must invest in data collection and reporting systems, employ specialized personnel to manage compliance and respond to issues that arise during the device's post-market life cycle. For high-risk devices, the regulatory agencies may require additional post-market studies or impose restrictions on how the device can be



used. These post-market requirements can be cost-prohibitive for smaller companies. In some cases, the cost of post-market surveillance can be so high that it dissuades companies from pursuing certain products altogether.

The medical device market is not only burdened by the financial and operational costs of strict regulatory approvals, but also by the unpredictable nature of the approval process itself. Even when companies comply with all regulatory requirements and provide comprehensive data on their devices, their products are not guaranteed to be approved promptly. Regulatory agencies may request additional data or impose new requirements during the review process, leading to delays. In some cases, companies may be required to redesign their devices or conduct additional clinical trials, extending the time to market. This unpredictability challenges companies in planning their product development timelines and allocating resources efficiently. For smaller companies, the uncertainty surrounding the approval process may mean they need to secure additional funding to cover unexpected delays or setbacks. The unpredictability of regulatory approvals also affects investor confidence, as the extended timelines and high costs associated with the process can reduce the return on investment for medical device development. This, in turn, can limit the availability of capital for startups and smaller companies.

However, regulatory bodies like the FDA and EMA are critical to patient safety. Any efforts to streamline the approval process must carefully balance safety with the desire to promote innovation. Initiatives such as the FDA's Breakthrough Devices Program and ongoing efforts to harmonize global regulations offer some hope for reducing the barriers to innovation while maintaining the high standards that patients and healthcare providers expect.

# Market Opportunities

## Improving Healthcare Infrastructure in Developing Economies

Growing healthcare infrastructure and economic development in countries like India, China and Brazil drive demand for medical devices. These markets represent significant potential for expansion in these countries, given their aging populations, rising incidences of chronic diseases and increasing government initiatives to improve healthcare accessibility. Emerging markets are experiencing rapid urbanization, higher disposable incomes and an increasing middle-class population, all of which contribute to a greater emphasis on quality healthcare services.

In India, for instance, the government has introduced programs to improve healthcare access and affordability, such as Ayushman Bharat, one of the world's most extensive health insurance programs. This initiative provides healthcare coverage to millions of people, boosting demand for medical devices, from diagnostic tools to surgical equipment and implants. With a population exceeding 1.4 billion, India is poised to become a critical market for medical device companies. Furthermore, India's ongoing efforts to modernize its healthcare infrastructure, including expanding private hospital chains and investing in rural healthcare, is driving demand for a wide array of medical technologies. For manufacturers, this creates an opportunity not only to sell devices but also to introduce affordable, locally adapted solutions that meet the unique challenges of India's healthcare environment, such as devices that are durable, easy to use and suitable for resource-limited settings.

China's healthcare system is transforming as the government invests heavily in modernizing hospitals, clinics and medical research facilities. The country's aging population, along with rising incidences of non-communicable diseases like diabetes, CVDs and cancer, has increased the demand for medical devices. Foreign medical device companies increasingly view China as a critical market. However, entering the Chinese market requires companies to navigate its unique regulatory environment and often collaborate



with local manufacturers or distributors. Nonetheless, the potential rewards are immense as China continues to build its healthcare infrastructure and expand access to modern medical treatments. Companies that adapt their products to China's specific needs and regulatory requirements stand to gain a significant competitive advantage.

Brazil, the largest economy in Latin America, also represents a growing market for medical devices due to its expanding middle class, increased government spending on public healthcare, and a rise in private healthcare investment. The country has a large and expanding aging population with a high prevalence of conditions such as diabetes and CVDs. The Brazilian government has also implemented policies to encourage domestic production of medical devices, further opening the market to global companies looking to partner with local manufacturers. Additionally, Brazil's participation in international trade agreements within the region offers opportunities for medical device companies to access broader Latin American markets through Brazil as a hub.

Economic development is pivotal in driving demand for medical devices in all these emerging markets. If the inhabitants of these countries have more disposable incomes, they would likely seek better healthcare services and more advanced medical treatments. This presents a lucrative opportunity for medical device companies that can offer high-quality products at competitive prices. Additionally, emerging markets often have a growing private healthcare sector, with private hospitals and clinics investing in the latest technologies. This creates a concomitant opportunity for medical device companies to target public and private healthcare providers.

Moreover, medical tourism is rising in countries like India and Brazil. Patients from across the globe travel to these regions seeking affordable yet high-quality medical treatments, including surgeries, cosmetic procedures and orthopedic care. The influx of medical tourists increases the demand for advanced medical devices. For medical device companies, this trend opens the door to supplying the latest medical innovations, including robotic surgery equipment, imaging devices and implants, to healthcare providers serving international patients.

Emerging markets such as India, China and Brazil represent significant growth opportunities for the global medical device industry. The combination of economic development, healthcare infrastructure improvements and increasing healthcare needs driven by aging populations and the prevalence of chronic diseases is fueling demand for a wide range of medical devices. Companies that can navigate regulatory environments, meet local market needs and offer cost-effective, high-quality products stand to capitalize on these regions' immense potential. As healthcare systems in these countries continue to evolve, the opportunities for innovation, expansion and growth in the global medical device market should increase, making emerging markets a critical focus for future industry developments.

# Market Challenges

## Cybersecurity Risks in the Medical Device Industry

The rapid growth of connected medical devices, which are increasingly integrated into healthcare systems, presents a new challenge: cybersecurity. Insulin pumps, pacemakers, defibrillators and even hospital equipment like imaging machines are now part of the Internet of Medical Things (IoMT). These devices transmit patient data, but their connectivity makes them susceptible to cyberattacks, raising concerns about patient safety and data privacy. With healthcare increasingly reliant on digital technologies, ensuring the security of these connected devices is paramount. The consequences of cyberattacks on medical devices range from unauthorized access to sensitive patient information to disruptions in device functionality that could lead to life-threatening situations.



Medical devices are especially vulnerable to cyberattacks because many were not designed with cybersecurity in mind. Older devices often lack encryption, authentication protocols, or the capacity to receive software updates, making them easier targets for hackers. Even newer devices can have vulnerabilities should manufacturers not prioritize cybersecurity during their development. Hackers who successfully infiltrate a connected medical device can alter its functionality, disrupt treatment, or steal personal health data, which can be used for identity theft or sold on the dark web.

A paramount concern regarding cybersecurity breaches in medical devices is the potential for attackers to gain control of vital life-support systems, including pacemakers, insulin pumps and ventilators. If a pacemaker is hacked, the attacker could manipulate its settings, leading to irregular heart rhythms that could endanger the patient's life. Hackers could similarly disrupt insulin pumps, potentially administering excessive or insufficient insulin. Many of these devices are implanted or worn by patients, which means that they cannot simply be turned off or easily replaced if compromised, further heightening the risks.

The protection of sensitive patient data also remains a significant concern. Connected medical devices collect and transmit a vast amount of personal health information, including details about a patient's medical history and treatment plans. If these devices are hacked, this confidential information can be exposed, leading to privacy violations and potential patient harm. Cybercriminals can use stolen health data to commit insurance fraud, manipulate healthcare records, or even blackmail individuals. The healthcare industry already faces challenges in safeguarding EHRs and the proliferation of connected medical devices adds another layer of complexity to ensuring patient data security.

The process of establishing regulations for cybersecurity in medical devices is ongoing. In the U.S., the FDA now issues guidelines for manufacturers on incorporating security features into their devices. These guidelines emphasize the need for manufacturers to build cybersecurity into the design phase of medical devices rather than treating it as an afterthought. The FDA also recommends that manufacturers provide ongoing software updates and patches to address any vulnerabilities that arise after a device is on the market. However, regulatory bodies can only do so much; the onus is on manufacturers to ensure that their devices meet high-security standards from the start.

Hospitals and healthcare providers are responsible for ensuring that the medical devices in their networks are regularly updated, that software patches are applied promptly and that all connected devices adhere to the organization's security protocols. Healthcare facilities are adopting tools to monitor network traffic and detect anomalies that could indicate a cyberattack. However, the challenge is that many healthcare organizations lack cybersecurity expertise and resources, leaving them vulnerable to attacks. Hospitals, for instance, may not always be able to manage the cybersecurity risks associated with many devices connected to their systems, from patient monitors to imaging equipment and infusion pumps.

The rise of ransomware attacks targeting healthcare systems adds another dimension to the cybersecurity challenge. In recent years, numerous high-profile cases of hospitals have been targeted by ransomware, where hackers encrypt critical systems and demand payment to restore access. Medical devices connected to these compromised networks could also be affected, further compounding patient safety risks and data security risks. Because hospitals rely heavily on connected devices for diagnostics, treatment and patient monitoring, a successful cyberattack can have devastating consequences, leading to delays in care, incorrect treatments or even fatalities.



To mitigate these risks, manufacturers must prioritize cybersecurity when designing medical devices, including security features such as encryption, authentication, and the ability to receive remote updates. Regulatory bodies must continue to enforce stringent cybersecurity standards and encourage manufacturers to conduct regular vulnerability assessments. Healthcare providers must invest in cybersecurity infrastructure and training, ensuring staff know the risks and how to respond to potential threats. Collaboration between manufacturers, regulators and healthcare organizations is essential to creating a secure ecosystem for connected medical devices.



# Chapter 4: Regulatory Landscape

# Regulatory Framework

Regulations play a vital role in the global healthcare industry. A company that intends to introduce a new product must fulfill the minimum standards set by the medical device regulating authorities described below. Medical device regulations vary significantly across national jurisdictions, presenting manufacturers with a complex and ambiguous environment. Because of a lack of common standards, a product certified in one country may not be suitable for certification in another. Global organizations such as the WHO, the International Organization for Standardization (ISO), and the International Medical Device Regulators Forum (IMDRF) emphasized the importance of standardized procedures. These entities strongly encourage the use of international standards in developing new regulations for medical devices by regulatory authorities.

### U.S.

The FDA regulates medical devices in the U.S. under the authority of the 1938 Food, Drug and Cosmetic Act, which was strengthened by the 1976 Medical Device Amendments, the Safe Medical Devices Act of 1990 and the Medical Devices Amendments of 1992. These laws grant the FDA the power to review and approve new devices before they enter the market, enforce quality standards, oversee recalls and ensure patient safety.

The FDA also supports the orderly development of new devices, starting with benchmarks and preclinical testing followed by clinical investigations in humans. An FDA authority independently reviews the clinical results and the marketing approval. This system has three goals:

- Eliminate product concepts that present safety concerns or lack demonstrable benefits.
- Provide early feedback about product issues related to design, technology or manufacturing.
- Provide information to physicians and patients about the device, including instructions for use, targeted medical conditions, and any technology or device-specific considerations related to both short-term and long-term effects.

The regulations that must be considered when marketing products in the U.S. differ based on whether the company is domestic or foreign. Marketing medical devices in the U.S. involves several steps, including product classification and company registration.



# Figure 3 Marketing Process for Medical Devices in the U.S.

Classify the medical device per the FDA classification database

Apply Quality Management System (QMS) according to quality system regulation (QSR)

Perform regular, random inspections for non-compliance of FDA QSR

Appointment of a U.S. local agent to address regulatory issues if the establishment is located outside the U.S.

Device listing and establishment registration performed according to the FURLS system

Annual renewal of the device listing and establishment registration (required)

FDA lists the device, authorizing it to be marketed as a medical device in the U.S.

Source: BCC Research

According to U.S. law, medical devices are classified into Class I, Class II or Class III), depending on the degree of risk associated with a particular device and the required controls to ensure the expected safety and efficacy. Class I devices are low-control (general control) devices for which safety and effectiveness can be ensured through adherence to a set of guidelines (labeling, adherence to Good Manufacturing Practices ([GMP], the FDA's Quality System Regulation, facility registration, product listing, maintenance of product compliance records and adverse medical events reporting). Class I devices are usually exempt from premarket notification requirements. However, some class I devices require premarket clearance by the FDA through the 510(k) process.

Class II devices are subject to general and unique controls like performance standards and FDA guidelines. These may also require clinical investigation before premarket approval. Premarket review and approval are accomplished through the 510(k) procedure, also known as premarket notification. A manufacturer is required to submit a 510(k) to the FDA for most Class II devices, demonstrating that the device is substantially equivalent to either:

- A device that was legally marketed before the Medical Device Amendments of 1976 was enacted.
- Another similar device from another manufacturer has been cleared through the 510(k) process.

The FDA reviews the 510(k) application and grants clearance if the authority agrees that the device is substantially equivalent. Although the FDA must clear a 510(k) within 90 days of applying, sometimes clearance takes longer due to a lack of required information and other process-related delays. In some cases, the FDA also requests further information (including clinical data) to decide regarding substantial



equivalence. If the FDA determines that the device or its intended use is not substantially equivalent, it may place the device into the Class III category, requiring rigorous premarketing requirements.

A Class III device is subject to the highest level of control because it has a new intended use or incorporates advanced technology that is not substantially equivalent to the use or technology of a legally marketed device. The safety and effectiveness of Class III devices cannot be monitored solely through general controls or other specific controls highlighted for Class II devices. Most Class III devices are life-sustaining or life-supporting and require rigorous clinical studies to demonstrate safety and effectiveness before approval. These devices need premarket approval (PMA) or approval for PMA supplements before marketing them for sale.

The PMA process, which is far more demanding and complex than the 510(k) premarket notification process, is intended to demonstrate device safety and efficacy through existing research material, preclinical studies and human clinical trials. The PMA application consists of detailed device information and information regarding target use, labeling, components (if any), methods, facilities and controls used for manufacturing. The FDA has 180 days to review a filed PMA application, but this review usually takes significantly longer, sometimes up to several years.

The FDA requires some form of post-market surveillance before approving a PMA application or clearing a 510(k) application. In this process, the manufacturer follows certain patient groups for several years and makes periodic reports to the FDA on the clinical status (when necessary to protect public health or provide additional safety and effectiveness data for the device). When the device is associated with a significant health risk (as defined by the FDA), the device sponsor must file an Investigational Device Exemption (IDE) application with the FDA and obtain IDE approval before starting a human clinical trial. However, if the device is considered a non-significant risk, IDE submission is not required, but a sponsor can submit approval from the Institutional Review Board overseeing the clinical trial. Human clinical studies are more often required for Class III devices than Class I and II devices.

#### FDA Policy for Low-Risk and General Wellness Devices

In 2018, the FDA issued guidelines to clarify the CDRH's compliance policy for low-risk products that promote a healthy lifestyle, such as wearable fitness monitors or sleep trackers. According to this new guideline draft, general wellness devices are not required to comply with premarket or post-market regulatory requirements. FDA Recalls and Safety Alerts FDA recalls are grouped into Classes I, II and III, with Class I considered the most serious. The FDA shares consumer information related to Class I recalls on its website and maintains a detailed database of these recalls. Any technical, manufacturing, or human error can cause a faulty device and may lead to device recall. This information can be found in the FDA medical device recall and safety alert database.



Table 5
Regulatory Approval: U.S. vs. Europe

U.S.	Europe
Centralized agency for approval.	Approval is decentralized and country-specific. Each agency has its own rules.
Strict regulatory requirements for approval of biologics.	No uniform approval procedure: country-dependent rules are often too permissive.
Support from regulatory bodies during approval process and more open-mindedness for innovative products.	Weak support from regulatory bodies and more conservative approach to innovative treatments.
Transparency during process.	in some countries, lack of transparency during process.
Access to the worldwide market upon approval.	Access only to national market due to country-specific approach.
Preclinical research must be completed before clinical trials begin.	Permission for distribution can be obtained at time of preclinical work, earlier than in the U.S.
When approved, reimbursement is not an issue.	Even after approval, reimbursement is dependent on proof of safety, efficacy and clinical durability in trials, which can take up to five years to complete.

Source: BCC Research

## European Union

In Europe, the commercialization of medical devices is monitored and regulated by the EU under the Medical Device Directive, which was enacted in 1995. It is the only body regulating simple to complex medical devices across the EU. The EU requires all medical products to carry the CE mark as a symbol of adherence to quality-assurance standards and demonstrated clinical effectiveness. The CE mark is a requirement for marketing any product in Europe. A product must meet minimum safety, performance and quality standards to obtain a CE mark. After receiving the CE mark, the Medical Device Directive (MDD) permits a manufacturer to affix it to its products. Although most medical devices do not need any clinical study before obtaining a CE mark, EU-competent authorities (such as government ministries of health) oversee human clinical studies and post-market surveillance of approved products.

All EU countries must comply with the requirements of the MDD. The government of each EU member state nominates a competent authority to monitor and ensure compliance with its provisions. The competent authority is responsible for:

- Designating notified bodies to carry out conformity assessment procedures.
- Handling applications for clinical investigations.
- Ensuring that adverse incidents are reported and evaluated within appropriate time frames.
- Withdrawing or removing unsafe devices from the market.
- Incorporating the directive into law through statutory instruments.
- Ensuring that only devices bearing the CE mark are allowed into the market.
- Informing the European Commission of any enforcement actions taken.

Each competent authority designates one or more notified bodies to execute and monitor conformity assessment procedures. A notified body is well qualified to perform all designated functions.



The competent authority notifies the European Commission and indicates that the notified bodies are subject to periodic audits by the competent authority to ensure continued adherence to these criteria. A list of the notified bodies is published and shared in the Official Journal of the European Communities. Non-EU medical device manufacturers must appoint an authorized European representative with contact details to represent and manage the business. Each medical device sold in the EU should have the representative's name, address and contact details on the packaging and labeling of the devices sold in the EU and associated countries. The U.S.-EU Medical Device Mutual Recognition Agreement (MRA), signed in 1998, is a bilateral agreement between the U.S. and the EU to establish limited reciprocity for medical device approvals designated for simple to complex indications. The MRA recognizes that certain European conformity assessment bodies conduct premarket reviews and quality system evaluations per U.S. regulatory requirements.

Similarly, it acknowledges that conformity assessment bodies in the U.S. conduct product-specific testing and quality system evaluations according to the EU MDD and ISO 13485. However, the MRA does not suggest that all U.S. FDA-approved products are automatically accepted in the EU or that all CE-marked products are automatically accepted in the U.S. without any regulatory screening. The U.S. and the EU have unique requirements and all medical devices must satisfy all criteria before marketing approval within each region.

U.S. manufacturers must contract with conformity assessment bodies in the U.S., followed by a subsequent recommendation to an EU-notified body to sell products in the EU. Similarly, European manufacturers must submit a 510(k) premarket application to a conformity assessment body in the EU for further review based on U.S. FDA requirements to receive approval from the FDA for concurrence. When the FDA accepts conformity assessment bodies' recommendations, an EU manufacturer can only sell its product in the U.S. market.

However, these marketing rights apply to only selected categories of low-to-moderate-risk Class I and Class II devices. U.S. conformity assessment bodies monitor and regulate U.S. manufacturing facilities according to ISO 12485 quality system requirements. Similarly, EU conformity assessment bodies monitor and inspect EU manufacturing facilities according to U.S. quality systems regulations. Manufacturing plant inspections apply to all U.S. and EU medical device manufacturing facilities. However, product approvals and EU-specific testing requirements are limited to certain specific devices identified and listed in the medical device annex of the MRA.

### Japan

Japan is the third-largest medical device and pharmaceutical market after the U.S. and the EU. Japan follows a complex regulatory process and each device must undergo what is called Shonin. This pathway involves examinations of the device's safety and efficacy before it can receive marketing approval. The Japanese regulatory environment for medical devices is considered relatively conservative and restrictive.

The Ministry of Health, Labor and Welfare (MHLW) regulates medical devices under pharmaceuticals and medical device law. This law applies to all medical devices manufactured in Japan or imported from other countries. The Japanese Pharmaceutical and Medical Devices Agency (PMDA) administers the MHLW and ensures strict regulation nationwide. The Pharmaceutical Affairs Law (PAL) is the primary governing regulation for medical devices in Japan. Implemented in 1943 and expanded in 1948, it calls for each medical device to undergo thorough safety examinations and demonstrate medical efficacy before it can be sold in Japan. This law also applies to companies that manufacture or import devices in Japan.



Clinical investigation applicable to all new medical devices for which no equivalent products have already been approved in Japan. This rule also applies to previously approved devices with some product-specific or technology-specific improvements or modifications that may improve the efficacy or expand the scope of the product for any new or existing disease condition. Clinical trials conducted in Japan are regulated and inspected under strict, good clinical practice standards, followed by standard post-marketing assessment reporting and a follow-up program. According to a 1986 agreement between the U.S. and Japan, foreign clinical data are accepted by Japanese authorities to support a device's safety and medical efficacy. However, this acceptance occurs in a minority of cases and Japanese authorities sometimes force the rejection of foreign clinical data to promote the interests of domestic manufacturers.

### **Rest of Asia**

Medical device regulatory systems vary among Asian countries such as China, Taiwan, Korea, India, Indonesia, Malaysia, the Philippines, Singapore, Thailand and Vietnam. Except for a few countries, the regulatory systems are not well-defined for all devices, unlike in the U.S., Europe and Japan.

#### China

China is one of the fastest-growing countries among the BRICS nations (Brazil, Russia, India, China and South Africa). In 2018, the China Food and Drug Administration (CFDA) announced new and updated regulations for medical device registration, testing and clinical trial requirements. According to the CFDA, "mobile medical device" refers to software and equipment that utilize non-invasive mobile computing terminals such as handheld smartphones, tablets and wearables as well as commercial off-the-shelf technologies that perform medical functions and require an "innovative medical registration" for technological devices such as wearables.

#### India

India has no specific regulatory structure (e.g., device registration and approval) for medical devices. However, the government is working toward setting a process in place. India mainly depends on imported medical devices and is considered an important market for foreign medical devices. The top 10 importers account for only 65% of the Indian market (World Trade Organization). Because India does not have up-to-date regulatory guidelines for wearable medical devices, manufacturers only need an import license to sell the devices there.

Regulatory frameworks in the wearable medical device market are meant to safeguard the use of an individual's health information and to prevent security breaches that may compromise or result in an unlawful disclosure of personal information.



# Table 6 Regulatory Framework in the Global Medical Device Market

Country	Regulatory Authority	Remarks
U.S.	FDA Health Information Technology for Economic and Clinical Health (HITECH) Act Health Insurance Portability and Accountability Act (HIPAA)	Medical devices are vulnerable to security breaches. As medical devices increasingly connect with hospital networks, internet and other medical devices, risks of security breaches increase. The FDA allows the marketing of only those devices that provide reasonable assurance that the benefits associated with the devices outweigh the risks. Potential cybersecurity threats have significantly increased with the increasing use of software and wireless technologies. For managing and mitigating cyber security threats, FDA recommends the following steps:  Healthcare facilities and medical device manufacturers should appropriately safeguard devices and networks against cybersecurity threats. Further, it is the responsibility of medical device manufacturers to remain vigilant about identifying hazards and risks associated with medical devices and taking appropriate steps to mitigate the problem to ensure patient safety and device performance.  Healthcare facilities and hospitals should ensure the safety of the network, evaluate network security and take appropriate measures to protect hospital systems.  Medical device manufacturers are responsible for remaining vigilant about identifying hazards and risks associated with their devices, including risks related to cybersecurity. They are also responsible for putting appropriate mitigations in place to address patient safety risks and ensure proper device performance.  The U.S. Department of Health and Human Services (HHS) has established national standards applicable to all states for processing electronic healthcare transactions. The HHS mandates that healthcare organizations implement secure electronic access to health data, which must comply with HHS-established privacy regulations.  The HIPAA Privacy Rule has established national standards to protect an individual's medical records and other personal health information. This rule applies to health plans, healthcare clearinghouses and healthcare providers that conduct healthcare transactions electronically.  Privacy rul
EU	NIS (Network and information systems) directive EU Regulation 2016/679	The NIS directive was adopted by the European Parliament on July 6, 2016, to safeguard and secure infrastructure that relies heavily on information and communication technology, such as healthcare, banking and financial market infrastructure.



Country	Regulatory Authority	Remarks
		The NIS directive mandates that EU member states be prepared against any cyber-attack. The member states must be equipped with a competent national NIS authority and Computer Security Incident Response Team (CSIRT).
		The EU Regulation 2016/679 on personal data protection was applicable starting May 28, 2018.
		The Data Protection Regulation (2016/679) sets clear principles that apply to all use of patients' data (personal/health condition) and to all data controllers who gather patient data. The principles underlined in the act are:
		Lawfulness, fairness and transparency—The data must be processed according to EU and Member State laws. Further, data controllers must be transparent with patients regarding the use of personal data.
		Purpose limitation: The data must be collected for a specific, legitimate and explicit purpose and not for other purposes beyond the underlined purpose. However, data processing for scientific research, statistical purposes, or archiving is considered incompatible with this principle. Hence, data may be reused for scientific or quantitative research.
		Data minimization data controllers, while gathering patient information, should ask patients only the information that is needed and relevant for the intended purpose.
		Accuracy: The data controllers are responsible for the accuracy of the data and if some discrepancy exists, the controller must take the necessary steps to rectify the same.
		Limited storage: The data should be stored for a limited period, except for archiving and scientific purposes.
		Integrity and confidentiality: The data processing must minimize risk to the integrity and confidentiality of the data.
	Nationality	The Chinese government has issued guidelines on healthcare IT to standardize big data for the healthcare IT industry, including a patient's basic information and conditions, as well as for disease prevention and control, food safety and lifestyles.
China	National Health and Family Planning Commission	The regulation will define the rules for collecting, owning and using the collected data to safeguard public security.
		The goal is to standardize data collection, reporting storage and security management in healthcare. The guideline calls for a uniform, centralized big data platform for healthcare that is expected to be established by 2020.

Source: Government websites and BCC Research

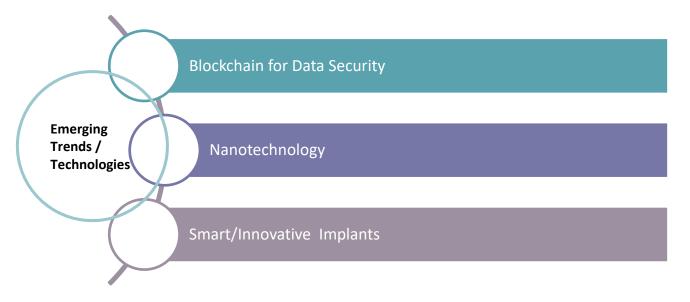


# Chapter 5: Emerging Technologies and Developments

# **Emerging Technologies**

The medical devices industry is evolving rapidly, fueled by technological advances and innovations revolutionizing healthcare. These emerging technologies enhance patient outcomes and optimize clinical workflows. From blockchain for data security to nanotechnology and smart implants, these innovations tackle diagnostics, treatment, patient monitoring and personalized medicine challenges.

Figure 4
Emerging Trends and Technologies in the Medical Device Industry



Source: BCC Research

# Blockchain for Data Security

Interconnected technologies have revolutionized healthcare delivery and management. Medical devices increasingly rely on real-time data exchange, cloud storage and interconnected systems to monitor patient conditions, administer treatments and enable personalized medicine. These digital capabilities come with the growing risk of cyberattacks and data breaches, which could compromise sensitive patient information and jeopardize patient safety. Blockchain technology has emerged as a tool to offer a decentralized, transparent and tamper-proof framework for storing and sharing information.

Blockchain provides a robust solution to secure the transmission and storage of sensitive patient data. Unlike centralized systems, where data is stored on a single server or within one organization's control, blockchain spreads data across multiple nodes, making it nearly impossible for hackers to manipulate or corrupt the information. Every transaction or update to the data is recorded as a block and then chained to previous blocks, creating a secure, chronological record that is immutable. This means that once data



is added to the blockchain, it cannot be altered or deleted without consensus from the network, offering a level of integrity and trust that is particularly valuable in healthcare settings.

One advantage of blockchain technology in medical device applications is its ability to enhance data security and privacy. With the proliferation of wearable devices and IoMT systems, which constantly collect and transmit health metrics, the risk of unauthorized access to this data has grown exponentially. Traditional healthcare databases are vulnerable to cyberattacks and breaches of medical records have become increasingly common. In 2022, over 45.9 million individuals in the U.S. had their medical records exposed in cyber incidents, highlighting the urgent need for more robust security measures in the healthcare industry (The HIPAA Journal, 2024). Blockchain addresses this vulnerability by encrypting data in a decentralized network, ensuring only authorized users can access it. For example, in a blockchain system, the personal health information generated by a patient's wearable device could be securely shared with healthcare providers without exposing the data to third-party vendors or external servers. This approach significantly reduces the risk of data interception or tampering.

Blockchain also facilitates safe and efficient information sharing across healthcare platforms. A big challenge in modern healthcare is interoperability: the ability of different healthcare systems, devices and providers to access and share patient data seamlessly. Due to inconsistent record-keeping practices and incompatible technologies, medical data is often fragmented across different institutions, making it difficult for a healthcare professional to view a patient's comprehensive medical history. Blockchain has the potential to overcome these interoperability issues by creating a unified platform where medical devices and healthcare providers can securely exchange data. For example, a blockchain-based system could transfer patients' health records from their wearable device to their primary care physician, specialist and pharmacist without relying on separate databases or communication channels. The transparency of the blockchain ensures that every data exchange is recorded and verified, reducing the likelihood of errors and streamlining care coordination.

Blockchain technology also improves traceability and accountability in the often complex medical device supply chain. Ensuring the authenticity and safety of medical devices is crucial, as counterfeit or poorly manufactured devices can lead to adverse health outcomes for patients. Blockchain enables real-time tracking of medical devices throughout their lifecycle, from production to patient use. Each step in the supply chain, including the output of a medical implant, transportation to a hospital, or implementation in a patient's treatment, can be logged on to the blockchain. This ensures that every stakeholder has access to a transparent, verifiable record of the device's history, making it easier to detect and address defects, recalls or counterfeiting.

Blockchain's ability to securely manage patient data and enhance the medical device supply chain is not just theoretical; it is being demonstrated in real-world applications worldwide. For instance, Estonia, known for its advanced e-governance infrastructure, has implemented a blockchain-based system for managing its citizens' healthcare records. The system allows Estonians to access their health data securely while enabling healthcare providers to exchange information seamlessly across different platforms. Similarly, several pilot projects in the U.S. and Europe are exploring blockchain's role in tracking medical devices, verifying clinical trials and even facilitating the secure sharing of genomic data for personalized medicine.

However, there are challenges to the widespread adoption of blockchain in healthcare and the medical devices industry. The regulatory landscape is one. Medical devices are subject to stringent regulations, particularly regarding data management and patient safety. Blockchain's decentralized nature can complicate compliance with data protection laws such as the U.S. Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR) in the EU. These regulations require healthcare providers to control where patient data is stored and who has access to



it, which may conflict with the distributed architecture of a blockchain system. Implementing blockchain in healthcare also requires large investments in technology infrastructure and expertise, which can challenge smaller healthcare organizations with limited budgets.

### Nanotechnology

Nanotechnology – the manipulation of matter at the atomic and molecular scale -- represents a groundbreaking medical device advance in the areas of drug delivery, diagnostics and tissue engineering.

Drug delivery is one of the most promising nanotechnology applications. Traditional methods of drug administration often face limitations related to drug efficacy and side effects. Because of their small size and large surface area-to-volume ratio, nanoparticles can be engineered to deliver drugs directly to specific cells or tissues. This targeted delivery approach enhances the therapeutic effects of medications while minimizing adverse side effects. For example, in cancer treatment, nanoparticles can be designed to carry chemotherapy drugs and release them specifically within tumor cells. Standard chemotherapy drugs are effective, however, they also cause adverse side effects by targeting both cancerous and healthy cells. By using nanoparticles, drugs can be directed precisely to cancer cells, reducing the impact on surrounding healthy tissues and improving the overall safety and efficacy of the treatment. This approach enhances the drug's effectiveness and allows for lower doses to be used, further reducing the risk of potential side effects.

Nanoparticles can also deliver a range of therapeutic agents, including proteins, nucleic acids and small molecules. This versatility extends to treatments for conditions such as CVDs and neurological disorders. The ability to precisely control the release and distribution of therapeutic agents through nanotechnology is a leap forward in personalized medicine, where treatments for individual patients are based on their unique genetic and biological profiles.

Nanotechnology is also transforming the field of diagnostics by enabling the development of nanosensors that can detect diseases at the molecular level. These sensors exploit nanoparticles' unique optical, electronic and magnetic properties to achieve high sensitivity and specificity in disease detection. Nanosensors can identify biomarkers associated with various diseases at deficient concentrations, including cancer, cardiovascular conditions and infectious diseases. For example, gold nanoparticles are commonly used in biosensors due to their distinct optical properties. When functionalized with specific biomolecules, these nanoparticles can bind to target disease markers and produce measurable color or light absorption changes. This enables the detection of biomarkers with high accuracy, even in microscopic samples. Such sensitivity is crucial for early disease detection, where identifying conditions at an early stage can significantly improve treatment outcomes.

Nanosensors can be integrated into portable diagnostic devices, allowing for point-of-care testing and real-time patient health monitoring. This is particularly valuable in remote or underserved areas with limited access to advanced medical facilities. By providing rapid, accurate diagnostic results at the patient's location, nanosensors enable timely interventions and better management of chronic conditions. For instance, portable nanosensor-based devices could facilitate rapid testing for infectious diseases, allowing prompt response to outbreaks and improving public health management.



#### Smart/Innovative Implants

Smart/innovative implants allow the delivery of medication directly to specific areas of the body. The deployment of intelligent implants is leading to improved efficacy and decreased side effects in managing chronic conditions and diseases.

At the core of smart implants is their ability to administer drugs in a targeted and controlled manner. Traditional methods of drug delivery, such as oral or intravenous administration, often lead to systemic exposure and potential side effects because the medication is distributed throughout the entire body. Smart implants, however, offer a solution by delivering drugs directly to the site of action. This localized delivery not only enhances the effectiveness of the treatment but also minimizes the impact on surrounding healthy tissues.

A key innovation in smart implant technology is the development of implantable drug delivery systems that can release medication at precise intervals or in response to specific physiological signals. These systems use a combination of sensors, microelectronics and drug reservoirs to manage the release of medication. For example, in chronic pain management, smart implants can be designed to release analgesics in response to real-time measurements of pain levels. This ensures that patients receive the appropriate dosage when needed, reducing the risk of overmedication or undermedication and improving overall pain control.

In oncology, smart implants are being developed to deliver chemotherapy drugs directly to tumor sites. Conventional chemotherapy treatments often affect both cancerous and healthy cells, leading to significant side effects such as nausea, fatigue and immune suppression. By using smart implants to deliver drugs specifically to tumor cells, these side effects can be minimized and the therapeutic effect of the medication can be maximized. This targeted approach improves the quality of life for cancer patients and enhances the overall efficacy of the treatment.

Chronic pain conditions, such as those associated with arthritis, neuropathy or spinal cord injuries, can be debilitating and challenging to manage with traditional medications. Smart implants designed for pain management can deliver analgesic agents directly to the affected area, providing localized relief without the systemic side effects of oral or intravenous pain medications. Intrathecal drug delivery systems are smart implants that release medication directly into the cerebrospinal fluid surrounding the spinal cord. This approach allows high concentrations of pain-relieving drugs to be delivered precisely where needed while minimizing exposure to the rest of the body. These systems can be programmed to adjust the dosage based on real-time feedback from sensors that monitor the patient's pain levels, ensuring that pain management is optimized and responsive to changing conditions.

Smart implants, utilized in pain management, oncology and autoimmune diseases, enable specific, localized treatments that enhance patient outcomes. Integrating new biomaterials in smart implants also enhances biocompatibility, durability and functionality. Additionally, mobile applications allow patients to monitor and manage these devices directly, for convenience and personalization.

# Patent Analysis

By examining patent filings, companies can identify key areas of R&D and track advances in specific medical fields such as diagnostic imaging, wearable devices and minimally invasive surgical tools. Patent data also helps assess competitors' IP strategies. Moreover, analyzing global patent trends offers insights into regulatory landscapes, enabling companies to adapt to evolving standards and secure market leadership in the highly competitive medical devices sector.



Table 7
Medical Device Technology Patents Granted, by Assignee Company, 2023
(Number)

Rank	Company	Number of Patents Granted
1	Johnson & Johnson	1,489
2	Medtronic	1,379
3	Fujifilm Holdings Corp.	1,133
4	Koninklijke Philips N.V.	651
5	Boston Scientific Corp.	491
6	Stryker Corp.	520
7	Abbott Laboratories	345
8	Becton, Dickinson and Co.	511
9	Shimadzu Corp.	184
10	Intuitive Surgical	240
11	Baxter International Inc.	184
12	Edward Lifesciences	157
13	Fresenius SE & Co.	163
14	Terumo Corp.	176
15	Smith & Nephew plc	163
16	3M	429
17	Danaher	256
18	Globus Medical	236
19	ResMed	161
20	Shanghai United Imaging Healthcare	177
21	Siemens AG	942
22	Olympus Corp.	284
23	Advanced Micro Devices Inc.	508

Source: Patent 300 Database



Table 8
Medical Device Technology Patents Granted, by Assignee Country, 2023
(Number)

Country	Number of Patents Granted
U.S.	113,865
European Patents	33,450
Australia	682
Canada	261
Russia	252
China	179
Mexico	51
U.K.	38
Malaysia	22
South Africa	15
Slovenia	9
Taiwan	7
Republic of Korea	4
Germany	3
Croatia	2
Portugal	2
Serbia	2
Spain	1
Saudi Arabia	1

Source: Lens.org



# Chapter 6: Sustainability in the Medical Devices Industry: An ESG Perspective

# Sustainability in the Medical Device Industry

The healthcare sector has historically relied on single-use products and non-biodegradable materials to ensure sterility and safety, leading to significant medical waste and ecological degradation. However, medical device makers are adopting sustainable practices, such as using eco-friendly materials, reducing energy consumption in manufacturing and developing reusable or recyclable products.

Creating biodegradable materials for disposable medical devices is important, as they break down naturally and help reduce medical waste. Circular economy principles promote the recycling and reprocessing of medical devices to extend their lifecycle. Also, sterilizable and reusable devices are helping to decrease waste and the carbon footprint associated with manufacturing and disposal. Sustainable transformation depends on energy-efficient manufacturing processes and environmentally friendly packaging.

As the focus on environmental, social and governance (ESG) grows, regulatory frameworks encourage sustainable practices. Healthcare providers are selecting suppliers that prioritize sustainability. The medical device industry is beginning to recognize that sustainability can coexist with patient safety and innovation, delivering both environmental and economic benefits in the long term.



Figure 5
ESG Metrics for Medical Device Companies

Environmental	Social	Governance
<ul> <li>Climate change and emissions</li> <li>Energy efficiency</li> <li>Waste management</li> <li>Water usage</li> </ul>	<ul> <li>Access to healthcare</li> <li>Diversity and inclusion</li> <li>Safety and health</li> <li>Employee engagement</li> </ul>	<ul> <li>Business ethics</li> <li>Data privacy and security</li> <li>Risk management</li> <li>Clinical trial transparency</li> </ul>

Source: Companies' sustainability reports

## Understanding the ESG Data

The following table shows the ESG risk ratings of medical device companies, as outlined by BCC Research.

Table 9
ESG Rankings for Major Medical Device Companies, 2024\*

Company	ESG Risk Rating Score	ESG Risk Rating	Industry Ranking
Medtronic	22.2	Medium	212 out of 634
Abbott Laboratories	22.2	Medium	215 out of 634
Johnson & Johnson	21.3	Medium	117 out of 909
Siemens Healthineers AG	18.1	Low	99 out of 634
F. Hoffmann-La Roche Ltd.	21.8	Medium	128 out of 909
General Electric	29.8	Medium	434 out of 634
Becton, Dickinson & Co.	23.7	Medium	263 out of 634
Stryker	23.6	Medium	262 out of 634
Cardinal Health	11.2	Low	8 out of 634
Koninklijke Philips N.V.	21.7	Medium	194 out of 634
Boston Scientific Corp.	22.1	Medium	210 out of 634
Canon Inc.	20.7	Medium	434 out of 667
Danaher	10.4	Low	1 out of 909
Baxter	21.8	Medium	201 out of 634
Hitachi Ltd.	26.3	Medium	14 out of 137



Company	ESG Risk Rating Score	ESG Risk Rating	Industry Ranking
Dentsply Sirona Inc.	12.1	Low	17 out of 634
Alcon AG	22.2	Medium	217 out of 634
Zimmer Biomet Holdings Inc.	26.2	Medium	325 out of 634
3M	21.2	Medium	2 out of 137
Fujifilm Holdings Corp.	24.4	Medium	7 out of 137
Terumo Corp.	22.6	Medium	231 out of 634
Edward LifeSciences Corp.	21.7	Medium	191 out of 634
Smith & Nephew plc	22.9	Medium	245 out of 634
Hologic Inc.	23.8	Medium	266 out of 634
Intuitive Surgical	19.5	Low	137 out of 634

Note: ESG Risk Rating Scale: 0-10: Negligible; 10-20: Low; 20-30: Medium; 30-40-High; 40+: Severe \*As of September 2024.

Source: Sustainalytics

#### **Environmental Performance**

The following table lists the environmental sustainability practices and goals of leading makers of medical devices.

Table 10
ESG: Environmental Performance in the Medical Device Industry

ESG Metric	Description	Example
Greenhouse gas	Measures a company's carbon footprint	Roche aims to reduce scope 1 and 2 GHG emissions by 40% by 2025 (from 2019 baseline). In 2023, the company reduced GHG scope 1 and 2 emissions by 6.9% from 2019 baseline.
emissions (GHGs)		In 2023, Medtronic achieved a 35% reduction in overall GHG emissions intensity compared to its 2020 baseline. This reduction aligns with the company's broader goal of achieving net-zero emissions by 2045.
Energy efficiency	Examines a company's energy consumption	By 2025, Roche plans to increase sustainable electricity consumption to 100%.
Man	Analyzes a company's management of waste generation and disposal	In 2022, Abbott made strides in waste management as part of its broader sustainability efforts. The company successfully diverted approximately 90% of its operational waste from landfills across its global operations.
Waste management		In 2022, Siemens reported managing 1.3 million tons of waste. Siemens aims to achieve zero waste to landfill across all of its operations by 2030. This involves enhancing recycling processes and minimizing waste generation.
Water usage	Analyzes a company's consumption of water and its discharge	Medtronic reported a total water withdrawal of 6.8 million cubic meters in 2022. Medtronic aims to reduce its water usage by 15% per unit of revenue by 2030, compared to a 2019 baseline.



ESG Metric	Description	Example
		Abbott reported using 4.5 million cubic meters of
		water in 2022. Abbott has set a goal to reduce its
		water usage intensity by 25% by 2030.

Source: Companies' sustainability reports

# Social Performance

With regards to social factors, the ESG initiatives of medical device companies focus on enhancing medicine access, increasing employee engagement, and broadening diversity and inclusion efforts.

Table 11
ESG: Social Factors Performance in the Medical Device Industry

ESG Metric	Description	Example
Access to healthcare	Evaluates a company's efforts to improve	In 2023, Abbott contributed over \$50 million to global health programs focused on improving access to essential healthcare services and medicines in low-income countries.
	healthcare access to the broader population	Koninklijke Philips N.V. introduced a new line of cost- effective and accessible portable ultrasound devices, with over 50,000 units distributed globally in 2023.
Gender diversity & inclusion	Comparing the number of women/diverse employees among all employees	Women hold 32% of Abbott's leadership positions, marking an increase from previous years. As of 2023, women constitute approximately 41% of Abbott's global workforce.
Health and safety	Analyzes a company's measures to ensure its employees' safety at the workplace	Roche annually holds two Live Well weeks across all its sites to promote healthy lifestyles and physical, mental and emotional well-being.
Employee engagement	Ensures a company's preparedness to assure the well-being of the employees	In 2023, Koninklijke Philips N.V. reported a 10% increase in employee engagement scores compared to previous years. Engagement scores are typically measured through surveys assessing job satisfaction, alignment with company goals and overall morale.

Source: Company sustainability reports



# **Governance Performance**

Transparency and governance are essential ESG issues in the global medical devices industry.

Table 12 ESG: Governance Performance in the Medical Device Industry

ESG Metric	Description	Example
Anti-corruption and business ethics	Examines a company's approach to preventing and addressing corruption and bribery	Medtronic has established a compliance monitoring system to detect and prevent corruption. This includes regular audits, risk assessments and compliance reviews to ensure adherence to anti-corruption policies.
Risk management	Examines how prepared a company is for any foreseen risks	Abbott has implemented operational controls and contingency plans to manage risks related to manufacturing, supply chain disruptions and product quality issues. Abbott has established crisis management teams and business continuity plans to handle emergencies and unforeseen disruptions. These plans include procedures for maintaining essential operations and communication during crises.
Stakeholder engagement	Evaluates a company's efforts in maintaining constructive relationships with its various stakeholders	Roche has patient platforms to understand their treatment needs. The company engages with its suppliers by running workshops and providing the required training.
Supply chain management	Evaluates a company's efforts on sustainable procurement practices	Medtronic increased its focus on sourcing materials to meet environmental and social sustainability criteria. It has committed to sourcing 100% of its critical materials from suppliers who meet Medtronic's sustainability standards by 2030.
Clinical trials	Ensures a company's measures to reduce animal use	Koninklijke Philips N.V. follows the 3Rs principle— replacement, reduction and refinement—to minimize animal use. This involves replacing animal tests with alternatives, reducing the number of animals used and refining procedures to minimize suffering.
	use	Roche is adopting innovative methods in preclinical research to replace animal testing.
Data privacy and cybersecurity	Examines a company's effort to prevent cyberattacks	Roche collects data in compliance with privacy laws such as the Swiss Federal Act on Data Protection, HIPAA and the EU General Data Protection Regulation. The company ensures that all its service providers and collaboration partners comply with data privacy laws.

Source: Company sustainability reports



# Concluding Remarks from BCC

The status of ESG implementation in the medical device industry could be high to medium. Companies have set short—and long-term goals for achieving sustainability but face the challenge of balancing innovation with sustainability. Developing new environmentally friendly technologies can be challenging.

Among medical device companies, the circular economy is an emerging practice. Roche prioritizes using eco-friendly materials and energy-efficient technologies to minimize its environmental impact. Medical device manufacturers increasingly work with suppliers and partners that adhere to sustainable practices, ensuring that raw materials and production processes contribute to a lower overall environmental impact. Roche and Koninklijke Philips N.V., are developing alternative methods to reduce animal testing in clinical trials. There is an increasing emphasis on reducing the use of animals in clinical trials.

Initiatives such as responsible sourcing practices, ethical marketing, and clinical trial transparency are gaining traction in the medical device industry. However, much work remains to reduce the industry's carbon footprint, waste generation, and overall environmental impact.



# Chapter 7: Competitive Intelligence

# Overview

Competition in the medical device market is fierce. Corporations work to expand market share and cut marketing costs by developing distribution networks and alliances with local firms to lower manufacturing expenses. The growing demand in regions such as Asia-Pacific, Latin America, and Africa offers revenue growth opportunities for manufacturers. However, businesses must continually adapt to rapidly changing economic and regulatory environments.

The medical device industry is fragmented, consisting of large, medium-sized and smaller companies, as well as startups that target specific regional or niche markets. R&D activity to develop innovative technologies is a focus at companies such as Medtronic, Abbott, Johnson & Johnson, Siemens Healthineers and Boston Scientific Corp. Expanding geographically by opening offices in new regions is another trend, particularly in high-potential markets outside the U.S.

# Strategies of Major Medical Device Manufacturers

Because regulations differ by country, medical device companies must strategically plan for operations in each region. Patient profiles and medical practices also differ. Governments set forth regulations that companies must follow when seeking approvals and certifications. They also mandate the disclosure of information and outline how companies can manufacture and distribute their products.

To make decisions aligned with their growth strategies, medical device makers should consider the following:

- Market sizing will help determine the most appropriate market before launching any product.
   Companies should also assess expected trends, demand drivers and potential markets for the product.
- Understanding the competitive landscape is a criterion for market success. By knowing the strengths, weaknesses, strategies and competitive intelligence of competitors, companies can shape their strategic approach.
- Companies must understand the clinical evidence, documentation and certifications required before introducing a new product to a market. This will ensure timely go-to-market timelines, which can be costly if a product launch is postponed or delayed due to compliance issues.
- Because each region has its own set of requirements, companies must understand and follow the specific regulations set by the relevant authorities.
- When deciding on a pricing strategy, companies should consider different regions, competitors and market trends. Ideally, the approach should be adaptable to changing market conditions.



#### **Distribution Networks**

A well-designed supply chain is essential for companies to distribute medical device technologies to their intended markets.

Many medical device companies entering the Asia-Pacific market do so by collaborating with local distributors. Establishing trust and personal relationships in this region is crucial; cold-calling and direct approaches rarely succeed. Unlike Western markets, which emphasize short-term gains, competitive capabilities and quick adaptations, Asia-Pacific businesses prioritize long-term relationships, integrity and trust. Asians value face-to-face meetings, flexible pricing and personal interaction beyond business matters. Companies must understand the local culture and methodologies to succeed.

**India:** In India, the lack of a comprehensive regulatory framework complicates the country's medical device market. Although India's rapidly expanding middle class is an appealing target, the country's distribution network poses a major obstacle. Its medical device market can be difficult to navigate, with multiple layers to penetrate before reaching the end users. Companies often partner with local distributors or form joint ventures to enter the market. Companies such as GE collaborate with local companies such as Wipro to distribute their devices. Smaller companies may establish offices for administrative tasks and local interactions. India's diverse regional buyers may require companies to work with multiple or larger nationwide distributors.

China: While China is an emerging medical device market driven by its large population and increasing adoption of healthcare technologies, regulatory hurdles and the diversity of its 22 provinces present challenges. To distribute medical devices in China, companies must have the appropriate facilities, quality testing personnel and the capacity to provide after-sales services. Local regulatory authorities require documentation and approval for Class II and III devices, and companies need a Medical Device Distributing Enterprise License, valid for five years, to distribute products legally. Compliance with these regulations is strictly enforced, with substantial penalties for distributing unregistered or malfunctioning devices. The National People's Congress's 14th five-year plan (2021-2025) sets standards for medical device development, focusing on diagnostic equipment and life support systems.

Japan: Delays in product approvals have historically been a significant issue in Japan's medical device market. However, recent changes like the PMD Act have streamlined the approval process, allowing third-party certification for lower-risk devices. Japan is now a high-potential market for advanced medical devices such as laser equipment and ultrasonic surgical tools. The country has also begun deregulating its distribution system, reducing regulatory layers and making it easier for foreign companies to enter the market. Partnerships, joint ventures or direct Internet marketing are effective strategies for smaller companies. However, foreign companies must adhere to Japan's stringent regulations, including acquiring the necessary licenses from the Ministry of Health, Labor and Welfare (MHLW) and translating product details into Japanese. Establishing an administrative office can facilitate market presence, but companies must establish subsidiaries or branches to conduct business.

**South Korea:** South Korea's medical device market centers around five major cities (Seoul, Busan, Incheon, Daegu, and Daejeon). Physicians trained in other countries and who are familiar with new technologies often influence hospital purchasing decisions. Essential imported products include knee implants, stents, imaging equipment and kidney dialysis devices. While the market presents challenges due to strict regulatory requirements, such as Korea Good Manufacturing Practice (KGMP) certification, the growing acceptance of foreign products offers opportunities for companies.

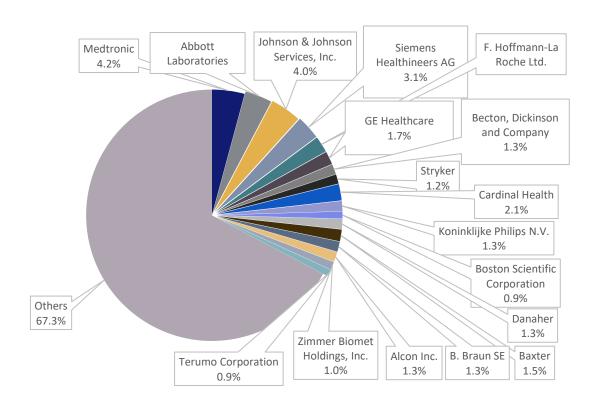
**U.S.:** The U.S. is the largest global medical device market. All entities involved in producing and distributing medical devices must register with the FDA through the establishment registration process, which



includes manufacturers, importers and foreign companies, although wholesale distributors that are not involved in manufacturing or importing are exempt. The FDA also mandates that all medical devices be listed to track their production and marketing. In the U.S., distribution networks for innovative products often focus on physicians and independent representatives, while more extensive networks handle generic products.

**Europe**: Europe is the second-largest medical device market, with three of this region's top five country markets. Medical devices can be sold across all European member countries once CE mark approval is obtained. Recent amendments, such as Regulation (EU) 2017/745, have increased the focus on clinical trial data and product safety. Companies must submit product-specific clinical data for high-risk devices and comply with post-market surveillance requirements. Europe's distribution system is highly regulated, with open tenders required for purchases above a specific value to ensure transparency.

Figure 6
Market Shares of Leading Medical Device Companies, 2023
(%)



Source: BCC Research



Table 13
Market Shares of Leading Medical Device Companies, 2023
(%)

Company	% Market Share
Medtronic	4.2
Abbott	3.5
Johnson & Johnson	4.0
Siemens Healthineers AG	3.1
F. Hoffmann-La Roche Ltd	2.1
GE Healthcare	1.7
Becton Dickinson	1.3
Stryker	1.2
Cardinal Health	2.1
Koninklijke Philips N.V.	1.3
Boston Scientific Corp.	0.9
Danaher Corp.	1.3
Baxter	1.5
B. Braun SE	1.3
Alcon Inc.	1.3
Zimmer Biomet Holdings Inc.	1.0
Terumo Corp.	0.9
Others	67.2

Source: BCC Research



# **Appendix**

# Methodology

A comprehensive research methodology, including a bottom-up approach (company analysis approach), was used to estimate the current market size.

Extensive secondary research was conducted to comprehend the technology and market insights. Key companies were identified and classified based on their revenue and product portfolio. Secondary sources such as research publications, analyst reports, company websites, financial reports, investor presentations and other publicly available sources were assessed to develop the current report framework.

Primary research included in-depth interviews and discussions with experts from the industry to gain critical insight into market drivers, opportunities, restraints and challenges and to validate market shares.

# **Abbreviations**

BCC Research assumes that readers of this report have at least some basic knowledge of the medical device industry. Still, we attempt to define many of the most important terms that are found in the report.

Table 14
Abbreviations Used in this Report

Abbreviation	Stands For	
Al	Artificial intelligence	
CE	Conformité Européenne (European conformity marking indicating compliance with EU regulations)	
ISO	International Organization for Standardization (sets global standards for quality and safety)	
IVD	In Vitro Diagnostics (devices used to perform tests on samples like blood or tissues)	
СРО	Contract packaging organization	
CRO	Contract research organization	
FDA	Food and drug administration	
FSP	Functional service partnership	
CLIA	Clinical Laboratory Improvement Amendments (U.S. regulations for laboratory testing)	
510(k)	A regulatory submission required by the FDA for clearance of medium-risk medical devices.	
ML	Machine learning	

Source: BCC Research



## Sources

# Table 15 Information Sources Used for this Report

#### **Source**

Lens.org Database. (2024). Lonza patent holdings.

MedTech Europe. https://www.medtecheurope.org/

AdvaMed - https://www.advamed.org/

Canada Medical Device -

https://ised-isde.canada.ca/site/canadian-life-science-industries/en/medical-devices/industry-profile

https://journals.innovareacademics.in/index.php/ijpps/article/view/41372/25189

Medical Devices- https://www.ibef.org/industry/medical-devices-presentation

Medtronic - https://investorrelations.medtronic.com/annual-meeting-reports

WHO - https://www.who.int/health-topics/medical-devices#tab=tab\_1

Pan American Health Organization - https://www.paho.org/en/topics/medical-devices

Medical Technology Association of India - https://mtaiindia.org/

The Association for the Advancement of Medical Instrumentation - https://www.aami.org/

Source: BCC Research

# Company Profiles

#### **ABBOTT**

100 Abbott Park Road Chicago, Illinois, 60064-6400 U.S.

Tel: +1-224-667-6100 Website: www.abbott.com



#### **Company Snapshot**

Table 16
Abbott: Company Snapshot

Corporate Category	Information
Ticker	NYSE: ABT
Year Founded/Incorporated	1894
Global Headquarters	Illinois, U.S.
Revenue 2023 (\$ Millions)	40,109
Number of Employees (2023)	114,000
Key Business Regions	U.S.
Primary Region/Country for Business	U.S., Germany, China, India, Switzerland, Japan, Netherlands and all other countries.
Main Business Segment	Medical Devices
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Abbott, a U.S.-based pharmaceutical and medical device manufacturing company, was incorporated in 1900. The company focuses on developing, manufacturing and commercializing a wide array of healthcare products and offers an extensive range of diagnostics, medical devices, nutrition and branded generic pharmaceuticals.

Abbott operates through four segments: established pharmaceutical products, diagnostic products, nutritional products and medical devices. The pharmaceutical segment offers products catering to the needs of women's health, gastroenterology, cardiology, metabolic disorders, respiratory, neuromodulators and primary care. The medical devices division manufactures endovascular, diabetes care and cardiac medical devices. Abbott's diagnostic portfolio spans immunoassay, clinical chemistry, hematology, blood screening, molecular, point of care and informatics products.

It has a global presence, operates in 160 countries and has a strong network of distributors and wholesalers. It employs over 114,000 people.

#### **Key Financial Highlights**

- Abbott's operating margin decreased from 19.2% in 2022 to 16.2% in 2023 due to COVID-19 testing, foreign exchange and increased manufacturing input costs.
- The company's targeted product lies in its Medical Device segment, which experienced a 19.6% increase in operating earnings in 2023 despite a decline in operating margin from 30.0% in 2022 to 31.4% in 2023.



 The 2023 increase in sales from 2022 is attributed to higher sales volumes in the Medical Devices businesses. In 2023, the Medical Device segment received various product approvals, such as the FDA approval for the AVEIR dual-chamber leadless pacemaker system and the CE Mark for the AVEIR single-chamber leadless pacemaker.

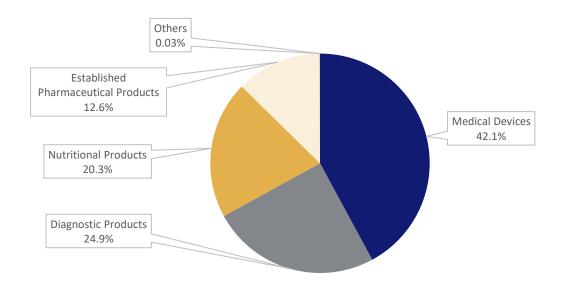
#### **Company Financials**

Table 17
Abbott: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	43,653	40,109
R &D	2,888	2,741
Operating Income	8,362	6,478
Net Income	6,933	5,723
Total Current Assets	25,224	22,670
Total Current Liabilities	15,489	13,841

Source: Company website; company annual report; and SEC filings

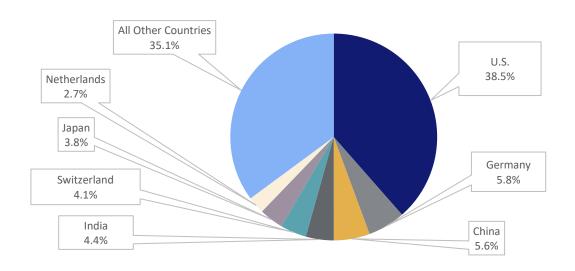
Figure 7
Abbott: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; and SEC filings



Figure 8
Abbott: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; and SEC filings

#### **Product Portfolio**

Table 18
Abbott: Product Portfolio

Product/Category	Description
Established pharmaceutical products	This segment offers a wide range of pharmaceutical products, including branded generic pharmaceuticals. The main categories include gastroenterology products, women's health products, cardiovascular and metabolic products, respiratory drugs and pain and central nervous system drugs.
Diagnostic products	This segment offers a broad range of diagnostic systems, including coronary lab systems, molecular diagnostic systems, point-of-care systems, rapid diagnostic systems, informatics and automation solutions.
Nutritional products	The main products offered are pediatric and adult nutritional products. Some major brands include Similac, NeoSure, PediaSure, Juven and others.
Cardiovascular and neuromodulation products	This segment offers a wide range of rhythm management (electrophysiology, heart failure, vascular and structural heart devices) for treating cardiovascular disease and neuromodulation devices for managing chronic pain and movement disorders.

Source: Company website



## **News/ Key Developments**

Table 19
Abbott: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Partnership	Abbott Enters Global Partnership to Connect Its World-Leading Continuous Glucose Monitoring System with Medtronic's Insulin Delivery Devices.
2024	Innovation	Abbott and YRGCARE Open New Innovative Outreach Centers in India, Providing Testing, Treatment and Support to Combat the Spread of HIV and Other Infectious Diseases.
2024	FDA Approval	Abbott Received U.S. FDA Clearance for Two New Over-the-Counter Continuous Glucose Monitoring Systems
2024	Product Launch	Abbott launched the Advanced XIENCE Sierra Stent in India, providing Cardiologists with Enhanced Care and Precision.
2024	Innovation	Abbott Accelerates Automation with the Launch of GLP Systems Track for Indian Laboratories.
2024	Product Launch	Abbott has introduced the world's most miniature rechargeable system for treating movement disorders, now featuring remote programming capabilities. The Liberta RC deep brain stimulation (DBS) system, recently approved by the U.S. FDA, includes the NeuroSphere Virtual Clinic for remote system programming. This innovative system boasts the most extended interval between charges among DBS technologies available, enabling patients to recharge the device just 10 times a year.
2023	FDA Approval	Abbott's New Lab Automation System, GLP Systems Track, Received FDA Approval, Providing Labs and Patients with Faster Results
2023	Innovation	Abbott Unveils New Al-Powered Coronary Imaging Software in India. The Ultreon 1.0 Software, a groundbreaking imaging solution, integrates optical coherence tomography (OCT) with advanced automation driven by Artificial Intelligence (AI).
2023	Acquisition	Abbott Completes Acquisition of Bigfoot Biomedical. Bigfoot Biomedical, a leader in developing smart insulin management systems for people with diabetes.
2023	FDA Approval	FDA Clears Abbott's Alinity h-series Lab Instruments, Enabling Advanced Testing of Patients' Complete Blood Counts.
2023	FDA Approval	Abbott Receives FDA Approval for TactiFlex Ablation Catheter for Treatment of Abnormal Heart Rhythm.
2023	FDA Approval	Abbott has received FDA clearance for the Assert-IQ Insertable Cardiac Monitor, which aids doctors in long-term monitoring of patients' heart rhythms.
2023	FDA Approval	Abbott has received FDA approval for its spinal cord stimulation systems to address chronic back pain in individuals with limited surgical alternatives.
2023	Acquisition	Abbott Completed Acquisition of Cardiovascular Systems Inc. Cardiovascular Systems Inc. (CSI) is a medical device company that manufactures an innovative atherectomy system for treating peripheral and coronary artery disease.
2023	FDA Approval	The FDA has approved the reader for Abbott's FreeStyle Libre 3 System. This latest generation of Abbott's FreeStyle Libre portfolio is



Year	Strategy	Description
		the most widely prescribed and cost-effective integrated continuous
		glucose monitoring (iCGM) system in the U.S
2023	FDA Approval	Abbott has received FDA approval for the Epic Max Tissue Valve, designed to address aortic valve disease. The Epic Max valve ensures superior blood flow for patients requiring heart valve replacement and is engineered to support future management options for their heart valve condition. Building on the established safety and durability of Abbott's Epic surgical valve platform, the Epic Max is intended for treating individuals with a leaky or narrowed aortic valve.
2023	FDA Approval	The U.S. FDA has approved Abbott's FreeStyle Libre 2 and FreeStyle Libre 3 sensors for integration with automated insulin delivery systems.
2023	Innovation & FDA Approval	Abbott Announces Approvals in the U.S. and Europe for New Technologies to Enhance the Treatment of Abnormal Heart Rhythms. The TactiFlex Ablation Catheter, Sensor Enabled, is the first and only ablation catheter with a flexible electrode tip and integrated contact force technology. It is now CE Mark approved for treating common arrhythmias such as atrial fibrillation. Additionally, the FlexAbility Ablation Catheter, Sensor Enabled, has received FDA approval for an expanded indication following positive study results for treating complex heart conditions.
2023	FDA Approval	The FDA has approved Abbott's spinal cord stimulation system for individuals suffering from painful diabetic peripheral neuropathy
2023	FDA Approval	Abbott has secured FDA approval for the Navitor, a cutting-edge TAVI system engineered to address aortic stenosis. The Navitor device incorporates enhances to improve patient outcomes, such as minimizing or eliminating the risk of blood leakage around the valve implant. This transcatheter aortic valve implantation (TAVI) system provides a minimally invasive alternative to traditional surgery for individuals suffering from aortic stenosis, a prevalent and severe heart valve condition.
2022	Product Launched	The company launched Amplatzer Talisman PFO Occlusion System in Europe. It is used to treat people with a patent foramen ovale (PFO) – a hole in the heart that doesn't close following birth.
2022	FDA Approval	The company received FDA approval for the commercialization and marketing of its Proclaim Plus spinal cord stimulation (SCS) system, used in the next generation of stimulation therapy. This system allows physicians to treat multi-site and evolving pain.
2022	FDA Approval	The company received FDA approval for commercialization and marketing in the US market for its Breakthrough Device used to investigate deep brain stimulation in treatment-resistant depression (TRD).
2022	R&D	The firm announced it is developing a bio wearable that continuously monitors glucose and ketone levels in one sensor.
2022	FDA Approval	The firm received FDA clearance for its Alinity m STI Assay. The test simultaneously detects and differentiates four common sexually transmitted infections. STIs, when left untreated, can lead to extreme health complications, including an increased risk of getting certain cancers and infertility.
2022	Innovation	The company announced the U.S. availability of its Amplatzer Steerable Delivery Sheath, which is used with its Amplatzer Amulet Left Atrial Appendage (LAA) Occluder to treat people with AF at risk of ischemic stroke.



Year	Strategy	Description
2022	Partnership	Abbott, Ypsomed and CamDiab announced a partnership to develop and commercialize an integrated automated insulin delivery system to reduce the burden of continuous diabetes management for individuals with diabetes. the initial emphasis of the partnership will be in European countries.
2022	FDA Approval	The firm received U.S. FDA approval of its Aveir, a single-chamber leadless pacemaker for the treatment of patients in the U.S. with slow heart rhythms.
2022	Innovation	The company announced the first patient implants of a dual-chamber leadless pacemaker system as part of its AVEIR DR i2i pivotal clinical study.
2022	FDA Approval	The firm received U.S. FDA approval of its new expanded magnetic resonance imaging (MRI) compatibility for its Proclaim XR Spinal Cord Stimulation System with Octrode leads.

Source: Company website

## ALCON INC.

Royce Bedward Chemin de Blandonnet 8 1214 Vernier, Geneva Switzerland

Tel: +41-58-911-2000 Website: www.alcon.com

#### **Company Snapshot**

Table 20 Alcon Inc.: Company Snapshot

Corporate Category	Information
Ticker	SWX: ALC
Year Founded/Incorporated	1947
Global Headquarters	Geneva, Switzerland
Revenue 2023 (\$ Million)	9,370
Number of Employees (2023)	25,315
Key Business Regions	U.S., Switzerland, Japan, China, Other
Primary Region/Country for Business	U.S.
Main Business Segment	Surgical and Vision Care
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases



#### **Company Overview**

Alcon Inc. is considered one of the largest eye care companies. Alcon earlier operated as a division of Novartis AG. In April 2019, Novartis completed its spinout of the Alcon eye unit and Alcon initiated operations as an independent standalone company headquartered in Switzerland. The company operates mainly as an eye care device company.

The company operates through two broad business segments: Surgical and Ophthalmic devices.

- Surgical: The surgical portfolio includes technologies and devices for cataract, retinal and
  refractive surgery, as well as advanced-technology intraocular lenses to treat cataracts and
  refractive errors, such as presbyopia and astigmatism.
- Vision Care: The portfolio offers a broad range of daily disposable, reusable and color-enhancing contact lenses and a comprehensive portfolio of ocular health products. These include products for dry eye, contact lens care, ocular allergies, ocular vitamins and redness relievers.

#### **Key Financial Highlights**

For the entirety of 2023, sales reached \$9.4 billion, reflecting an 8% rise on a reported basis and a 10% increase on a constant currency basis when juxtaposed with the figures from the full year of 2022.

#### **Financial Performance**

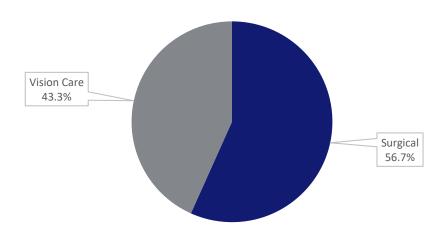
Table 21
Alcon Inc.: Financial Performance, FY 2022 and 2023
(\$ Millions)

Revenue	2022 Value (\$ Million)	2023 Value (\$ Million)
Net Revenue	8,654	9,370
R&D	(702)	(828)
Operating Income	672	1,039
Net Income	335	974
Total Current Assets	5,193	5,647
Total Current Liabilities	2,738	2,480

Source: Company website; company annual report; and SEC filings



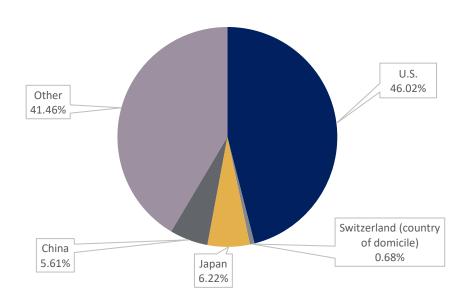
Figure 9
Alcon Inc.: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; SEC filings



Figure 10
Alcon Inc.: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; SEC filings

#### **Product Portfolio**

Table 22
Alcon Inc.: Product Portfolio

Product/Category	Description
AcrySof IOLs (Intraocular Lenses)  These lenses are used in cataract surgery to replace the eye's natural ler in various types, including monofocal, multifocal and toric options, design improve vision at different distances and correct astigmatism.	
Dailies Contact Lenses	Dailies are disposable contact lenses designed for daily use. They offer convenience and comfort with the benefit of a fresh pair each day, reducing the risk of eye infections and eliminating the need for cleaning solutions.
AIR OPTIX Plus HydraGlyde	Air Optix lenses are known for their breathable materials, which enhance comfort and reduce dryness. They come in various types, including options for astigmatism, presbyopia and color contact lenses.
Systane eye drops are designed to provide relief from dry eye symptoms. They in various formulations, including preservative-free options and gels, to offer hydration and comfort throughout the day	
Centurion Vision System	This is a sophisticated surgical platform used for cataract surgery. It incorporates advanced technology to enhance precision and control during the procedure, aiming for better patient outcomes and faster recovery.

Source: Company website



#### **News/ Key Developments**

Table 23
Alcon Inc.: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Acquisition	Alcon Completed Acquisition of BELKIN Vision, Expanding Glaucoma Portfolio with Direct Selective Laser Trabeculoplasty (DSLT) Device.
2024	FDA Approval	Alcon's Latest Equipment, Breakthrough Technologies, Unity VCS and Unity CS, Received U.S. FDA 510(k) Clearance.
2023	Product Launch	Alcon Launched TOTAL30 Multifocal Contact Lenses for Patients with Presbyopia.
2023	Product Launch	Alcon had introduced a Premium, Reusable Toric Lens with the Launch of TOTAL30 for Astigmatism.
2022	Acquisition	Alcon Acquired Aerie Pharmaceuticals Inc., Enhancing its Ophthalmic Pharmaceutical Portfolio.
2022	Innovation	Alcon Elevated Dry Eye Care with its Innovation, Systane iLux MGD Thermal Pulsation System.
March 2022	Product Launch	Alcon had strengthened its leadership in IOL innovation with the launch of Clareon Portfolio in the U.S.
2022	Product Launch	Alcon launched DAILIES TOTAL1 Contact Lenses in the U.S. for Patients with Astigmatism.
2022	Acquisition	Alcon Completed the Acquisition of Ivantis Inc., Bringing Hydrus Microstent into Its Global Surgical Portfolio.

Source: Company website

## ALIGN TECHNOLOGY INC.

410 North Scottsdale Road, Suite 1300, Tempe, Arizona 85281 U.S.

Tel: +1-602-742-2000

Website: www.aligntech.com



#### **Company Snapshot**

Table 24
Align Technology Inc.: Company Snapshot

Corporate Category	Information
Ticker	NASDAQ: ALGN
Year Founded/Incorporated	1997
Global Headquarters	Arizona, U.S.
Revenue 2023 (\$ Millions)	3,862.2
Number of Employees (2023)	21,610
Key Business Regions	U.S.
Primary Region/Country for Business	U.S., Switzerland and Other international.
Main Business Segment	Medical Devices
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Founded in 1997 and headquartered in Arizona, Align Technology Inc. is a medical device company specializing in designing, producing and commercializing comprehensive digital treatment solutions, including clear aligners and intraoral scanners. The company's offerings feature invisible aligners for teeth straightening, providing clinical guidance and support to doctors throughout treatment. This includes assistance with case selection, treatment planning, appointment scheduling, tracking the delivery of aligners and addressing minor crowding and spacing issues, often before cosmetic treatments.

Align Technology also provides clear thermoplastic retainers for post-treatment maintenance for both Invisalign and non-Invisalign patients. The company serves dental professionals in the orthodontic and restorative dentistry sectors and offers imaging solutions through its iTero systems and services. Its products are sold through a direct sales force and distributed globally across the Americas, Europe, Asia-Pacific, Middle East and Africa.

#### **Key Financial Highlights**

- Align Technology reported revenues of \$3,862.3 million for the year, marking a 3.4% increase year-over-year. Clear Aligner revenues accounted for \$3,199.3 million, up 4.1% year-over-year. In the Americas, Clear Aligner case revenues were \$1,463.0 million, a slight decline of 0.6%, while international case revenues rose by 7.4% to \$1,449.5 million. The overall Clear Aligner volume increased by 0.4%, with a notable 7.8% rise in volume for teenage patients. Imaging Systems and CAD/CAM Services contributed \$662.9 million, reflecting a 0.1% growth.
- The company reported an income from operations of \$643.3 million, yielding an operating margin of 16.7%, with an effective tax rate of 30.6%. Net income stood at \$445.1 million,



translating to a diluted net income per share of \$5.81. As of December 31, 2023, Align held cash, cash equivalents and marketable securities totaling \$980.8 million, with an operating cash flow of \$785.8 million and capital expenditures of \$177.7 million, primarily for property and equipment purchases.

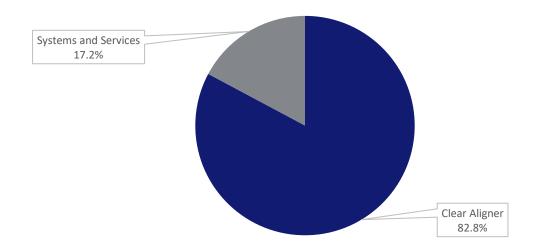
#### **Company Financials**

Table 25
Align Technology Inc.: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	3,734.6	3,862.2
R &D	305.2	346.8
Operating Income	642.6	643.3
Net Income	361.5	445.1
Total Current Assets	2,424.3	2,446.6
Total Current Liabilities	1,925.8	2,066.6

Source: Company website; company annual report; and SEC filings

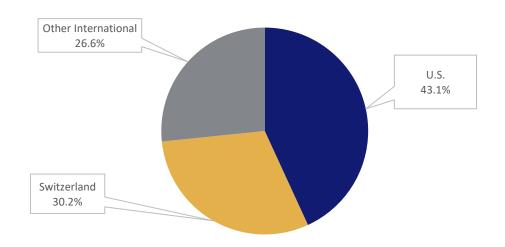
Figure 11
Align Technology Inc.: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; and SEC filings



Figure 12
Align Technology Inc.: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; and SEC filings

#### **Product Portfolio**

Table 26
Align Technology Inc.: Product Portfolio

Product/Category	Description	
Clear Aligners	Invisalign Clear Aligners: Custom-made, removable aligners designed to straighten teeth discreetly. They provide a series of aligners that progressively shift teeth into the desired position, supported by clinical guidance for treatment planning.	
Retainers	Invisalign Retainers: Clear thermoplastic retainers designed to maintain teeth' positions after orthodontic treatment. They are suitable for both Invisalign and non-Invisalign patients.	
Imaging Systems	iTero Intraoral Scanners: Digital scanning devices used to create detailed 3D images of patients' teeth and gums. These images assist in treatment planning for aligners and other dental procedures.	
Clear Aligner and CAD/CAM Services and Ancillary Products	Invisalign Express Package Invisalign Lite Package Invisalign Go Limited Movement (GP) Invisalign Moderate Package Invisalign Comprehensive Package Scanner iTero Scanner Restorative software for iTero Orthodontic software for iTero Ancillary Products Third-party scanners and Digital scans for Invisalign treatment	



Product/Category	Description	
	iTero Applications and Tools iTero Models and Dies	
	Invisalign 3D Assessment tool.	
CAD/CAM Services	iTero Workflow Solutions: Software and services that integrate with iTero scanners to streamline the workflow for dental professionals, enhancing the	
	efficiency of treatment planning and patient management.	

Source: Company website

**News/Key Developments** 

Table 27
Align Technology Inc.: News/Key Developments, 2022-2024

Year	Strategy	Description	
2024	Innovation	Align Technology Introduced iTero Design Suite, Enabling Intuitive Design Capabilities for In-Practice 3D Printing to Boost Practice Efficiency.	
2024	Product Commercializ ation	Invisalign Palatal Expander System by Align Technology is now available in Australia and New Zealand for Skeletal and Dental Expansion in Growing Patients.	
2024	Acquisition	Align Technology completed the acquisition of Cubicure, a Pioneer of Direct 3D Printing Solutions for Polymer Additive Manufacturing.	
2023	FDA Approval	Align Technology Received U.S. FDA 510(k) Clearance for the Invisalign Palatal Expander System to Address Skeletal and Dental Expansion in Growing Patients, Including Teenage Patients, Who Represent the Majority of Orthodontic Case Starts Globally.	
2023	Innovation	Align Technology Introduced New SmartForce Attachment-free Aligner Activation Feature	
2022	Strategic Collaboration	Align Technology and Desktop Metal Announced Strategic Collaboration to Make iTero Element Flex the Preferred Restorative Intraoral Scanner for Desktop Labs' Customers Serving General Dentists.	
2022	Strategic Partnership	Align Technology and Asana Announced a Strategic Partnership with Asana Smiles for Align, a New Work Management Solution for Invisalign-trained doctors in the U.S	
2022	Innovation	Align Technology launched New Invisalign System Innovations for Orthodontic and Restorative Dental Treatment Planning with Integration of CBCT into ClinCheck Treatment Planning Software.	

Source: Company website



#### B. BRAUN SE

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Website: www.bbraun.com

#### **Company Snapshot**

# Table 28 B. Braun SE: Company Snapshot

Corporate Category	Information	
Year Founded/Incorporated Year	1839	
Global Headquarters	Hessen, Germany	
Revenue 2023 (\$ Millions)	9,469.4	
Number of Employees (2023)	63,011	
Key Business Regions	North America, Asia-Pacific, Europe	
Primary Region/Country for Business	Europe	
Main Business Segment	Hospital care	
Entity Type	Private	
Ownership Type	Parent	

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Based in Germany and founded in 1839, B. Braun Melsungen AG is a global provider of healthcare products and services. The company develops an extensive portfolio of medical solutions, including products for intensive care units, anesthesia and emergency care, extracorporeal blood treatment, cardiology, surgical core procedures, nutritional therapy, etc.

The company operates through four divisions: B. Braun Hospital Care, B. Braun Aesculap, B. Braun Outpatient Market and B. Braun Avitum. B. Braun Aesculap focuses on therapeutic areas, including abdominal surgery, cardiothoracic surgery, interventional vascular therapy, neurosurgery orthopedic surgery, spine surgery and sterile goods management. It offers surgical and interventional products under this segment.

B. Braun has over 63,000 employees across over 300 subsidiaries in 64 countries. Its portfolio includes 5,000 healthcare products.

#### **Key Financial Highlights**

 The Hospital Care division reported a 3.4% increase in sales, reaching \$5,077.4 million in 2023, compared to \$4,785.5 million in the previous year. At constant exchange rates, the growth was



7.0%. This growth for the 2023 fiscal year was primarily driven by strong performance in Western Europe and Latin America.

- In the last fiscal year, the Aesculap division reported sales of \$2340.9 million, representing an increase of 5.2% over the previous year's sales of \$2,166.8 million. At constant exchange rates, the growth was 8.7%. The division achieved solid sales growth in Europe, the U.S. and certain countries in Latin America.
- Sales in the Avitum division showed little change in the reporting year, with a slight decrease of 0.7%; this minor decline was largely due to reduced demand for infection prevention and control products, like gloves and masks, as sales had been unusually high in the previous year due to the coronavirus pandemic.

#### **Financial Performance**

Table 29

B. Braun SE: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	8,950.7	9,469.4
R&D	569.9	524.1
Operating Income	261.1	342.0
Net Income	149.7	135.4
Total Current Assets	3,972.7	4,113.3
Total Current Liabilities	2,769.5	2,601.8

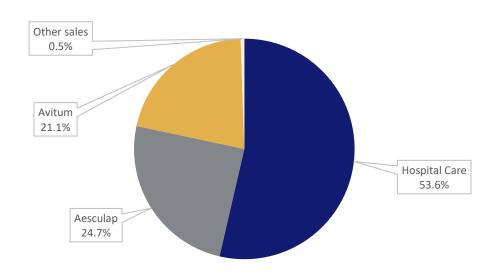
Note: Euro to USD converted 2022 averages 1.0530 and 2023 averages 1.0816

Source: Company website; company annual report; and SEC filings



Figure 13

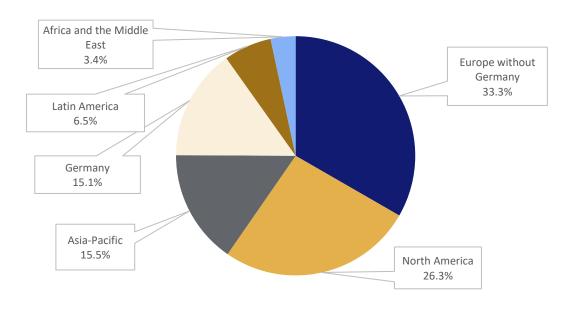
B. Braun SE: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; and SEC filings

Figure 14

B. Braun SE: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; and SEC filings



## **Product Portfolio**

# Table 30 B. Braun SE: Product Portfolio

Segment/Category	Description	
Hip arthroplasty	<ul> <li>Aesculap Total Hip Solution</li> <li>Metha Short Hip Stem System</li> <li>Excia T Standard Hip Stem System</li> <li>Bipolar Head</li> <li>Plasmafit PROAcetabular System with Vitelene Liner</li> </ul>	
Knee arthroplasty	<ul> <li>VEGA System</li> <li>Columbus Knee System</li> <li>Advanced Surface Technology</li> <li>MIOS</li> <li>univation X</li> <li>Columbus AS Revision Knee System</li> <li>EnduRo AS Knee Revision System</li> </ul>	
orthopedic navigation systems	<ul><li>orthoPilot Navigation System</li><li>KneeSuite</li></ul>	
Spine solutions	<ul> <li>activL Artificial Disc</li> <li>Quintex</li> <li>CeSpace</li> <li>Plasmapore</li> <li>Quintex Cervical Plating System</li> <li>ABC2 Cervical Plating System</li> <li>Spectrum Cervical Plating System</li> <li>S4 Cervical Fixation System</li> <li>SecureSpan Laminoplasty System</li> <li>CeSpace XP Interbody System</li> <li>CASPAR Retractor (CCR)</li> <li>CASPAR Distractor (CCD)</li> <li>Apfelbaum Odontoid Fixation</li> <li>Modulift Expandable Vertebral Body Replacement System</li> <li>MACS TLMACS TL Plating System with MACS II Instrumentation</li> <li>S4 Element MIS System</li> <li>S4 Spinal System</li> <li>S4 Spinal System</li> <li>S4 Spondylolisthesis Reduction Instrumentation (SRI)</li> <li>S4 MIS Cannulated Pedicle Screw System</li> <li>S4 Fracture Reduction Instrumentation (FRI)</li> <li>ProSpace Bone TLIF</li> <li>ProSpace Bone PLIF</li> <li>ProSpace Bone ALIF</li> <li>Arcadius XP L Stand Alone Interbody Device (SIBD) Spinal System</li> <li>a-Space Stand Alone Interbody Device (SIBD) Spinal System</li> <li>activL Artificial Disc</li> <li>Spyder Retractor System</li> </ul>	



Segment/Category	Description
	<ul> <li>Micro Lumbar Disectomy (MLD) Retractor System</li> <li>CASPAR Lumbar Retractor (CLR) System</li> <li>miaspas</li> <li>miaspas mini TTA</li> <li>S4 Element MIS System</li> <li>S4 Spinal System</li> <li>S4 MIS Cannulated Pedicle Screw System</li> <li>Spyder Retractor system</li> <li>TSpace PEEK</li> <li>Modulift Expandable Vertebral Body Replacement System</li> <li>MACS TL Plating System with MACS II Instrumentation</li> <li>S4 Spinal System</li> <li>S4 Element Spinal System</li> <li>miaspas TL</li> <li>miaspas Mini TTA</li> <li>S4 Fracture Reduction Instrumentation (FRI)</li> <li>CeSpace XP Interbody System</li> <li>Arcadius XP L Stand Alone Interbody Device (SIBD) Spinal System</li> <li>ProSpace XP Interbody System</li> <li>TSpaceXP Interbody System</li> <li>TSpaceXP Interbody System</li> <li>ProSpace DBM</li> </ul>

## **News/ Key Developments**

Table 31

B. Braun SE: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Expansion	B. Braun Medical opens a new factory in Sempach. B. Braun Medical AG is a subsidiary of B. Braun SE, which is headquartered in Melsungen, Germany.
2022	Distribution Agreement	Aesculap secured distribution rights for a digital surgical microscope. With the conclusion of a distribution agreement, B. Braun surgery division Aesculap strengthened its long-term partnership with True Digital Surgery. This Californian company is an expert in robotically controlled 3D digital visualization.
2022	Acquisition	B. Braun acquired Intermedt Medizin & Technik GmbH, a specialist in the preparation of dialysis concentrates
2022	Expansion	B. Braun expanded its footprint in Vietnam with the groundbreaking of a new factory.

Source: Company website



## **BAXTER**

One Baxter Parkway Deerfield, Illinois, 60015 U.S.

Tel: +1-224-948-2000 Website: www.baxter.com

#### **Company Snapshot**

Table 32
Baxter: Company Snapshot

Corporate Category	Information
Ticker	NYSE: BAX
Year Founded/Incorporated	1931
Global Headquarters	Illinois, U.S.
Revenue 2023 (\$ Millions)	14,813
Number of Employees (2023)	60,000
Key Business Regions	U.S., emerging markets and Rest of The World
Primary Region/Country for Business	U.S.
Main Business Segment	Kidney Care
Entity Type	Public
Ownership Type	Parent

Source: Company website; annual reports; investor presentations; press releases

### **Company Overview**

Baxter International Inc. focuses on various crucial healthcare products, offering products and therapies for hospitals, clinics, emergency rooms, operation rooms, pharmacies and intensive care units. The company provides dialysis therapies, infusion systems, pharmaceuticals and various medical products. Hospitals, nursing homes, dialysis centers and rehabilitation centers utilize these products and systems. As of December 31, 2023, the company employed nearly 60,000 people and it manufactured products and solutions in more than 20 countries while marketing them in more than 100 countries.

Baxter International Inc. operates its business through its geographic segments: the Americas, which includes North and South America; Europe, the Middle East and Africa (EMEA); and the Asia-Pacific region, with each segment offering a broad range of healthcare products. The company offers nutritional products, including ready-to-use premixes of parenteral nutrition with nutritionally balanced formulations.

Baxter is continuously working to improve the healthcare sector. It recently acquired Hill-Rom, a medical technology company engaged in frontline care products, patient support systems and surgical solutions. This acquisition aims to create a changing healthcare system and to increase global patient care through collaboration among the top MedTech companies.



### **Key Financial Highlights**

- 2023 was a successful year for Baxter operationally. It registered a significant increase in sales, with a rise of 8.7%.
- The targeted products are in the company's Medical Products and Therapies segment under the Advanced Surgery product line. Sales of Advanced Surgery increased by 5% in 2023 compared to 2022.

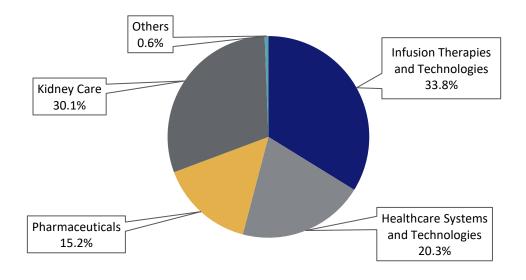
#### **Financial Performance**

Table 33
Baxter: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	14,506.0	14,813.0
R&D	602.0	667.0
Operating Income	-2,243.0	390.0
Net Income	-2,421.0	2,663.0
Total Current Assets	8,011.0	9,600.0
Total Current Liabilities	4,745.0	6,503.0

Source: Company website; company annual report; SEC filings

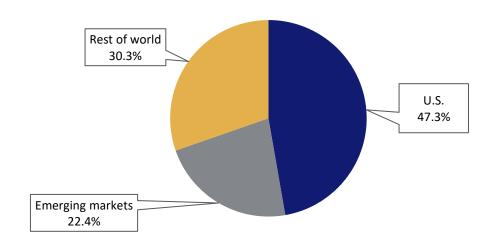
Figure 15
Baxter: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; SEC filings



Figure 16
Baxter: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; SEC filings

### **Product Portfolio**

Table 34
Baxter: Product Portfolio

Segment/Category	Description	
Accusol dialysis solution	A dialysis solution for patients' continuous renal replacement therapy (CRRT) needs.	
Spectrum IQ Infusion System	The Spectrum IQ Infusion System aims to establish a new benchmark in medication administration by providing a streamlined and standardized user experience, which helps minimize human programming errors.	
Renaflo II hemofilter	A hemofilter for CRRT therapy contains a semipermeable membrane with a hollow fiber design.	
HomeChoice automated peritoneal dialysis (APD) system and PRO APD system	A small and portable APD system is used at night for APD therapy and remotely monitors patients' therapy using customized clinical software and a particular data card.	
Ultrabag system	A continuous ambulatory peritoneal dialysis (CAPD) delivery system that helps minimize the potential for touch contamination.	
Hemodialysis dialyzers	A wide range of dialyzers for individual treatment needs. They function as an artificial kidney during hemodialysis treatments, allowing for the effective removal of toxins and maintaining fluid balance.	
Airway Clearance Systems	Regular therapy to clear airways of secretions and mucus is essential for patients with certain respiratory conditions. High-frequency chest wall oscillator (HFCWO) therapy can accomplish this through a vest that gently vibrates the chest.	



Segment/Category	Description
Mobile Noninvasive Ventilation	For a patient with a chronic respiratory condition requiring continuous ventilation, even modest activities may be challenging. The company is committed to helping patients have fewer restrictions with non-invasive ventilation system that provides portable, lightweight and mask-free breathing support.
Surgical Instruments (Surgical care)	A variety of surgical tools and devices are used during medical procedures.  Baxter's portfolio includes items for general surgery and specialized instruments for specific types of surgery.

**News/ Key Developments** 

Table 35
Baxter: News/Key Developments, 2022-2024

Year	Strategy	Description	
2024	Divesting	Baxter Announced Definitive Agreement to Divest Its Vantive Kidney Care Segment to Carlyle for \$3.8 Billion.	
2024	FDA Approval	Baxter secures FDA approval for Clinolipid (Lipid Injectable Emulsion) Neonatal and Pediatric Indication.	
2024	FDA Approval	Baxter Announced U.S. FDA Clearance of Novum IQ Large Volume Infusion Pump and Dose IQ Safety Software, Advancing Connected and Intelligent Infusion Therapy	
2023	Innovation	Baxter Advances First Intravenous (IV) Bag Recycling Pilot for U.S. Hospitals.	
2023	Innovation	Baxter Launched Digital Image Capture Capability for PanOptic Plus Ophthalmoscope.	
2023	Innovation	Baxter Launched PERCLOT Absorbable Hemostatic Powder. The launch of PERCLOT Absorbable Hemostatic Powder in the U.S. PERCLOT is a passive, absorbable hemostatic powder ready to use and designed for patients with intact coagulation to address mild bleeding.	
2023	Product Launched	Baxter Launched Progressa+ Next Gen ICU Bed to Help Address Complex Critical Care Needs. Developed in collaboration with nurses and therapists to help ease the burden on critical care teams.	
2023	Collaborative Research Agreement	Miromatrix and Baxter had announced a Collaborative Research Agreement Aiming to Advance Care for Patients with Acute Liver Failure.	
2022	Product Launched	Baxter had introduced ExactaMix Pro, Next-Generation Automated Nutrition Compounder, at ASHP Meeting. ExactaMix Pro enhances security, improves customer experience and offers more vital data reporting capabilities.	
2022	Approval	The company received FDA approval for commercializing and marketing its Novum IQ Syringe Infusion Pump with Dose IQ Safety Software.	
2022	FDA Approval	Baxter announced the U.S. FDA Clearance of the ST Set Used to Treat Acute Kidney Injury Patients in the Hospital. ST Set previously obtained FDA Emergency Use Authorization (EUA) to help meet the increased	



Year	Strategy	Description	
		demand for continuous renal replacement therapy (CRRT) products during the COVID-19 pandemic.	
2022	Partnership	Digital Diagnostics and Baxter had announced a Partnership to Advance Diabetic Retinopathy Detection. The partnership includes plans to offer Digital Diagnostics' industry-leading IDx-DR autonomous AI software as a diagnostic service combined with the Welch Allyn RetinaVue 700 Imager.	

# BD

## **Becton, Dickinson and Company**

1 Becton Drive Franklin Lakes, New Jersey, 07417-1880 U.S.

Tel: +1-201-847-6800 Website: www.bd.com

# **Company Snapshot**

Table 36 BD: Company Snapshot

Corporate Category	Information
Ticker	NYSE: BDX
Year Founded/Incorporated	1897
Global Headquarters	New Jersey, U.S.
Revenue 2022 (\$ Millions)	19,372.0
Number of Employees (2023)	73,000
Key Business Regions	U.S. and international
Primary Region/Country for Business	U.S.
Main Business Segment	BD Medical
Entity Type	Public
Ownership Type	Parent

Source: Company website; annual reports; investor presentations; press releases

# **Company Overview**

Becton, Dickinson & Co. (BD) manufactures and sells various medical devices, diagnostic products and laboratory equipment for healthcare institutions, biopharmaceutical companies, life science research institutes and clinical laboratories.



The company has three divisions: BD Medical, BD Life Sciences and BD Interventional. The BD Medical segment offers insulin delivery technologies. BD, which had 75,000 employees as of September 2023, operates in 190 countries.

## **Key Financial Highlights**

- The BD revenue for 2023 is \$19.4 billion, which shows an increase of 2.7% from the previous year.
- Its targeted products lie in its Medical Segment under the Medication Delivery Solutions and Pharmaceutical Systems. There was a continuous demand for pre-fillable solutions in a growing market.

### **Financial Performance**

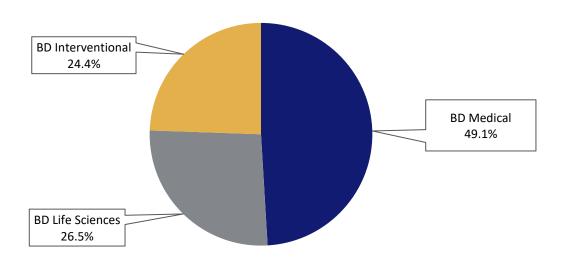
Table 37
BD: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	18,870.0	19,372.0
R&D	1,256.0	1,237.0
Operating Income	2,282.0	2,111.0
Net Income	1,779.0	1,484.0
Total Current Assets	8,141.0	8,676.0
Total Current Liabilities	7,811.0	6,641.0

Source: Company website; company annual report; SEC filings

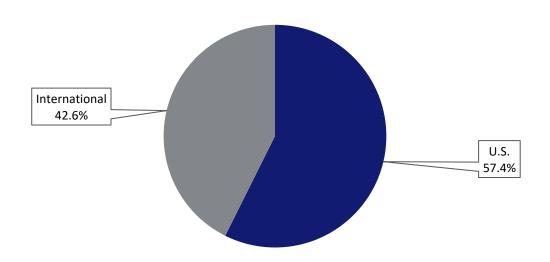


Figure 17
BD: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; SEC filings

Figure 18
BD: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; SEC filings



## **Product Portfolio**

Table 38 BD: Product Portfolio

Segment/Category	Description
BD Ultra-Fine Lancet	50% thinner than other lancets, tear-off safety strip, improved point geometry, compatible with most lancet devices.
BD BBL and BD Difco	BBL and Difco products meet industrial and clinical microbiological needs.
BD Microtainer	Blood collection tubes are designed for ease of use, ensuring quality capillary blood sample collection.
BD Insyte-W	The BD Insyte Autoguard BC-shielded IV catheter with blood control technology has been clinically demonstrated to reduce the risk of blood exposure by 95%.
BD Durasafe Plus Anaesthesia Systems	The epidural lock CSE needle set combines traditional BD CSE products and critical design elements.
BD IV Catheters	Catheters are used for intravenous access to administer fluids, medications, or blood. BD's catheters are designed to enhance patient comfort and reduce the risk of complications.
BD Diagnostics	Diagnostic systems and devices for detecting and monitoring diseases and infections. This includes products for molecular diagnostics, microbiology and point-of-care testing.
BD Surgical Instruments	A range of tools used in surgical procedures, including forceps, scissors and needles. BD provides instruments designed for precision and reliability in the operating room.
BD Endoscopes	Flexible instruments used for visual examination of internal body cavities and organs. BD's endoscopes are used in various diagnostic and surgical procedures.

Source: Company website



# **News/ Key Developments**

Table 39 BD: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Acquisition	BD Completes the Acquisition of Critical Care from Edwards Lifesciences. This expands BD's innovative connected care solutions portfolio with leading monitoring technologies, including advanced AI-enabled clinical decision tools. The combination of leading monitoring and infusion platforms enables future innovation opportunities for closed-loop monitoring and treatment, integrating combined company data sets and interoperability capabilities.
2024	Collaboration	BD and Quest Diagnostics Joined Forces to Develop Companion Diagnostics for Cancer and other Diseases. This global collaboration agreement to develop, manufacture and commercialize flow cytometry- based companion diagnostics (CDx) is intended to help select the best treatment for patients with cancer and other diseases.
2024	Expansion	BD increased domestic production to Support the U.S. Healthcare Need for Syringes.
2024	Partnership	BD Partnered with Camtech Health to Increase Access to Cervical Cancer Screening in Singapore. This strategic partnership with Camtech Health, a digital health company focused on at-home health testing, advances cervical cancer screening by offering the first-ever option for women in Singapore to self-collect a sample in the privacy of their own homes.
2024	Strategic Collaboration	BD Techcyte announced a Strategic Collaboration to Offer an AI-based digital Cervical Cytology System for Pap Testing. The agreement enables BD to deliver a complete solution that aims to reduce the potential for human error and allow greater throughput so that labs can achieve their results with greater standardization, reproducibility and efficiency from a Pap test, also known as a Pap smear.
2024	Collaboration	BD and Hamilton collaborated to Standardize Single-Cell Multiomics Experiments Using Robotics. In this collaboration, BD aims to deliver a suite of BD Rhapsody Single-Cell Analysis Library Preparation Reagent Kits that can be performed on the Hamilton Microlab NGS STAR robotic liquid-handling platform. The combination will automate steps, including pipetting and thermal cycling, to produce DNA samples or "libraries" ready for genetic sequencing.
2023	FDA Approval	BD received FDA 510(k) Clearance for a potentially transformative Fingertip Blood Collection Device.
2023	Product Launch	BD launched an advanced Vascular Access Ultrasound System Designed to Improve Clinician Efficiency.
2023	Collaboration	BD and Bio Farma Collaborated to Help Eliminate Tuberculosis in Indonesia by 2030. Bio Farma, a state-owned life science company in Indonesia, signed a memorandum of understanding (MOU) for a joint effort to combat tuberculosis (TB) by providing access to BD's innovative TB diagnostics portfolio and establishing a partnership to optimize the supply chain for TB solutions in Indonesia.
2023	Product Launch/Innovation	BD advanced the "One-Stick Hospital Stay" Vision and launched Next-Generation Needle-Free Blood Draw Technology.
2023	Environmental Collaboration	BD, Casella Completed Industry-First Pilot Recycling 40,000 Pounds of Used Medical Devices. Casella, a solid waste, recycling and resource



Year	Strategy	ategy Description	
		management services company, completed a recycling pilot to manage	
		discarded syringes and needles.	
2023	FDA Approval	BD had received U.S. Food and Drug Administration (FDA) 510(k) clearance for the BD Respiratory Viral Panel (RVP) for BD MAX System, a single molecular diagnostic combination test that identifies and distinguishes SARS-CoV-2, influenza A, influenza B and Respiratory Syncytial Virus (RSV) in approximately two hours.	
2023	FDA Approval	BD received FDA clearance for the updated BD Alaris Infusion System. BD Alaris Infusion System is the only modular and most comprehensive infusion system on the U.S. market. It includes large-volume pumps, syringe pumps, patient-controlled analgesia (PCA) pumps, respiratory monitoring, auto-identification, dose error reduction software and EMR interoperability.	
2023	Acquisition by STERIS	BD, had signed a definitive agreement to sell its Surgical Instrumentation platform to STERIS for \$540 million.	
2023	Product Launch	BD launched a new robotic system to automate clinical flow cytometry. The BD FACSDuet Premium System Leverages Robotics to Automate Sample Preparation for Greater Standardization in Clinical Flow Cytometry Diagnostics.	
2023	Expansion/Investment	BD opened a €4 Million R&D Centre in Dublin and will invest an additional €30 million in an Enniscorthy manufacturing plant.	
2023	Product Launch	BD launched the world's first spectral cell sorter with high-speed cell imaging.	
2023	FDA Approval	BD received clearance from the U.S. Food and Drug Administration (FDA) for the new BD Kiestra Methicillin-resistant Staphylococcus aureus (MRSA) imaging application. This application uses artificial intelligence to interpret bacterial growth and release negative specimens with minimal human interaction.	
2023	Product Launch	BD launched a new, easy-to-use advanced ultrasound device with a specialized probe designed to provide clinicians with optimal IV placement.	
2023	FDA Approval	BD had received FDA Clearance for a First-of-Its-Kind High-Throughput Diagnostic Test for Infectious Vaginitis.	
2023	FDA Approval	BD Onclarity HPV Assay Received FDA Approval for Use with Both BD SurePath Liquid-based Pap Test and Hologic ThinPrep Pap Test.	
2022	Expansion	BD opened a \$38.6 million Medication Management Manufacturing Facility in Tijuana.	
2022	Agreement	BD, Biocorp Signed Agreement to Bring Connectivity, Traceability to Self-Administered Injectable Drugs.	
2022	Product launch	BD launched a next-generation, disposable vaccine syringe designed to be reliable and efficient.	
2022	Commercial Collaboration	BD and Accelerate Diagnostics Inc. an innovator of rapid in-vitro diagnostics in microbiology, had commercial collaborated agreement where BD will offer Accelerate's rapid testing solution for antibiotic resistance and susceptibility offering results in hours, versus one to two days with some traditional laboratory methods.	
2022	Commercial Launch	BD, CerTest Biotec announced Commercial Launch of Monkeypox Test.	
2022	Product Launch	BD Launched High-Throughput Molecular Combination Test for COVID-19 and Influenza A/B.	
2022	Product Launch	BD Launched Fully Automated, High-Throughput Infectious Disease Molecular Diagnostic Platform in the U.S.	



Year	Strategy	Description
2022	Strategic Partnership	Babson, BD expanded its strategic partnership to advance diagnostic blood collection in new care settings.
2022	Acquisition	BD expanded from Cancer Discovery and Diagnosis into Post-Treatment Monitoring with the Acquisition of Cytognos from Vitro S.A. Cytognos, a privately held company headquartered in Salamanca, Spain, specializing in flow cytometry solutions for blood cancer diagnosis, minimal residual disease (MRD) detection and immune monitoring research for blood diseases.
2022	FDA Approval	BD introduced Smart Connected Robotics to Automate Microbial Identification. BD received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the BD Kiestra IdentifA system, which is designed to automate the preparation of microbiology bacterial identification testing.

# BIO-RAD LABORATORIES INC.

1000 Alfred Nobel Drive Hercules, California, 94547 U.S.

Tel: +1-510-724-7000 Website: www.bio-rad.com

**Company Snapshot** 

Table 40
Bio-Rad Laboratories Inc.: Company Snapshot

Parameter	Information	
Ticker	NYSE: BIO	
Year Founded/Incorporated	1952	
Global Headquarters	California, U.S.	
Revenue 2023 (\$ Millions)	2,671.3	
Number of Employees (2023)	8,030	
Key Business Regions	U.S., Europe, Asia, Other (primarily Canada and Latin America)	
Primary Region/Country for Business	U.S.	
Main Business Segment	Life Science	
Entity Type	Public	
Ownership Type	Parent	

Source: Company website, annual reports, investor presentations and press releases



#### **Company Overview**

Bio-Rad primarily focuses on creating, producing and distributing cutting-edge products for the clinical diagnostic and life science research markets. Some of their clients are universities, research institutes, hospitals, commercial and public health laboratories, biotechnology, pharmaceutical companies and applied laboratories dealing with environmental quality and food safety.

The two primary business segments of Bio-Rad are Life Science and Clinical Diagnostics, which operate globally.

#### **Key Financial Highlights**

- Net sales decreased by 4.7% to \$2.67 billion for the year ending December 31, 2023, from \$2.80 billion for December 31, 2022. Comparing the year ended December 31, 2022, to the year ended December 31, 2023, COVID-related sales were roughly \$3.6 million instead of approximately \$109.2 million. On a currency-neutral basis, sales for the year ended December 31, 2023, fell by approximately 4.1% compared to the same period in 2022.
- Sales for the Clinical Diagnostics segment reached \$1.49 billion at the end of 2023, up 2.6% from
  the previous year's end of December 31, 2022. Increased demand, particularly in Asia-Pacific
  and EMEA, for diagnostic testing systems—diabetes, blood typing and quality control products—
  was the main driver of the currency-neutral sales increase. This was somewhat offset by a
  decline in infectious disease products and lower sales due to the sanctions against Russia.

#### **Financial Performance**

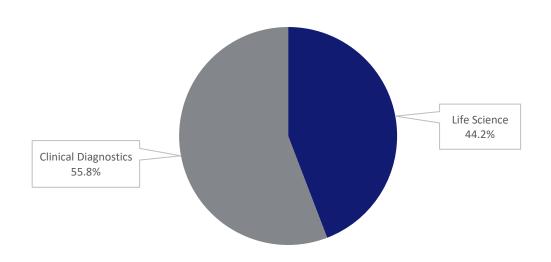
Table 41
Bio-Rad Laboratories Inc.: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	2,802.3	2,671.3
R&D Expenses	256.9	247.4
Operating Income	482.6	337.8
Net Income	-3,627.5	-637.3
Total Current Assets	3,158.0	3,048.3
Total Current Liabilities	568.7	522.8

Source: Company website; company annual report; and SEC filings

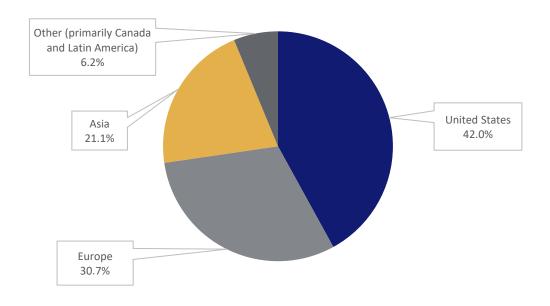


Figure 19
Bio-Rad Laboratories Inc.: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; SEC filings

Figure 20
Bio-Rad Laboratories Inc.: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; SEC filings



## **Product Portfolio**

Table 42
Bio-Rad Laboratories Inc.: Product Portfolio

Product/Category/Application	Description
	Bio-Plex 2200 ANA Screen with MDSS
	Bio-Plex 2200 APLS IgG
Multiplex diagnostics	Bio-Plex 2200 APLS IgM
	Bio-Plex 2200 APLS IgA Bio-Plex 2200 Vasculitis
	Bio-Plex 2200 Anti-CCP
Retrovirus	Genscreen ULTRA HIV Ag-AB Assay
	Genscreen ULTRA HIV Ag-AB Assay
	Genscreen HIV 1/2 Version 2 Assay
	Genscreen HIV 1/2 Version 2 Assay
	Genscreen HIV-1 Ag Assay
	Monolisa HAV IgM PLUSAssay
	Monolisa HBs Ag ULTRA Assay
	Monolisa HBs Ag ULTRA Assay
	Monolisa HBs Ag ULTRA Confirmatory Assay
	Monolisa Anti-HBs PLUSAssay
	Monolisa Anti-HBc PLUSAssay
Enzyme immunoassay (Hepatitis)	Monolisa Anti-HBc PLUSAssay
	Monolisa HBc IgM PLUSAssay
	Monolisa HBe Ag-AB PLUSAssay
	Monolisa HCV Ag-AB ULTRA V2 Assay
	Monolisa HCV Ag-AB ULTRA V2 Assay
	Monolisa Anti-HCV PLUSVersion 3 Assay
	Monolisa Anti-HCV PLUSVersion 3 Assay
	ETI-AB-DELTAK-2 HDV Total
	ETI-DELTAK-2 HDV Ag
	ETI-DELTA-IGMK-2 HDV IgM
	Monolisa Total Anti HAV PLUSAssay
	Platelia EBV-VCA IgM
Infectious mononucleosis	Platelia EBV-VCA IgG
	Platelia EBV-EA-D IgG
	Platelia EB-NA IgG
	Platelia VZV IgG
	Platelia VZV IgM
Pediatric diseases	Platelia Measles IgG
	Platelia Measles IgM
	Platelia Mumps IgG



Product/Category/Application	Description	
	Platelia Mumps IgM	
	Platelia Toxo IgG	
	Platelia Toxo IgM	
	Platelia Toxo IgA	
	Platelia Toxo IgG Avidity	
	Platelia Rubella IgG	
	Platelia Rubella IgM	
	Platelia CMV IgG	
	Platelia CMV IgM	
Prenatal and congenital diseases	Platelia CMV IgG Avidity	
(Torch)	Platelia CMV IgG	
	Platelia CMV IgM	
	CMV Total Antibody EIA	
	CMV Total Antibody EIA	
	Platelia HSV 1 IgG	
	Platelia HSV 2 IgG	
	Platelia HSV 1+2 IgM  Platelia HSV (1+2) IgG	
	Platelia HSV (1+2) IgM	
Respiratory diseases	Platelia Mycoplasma pneumoniae IgG	
	Platelia Mycoplasma pneumoniae IgM  Bio-Plex 2200 System, Elite, EVOLIS Systems (EVOLIS Premium System,	
Equipment	EVOLIS Twin Plus System, EVOLIS Software), PW 40 Microplate Washer,	
4. 6. 5. 5	IPS Microplate Incubator, Autoblot 3000, PhD lx System	
	Syphilis Total AB	
Sexually transmitted diseases	Syphilis Total AB	
	Syphilis Total EIA	
	Malaria EIA Assay	
	Malaria EIA Assay	
	Brucella IgG	
	Brucella IgM	
Febrile and tropical diseases	Syphilis Total EIA	
	Platelia Dengue NS1 Ag	
	Platelia Dengue IgA Capture	
	Platelia Dengue IgM Capture	
	Platelia Aspergillus Ag	
	Platelia Aspergillus IgG	
Fungal diseases	Platelia Candida Ag Plus	
	Platelia Candida AB Plus	
	Platelia Helicobacter pylori IgG	
Others infectious diseases	Platelia Rabies II	
	Platelia Lyme IgM	
	riacena zyme igiti	



Product/Category/Application Description	
	Platelia Lyme IgG
	Anti-dsNA
	ENA (+) Screen
	Anti-SS-a
	Anti-SS-B
	Anti-Sm
	Anti-SmRNP
Systemic	Anti-Scl-70
	Anti-Jo-1
	Anti-Screen
	ANA-6 Profile Test
	Anti-Centromere
	Kallestad Anti-Centromere
	Kallestad Anti-dsDNA
	Kallestad Anti-Thyroglobulin
Thyroid	Kallestad Anti-Thyroid Peroxidase (TPO)
	Anti-Myeloperoxidase (MPO)
	Anti-Proteinase 3 (PR3)
	Anti-Glomerular Basement Membrane (GBM)
Vasculitis	Kallestad Anti-Glomerular Basement Membrane
	Kallestad Anti-Myeloperoxidase (pANCA)
	Kallestad Anti-Proteinase 3 (cANCA)
	Anti-Cardiolipin IgG
	Anti-Cardiolipin IgM
	Anti-Cardiolipin IgA
	Anti-ß2 Glycoprotein I IgG
Antiphospholipid syndrome	Anti-ß2 Glycoprotein I IgM
	Anti-ß2 Glycoprotein I IgA
	Anti-Phosphatidylserine IgG
	Anti-Phosphatidylserine IgM
	Anti-Phosphatidylserine IgA
Autoimmune hepatitis	Kallestad Anti-Mitochondrial
	Anti-tissue Transglutaminase IgA
	Anti-tissue Transglutaminase IgG
	Anti-Gliadin IgA
Gastrointestinal test	Anti-Gliadin IgG
	Anti-Saccharomyces Cerevisiae Antibodies IgA
	Anti-Saccharomyces Cerevisiae Antibodies IgG
	HEp-2 IFA (HEp-2 Complete Kits, HEp-2 Components, ANA Controls)
Immunofluorescence assay (Autoimmune)	Anti-DNA IFA (Crithidia luciliae IFA Complete Kits, Crithidia luciliae IFA Components and dsDNA Control)



Product/Category/Application	Description
	Kallestad IFA assays (autoantibodies against cytoplasmic and perinuclear antigens (ANCA) [ANCA Complete Kit, ANCA Slides and Components ANCA Controls]
	Anti-Glomerular Basement Membrane (GBM)
	Rodent Tissues IFA (Mouse Complete Kits for anti-mitochondrial (AMA), anti-smooth muscle (ASMA), anti-parietal cell (APCA), Accessories, Tissue Controls and Components)
	Kallestad Monkey Tissue Autoimmune IFAs
	Rare Tissue Autoimmune IFA (Diabetes Assays, Pemphigus Assays, Rat Tissues, Monkey Tissues and Monkey Tissues – Accessories

News/ Key Developments

Table 43
Bio-Rad Laboratories Inc.: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Product Launch	Bio-Rad Laboratories Inc. launched annexin V conjugated to eight StarBright Dyes: SBUV400, SBUV795, SBV440, SBV515, SBV790, SBB675, SBB765 and SBY800.
2024	Expansion	Bio-Rad Laboratories Inc. announced the expansion of its Pioneer Antibody Discovery Platform services with the addition of fast generation and screening of bispecific antibodies based on the company's proprietary SpyLock Technology.
2023	Product Launch	Bio-Rad Laboratories Inc. launched the IH-500TM NEXT System, a fully automated system for ID cards.
2022	Product Launch	Bio-Rad Laboratories Inc. launched its CHT prepacked Foresight Pro Columns, designed to support downstream process-scale chromatography applications across different biological drug development and production stages.

Source: Company website



## BOSTON SCIENTIFIC CORP.

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Website: www.bostonscientific.com

### **Company Snapshot**

Table 44
Boston Scientific Corp.: Company Snapshot

Corporate Category	Information	
Ticker	NYSE: BSX	
Year Founded/Incorporated	1979	
Global Headquarters	Massachusetts, U.S.	
Revenue 2023 (\$ Millions)	14,240.0	
Number of Employees (2023)	48,000	
Key Business Regions	U.S.	
Primary Region/Country for Business	U.S., Europe, Middle East, Africa, Asia-Pacific, Latin America and Canada.	
Main Business Segment	Cardiovascular and Medsurg	
Entity Type	Public	
Ownership Type	Parent	

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Boston Scientific Corp. was founded in New York in 1979 and headquartered in Massachusetts, U.S. It manufactures and sells innovative medical devices. The company operates its business through two reportable segments, MedSurg and Cardiovascular while serving eight core businesses - Cardiac Rhythm Management, Electrophysiology, Endoscopy, Interventional Cardiology Therapies, Neuromodulation, Peripheral Interventions, Urology and WATCHMAN.

As of December 31, 2023, the company employed around 48,000 associates and had operations in around 140 countries globally, with a strong market presence in the U.S.

### **Key Financial Highlights**

- The company generated 12.3% growth in 2023 from 2022 in net sales, owing to the recent acquisitions in 2023.
- Targeted products lie in the company's reportable segments, MedSurg and Cardiovascular and both segments experienced an increase in net sales—10.4% and 12.6%, respectively, in 2023, compared to 6.0% and 8.1% in 2022.



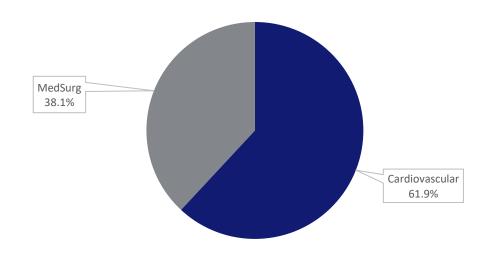
## **Company Financials**

Table 45
Boston Scientific Corp.: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	12,682	14,240
R &D	1,323	1,414
Operating Income	(1,649)	(2,343)
Net Income	(698)	(1,592)
Total Current Assets	5,760	6,514
Total Current Liabilities	3,803	4,933

Source: Company website; company annual report; and SEC filings

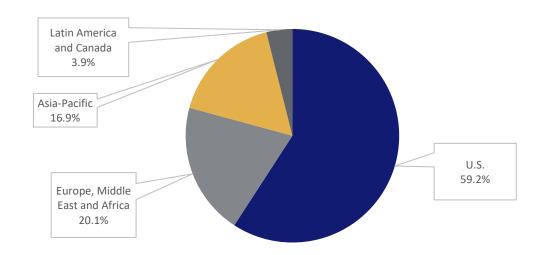
Figure 21
Boston Scientific Corp.: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; and SEC filings



Figure 22
Boston Scientific Corp.: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; and SEC filings



## **Product Portfolio**

Table 46
Boston Scientific Corp.: Product Portfolio

Segment/Category	Description
Cardiac rhythm management	a portfolio of products and solutions for the treatment of irregular heart rhythms, heart failure and to provide protection against sudden cardiac arrest.
Electrophysiology	Products that use technologies such as mapping catheters, radiofrequency energy and cryogenics to diagnose and treat heart rhythm disorders.
Endoscopy	Solutions and products that diagnose and treat diseases of the digestive system, airway and lungs.
Interventional cardiology	a set of devices, including drug-eluting stents, bare-metal stents, catheters, balloons, guide wires, coronary atherectomy and coronary intravascular ultrasound.
Neuromodulation	Therapies that use microelectronic implantable technologies to manage chronic neuropathic pain.
Peripheral interventions	Products that treat vascular system blockages in areas such as carotid and renal arteries and the lower extremities, including carotid artery stenting, embolic protection balloon catheters, vascular protection and renal solutions.
Urology and women's health	Devices and solutions, including endometrial ablation, holmium laser ablation of the prostate (HoLAP), stone retrieval/lithotripsy, pelvic floor reconstruction, mid-urethral slings and urethral bulking.

Source: Company website

# **News/Key Developments**

Table 47
Boston Scientific Corp.: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Acquisition	Boston Scientific announced an agreement to Acquire Silk Road Medical Inc.
2024	FDA Approval	Boston Scientific Receives FDA Approval for the AGENT Drug- Coated Balloon.
2024	FDA Approval	FDA approved Boston Scientific Spinal Cord Stimulator Systems for Treatment of Non-Surgical Back Pain.
2024	FDA Approval	Boston Scientific Received FDA Approval for FARAPULSE Pulsed Field Ablation System.
2024	Acquisition	Boston Scientific announced an agreement to acquire Axonics Inc. Axonics Inc., a medical technology company primarily focused on developing and commercializing differentiated devices to treat urinary and bowel dysfunction.



Year	Strategy	Description
2023	FDA Approval	Boston Scientific received FDA Approval of Spinal Cord Stimulation Therapy for People Living with Diabetic Peripheral Neuropathy.
2023	Acquisition	Boston Scientific announced an agreement to Acquire Relievant Medsystems Inc.
2023	FDA Approval	Boston Scientific received FDA Approval for the Latest- Generation WATCHMAN FLX Pro Left Atrial Appendage Closure Device.
2023	FDA Approval	Boston Scientific received FDA Approval for the POLARx Cryoablation System.
2023	FDA Approval	Boston Scientific received FDA Approval for the Next Innovation in Image Guided Programming Software for Deep Brain Stimulation.
2023	FDA Approval	Boston Scientific received FDA Clearance for LithoVue Elite Single-Use Digital Flexible Ureteroscope System.
2022	Investment	Boston Scientific announced a strategic investment to acquire the majority stake in Acotec Scientific Holdings Limited.
2022	Approval	The company received FDA approval for commercializing and marketing its WATCHMAN FLX LAAC Device for Dual Anti-Platelet Therapy as a Post-Procedural Medication Option.
2022	Acquisition	The company completed acquisition of Obsidio Inc., a U.Sbased company that has developed the Gel Embolic Material (GEM) technology used for embolization of blood vessels in the peripheral vasculature.
2022	Agreement	The company signed an agreement to purchase a majority stake of M.I.Tech Co. Ltd from Synergy Innovation Co. Ltd
2022	Approval	The company received FDA approval for the commercialization and marketing of its EMBOLD Fibered Detachable Coil
2022	Approval	The company received FDA approval for the commercialization and marketing of its latest image-guided programming software, Vercise Neural Navigator with STIMVIEW XT.
2022	Acquisition	The company acquired Baylis Medical Company Inc.

# **BRUKER**

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#### **Company Snapshot**

Table 48
Bruker: Company Snapshot

Parameter	Information
Ticker	NASDAQ: BRKR
Year Founded/Incorporated	1960
Global Headquarters	Massachusetts, U.S.
Revenue 2023 (\$ Millions)	2,964.5
Number of Employees (2023)	9,707
Key Business Regions	U.S., Europe, Asia-Pacific, Rest of world
Primary Region/Country for Business	U.S.
Main Business Segment	BSI Nano
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

## **Company Overview**

Bruker develops, produces and distributes high-performance scientific instruments as well as analytical and diagnostic tools that let users investigate materials and life at the microscopic, molecular and cellular levels. Detecting, measuring and visualizing the structural properties of chemical, biological and industrial material samples are common uses for many of their products. In the fields of life science research, pharmaceuticals, biotechnology, applied markets, cell biology, clinical research, microbiology, in-vitro diagnostics, nanotechnology and materials science research, their products and solutions meet the constantly changing needs of a wide range of clients.

Bruker Scientific Instruments (BSI) BioSpin, BSI CALID, BSI Nano and Bruker Energy & Supercon Technologies (BEST) are the company's four reportable segments. The company has direct sales representatives in China, Japan, Europe, North America and other Asia-Pacific countries. To reach customers, they also use indirect sales channels.

### **Key Financial Highlights**

- Revenue increased by \$433.8 million, or 17.1%, to \$2,964.5 million for the year that ended on December 31, 2023, from \$2,530.7 million for the comparable period in 2022. Organic revenue, a non-GAAP metric, increased by \$366.4 million, or 14.5% when the effects of changes in foreign exchange rates and recent acquisitions were revealed.
- For the year that ended on December 31, 2023, the gross profit margin dropped to 51.0% from 51.6% during the same period in 2022. This was mostly due to the unfavorable impact of fluctuations in foreign exchange rates, which was somewhat offset by improvements in mix, pricing and acquisitions when compared to 2022.



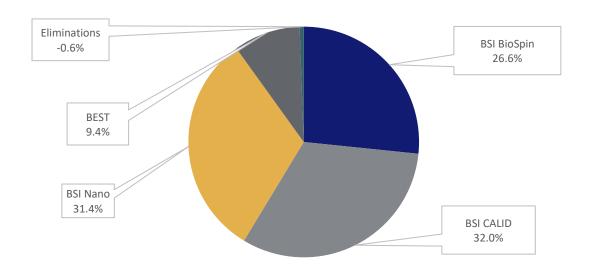
#### **Financial Performance**

Table 49
Bruker: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	2,530.7	2,964.5
R&D	235.9	294.8
Operating Income	432.7	436.9
Net Income	296.6	427.2
Total Current Assets	2,113.2	2,164.2
Total Current Liabilities	914.3	1,202.1

Source: Company website; company annual report; and SEC filings

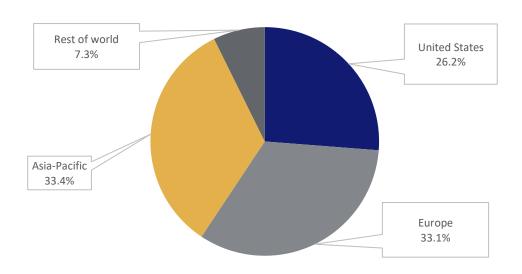
Figure 23
Bruker: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; SEC filings



Figure 24
Bruker: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; SEC filings

### **Product Portfolio**

Table 50 Bruker: Product Portfolio

Product/Category	Description	
Mass spectrometry and separations	<ul> <li>MALDI-TOF/TOF</li> <li>MALDI Biotyper Systems</li> <li>ESI-QqTOF</li> <li>ESI-ITMS</li> <li>ESI-Triple Quad-MS</li> <li>UHPLC and nanoLC for LC/MS</li> <li>GC-Triple Quad MS</li> <li>MRMS</li> <li>HDX Solution</li> <li>Toxtyper</li> <li>TargetScreener HR</li> <li>MS Software</li> </ul>	
Preclinical imaging	<ul> <li>MR Imaging</li> <li>Nuclear Molecular Imaging</li> <li>Magnetic Particle Imaging (MPI)</li> <li>microCT</li> </ul>	
Superconductors and metal composite materials	Cuponal	



Product/Category	Description
	Superconductors
Infrared, near-infrared and raman spectroscopy	<ul> <li>FT-IR Microscopes, Raman Microscopes</li> <li>FT-NIR Spectrometers</li> <li>FT-IR Routine Spectrometers</li> <li>FT-IR Research Spectrometers</li> <li>FTIR/NIR for Process</li> <li>Dairy Analyzers</li> <li>Gas Analysis</li> <li>Remote Sensing</li> <li>Terahertz</li> <li>Raman</li> <li>OPUS- Spectroscopy Software</li> </ul>
Fluorescence microscopes	<ul> <li>Ultima Multiphoton Microscopy</li> <li>Opterra Confocal Microscopy</li> <li>Vutara Super Resolution Microscopy</li> <li>Luxendo Light-Sheet Microscopy</li> </ul>
Molecular diagnostics	Real-Time PCR
X-ray diffraction and elemental analysis	<ul> <li>X-ray Fluorescence</li> <li>X-ray Diffraction</li> <li>Single Crystal X-ray Diffraction</li> <li>Small-Angle X-ray Scattering</li> <li>Handheld XRF</li> <li>LIBS</li> <li>Micro-XRF and TXRF</li> <li>X-ray Metrology</li> <li>EDS, WDS, EBSD, SEM Micro-XRF</li> <li>Optical Emission Spectrometry</li> <li>CS/ONH-Analysis</li> </ul>
Microtomography	<ul> <li>Micro-CT for Material Science</li> <li>Micro-CT for Life Science</li> <li>Micro-CT software</li> </ul>
Surface plasmon resonance	<ul><li>Sierra SPR-24</li><li>Sierra SPR-32</li></ul>
Magnetic resonance	<ul> <li>NMR</li> <li>MR in Pharma</li> <li>NMR Food Screening</li> <li>NMR Preclinical Screening</li> <li>EPR</li> <li>Preclinical MRI</li> <li>TD-NMR</li> <li>NMR Software</li> <li>EPR Software</li> </ul>
CBRNE detection	<ul> <li>CBRNet</li> <li>IMS</li> <li>GC-MS</li> <li>FT-IR</li> <li>Radiological Detection</li> </ul>
Arxspan laboratory software	<ul><li>Electronic Laboratory Notebook</li><li>Arxspan Assay</li></ul>



Product/Category	Description
	<ul><li>Arxspan Registration</li><li>Arxspan Inventory</li></ul>
Surface and dimensional analysis	<ul> <li>Atomic Force Microscopes</li> <li>3D Optical Microscopes</li> <li>Stylus Profilometers</li> <li>Nanomechanical Test Instruments</li> <li>Tribometers and Mechanical Testers</li> <li>Nanoscale Infrared Spectrometers</li> <li>Alicona Dimensional Metrology Systems</li> </ul>
Semiconductor metrology	<ul> <li>Automated AFM</li> <li>X-ray metrology for Silicon</li> <li>X-Ray Metrology for Compound Semiconductor</li> <li>X-Ray Defect Inspection</li> <li>Process Equipment</li> <li>Photomask Repair</li> </ul>

**News/ Key Developments** 

Table 51
Bruker: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Product Commercialization	Bruker Corp. announced the successful installation and acceptance of a 1.2 GHz Avance Nuclear Magnetic Resonance (NMR) spectrometer at the Korea Basic Science Institute (KBSI). As the first 1.2 GHz NMR system in the Asia-Pacific region, it sets a new benchmark for molecular, cell biology and disease research using ultra-high-field NMR.
2024	Collaboration	Bruker and NovAliX collaborate strategically to develop novel drug discovery technologies and methods, intending to enable new paradigms in leveraging biophysical methods for drug discovery.
2024	Product Launch	Bruker launched Transformative neofleX MALDI-TOF System for Spatial Biology Mass Spec Imaging (MSI) Applications.
2024	Product Launch	Bruker launched Ultimate Sensitivity timsTOF Ultra 2 to Enable New Research Paradigms in Single-Cell and Subcellular Proteomics.
2024	Asset Acquisition	Bruker Corp. closed its asset acquisition of the NanoString Technologies Inc. business, headquartered in Seattle, Washington. NanoString Technologies is a leading provider of life-science research solutions for spatial transcriptomics and gene expression analysis.
2024	Acquisition	Bruker Corp. acquired ELITechGroup ("ELITech") for €870 million in cash, excluding the carved-out ELITech clinical chemistry business. ELITech is a differentiated, fast-growing and profitable provider of systems and assays for molecular diagnostics (MDx), biomedical systems/specialty IVD and microbiology, with FY 2023 revenue of



Year	Strategy	Description
		approximately EUR 150 million and more than 80% consumables revenue.
2024	Acquisition	Bruker acquired Spectral Instruments Imaging, the performance leader in preclinical in-vivo optical imaging systems. This acquisition fills a gap in the technology and Product Portfolioof the Bruker BioSpin Preclinical Imaging (PCI) division, broadening its range of preclinical solutions for disease research.
2024	Acquisition	Bruker Corp. announced a definitive agreement to acquire Chemspeed Technologies AG, a Swiss provider of vendor-agnostic automated laboratory R&D and QC workflow solutions. Chemspeed is focused on modular automation and robotics solutions for chemical research, pharmaceutical drug formulation, materials research for cleantech and consumer applications.
2024	Acquisition	Bruker acquired Nion, a privately held company that develops and manufactures innovative high-end scanning transmission electron microscopes (STEM). Nion was the first company to introduce aberration correction for STEM instruments with ultra-high stability for the highest-resolution images. It is also the world leader in ultra-high energy and spatial resolution electron energy-loss spectroscopy (EELS).
2023	Acquisition	Bruker Corp. announced that it has completed the acquisition of PhenomeX, a leading provider of single-cell biology research tools, for \$108 million in cash.
2023	Innovation	Bruker Corp. announced the release of the Hysitron TI 990 Tribolndenter, which brings superior performance, automation and productivity to nanomechanical testing.
2023	Innovation	Bruker Corp. introduced novel technology and improved mass spec workflows to meet the applied markets' requirements for robustness, ease of use and highest confidence in food/beverage, forensic/toxicology, industrial and environmental analysis.
2023	Product Launch	Bruker launched the timsTOF Ultra Mass Spectrometer with Transformative Sensitivity, 300 Hz PASEF MS/MS and VistaScan for Enhanced dia-PASEF 4D proteomics.
2023	Acquisition	Bruker Corp. closed the acquisition of ZONTAL Inc. (www.zontal.io), an innovative platform provider for the digital transformation of the analytical laboratory and integrated biopharma technical data solutions.
2023	Collaboration	Bruker Corp. launched significant bioinformatics for 4D proteomics on the timsTOF platform. In collaboration with Rapid Novor Inc., a novel de novo sequencing algorithm was developed, using over 1.7 million PASEF data points to improve accuracy and speed for immunopeptidomics in real-time.
2023	Acquisition	Bruker Corp. announced the acquisition of ACQUIFER Imaging GmbH, a pioneer in big-data management solutions for bioimaging and high-content microscopy.
2022	Acquisition	Bruker Corp. had signed the definitive agreement to purchase 100% of Neurescence Inc.'s shares. Neurescence Inc. is an innovative ultralight fiber-bundle Multiscopes provider for simultaneous multiregion, optical functional neuroimaging.
2022	Acquisition	Bruker Corp. had announced the acquisition of Inscopix Inc., a neuroscience pioneer and market leader of miniaturized microscopes, known as miniscopes, for freely moving animal brain imaging.



Year	Strategy	Description
2022	Product Launch	Bruker Corp. announced further advances in its market-leading MALDI Biotyper (MBT) platform and launched new multiplex PCR infectious disease assays that are based on its proprietary LiquidArray technology.
2022	Acquisition	Bruker Corp. acquired Prolab Instruments GmbH, a Swiss technology company specializing in low-flow, high-precision liquid chromatography technology and systems.

## CARDINAL HEALTH

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Website: www.cardinalhealth.com

### **Company Snapshot**

Table 52
Cardinal Health: Company Snapshot

Corporate Category	Information
Ticker	NYSE: CAH
Year Founded/Incorporated	1971
Global Headquarters	Ohio, U.S.
Revenue 2023 (\$ Millions)	205,012
Number of Employees (June, 2024)	48,900
Key Business Regions	U.S. and International
Primary Region/Country for Business	U.S.
Main Business Segment	Pharmaceutical
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

### **Company Overview**

Cardinal Healthis a distributor of pharmaceuticals, a global manufacturer and distributor of medical and laboratory products and a provider of performance and data solutions for healthcare facilities. The company manages its business in two segments: Pharmaceutical and Medical. The Medical segment manufactures, sources and distributes Cardinal Health branded medical, surgical and laboratory products sold in North America, Europe, Asia and other markets. The company's pharmaceutical



segment distributes branded and generic drugs, specialty drugs and over-the-counter (OTC) healthcare and consumer products in the U.S.

The Pharmaceutical segment's Nuclear and Precision Health Solutions division operates more than 130 nuclear pharmacies and 30 PET biomarker manufacturing facilities, which manufacture, formulate and deliver PET and SPECT radiopharmaceuticals in healthcare facilities in the U.S. The Pharmaceutical segment also contract manufactures Xofigo (radium Ra 223 dichloride) and holds the North American rights to manufacture and distribute Lymphoseek (technetium Tc 99m tilmanocept). The company is also the exclusive U.S. distributor of the IRE ELIT Galli Eo 68 Ge/68 Ga generator.

## **Key Financial Highlights**

- For fiscal year 2023, Cardinal Health's medical devices segment showed mixed performance. The
  Medical segment generated \$15.0 billion in revenue, a 5% decline from the previous year,
  primarily due to decreased demand and lower pricing for personal protective equipment (PPE).
  However, the segment's profit improved to \$111 million, down 49% year-over-year, but notably
  rebounded in the fourth quarter with \$82 million in profit, compared to a \$16 million loss in the
  prior year.
- In FY 2023, the pharmaceutical segment profit increased, primarily driven by the positive performance of its generics program and an increased contribution from branded and specialty drugs.

#### **Financial Performance**

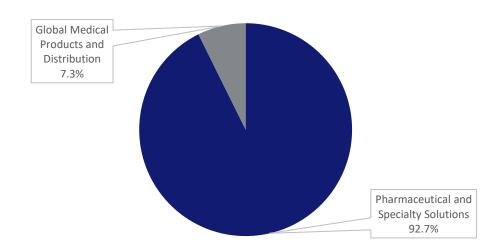
Table 53
Cardinal Health: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	181,364	205,012
Operating Income	(596)	727
Net Income	(932)	262
Total Current Assets	33,737	34,884
Total Current Liabilities	33,740	35,640

Source: Company website; company annual report; and SEC filings

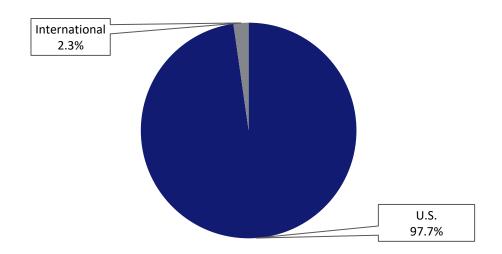


Figure 25
Cardinal Health: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; SEC filings

Figure 26
Cardinal Health: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; SEC filings



### **Product Portfolio**

Table 54
Cardinal Health: Product Portfolio

Product	Description	
Medi-Vac suction canister systems	A portfolio of suction canister systems: CRD Flex Advantage liners, Guardian suction systems and Guardian Large Volume Collection (LVC) canisters in different sizes and varieties to meet suction collection needs.	
Medi-Vac suction tubing and Medi-Vac suction handles	Sterile suction tubing and handles in various sizes with features to meet varied needs.	
Medi-Vac plastic connector products	A range of sterile and nonsterile connectors, available in different sizes.	
SAF-T pump system	The SAF-T pump system empties canisters containing infectious liquid medical waste directly into the sanitary sewer.	
Pulse Wave laparoscopic suction/irrigation system	The system includes the Pulse Wave pump, a handheld trumpet valve and Primeflo insufflation tubing.	
Diagnostic procedure trays	Components may include safety scalpels, hypodermic needles, particulate matter filters for drawing medication from glass ampules and needle blocks for sharps safety.	
MYNX Ace	Vascular closure device to achieve hemostasis securely adheres to arteriotomy and dissolves within 30 days.	
MYNXGrip	A vascular closure device with the proprietary GRIP sealant is also indicated to close femoral venous access sites.	
Flash Ostial System	Dual Balloon Angioplasty Catheter to overcome challenges of aorto-ostial stenting.	

Source: Company website

# **News/ Key Developments**

Table 55
Cardinal Health: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Expansion	Cardinal Health opened a distribution center in Greenville, South Carolina.
2024	Expansion	Cardinal Health expands its medical product distribution footprint in Northeast Ohio.
2024	Approval	Cardinal Health announced that the company has received the Science Based Targets Initiative (SBTi) approval for its near-term science-based greenhouse gas (GHG) emissions reduction targets. Targets are considered science-based if they align with what the latest climate science says is necessary to limit global warming to 1.5°C above pre-industrial levels.



Year	Strategy	Description
2024	Acquisition	Cardinal Health will acquire Specialty Networks and its PPS Analytics platform, a technology-enabled multi-specialty group purchasing and practice enhancement organization.
2023	Product Launch	Cardinal Health launched SmartGown EDGE Breathable Surgical Gown with ASSIST Instrument Pockets.
2024	Product Launch	Cardinal Health launched Kangaroo OMNI Enteral Feeding Pump. Kangaroo OMNI Enteral Feeding Pump is designed to help provide enteral feeding patients with more options to meet their personalized needs throughout their enteral feeding journey.
2023	Product Launch	Cardinal Health launched a Next Generation Medical Device to Improve Neonatal Feeding.
2023	Innovation	Cardinal Health launched the Stray Away Hair Management Drape in collaboration with MedStar Health's Institute for Innovation.
2023	Collaboration	Cardinal Health's Outcomes business collaborates with Signify Health to offer in-home medication therapy management.
2022	Approval	The company received FDA approval to commercialize and market its latest image-guided programming software, Vercise Neural Navigator with STIMVIEW XT.
2022	Acquisition	The company acquired Baylis Medical Company Inc.

# COCHLEAR LTD.

1 University Avenue Macquarie University New South Wales, 2109 Australia

Tel: +61-2-9428-6555

Website: www.cochlear.com



#### **Company Snapshot**

Table 56
Cochlear Ltd.: Company Snapshot

Corporate Category	Information
Ticker	ASX: COH
Year Founded/Incorporated	1981
Global Headquarters	New South Wales, Australia
Revenue 2023 (\$ Millions)	1,549.8
Number of Employees (2024)	5,000
Key Business Regions	Americas, Europe, Middle East and Africa and Asia-Pacific
Primary Region/Country for Business	Americas
Main Business Segment	Cochlear Implants and Acoustics
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

### **Company Overview**

Cochlear Ltd. is an Australian-based hearing implant company that focuses on addressing hearing loss globally. It is one of the pioneering manufacturers of implantable hearing solutions, collaborating with over 100 research programs. Specializing in hearing loss treatments, the company's flagship product is the cochlear implant, designed for individuals with moderate to profound hearing impairment. Founded in 1981, Cochlear has expanded its product offerings to include bone conduction implants and acoustic implants. The company focuses on innovation, investing heavily in research and development. Its products are widely adopted in both pediatric and adult populations, contributing significantly to quality of life by restoring hearing function.

The company employs around 4,800 associates based in 50 countries and operates in around 180 countries globally, with six manufacturing locations.

#### **Key Financial Highlights**

- The company's net sales increased by 19% in 2023 compared to 2022. This revenue increase is due to the sales of cochlear implants (units), which is 16%, i.e., 44,156 units in 2023.
- The company's targeted products are Cochlear implants and Acoustics and both segments experienced increases in net sales of 21% and 19%, respectively, in 2023.



## **Company Financials**

Table 57
Cochlear Ltd.: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	1,316.4	1,480.7
R&D	164.8	181.6
Operating Income	266.6	331.0
Net Income	205.4	253.5
Total Current Assets	916.4	952.1
Total Current Liabilities	389.1	414.1

<sup>\*</sup>AUD to USD converted 2023 averages 0.655682 and 2022 average 0.6731

Source: Company website; company annual report; and SEC filings

Figure 27
Cochlear Ltd.: Revenue Share, by Business Unit, FY 2023
(%)

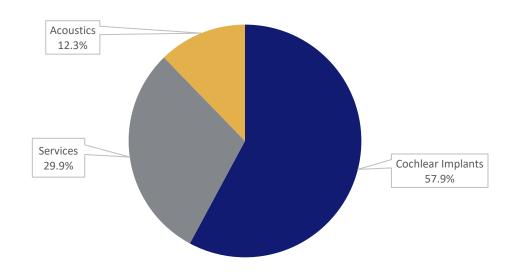
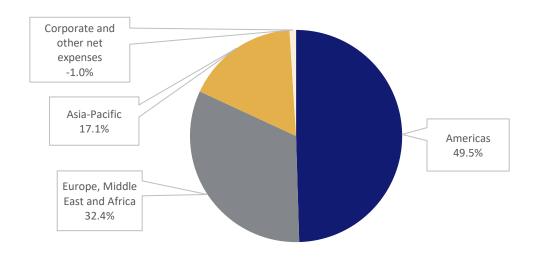




Figure 28
Cochlear Ltd.: Revenue Share, by Country/Region, FY 2023
(%)



#### **Product Portfolio**

Table 58
Cochlear Ltd.: Product Portfolio

Segment/Category	Description	
Cochlear Implants	<ul> <li>Cochlear Nucleus Implants: These advanced cochlear implants provide hearing for individuals with severe to profound hearing loss. They convert sound into electrical signals, stimulating the auditory nerve.</li> <li>Cochlear Nucleus 7: The first smart cochlear implant that connects directly to smartphones, allowing users to stream audio and adjust settings via an app.</li> </ul>	
Bone Conduction Solutions		



Segment/Category	Description	
Hearing Aids & Accessories	<ul> <li>Cochlear True Wireless Hearing Aids: Although less central to their product line, Cochlear also offers hearing aids designed for various levels of hearing loss, incorporating advanced sound processing technology.</li> <li>Cochlear Wireless Accessories: A range of accessories that enhance the listening experience, including remote microphones and TV streamers that connect with cochlear implants and hearing aids.</li> </ul>	

**News/Key Developments** 

Table 59
Cochlear Ltd.: News/Key Developments, 2022-2024

Year	Strategy	Description	
2024	FDA Clearance	Cochlear received FDA clearance to lower the age for the Osia System to 5 years old.	
2023	ISO/IEC 27001 certification	Cochlear is the first manufacturer to receive ISO/IEC 27001 certification for information security management.	
2022	FDA Clearance	FDA-approved Cochlear Nucleus Implants for unilateral hearing loss/single-sided deafness.	
2022	FDA Clearance	FDA approved Cochlear's Nucleus 8 Sound Processor, smaller, smarter, better connected cochlear implant technology.	

Source: Company website

## DANAHER CORP.

2200 Pennsylvania Avenue, Northwest Suite 800W Washington, District of Columbia 20037-1701 U.S.

Tel: +1-202-828-0850

Website: www.danaher.com



#### **Company Snapshot**

Table 60
Danaher Corp.: Company Snapshot

Corporate Category	Information
Ticker	NYSE: DHR
Year Founded/Incorporated	1984
Global Headquarters	Washington, D.C., U.S.
Revenue 2023 (\$ Millions)	23,890
Number of Employees (2023)	63,000
Key Business Regions	North America
Primary Region/Country for Business	North America and Western Europe
Main Business Segment	Diagnostics
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

### **Company Overview**

Danaher Corp. develops, manufactures and markets medical, industrial and commercial products and services in major markets. It operates its manufacturing facilities in more than 60 countries and employs 63,000 people in manufacturing, research and development, sales, distribution and administrative services. Headquartered in the U.S., Danaher is in more than 125 countries. It generates revenues through five key segments: test and measurement, environmental, dental, life sciences and diagnostics and industrial technologies.

Danaher distributes its products from key brands, such as Molecular Devices, AB Sciex, Radiometer, Leica Microsystems and Beckman Coulter. The products are distributed under Danaher's Life Sciences and Diagnostics segment, which incorporates chromatography analysis.

### **Key Financial Highlights**

 In 2023, the company's total segment sales decreased by 11.5% due to lower sales in molecular diagnostics tests. The lower sales were observed in North America and to a lesser extent in Western Europe. Core sales of clinical diagnostics businesses grew in North America and China. Moreover, the price of the segmental products increased in 2023, contributing 1% to sales growth compared to 2022.



#### **Financial Performance**

Table 61
Danaher Corp.: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	26,643	23,890
R &D	(1,528)	(1,503)
Operating Income	7,146	5,044
Net Income	7,209	4,764
Total Current Assets	15,883	13,937
Total Current Liabilities	8,389	8,274

Source: Company website; company annual report; and SEC filings

Figure 29
Danaher Corp.: Revenue Share, by Business Unit, FY 2023
(%)

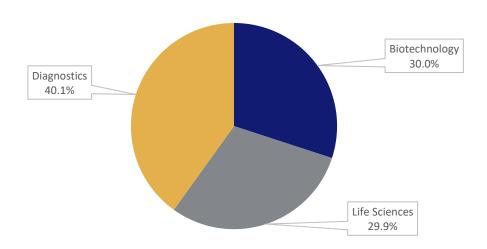
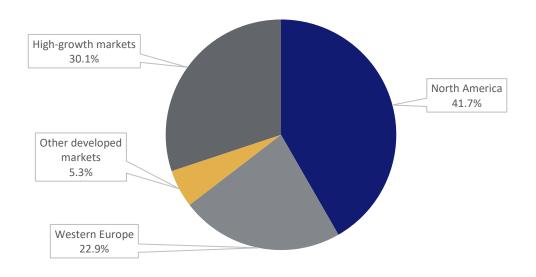




Figure 30
Danaher Corp.: Revenue Share, by Country/Region, FY 2023
(%)



## **Product Portfolio**

Table 62
Danaher Corp.: Product Portfolio

Segment/Category	Description	
AB SCIEX TripleTOF 5600 system	The system integrates qualitative exploration, rapid profiling and high-resolution quantitation workflows on a single platform.	
AB SCIEX Triple Quad 5500 LC/MS/MS system	Triple quadrupole mass spectrometer designed to deliver sensitivity and robustness for complex and demanding matrices.	
Beckman Coulter CESI 8000	Based on front-end separation and ionization technology called CESI, which fully integrates high efficiency and ultra-low flow characteristics of capillary electrophoresis (CE) with electrospray ionization (ESI) in a single process within the same device.	
Leica Biosystems routine and special staining	Both the Leica ST5010 and ST5020 are available as standalone instruments or as workstation solutions.	
Leica Biosystems bond IHC/ISH instruments	Combination of Leica BOND automated IHC and ISH stainers with Novocastra reagents for high-definition staining.	
Leica Biosystems pathology imaging	A product range for each step in the pathology process, from sample preparation and staining to imaging and reporting.	
Leica Microsystems premium surgical microscope Leica M720 OH5	Microscope for neurosurgery, otolaryngology and reconstructive microsurgery.	



Segment/Category	Description	
Molecular Devices IonWorks Barracuda Plus system	A solution for voltage and ligand-gated ion channel research for drug discovery screening and safety assessment.	
Molecular Devices FLIPR Tetra high-throughput cellular screening system	Real-time kinetic cellular assay screening system to identify early leads against GPCR and ion channel receptors.	
Molecular Devices Image- Xpress Ultra-Confocal high- content screening system	A solution for research-quality images of fixed- or live-cell assays.	
Radiometer ABL90 FLEX blood gas analyzer	Explicitly designed for demanding hospital wards such as the ICU, the NICU and the emergency department.	
Radiometer AQT90 FLEX analyzer	Immunoassay analyzer offering a cardiac panel and markers for coagulation, infection and pregnancy.	
Radiometer Transcutaneous monitoring systems	A portfolio of patient ventilation and oxygenation monitoring systems.	

## **News/ Key Developments**

Table 63
Danaher Corp.: News/Key Developments, 2022-2024

Year	Strategy	Description	
2024	Expansion	Danaher announced Two New Centers of Innovation in Diagnostics to Transform Precision Medicine Development.	
2024	Collaboration	Danaher launched Beacon Research, a Collaboration with Stanford University, to Build the Next Generation of Smart Microscopes for Cancer Drug Screening.	
2024	Collaboration	Danaher launched a collaboration with Johns Hopkins University, aiming to Improve Neurological Diagnosis.	
2024	Collaboration	Danaher launched a Collaboration with Cincinnati Children's Hospital Medical Center, Aiming to Improve Patient Safety in Early Drug Development.	
2023	Acquisition	Danaher completed the Acquisition of Abcam.	
2023	Partnership	Danaher Partnered with the University of Pennsylvania's Center for Cellular Immunotherapies to Address Manufacturing Challenges Impacting the Uptake of Cell Therapies.	

Source: Company website



#### DEXCOM INC.

6340 Sequence Drive San Diego, California 92121 U.S.

Tel: +1-858-200-0200 Website: www.dexcom.com

#### **Company Snapshot**

Table 64

Dexcom Inc.: Company Snapshot

Corporate Category	Information
Ticker	NASDAQ: DXCM
Year Founded/Incorporated	1999
Global Headquarters	California, U.S.
Revenue 2023 (\$ Millions)	3,622.3
Number of Employees (2023)	9,600
Key Business Regions	U.S., International
Primary Region/Country for Business	U.S.
Entity type	Public
Ownership type	Parent

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Dexcom Inc. is a prominent medical device company specializing in continuous glucose monitoring (CGM) systems for people with diabetes. Founded in 1999 and headquartered in San Diego, California, Dexcom's core product line focuses on devices that provide real-time glucose monitoring, primarily for individuals with Type 1 and Type 2 diabetes. The company's flagship product, the Dexcom G6 CGM system, continuously tracks glucose levels using a small sensor inserted under the skin. It transmits data wirelessly to a smartphone or receiver, allowing users to manage their blood sugar levels more effectively.

Dexcom's CGM technology eliminates the need for routine fingerstick and provides actionable data that helps patients and healthcare providers optimize diabetes treatment. The G6 system is particularly known for its accuracy, ease of use and integration with other diabetes management technologies, such as insulin pumps. Dexcom also recently introduced the Dexcom G7, which offers a smaller, more discreet sensor with enhanced features, further improving patient comfort and usability. Through ongoing innovation, Dexcom has established itself as a leader in diabetes management, offering lifechanging technology to millions of people globally.



#### **Key Financial Highlights**

- Dexcom's financial performance in 2023 demonstrated robust commercial growth, driven by expanded coverage and rising global awareness of its continuous glucose monitoring (CGM) systems. The company achieved \$3.62 billion in revenue, reflecting a substantial increase of over \$700 million compared to 2022, marking a 24% growth year-over-year.
- In 2023, Dexcom successfully enhanced operating margins despite scaling up production of its Dexcom G7 system and launching a new manufacturing facility in Malaysia. As the company enters 2024, it is well-positioned financially to continue pursuing key business goals and invest in strategic growth opportunities.

#### **Financial Performance**

Table 65
Dexcom Inc.: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	2,909.8	3,622.3
R&D	484.2	505.8
Operating Income	391.2	597.7
Net Income	341.2	541.5
Total Current Assets	3,668.8	4,425.9
Total Current Liabilities	1,839.3	1,556.0



Figure 31
Dexcom Inc.: Revenue Share, by Sales Channel, FY 2023
(%)

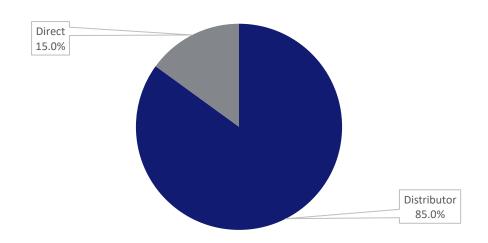
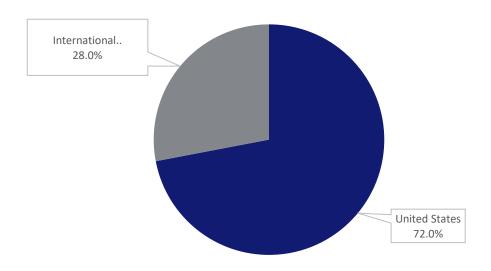


Figure 32
Dexcom Inc.: Revenue Share, by Country/Region, FY 2023
(%)





## **Product Portfolio**

Table 66
Dexcom Inc.: Product Portfolio

Segment/Category	Description	
Dexcom G6	A user-friendly CGM that provides real-time glucose readings and alerts without needing a fingerstick, featuring a small sensor worn on the abdomen or arm.	
Dexcom G7	The next-generation CGM is designed for improved accuracy and faster warm-up time. It has a sleek design and enhanced integration with other devices and apps.	
Dexcom ONE	Dexcom ONE is a continuous glucose monitoring (CGM) system designed for simplicity and ease of use. It provides real-time glucose readings, alerts for high and low levels and features a user-friendly app for tracking trends.	
Dexcom Real-Time API	The Dexcom Real-Time API allows developers to access and integrate real-time glucose data from Dexcom CGM devices into their applications. This API enables seamless data sharing for better diabetes management and provides features like alerts, trends and historical data analysis.	
Dexcom Share	The Dexcom Share remote monitoring system, compatible with all current Dexcom devices, utilizes an app on the patient's compatible iPhone, iPod touch, iPad, or Android mobile device to securely and wirelessly transmit glucose data to the cloud. This information is then accessible to up to five designated recipients, who can remotely monitor the patient's glucose levels and receive alert notifications wherever they have a wireless connection.	
Dexcom Stelo	The company is pursuing regulatory approvals for Dexcom Stelo, the first product designed specifically for people with type 2 diabetes who do not use insulin and are not at risk for hypoglycemia. Stelo was submitted for FDA review in the fourth quarter of 2023.	

Source: Company website

**News/ Key Developments** 

Table 67
Dexcom Inc.: News/Key Developments, 2022-2024

Year	Strategy	Description	
2024	Product Launch	Stelo by Dexcom, the first over-the-counter glucose biosensor in the U.S., is now on the market.	
2024	Product Launch	Dexcom has launched Dexcom One+ and introduced advanced diabetes management technology to a broader audience.	
2023	Product Commercialization	The Next-Generation Dexcom G7 Continuous Glucose Monitoring System was made available in Canada. Dexcom G7 is available for people with all types of diabetes ages two and older, giving more Canadians than ever access to a simple, accurate and effective diabetes management solution.	



Year Strategy		Description	
2023	Product Commercialization	Dexcom Inc. has launched its Dexcom G6 CGM System in Singapore for individuals with diabetes aged two and older, including pregnant women. DKSH Singapore Pte Ltd has also been appointed sales, marketing and distribution service provider.	
2022	FDA Clearance	Dexcom G7 received FDA Clearance, the most Accurate Continuous Glucose Monitoring System cleared in the U.S.	
2022	Product Launch	Dexcom G7 launched in the UK, Ireland, Germany, Austria and Hong Kong. Initiated global Rollout of the World's Most Powerful Continuous Glucose Monitoring System.	

## **DENTSPLY SIRONA**

13320-B, Ballantyne Corporate Place Charlotte, North Carolina, 28277 U.S.

Tel. +1-800-877-0020

Website: www.dentsplysirona.com

### **Company Snapshot**

Table 68
Dentsply Sirona: Company Snapshot

Corporate Category	Information
Ticker	NASDAQ: XRAY
Year Founded/Incorporated	1899
Global Headquarters	North Carolina, U.S.
Revenue 2023 (\$ Millions)	3,965.0
Number of Employees (2023)	15,000
Key Business Regions	U.S.
Primary Region/Country for Business	U.S., Europe, Rest of the World
Main Business Segment	Dental Equipment
Entity Type	Public
Ownership Type	Independent

Source: Company website, annual reports, investor presentations and press releases

## **Company Overview**

Dentsply Sirona is a leading global manufacturer of dental equipment and consumables, headquartered in North Carolina. With factories in 21 countries, the company markets its products in over 120 countries worldwide. Formed in 2016 through the merger of Dentsply International, founded in 1899 and Sirona Dental Systems, established in 1877, Dentsply Sirona operates under the brand name "The



Dental Solutions Co." and is currently the largest manufacturer of dental products and equipment globally. The company consists of 51 divisions, most of which function regionally.

Dentsply Sirona's imaging portfolio includes 2D and 3D extraoral units, large field of view CBCT and intraoral imaging systems designed for integrated dental specialty treatment. The company invests heavily in innovation, new product development and clinical education, with the Dentsply Sirona Academy educating approximately 350,000 dentists annually, thereby driving technological advances in the field. Its diversified geographical reach and product portfolio provide a competitive advantage. However, political instability and slow growth in the U.S. dental market may negatively affect revenue and hinder growth. The company maintains a strong presence in the European market, particularly in Germany, Sweden, France, the U.K., Switzerland, Italy and Canada, as well as significant market share in the Commonwealth of Independent States, Central and South America, the Middle East and the Pacific Rim.

### **Key Financial Highlights**

- Dentsply Sirona has consistently reported substantial revenues, often exceeding \$3 billion annually, driven by a diverse product portfolio and a broad geographical presence.
- The company typically maintains healthy operating margins, often 20-25%, reflecting efficient
  operations and strong demand for its products. Dentsply Sirona allocates a significant portion of
  its revenue to research and development, often around 5-6%, to foster innovation and new
  product development.

#### **Financial Performance**

Table 69
Dentsply Sirona: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	3.922	3,965
R &D	174	184
Operating Income	(937)	(85)
Net Income	(950)	(132)
Total Current Assets	1893	1,973
Total Current Liabilities	1,170	1,425



Figure 33
Dentsply Sirona: Revenue Share, by Business Unit, FY 2023
(%)

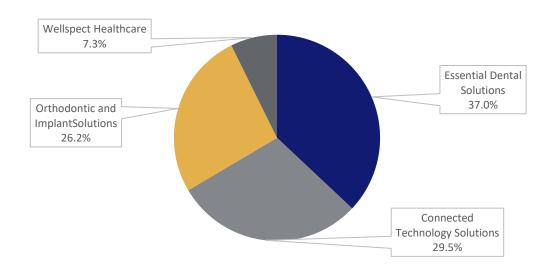
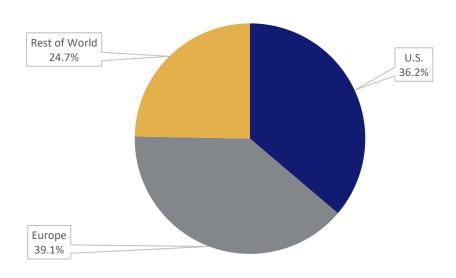


Figure 34
Dentsply Sirona: Revenue Share, by Country/Region, FY 2023
(%)





## **Product Portfolio**

Table 70
Dentsply Sirona: Product Portfolio

Segment/Category	Description	
Imaging Products	<ul> <li>Orthophos CBCT: Cone beam computed tomography systems that provide 3D imaging for precise diagnostics and treatment planning in dentistry, enhancing the accuracy of procedures.</li> <li>Cameron Intraoral Cameras: High-resolution cameras allow dentists to capture detailed images of a patient's oral cavity, aiding in diagnostics and patient education.</li> </ul>	
CAD/CAM Solutions	<ul> <li>CEREC System: A digital chairside solution that allows dentists to design, create and place custom dental restorations in a single appointment, improving patient convenience and outcomes.</li> <li>inLab Software: Comprehensive CAD software for dental laboratories, enabling the design and production of dental prosthetics and restorations with high precision</li> </ul>	
Restorative Products	<ul> <li>Filtek Universal Restorative: A range of composite resins used for direct restorations in anterior and posterior teeth, offering aesthetic results and durability.</li> <li>Dentsply Sirona's Dentin Adhesives: Adhesive systems designed to bond dental materials to tooth structure, ensuring strong and lasting restorations</li> </ul>	
Endodontic Products	ProTaper Next Files: Advanced rotary instruments used in root canal treatments, designed for efficient and effective cleaning and shaping of root canals.	
Preventive Products	Nupro Prophy Paste: A dental polishing paste used in professional cleanings, available in various flavors and formulas to meet patient preferences.	
Surgical Products	X-Smart Plus: A rotary endodontic motor used for root canal procedures, providing precise control and efficiency during treatment.	

Source: Company website



## **News/ Key Developments**

Table 71
Dentsply Sirona: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Innovation	Dentsply Sirona introduced Primescan 2 powered by DS Core: The first cloud-native intraoral scanning solution.
2024	Partnership	Dentsply Sirona partnered with Alexandria University in Egypt to develop innovative dental facilities.
2024	Innovation	Dentsply Sirona's open cloud platform offers lab-focused features for efficient collaboration and intelligent workflows.
2024	Collaboration	Dentsply Sirona and Siemens Healthineers develop the first dental-dedicated MRI system.
2024	Product Launch	Dentsply Sirona launched the Lucitone Digital Print Denture System for digital denture manufacturing with Primeprint Solution.
2024	Partnership	Dentsply Sirona partnered with iADH to increase dental care access for disabled people.
2023	Expansion	Dentsply Sirona announced the expansion of its DS Academy clinical education with the launch of the new DS Campus.
2023	Partnership	Dentsply Sirona Signed New Partnership with the National Dental Association to Promote Diversity in Dental Education
2022	Partnership Dentsply Sirona and Amazon Doctors marked five years of partnership to provide dental care to Brazilian indigenous communities.	
2022	Partnership	Dentsply Sirona announced a strategic partnership with the Platform for Better Oral Health in Europe.

Source: Company website

# DRAGERWERK AG & CO. KGAA

Moislinger Allee 53–55 23558 Lübeck Germany

Tel: +49-451-882-2685 Website: www.draeger.com



#### **Company Snapshot**

Table 72
Drägerwerk AG & Co. KGaA: Company Snapshot

Corporate Category	Information
Ticker	ETR: DRW3
Year Founded/Incorporated	1889
Global Headquarters	Lübeck, Germany
Revenue 2023 (\$ Millions)	3,648.7
Number of Employees (2023)	16,329
Key Business Regions	Europe, Americas, Africa, Asia and Australia
Primary Region/Country for Business	Europe
Main Business Segment	Safety division
Entity Type	Public
Ownership Type	Subsidiary

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Drägerwerk AG & Co. KGaA manufactures medical and safety equipment for clinical and industrial applications. It provides its product offerings through two business divisions: the medical and safety divisions. The medical division includes products for acute point of care (APOC), including perioperative, intensive and emergency care. It provides products for anesthetics, ventilation, warming therapy and other related accessories and consumables. The safety division develops and produces devices, system solutions, firefighting equipment, firefighter training, industrial PPE, services for personal protection, gas detection, integrated hazard management, alcohol and drug testing devices. The flame detector is provided under the safety division business segment.

The company has a strong presence in more than 190 countries globally. It has sales and service subsidiaries in more than 50 countries. Drägerwerk AG & Co. KgaA has 20 production and development facilities based in Germany, Chile, the Czech Republic, China, France, India, Serbia, South Africa, Lithuania, Norway, Sweden, Switzerland, the UK and the U.S.

### **Key Financial Highlights**

- The company witnessed an increase in net sales in 2023 by 13.8%, owing to increased demand for products and services.
- It has achieved a growth of 17.3% in the safety division segment, wherein the flame detectors are provided. The growth in the segment is primarily attributed to the introduction of nine safety technology products.



#### **Financial Performance**

Table 73

Drägerwerk AG & Co. KGaA: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value \$ Millions	2023 Value \$ Millions
Net Revenue	3,206.7	3,648.7
R&D	(361.7)	(351.9)
Operating Income	-93.3	180.0
Net Income	-67.0	121.1
Total Current Assets	2,003.6	2,020.7
Total Current Liabilities	1,283.2	1,103.7

#### Note:

- The currency conversion for 2022 is 1 EUR=1.053049 USD and for 2023 is 1 EUR=1.081574 USD.
- Company fiscal year ended December 31st for 2022 and 2023.

Source: Company website; company annual report; and SEC filings

Figure 35
Drägerwerk AG & Co. KGaA: Revenue Share, by Business Unit, FY 2023
(%)

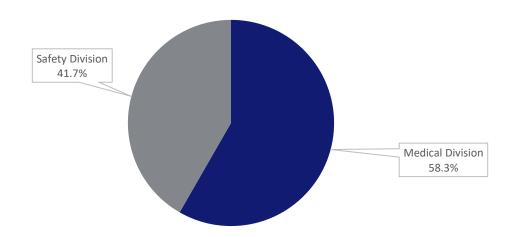
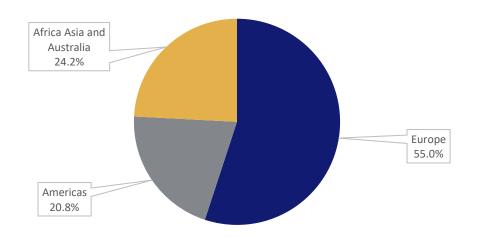




Figure 36
Drägerwerk AG & Co. KGaA: Revenue Share, by Country/Region, FY 2023
(%)



#### **Product Portfolio**

Table 74
Drägerwerk AG & Co. KGaA: Product Portfolio

Product	Description	
Alcohol and drug screening devices	Devices providing alcohol and drug analysis for medical applications.	
Anesthesia workstations	A portfolio of anesthesia workstations and systems with related essentials such as vaporizers, patient monitors, accessories and consumables.	
Respiratory care solutions	A range of respiratory monitoring systems from basic ventilation to high-end with ventilation modes.	
Neonatal care	Thermoregulation, non-invasive ventilation, jaundice management, monitoring and workplace solutions for newborns.	
Patient monitoring systems	Scalable, configurable monitoring systems to meet diverse clinical settings and patient acuity levels.	
Clinical information management system	Mobile and stationary patient monitors and surgical procedure monitors and central monitoring stations.	
Oxylog 1000	The Oxylog 1000 offers first aid ventilation for patients in emergency situations.  Designed to be used outdoors, its intuitive operation, robustness and transportability make the Oxylog 1000 complete in its class. the ventilator has integrated audible and visual alarms that monitor both the airway pressure and supply pressure to aid in patient safety.	



Product	Description
Oxylog 2000 Plus	The Oxylog 2000 plus gives not only a selection of volume-controlled modes, but also offers support modes for both invasive and noninvasive ventilation. Pressure support and noninvasive ventilation are available, enabling support for patients with insufficient breathing and to help prevent intubation at the earliest stage possible.
Oxylog 3000 Plus	The Oxylog 3000 plus offers a complete range of volume and pressure-controlled ventilation modes, including VC-CMV, VC-AC, VC-SIMV, Spn-CPAP and PC-81PAP. Noninvasive ventilation with sophisticated leak compensation and pressure support is also standard. with the AutoFlow option, clinicians can provide volume-controlled ventilation with minimized peak inspiratory pressure for advanced patient care.
Drager T1500 Globe- Trotter Neonatal Transport System	The Dräger TISOO Globe-Trotter Neonatal Transport System is designed to transport infants in a thermal neutral environment and provide integrated ventilatory support. the system can be configured with ventilation and oxygen analyzers to meet the specific needs of each patient.
Evita XL	The Dräger Evita XL is designed to deliver a comprehensive array of both controlled and assisted ventilation modes. the Evita XL combines a broad range of performance capabilities with many advanced application functionalities, providing outstanding ventilation therapy and easy-to-use operations encompassing the entire scope of the ventilation process.
Evita V300	The Evita V300 is a scalable device that offers high ventilation quality. the flexible equipment is suitable for everyday hospital work.

## **News/ Key Developments**

Table 75
Drägerwerk AG & Co. KGaA: News/Key Developments, 2024

Year	Strategy	Description
2024	Expansion	The Dräger Group announced plans to acquire land for a potential new facility in Northeast England.
2024	Partnership	Tata Elxsi and Dräger Established an Innovative Partnership to Drive Critical Care Innovation in India.

Source: Company website

## F. HOFFMANN-LA ROCHE LTD.

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Tel: +41-61-688-1111 Website: www.roche.com



#### **Company Snapshot**

Table 76
F. Hoffmann-La Roche Ltd.: Company Snapshot

Corporate Category	Information
Ticker	SWX: ROG
Year Founded/Incorporated	1896
Global Headquarters	Basel, Switzerland
Revenue 2023 (\$ Millions)	65,372.8
Number of Employees (2023)	103,605
Key Business Regions	North America
Primary Region/Country for Business	Europe, North America, Africa, Australia, Oceania, Latin America and Asia
Main Business Segment	Diagnostics
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Roche manufactures devices and chemicals for medical research and diagnostics. The company is headquartered in Basel, Switzerland and is in approximately 150 countries. Roche Diagnostics develops diagnostic tests and systems for key market segments, including scientific research, clinical laboratory systems and patient self-monitoring. The company's key business areas are professional diagnostics, diabetes care, molecular diagnostics and tissue diagnostics. The company also focuses on healthcare applications and applied science, supplying specialty biochemicals and manufacturing research reagents and systems for life sciences research. Roche mainly focuses on diagnostics and pharmaceuticals. Moreover, it is focused on translating excellence in science into effective medicines for patients.

## **Key Financial Highlights**

• Roche Group sales declined by 2.5%, with \$67.2 billion in 2023. This is mainly due to sharp decline inCOVID-19 related tests



#### **Financial Performance**

Table 77

F. Hoffmann-La Roche Ltd.: Financials, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Values (\$ Millions)	2023 Values (\$ Millions)
Net Revenue	66,304.2	65,372.8
R&D	-15,952.4	-15,809.9
Operating Income	17,107.0	15,675.2
Net Income	14,177.4	13,759.1
Total Current Assets	35,431.6	37,237.9
Total Current Liabilities	-28,540.3	-27,638.4

<sup>\*</sup>Swiss franc USD conversion for 2022 was 1.0478 and 1.1134 for 2023

Source: Company website; company annual report; and SEC filings

Figure 37
F. Hoffmann-La Roche Ltd.: Revenue Share, by Business Unit, FY 2023 (%)

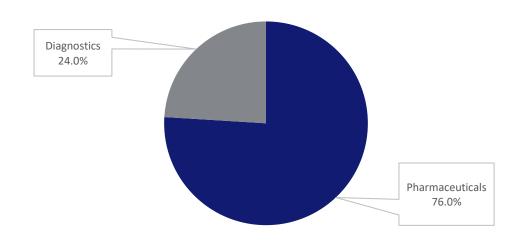
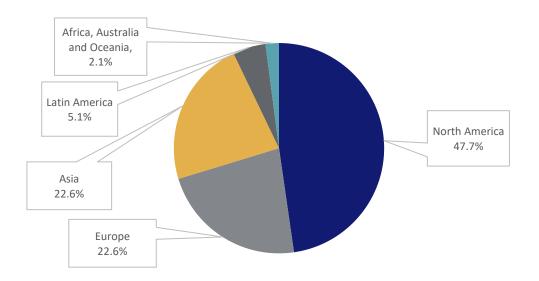




Figure 38

F. Hoffmann-La Roche Ltd.: Revenue Share, by Country/Region, FY 2023
(%)



## **Product Portfolio**

Table 78
F. Hoffmann-La Roche Ltd.: Product Portfolio

Segment/Category	Description
Blood gas analyzers and blood screening	A portfolio of Cobas systems for multiple blood gas and biochemistry time critical parameters and for PCR- based nucleic acid tests and automation.
Cancer screening	A portfolio of BenchMark, Cobas, Discovery and Vantage systems for cancer monitoring.
Cardiac markers	A range of diagnostic markers for early detection, diagnosis and monitoring of cardiovascular diseases.
Cholesterol and coagulation monitoring	Monitoring of metabolic disorders and risk factors for cardiovascular disease and monitoring patents on vitamin K antagonist therapy.
Coagulation routine and specialty testing	Coagulation analyzer for laboratories with different throughput dedicated for routine and special coagulation testing.
Diabetes monitoring	Blood glucose systems for patient self-testing and glucose monitoring systems.
Heterogeneous immunochemistry	Instruments to measure hundreds of different parameters in blood, serum or urine.
Infectious diseases	Solutions from Cobas, Lifecycler and others for early detection and treatment of infectious diseases.



Segment/Category	Description
Multiplate analyzer	Instrument to determine platelet function in small quantities of whole blood.
PCR clinical diagnostics	PCR technology and full menu to minimize the need for repeated testing or dilutions.
Diabetes monitoring	Blood glucose systems for patient self-testing and glucose monitoring systems.

**News/ Key Developments** 

Table 79
F. Hoffmann-La Roche Ltd.: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Acquisition	Roche closes acquisition of LumiraDx's Point of Care technology to expand primary care diagnostic testing access.
2024	European Commission Approval	European Commission approves Roche's Vabysmo for retinal vein occlusion (RVO) treatment.
2024	Innovation	Roche received a CE Mark for its AI-enabled continuous glucose monitoring solution, which offers critical predictions to people with diabetes.
2024	FDA Approval	FDA approves Roche's Vabysmo prefilled syringe (PFS) for three leading causes of vision loss.
2024	Product Launch	Roche launched a new highly sensitive test to diagnose patients who may have B-cell lymphoma more easily.
2024	FDA Emergency Approval	Roche's four-in-one molecular test for SARS-CoV-2, Influenza A/B viruses and RSV receives U.S. FDA Emergency Use Authorization.
2024	FDA Approval	Roche granted FDA Breakthrough Device Designation for blood test measuring Lp(a) – a key marker for hereditary cardiovascular risk.
2024	FDA Approval	Roche announced FDA approval of one of the first HPV self-collection solutions in the U.S., expanding access and screening options to help eliminate cervical cancer.
2024	FDA Approval	Roche received FDA approval for the first molecular test to screen for malaria in blood donors.
2024	FDA Approval	Roche granted FDA Breakthrough Device Designation for blood tests to support earlier Alzheimer's disease diagnosis.
2023	Merger Agreement	Roche entered a definitive merger agreement to acquire Carmot Therapeutics, including three clinical-stage assets with best-in-class potential in obesity and diabetes.
2023	Expansion	Roche expanded its hepatitis diagnostics portfolio to help clinicians diagnose and monitor patients with acute or chronic hepatitis B infection.
2023	Product Launch	Roche launched automated serology hepatitis E virus tests, including a test to detect acute HEV infections, recommended in the new WHO 2023 Essential Diagnostics List.



Year	Strategy	Description
2023	FDA Approval	Roche IL-6 is the first immunoassay approved to aid sepsis diagnosis in newborns.
2023	Partnership	Roche entered a partnership with Alnylam to co-develop and co- commercialize the RNAi therapeutic zilebesiran, which treats hypertension in patients with high cardiovascular risk.
2023	Expansion/Innovation	Roche launched the Institute of Human Biology to accelerate breakthroughs in R&D by unlocking the potential of human model systems.
March 2023	Collaboration	Roche announced a collaboration with Lilly to enhance early diagnosis of Alzheimer's disease.
June 2022	Product Launch	Roche launched the BenchMark ULTRA PLUS system for cancer diagnostics, enabling timely, targeted patient care.
June 2022	Product Launch	Roche launched human papillomavirus (HPV) self-sampling solution, expanding cervical cancer screening options.
May 2022	FDA Approval	U.S. FDA approved FoundationOne CDx as a companion diagnostic for Roche's Rozlytrek (entrectinib).
May 2002	Partnership	Roche partnered with the Global Fund to support low- and middle-income countries in strengthening critical diagnostics infrastructure.
May 2022	Innovation	Roche developed unique PCR tests to detect the monkeypox virus.
January 2022	FDA Approval	Roche's Evrysdi (risdiplam) got FDA priority review for the treatment of pre-symptomatic babies under two months of age with spinal muscular atrophy (SMA).
January 2022	Product Launch	Roche launched the Cobas pulse system, the industry's first professional blood glucose management solution with mobile digital health capabilities to improve patient care.

## GE HEALTHCARE

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Website: www.gehealthcare.com



#### **Company Snapshot:**

Table 80
GE HealthCare: Company Snapshot

Corporate Category	Information
Ticker	NASDAQ: GEHC
Year Founded/Incorporated	2023
Global Headquarters	Illinois, U.S.
Revenue 2023 (\$Million)	19,552
Number of Employees (2023)	51,000
Key Business Regions	U.S. and Canada
Primary Region/Country for Business	U.S. & Canada, Europe, the Middle East & Africa, China Region, Rest of World
Main Business Segment	Imaging and PDx
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

GE HealthCare was a subsidiary of GE Electrical Company; in 2023, it spun off from the parent company. GE Healthcare is one of the established players in the medical devices industry. It offers a complete range of diagnostic products, including ultrasound, imaging, patient care solutions, pharmaceutical imaging agents, digital solutions, parts and accessories and refurbished systems.

It also provides many services in the healthcare segment. GE HealthCare is one of the leading suppliers of theranostics products. Its products include cyclotrons, tracer production facility solutions and PET radiochemistry systems.

#### **Key Financial Highlights**

- The total revenue of GE HealthCare increased by 7% from 2022 to 2023. It generated \$19.5 billion in revenue in 2023; in 2022, it generated \$18.3 billion. The increase in revenue was due to the rise of 18% in the pharmaceutical diagnostics segment. Additionally, there was an increase in income in the U.S. and China.
- The imaging segment accounted for a revenue of \$10 581 million in the year 2023, an increase of 6% over the previous year; the growth was due to MI/CT products and Magnetic resonance due to increases in price, supply chain fulfillment and new product introduction.
- The highest growth was seen in the pharmaceutical diagnostics segment, a growth of 18% due to increased demand and prices across regions.



#### **Financial Performance**

Table 81
GE HealthCare: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	18,341	19,552
R &D	1,026	1,205
Operating Income	2,522	2,435
Net Income	1,967	1,614
Total Current Assets	8,318	9,410
Total Current Liabilities	7,191	8,981

Source: Company website; company annual report; and SEC filings

Figure 39
GE HealthCare: Revenue Share, by Business Unit, FY 2023
(%)

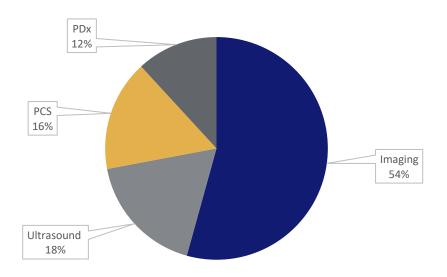
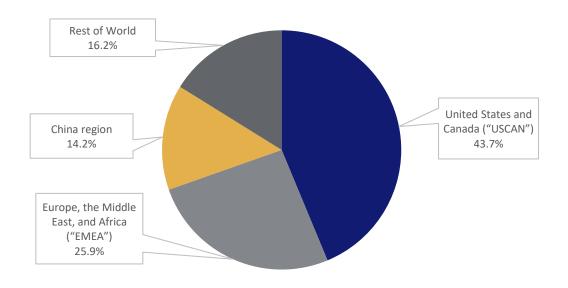




Figure 40
GE HealthCare: Revenue Share, by Country/Region, FY 2023
(%)



## **Product Portfolio**

Table 82
GE HealthCare: Product Portfolio

Segment/Category	Description
Anesthesia delivery	A portfolio of anesthesia delivery systems and solutions for clinicians.
Computed tomography (CT)	A portfolio of CT systems to match imaging needs.
Diagnostic ECG	A cardiology portfolio, including resting, ECG analysis programs, ambulatory ECG, PC-based diagnostic solutions and cardiology data management for diagnosis and cardiology data management.
Electrophysiology (EP) recording	A suite of products with signal-processing algorithms to help diagnose and treat cardiac conditions.
Surgical imaging	Solutions for orthopedic, vascular, general, urology and pain management procedures.
Interventional image-guided systems (IGS)	All digital imaging systems, including IGS for interventional cardiology, IGS for EP, IGS for interventional oncology and IGS for interventional neuroradiology.
Life sciences	Tools for a wide range of applications, including basic research of cells and proteins and drug discovery research.



Segment/Category	Description
MRI	MRI platforms and various applications for neuro, vascular, body, breast and cardiac imaging.
Mammography	Mammography systems, workstation solutions and advanced applications for personalized care
Patient monitoring	A portfolio of patient monitors, parameters, wireless devices, workflows and integrated IT solutions to create a fluent clinical intelligence system.
Radiography and fluoroscopy	R&F solutions with performance and productivity enhancing features to ensure image quality and dose efficiency.
Critical care ventilation	A range of respiratory and sleep systems designed to expand clinical capabilities.

**News/ Key Developments** 

Table 83
GE HealthCare: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Collaboration	GE Healthcare and AWS announced a strategic collaboration to accelerate healthcare transformation with generative AI.
2024	Acquisition	GE HealthCare announced an agreement to acquire a clinical artificial intelligence business from Intelligent Ultrasound.
2024	Product Launch	GE HealthCare's MIM Software introduced MIM Symphony HDR Prostate for MR Image guidance during procedures.
2024	Innovation	GE Healthcare and MediView announced the World's First Installation and Clinical Use of an Augmented Reality Interventional Suite that Aims to Transform the Practice of Interventional Radiology.
2024	Collaboration	GE Healthcare and Salud Digna extend collaboration to improve patient care in Mexico.
2024	Partnership	GE Healthcare and Tampa General Hospital Expand Long-Term Partnership to Benefit Patients and Clinicians Across the State of Florida.
2024	Collaboration	GE Healthcare and Medis Medical Imaging Announced a Collaboration focused on Non-Invasive Coronary Assessments to Help Advance Precision Care in treating coronary artery disease.
2024	Collaboration	NBA, NBPA and NGBPU Collaborated with GE HealthCare and MedStar Health on Musculoskeletal and Joint Health Study.
2024	Collaborated	University of Wisconsin–Madison's N+1 Institute and GE HealthCare Collaborate to Accelerate Biohealth Innovation and Provide Valuable Real-World Education for Students.
2024	Collaboration	GE HealthCare's MIM Software collaborated with Elekta to help enhance radiation therapy treatments and improve patient outcomes.
2024	Innovation	GE HealthCare introduced AI-Enhanced Voluson Signature 20 and 18 Ultrasound Systems to Advance Women's Health Imaging.



Year	Strategy	Description
2024	Innovation	GE HealthCare Introduced Caption AI on Vscan Air SL Wireless Handheld Ultrasound System to Help More Clinicians Capture Diagnostic-Quality Cardiac Images.
2024	Acquisition	GE HealthCare closed the MIM Software acquisition, bolstering its portfolio and advancing its precision care strategy.
2024	Collaboration	GE Healthcare and Hartford HealthCare Renew and Evolve 7-Year Collaboration to Advance Patient Care and Access in Connecticut.
2024	Collaboration	GE Healthcare and MedQuest Associates Collaborated to Provide Innovative Medical Device Technology and Digital Tools for Outpatient Imaging Centers
2024	Acquisition	GE HealthCare announced an agreement to acquire MIM Software.
2023	Innovation/FDA Clearance	GE HealthCare announced a New Version of Digital Expert Access, the First FDA 510(k)-Cleared Device to Enable Remote Patient Scanning and Exclusive Distribution Agreement with IONIC Health.
2023	Collaboration	GE Healthcare and Masimo collaborated to Bring Masimo SET Pulse Oximetry to the Wireless and Wearable GE HealthCare Portrait Mobile Platform.
2023	Collaboration	GE Healthcare and reLink Medical Collaborated to Help Reduce Medical Device Waste for Healthcare Providers.
2023	Collaboration	GE Healthcare and Novo Nordisk collaborated to Advance a Novel non-invasive treatment for Type 2 Diabetes and Obesity with Ultrasound.
2023	FDA Clearance	GE Healthcare received FDA Clearance for Allia IGS Pulse - the Next Generation of Image-Guided Systems Designed for Cardiac Imaging Excellence.
2023	Contract	GE HealthCare signed a \$44 million contract with BARDA to develop artificial intelligence-augmented ultrasound technology to aid clinicians in diagnosing and treating traumatized injuries and enhance national preparedness for mass casualty incidents.
2023	Collaboration	Mayo Clinic and GE HealthCare entered a strategic collaboration to advance medical imaging and theranostics innovation.
2023	Collaboration	GE Healthcare and Mass General Brigham Collaborated on an Al Algorithm to Predict Missed Care Opportunities.
2023	Product Launch	GE HealthCare introduced Vscan Air SL, a wireless handheld ultrasound device for rapidly assessing cardiac and vascular patients.
2023	Product Launch	GE HealthCare launched CardioVisio for Atrial Fibrillation, a Digital, Patient-Centric Clinical Decision Support Tool to Enable Precision Care.
2023	FDA Clearance	GE Healthcare received FDA Clearance for Portrait Mobile, A First-Of-Its-Kind Wireless Monitoring Solution That Aids in the Early Detection of Patient Degradation.
2023	Collaboration	GE Healthcare collaborated with DePuy Synthes to bring Advanced 3D Precision Imaging Innovation to Spine Practices in the U.S.
2023	FDA Clearance	GE HealthCare Introduced Sonic DL: A Groundbreaking, FDA- Cleared AI Deep Learning Technology for Faster MRI.
2023	FDA Clearance	GE Healthcare received FDA Clearance for a New Deep Learning Solution for Enhanced Image Quality in PET/CT, Advancing its Leadership Position in AI.



Year	Strategy	Description	
2023	FDA Clearance	GE HealthCare's CARESCAPE Canvas Patient Monitoring Platform received FDA Clearance.	
2023	Innovation	Advancing Precision Care - GE HealthCare Introduced an Innovative Solution to Help Expand Interventional CT Access.	
2023	Agreement	Advantus Health Partner and GE HealthCare announced a Multi- Year Agreement to expand access to healthcare technology management services.	
2023	Acquisition	GE HealthCare announced it would acquire Caption Health, Expanding Ultrasound to Support New Users Through FDA- cleared, AI-powered image Guidance.	
2023	Acquisition	GE Healthcare acquired IMACTIS to Strengthen Capabilities in Interventional Guidance.	
2022	Collaboration/Innovation	GE Healthcare and MediView XR Inc., a leading clinical augmented reality med-tech company, collaborated to integrate medical imaging into mixed-reality solutions by developing the OmnifyXRTM Interventional Suite System.	
2022	Collaboration	GE Healthcare and Accuray collaborated to Expand Access and advance the Practice of Precision Radiation Therapy.	
2022	Partnership	GE Healthcare and AMC Health partnered in Remote Patient Monitoring to Provide Patients with Chronic and Post-Acute Care in the Home.	
2022	Collaboration	GE Healthcare collaborated to advance the digital transformation of pathology. The collaboration aimed to integrate Tribun's Health Suite data with GE Healthcare's solutions, like Edison Datalogue, to enhance digital pathology.	
2022	Expansion/Partnership	The partnership with Telix expanded GE Healthcare's immuno- diagnostics offering to the global clinical research market.	
2022	Product Launch	GE Healthcare introduced Omni Legend, A First-of-its-Kind All- Digital PET-CT System to Drive Efficiency, Enhance Diagnostics and Deliver Precision Medicine.	
2022	FDA Approval	GE Healthcare's AIR Recon DL received FDA clearance for 3D and Motion-Insensitive Imaging Applications for Next-Level Image Quality and Patient Experience in MRI.	
2022	Collaboration	GE Healthcare and Wayra collaborated with seven health tech start-ups to drive the digital transformation of healthcare across Europe, the Middle East and Africa.	
2022	Collaboration	In collaboration with Nex Cubed, GE Healthcare selected six digital health start-ups for the inaugural Edison Accelerator in Canada.	
2022	Product Launch	GE Healthcare unveils the latest ultra-premium ultrasound in Women's Health's portfolio.	
2022	Innovation	GE Healthcare introduced its first '5G Innovation Lab' to transform remote care.	
2022	Innovation	GE Healthcare had introduced a Wireless Patient Monitoring Solution to Help Clinicians Detect Early Patient Deterioration.	
2022	Launch	The company is proud to provide cutting-edge molecular imaging solutions that enable and increase access to precision health and theragnostic to help improve patient outcomes across care areas, including prostate cancer.	
2022	Agreement	The company agreed to invest up to \$50 million in Israeli start-up Pulsenmore, marking another strategic step forward in enabling precision health. This investment aims to accelerate the global	



Year	Strategy	Description	
		adoption of Pulsenmore's homecare ultrasound solutions and will also support its goal to pursue U.S. FDA clearance and commercial expansion.	
2022	Collaboration	The company announced a new collaboration with the National Cancer Centre Singapore (NCCS), which focuses on how artificial intelligence (AI)- driven research can improve cancer care.	
2022	Agreement	The company signed an agreement with Alliance Medical to create a digital solution to enhance productivity within hospital radiology departments in the U.K.	
2022	Collaboration	The firm agreed to collaborate with RaySearch Laboratories AB (publ) to develop a new radiation therapy simulation and treatment planning workflow solution designed to simplify how radiation will be targeted to shrink a tumor.	
2022	Agreement	Unilabs, the leading European diagnostic services provider, agreed to partnered with GE Healthcare to provide imaging equipment and digital technology in Portugal.	
2022	Collaboration	GE Healthcare and Elekta signed a global commercial collaboration deal in radiation oncology, enabling the two firms to provide hospitals with a comprehensive offering in imaging and treatment for cancer patients needing radiation therapy.	
2022	Expansion	Wipro GE Healthcare launched its new manufacturing facility in Bengaluru, India, under the Indian government's Production Linked Incentive Scheme. The new plant is aligned with the National Agenda of 'Atmanirbhar Bharat' and will further promote local manufacturing of medical devices in India. It is a 100% subsidiary of Wipro GE Healthcare and has been set up as a greenfield legal entity.	
2022	Approval	The company has declared that it has received approval from the European Medicines Agency (EMA) for additional imaging modalities for its stress agent Rapiscan (Regadenoson).	

## GERRESHEIMER AG

Klaus Bungert Str. 4 40468 Düsseldorf Germany

Tel: +49-211-618-100

Website: www.gerresheimer.com



#### **Company Snapshot**

Table 84
Gerresheimer AG: Company Snapshot

Corporate Category	Information	
Ticker	ETR: GXI	
Year Founded/Incorporated	1864	
Global Headquarters	Düsseldorf, Germany	
Revenue 2023 (\$ Millions)	2,147.6	
Number of Employees (2023)	11,660	
Key Business Regions	Germany, Other Europe, North America, emerging markets and Other regions.	
Primary Region/Country for Business	Other Europe	
Main Business Segment	Primary packaging glass	
Entity Type	Public	
Ownership Type	Parent	

<sup>\*</sup>Euro to USD converted November 2023 average 1.0789 and November 2022 average 1.0594.

Source: Company website; annual reports; investor presentations; press releases

## **Company Overview**

Gerresheimer is a global developer and solution provider of primary packaging for drugs and cosmetics for biotech, healthcare, pharma and cosmetic companies. Its product portfolio includes drug delivery systems, medical devices, pharmaceutical containment solutions and various other products for the health industry. The product line offers auto-injectors, syringes, medication pumps, pens, inhalers, ampoules and vials.

The company has approximately 11,660 global employees. It has a strong network in North America, Europe (e.g., Germany) and its emerging sectors (e.g., China, India, Brazil, Mexico).

#### **Key Financial Highlights**

- The Gerresheimer AG generated a revenue of \$2,147.6 million (€ 1,990.5 million) in 2023, an increase of 10.4% from the previous year.
- Primary Packaging Glass, the market target segment, marks a 6.5% growth in revenues compared to the fiscal year due to the well-performed business from pharma and cosmetics.



#### **Financial Performance**

Table 85
Gerresheimer AG: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	1,925.0	2,147.6
R&D	-22.9	-17.4
Operating Income	179.4	230.2
Net Income	108.3	129.6
Total Current Assets	858.2	916.6
Total Current Liabilities	1,166.8	1,033.5

<sup>\*</sup>Euro to USD converted November 2023 average 1.0789 and November 2022 average 1.0594.

Source: Company website; company annual report; SEC filings

Figure 41
Gerresheimer AG: Revenue Share, by Business Unit, FY 2023
(%)

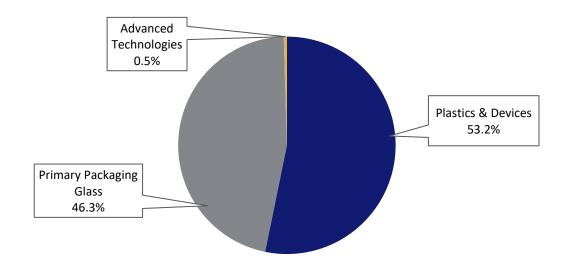
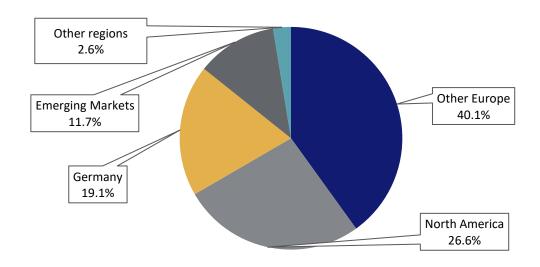




Figure 42
Gerresheimer AG: Revenue Share, by Country/Region, FY 2023
(%)



## **Product Portfolio**

Table 86
Gerresheimer AG: Product Portfolio

Segment/Category	Description
Autoinjectors	Used primarily for treating diabetes and obesity, Gerresheimer's autoinjectors are designed to offer precise dosing and easy selfadministration, ensuring patient comfort and compliance.
Inhalers	These are used for respiratory therapies, delivering precise medications like those for asthma and COPD. Their design helps ensure consistent dosing and easy use.
Infusion Set Components	Gerresheimer manufactures components for infusion sets vital for therapies requiring precise fluid administration, such as intravenous drug delivery.
Microinjectors	Used in specialized medical applications like insulin delivery, microinjectors offer high precision in administering small doses of drugs.
Test Cards for Microbiological Tests:	These are used for rapid diagnostics in medical settings, helping identify infections or conditions that require immediate intervention.

Source: Company website



# **News/Key Developments**

Table 87
Gerresheimer AG: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Innovation	Gerresheimer, a global pharma and biotech industry partner, will present its innovative silicone oil-free pre-fillable syringe systems for ophthalmic applications at CPHI Worldwide 2024.
2022	Agreement	ISR signed an agreement with Gerresheimer for clinical-scale production of IcoOne nasal inhalers.
2022	Expansion	Gerresheimer ceremoniously took possession of a new facility in Berlin, Ohio.  The site is intended for the future production of square plastic containers from the Duma Twist-Off Q brand, specifically those with a 40-ml capacity. These containers will feature child-resistant closures and desiccants and will be manufactured in a clean room environment to serve the North American market.

Source: Company website

# INTUITIVE SURGICAL

1020 Kifer Road Sunnyvale, California, 94086-5304 U.S.

Tel: +1-408-523-2100 Website: www.intuitive.com

Table 88
Intuitive Surgical: Company Snapshot

Parameter	Information
Ticker	NASDAQ: ISRG
Year Founded/Incorporated	1995
Global Headquarters	California, U.S.
Revenue 2023 (\$ Millions)	7,124.1
Number of Employees (2023)	13,676
Key Business Regions	U.S.
Primary Region/Country for Business	U.S.
Main Business Segment	Instruments and Accessories
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations



#### **Company Overview**

Intuitive Surgical specializes in robotic assisted minimally invasive surgery (MIS) devices. Its comprehensive portfolio serves surgical specialties such as urological, thoracic, gynecological, cardiac, colorectal, pediatric and general surgery. The company distributes its products through direct sales organizations and distributors across North America, South America, Europe, Asia-Pacific, the Middle East and Africa, with additional offices in Europe and Asia-Pacific.

#### **Key Financial Highlights**

Revenue surged by 14%, reaching \$7.1 billion for the fiscal year ending December 31, 2023, compared to \$6.2 billion in the preceding year ending December 31, 2022.

The utilization of da Vinci surgical systems, as measured by procedures per system per year, experienced a 9% increase compared to the previous year, 2022.

#### **Financial Performance**

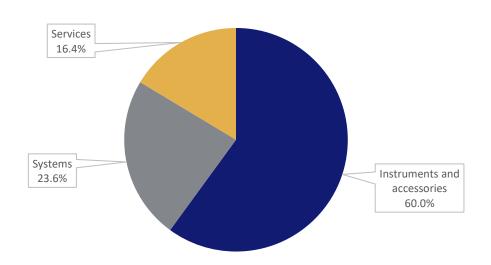
Table 89
Intuitive Surgical: Financial Performance, FY 2022 and 2023
(\$ Millions)

Financial Metric	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	6,222.2	7,124.1
R&D	879.0	998.8
Operating Income	1,577.1	1,766.8
Net Income	1,344.4	1,817.3
Total Current Assets	6,253.0	7,888.0
Total Current Liabilities	1,422.1	1,658.7

Source: Company website, company annual report and SEC filings

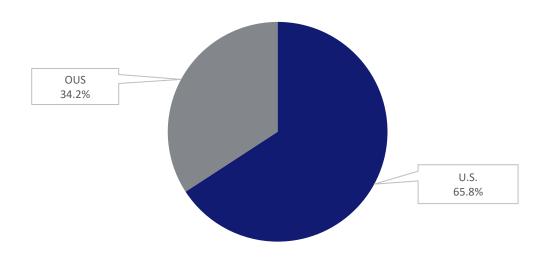


Figure 43
Intuitive Surgical: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website, company annual report, SEC filings

Figure 44
Intuitive Surgical: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website, company annual report, SEC filings



#### **Product Portfolio**

Table 90
Intuitive Surgical: Product Portfolio

Segment/Category	Description
da Vinci Surgical Robot	The core robotic system is used for minimally invasive surgeries. It features robotic arms that hold and maneuver surgical instruments while the surgeon operates from a console with a high-definition 3D view of the surgical site.
SureForm Staplers	SureForm is a new breed of stapler. At its core, SmartFire technology monitors tissue compression before and during firing, making automatic adjustments to optimize the staple line.
Endowrist Instruments	Specialized tools that attach to the robotic arms and can perform a variety of surgical tasks.
Vision System	The Vision System delivers high-definition, 3D views of the surgical area, allowing for detailed and precise visualization during procedures.
Console	The Console is where the surgeon sits to control the robotic arms with precision, using the enhanced visual feedback from the Vision System to guide the surgery.

Source: Company website

# **News/ Key Developments**

Table 91
Intuitive Surgical: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	FDA Clearance	Intuitive announced FDA Clearance of Revised da Vinci Xi and X Labeling on Radical Prostatectomy.
2024	FDA Clearance	Intuitive announced FDA Clearance of Fifth-Generation Robotic System, da Vinci 5.
2023	FDA Clearance	Intuitive received FDA clearance of da Vinci SP for simple prostatectomy
2022	Regulatory Clearance	Japan regulatory agency clears Intuitive's single-port robotic surgical system.
2022	Innovation	Intuitive and Siemens Healthineers enhance scanning integration for Ion Endoluminal procedures.

Source: Company website



## JOHNSON & JOHNSON SERVICES INC.

One Johnson & Johnson Plaza New Brunswick, New Jersy 08933 U.S.

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## **Company Snapshot**

Table 92
Johnson & Johnson Services Inc.: Company Snapshot

Corporate Category	Information
Ticker	NYSE: JNJ
Year Founded/Incorporated Year	1886
Global Headquarters	New Jersey, U.S.
Revenue 2023 (\$ Millions)	85,159
Number of Employees (2023)	131,900
Key Business Regions	U.S., Europe, Asia-Pacific
Primary Region/Country for Business	U.S.
Main Business Segment	Innovative Medicine
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Johnson & Johnson reorganized into two business segments—Innovative Medicine and MedTech—following the separation of its Consumer Health business (Kenvue) in August 2023. The company and its subsidiaries employ approximately 134,400 people globally and focus on researching, developing, manufacturing and selling a wide range of healthcare products.

The MedTech segment includes a broad portfolio of products used in the Interventional Solutions orthopedics, Surgery and Vision categories. Interventional Solutions include electrophysiology products (Biosense Webster) to treat heart rhythm disorders, the heart recovery portfolio (Abiomed), which provides technologies to treat severe coronary artery disease requiring high-risk PCI or AMI cardiogenic shock and Neurovascular care (Cerenovus) that treats hemorrhagic and ischemic stroke. The Orthopaedics portfolio (DePuy Synthes) includes products and enabling technologies that support Hips, Knees, Trauma and Spine, Sports & Others. The company has manufacturing capabilities for biologics, small molecules and strong commercialization entities that market the products in more than 175 countries and have more than 250 operating companies.

#### **Key Financial Highlights**

• Sales by U.S. companies reached \$46.4 billion in 2023, up from \$42.0 billion in 2022, reflecting an increase of 10.6% in 2023 and 3.3% in 2022. International company sales were \$38.7 billion in



2023, compared to \$38.0 billion in 2022, marking a 1.9% increase in 2023 and a 0.2% decrease in 2022.

• Innovative Medicine segment sales in 2023 reached \$54.8 billion, reflecting a 4.2% increase from 2022, with operational growth contributing 4.8%.

#### **Financial Performance**

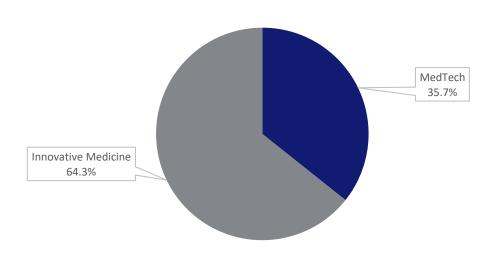
Table 93
Johnson & Johnson Services Inc.: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	79,990	85,159
R&D	14,135	15,085
Operating Income	19,359	15,062
Net Income	17,941	35,153
Total Current Assets	55,294	53,495
Total Current Liabilities	55,802	46,282

Source: Company website; company annual report; and SEC filings

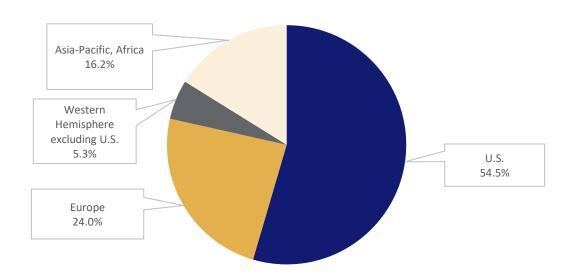


Figure 45
Johnson & Johnson Services Inc.: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; and SEC filings

Figure 46
Johnson & Johnson Services Inc.: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; and SEC filings



# **Product Portfolio**

Table 94
Johnson & Johnson Services Inc.: Product Portfolio

Segment/Category	Description
Hip replacement	<ul> <li>CORAIL PINNACLE Construct</li> <li>CORAIL Hip System</li> <li>PINNACLE Hip Solutions</li> <li>Direct Anterior Approach</li> <li>GRIPTION Porous Coating</li> <li>POROCOAT Porous Coating</li> <li>MARATHON Crosslinked Polyethylene</li> <li>ALTRX Altra-Linked Polyethylene</li> <li>DURALOC Cementless Acetabular Reconstruction</li> <li>C-STEM AMT</li> <li>SUMMIT Tapered Hip System POROCOAT and DUOFIX HA</li> <li>TRI-LOCK Bone Preservation Stem</li> <li>CORAIL Revision Stem</li> <li>PINNACLE Revision Acetabular Cup System</li> <li>GRIPTION TF Acetabular Revision System</li> <li>GRIPTION Porous Coating</li> <li>RECLAIM Modular Hip System</li> <li>REEF</li> <li>Revision Solutions Hip Extraction Instrumentation</li> <li>S-ROM NOILES Knee System</li> <li>SOLUTION SYSTEM</li> <li>PROTRUSIO Cage</li> </ul>
Knee Reconstruction	<ul> <li>ATTUNE Knee System</li> <li>LCS COMPLETE Revision Knee System</li> <li>LCS Knee System</li> <li>LCS-RPS</li> <li>LPS Limb Preservation System</li> <li>P.F.C. SIGMA TC3 Knee System</li> <li>S-ROM NOILES Knee System</li> <li>SIGMA High-Performance Partial Knee System</li> <li>SIGMA Total Knee System</li> <li>TRUMATCH Personalized Solutions</li> </ul>
Shoulder reconstruction	<ul> <li>Anchor Peg Glenoid</li> <li>Anatomic</li> <li>DELTA XTEND Reverse Shoulder System</li> <li>GLOBAL ADVANTAGE</li> <li>GLOBAL APG+ Instrumentation</li> <li>GLOBAL AP Shoulder System</li> <li>GLOBAL CAP and GLOBAL CAP CTA Shoulder Systems</li> <li>GLOBAL ENABLE Glenoid Exposure System</li> <li>GLOBAL FX Shoulder System</li> <li>GLOBAL UNITE Shoulder System</li> <li>LUPINE BR</li> </ul>



Segment/Category	Description
Trauma	<ul> <li>ASLS Angular Stable Locking System</li> <li>BME Continuous Compression Implants (BME CCI)</li> <li>Bone Reduction Forceps</li> <li>Cable System</li> <li>Cannulated Pediatric Osteotomy System (CAPOS)</li> <li>Distal Radius Sterile Kit</li> <li>Distraction Osteogenesis Ring System (DO)</li> <li>Elbow Hinge Fixator</li> <li>Expert Adolescent Lateral Femoral Nail (ALFN)</li> <li>Expert Hindfoot Arthrodesis Nail</li> <li>Expert Lateral Femoral Nail (LFN)</li> <li>Expert Retrograde/Antegrade Femoral Nail (R/AFN)</li> <li>Expert Tibial Nail</li> <li>Expert Tibial Nail PROtect</li> <li>Headless Compression Screws 1.5, 2.4, 3.0</li> <li>Headless Compression Screws 4.5 and 6.5</li> <li>LCP Broad Curved Plate</li> <li>LCP Clavicle Hook Plate</li> <li>LCP Compact Hand</li> <li>LCP Distal Ulna Plate 2.0</li> <li>LCP Dynamic Hip Screw (DHS) incl. DHS Blade and Locking Trochanter Stabilization Plate (LTSP)</li> <li>LCP Hook Plate</li> <li>LCP Locking Compression Plate</li> <li>LCP Locking Compression Plate</li> <li>LCP Medial Proximal Tibial Plates 4.5/5.0</li> </ul>
Spine	<ul> <li>ACIS Anterior Cervical Interbody Spacer</li> <li>ARCH ODL Spacer</li> <li>ATB Anterior Tension Band Plate</li> <li>Arch Fixation System</li> <li>Arcofix Anterior Only Reduction Plate</li> <li>BENGAL Stackable Cage System</li> <li>CONCORDE Inline Lumbar Interbody System</li> <li>CONCORDE Bullet Lumbar Interbody System</li> <li>CONFIDENCE Spinal Cement System</li> <li>CSLP Cervical Spine Locking Plate</li> <li>EXPEDIUM 4.5 System</li> <li>EXPEDIUM 5.5</li> <li>EXPEDIUM 6.35 System</li> <li>EXPEDIUM Anterior Spine System</li> <li>EXPEDIUM Offset and Plates Systems</li> <li>EXPEDIUM Sacropelvic Collection System</li> <li>EXPEDIUM Universal Connector Set</li> <li>EXPEDIUM Verse</li> <li>EXPEDIUM Vertebral Body Derotation (VBD) System</li> <li>FACET Wedge</li> <li>INSIGHT Access Retractor System</li> <li>KICK System with FluoroExpress Software Module</li> <li>MATRIX Spine System</li> <li>MOUNTAINEER OCT Spinal System</li> <li>MOUNTAINEER Laminoplasty System</li> </ul>



Segment/Category	Description
	OPAL Cage System PLIVIOS REVOLUTION PRODISC -L Total Disc Replacement PRODISC -C Nova Total Disc Replacement PRODISC C Vivo Total Disc Replacement SPOTLIGHT Access System SYNAPSE System SYNEX Vertebral Body Replacement SYNFIX-LR System Anterior Lumbar Interbody Fusion (ALIF) SYNFLATE SYNMESH Vertebral Body Replacement System Synfix Evolution TELEFIX Implant System TPAL System: Available in PEEK and Titanium TPAL System: Available in PEEK and Titanium TSLP Thoracolumbar Spine Locking Plate UNIPLATE 2 Anterior Cervical Plate System USS II Deformity Set USS II Deformity Set USS Low Profile Set USS Low Profile Set USS Pediatric VBS (Vertebral Body Stent) VEPTR and VEPTR II VERTECEM V+ Cement Kit VIPER SAI VIPER SAI VIPER SD MIS Correction Set VIPER Cortical Fix Fenestrated Screw System ZERO-P Spacer ZERO-P Stand-Alone Spacer
CMF	<ul> <li>Alveolar Distractor</li> <li>Curvilinear Distractor</li> <li>DBX Material</li> <li>External Midface Distractor System</li> <li>FLAPFIX System</li> <li>IMF Screw Set</li> <li>MatrixMANDIBLE Preformed Reconstruction Plates</li> <li>MatrixMANDIBLE Subcondylar Plates</li> <li>MatrixMANDIBLE System</li> <li>MatrixMIDFACE</li> <li>MatrixNEURO</li> <li>MatrixORBITAL System</li> <li>MatrixORTHOGNATHIC</li> <li>MatrixORTHOGNATHIC LOCK</li> <li>MatrixWAVE MMF System</li> <li>MatrixWAVE MMF System</li> <li>Maxillary Distractor</li> <li>Midface Distractor System</li> <li>NORIAN Reinforced System</li> </ul>



Segment/Category	Description
	<ul> <li>PSI Patient Specific Implant</li> <li>RAPIDSORB Cranial Clamp</li> <li>RAPIDSORB Fixation System</li> <li>Single Vector Distractor (Stainless Steel)</li> <li>Single Vector Distractor</li> <li>Sternal ZIPFIX System</li> <li>SynPOR HD Facial Shape System</li> <li>SynPOR Smooth System</li> <li>TRUMATCH CMF Solutions</li> <li>TRUMATCH CMF Patient Specific Plates for Mandible</li> <li>Titanium Multi-Vector Distractor</li> <li>Titanium Sternal Fixation System</li> <li>XCM BIOLOGIC Tissue Matrix</li> </ul>
Biomaterials	<ul> <li>Bone Access Needle Biopsy Needle</li> <li>DBX Material</li> <li>NORIAN Reinforced System</li> <li>RAPIDSORB Cranial Clamp</li> <li>RAPIDSORB Fixation System</li> <li>SynPOR Smooth System</li> <li>TRAUMACEM V+</li> <li>VERTECEM V+ Cement Kit</li> <li>VERTECEM V+ Syringe Kit</li> <li>Vertebroplasty Needle Kit Biopsy Kit</li> <li>chronOS Granules and Preforms System</li> <li>chronOS Inject Bone Void Filler</li> <li>chronOS Strip System</li> </ul>

**News/ Key Developments** 

Table 95
Johnson & Johnson Services Inc.: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Product Launch	Shockwave Medical Inc., part of Johnson & Johnson MedTech and a global leader in the field of circulatory restoration, announced the full U.S. launch of the Shockwave E8 Peripheral IVL Catheter following clearance by the U.S. Food and Drug Administration (FDA)
2024	Acquisition	Johnson & Johnson1 announced that it has entered into a definitive agreement to acquire V-Wave Ltd., a privately held company focused on developing innovative treatment options for patients with heart failure.
2023	Acquisition	Johnson & Johnson MedTech acquired Laminar Inc., a privately held medical device company focused on eliminating the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation (AFib).
2022	Partnership	Johnson & Johnson Medical Devices Companies announced a Strategic Partnership with Microsoft to Enable its Digital Surgery Solutions Further.



Year	Strategy	Description	
2022	Expansion	Johnson & Johnson opened a State-of-the-Art Science and Technology Campus in the San Francisco Bay Area.	
2022	Acquisition	Johnson & Johnson completed the acquisition of Abiomed.	

## KONINKLIJKE PHILIPS N.V.

High Tech Campus 52 5656 AG, Eindhoven The Netherlands

Tel: +31-20-5977-777 Website: www.philips.com

**Company Snapshot** 

Table 96
Koninklijke Philips N.V.: Company Snapshot

Corporate Category	Information	
Ticker	AMS: PHIA	
Year Founded/Incorporated	1891	
Global Headquarters	Amsterdam, the Netherlands	
Revenue 2023 (\$ Millions)	19,651.1	
Number of Employees (2023)	69,656	
Key Business Regions	North America, Western Europe, Other mature geographies, Growth geographies	
Primary Region/Country for Business	North America	
Main Business Segment	Connected Care	
Entity type	Public	
Ownership type	Parent	

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Koninklijke Philips N.V. is the parent company of Philips Group. As of January 30, 2023, Philips has shifted its business model to end-to-end businesses under a single responsibility structure in an effort to increase the company's agility in its pursuit of value creation with a long-term influence. The four business segments, diagnosis & treatment, connected care, personal health and others, are individually in charge of managing their business operations globally. Furthermore, Royal Philips designates the Other section. The connected care segment includes continuous monitoring and workflow solutions powered by sophisticated interoperability and patient data insights; ambulatory, home-based and inhospital monitoring and diagnosis solutions and services supporting the patient journey. A combination of distributors and a direct sales force, depending on the product, market and price range, are used as



sales channels. A direct sales force with an in-depth understanding of clinical settings, patient-specific diagnosis and treatment is primarily responsible for driving sales. In order to co-create solutions, promote commercial innovation and adjust to new business models like software-as-a-service and monitoring-as-a-service, Philips works with partners and customers. By the end of 2023, the Connected care segment employed 17,549 people globally.

# **Key Financial Highlights**

- The sales increased with a nominal 2% rise. Sales increased 6% on a comparable basis as a result of supply chain enhancements. In terms of comparable sales, there was a 1% increase in connected care, a 3% increase in personal health and an 11% increase in diagnosis & treatment.
- R&D expenses in 2023 were 10.4% of sales as compared to 11.7% of sales in 2022. The primary
  factors contributing to the decline were reduced restructuring, acquisition-related and other
  costs, as well as a positive foreign exchange effect.

#### **Financial Performance**

Table 97
Koninklijke Philips N.V.: Financial Performance, FY 2022 and 2023
(\$ Millions)

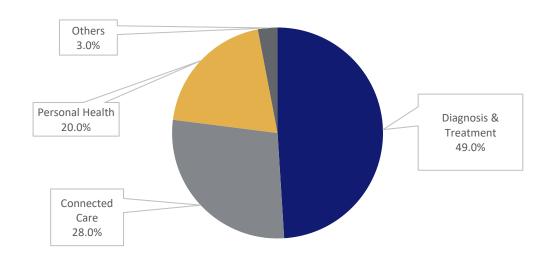
Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net revenue	18,772.7	19,651.1
R&D	-2,201.9	-2,044.2
Operating income	-1,610.1	-124.4
Net income	-1,690.1	-500.8
Total current assets	10,803.2	10,750.8
Total current liabilities	8,354.9	8,963.0

<sup>\*</sup>Exchange rate used for 2022 is 1 EURO= 1.053 USD and 2023 is 1 EURO=1.082 USD

Source: Company website, company annual report and SEC filings

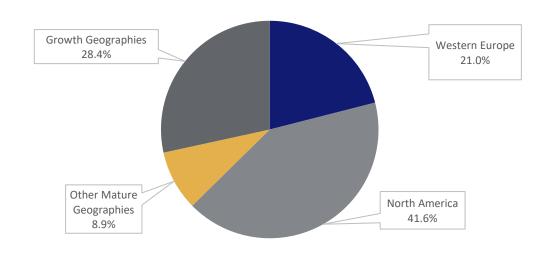


Figure 47
Koninklijke Philips N.V.: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website, company annual report, SEC filings

Figure 48
Koninklijke Philips N.V.: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website, company annual report, SEC filings



# **Product Portfolio**

Table 98 Koninklijke Philips N.V.: Product Portfolio

Segment/Category	Description	
CT scanners	a portfolio of CT scanners, including advanced multi-slice scanners and workflow solutions.	
Diagnostic ECG	a portfolio of algorithms, cardiographs, monitors, stress-test systems and ECG information management systems to streamline workflow.	
Emergency care and resuscitation solution	the range includes automated external defibrillators, advanced life sciences products, temperature modulation therapy and data management solutions.	
Interventional and diagnostic fluoroscopy	Universal radiography and fluoroscopy systems for orthopedics, pain management, urology, vascular and general radiographic work.	
Interventional X-ray	Cardiovascular X-ray systems for interventional cardiac, vascular and neuro procedures.	
MRI	the MRI systems portfolio includes cardiac MRI, clinical solutions and MRI coils.	
Monitoring	a portfolio of products, including patient monitors, clinical measurements and fetal and maternal monitors.	
Radiation oncology systems	Advanced visualization tools for pre-planning and treatment planning, as well as CT scanners.	
Respiratory care	Noninvasive and invasive ventilation solutions.	
Temperature modulation therapy	Endovascular and surface cooling and warming systems, including the RTx Endovascular System, NEW STx+ Surface Pad System, Accutrol Catheter and CoolRepeat.	
Ultrasound	a range of ultrasound systems for cardiology, critical care, general imaging and regional anesthesia.	
Phoenix guidewires	Silicone coated, nitinol core atherectomy system guidewire to support both tracking and deflecting catheters as they negotiate the vascular system.	
Phoenix Atherectomy System	Hybrid atherectomy system that combines the benefits of existing atherectomy systems. It cuts, captures and clears diseased tissue with one insertion.	
Visions PV .018	Digital IVUScatheter with a 135 cm working length and 24 mm max imaging diameter for 0.018" guide wire interventional procedures, the device aids in peripheral artery disease diagnosis.	
Visions PV .035	Digital IVUScatheter with a 90 cm length and 60 mm max imaging diameter for 0.035" guide wire interventional procedures, the device aids in peripheral artery disease diagnosis and venous disease.	
Visions PV .014P	Digital IVUScatheter with a 150 cm working length, 20 mm max imaging diameter for .014" guide wire interventional procedures, the device aids in peripheral artery disease diagnosis.	
Visions PV .014P RX	55% stiffer shaft to facilitate greater pushability while preserving the equivalent level of trackability.	
Verrata Plus	Physiology pressure guide wire with flat-tip construction to measure FFR or iFR.	



Segment/Category	Description	
Verrata	Clip connector to provide multiple backup contact points for a secure signal to measure FFR or iFR.	
FloWire	Doppler guidewire that provides direct measurement of intracoronary flow.	
ComboWire XT	Pressure and flow velocity measurement of FFR and CFR.	
EagleEye Platinum	Coronary imaging catheter with Intravascular imaging using GlyDx hydrophilic coating for increased lubricity.	
Revolution	Coronary imaging catheter with 45 MHz coronary imaging.	
EagleEye Platinum ST	Coronary imaging catheter with 2.5 mm tip-to-imaging distance designed to access more of the vessel than standard catheters.	
EPIQ 5	EPIQ 5 features nSIGHT technology that creates images with optimal resolution down to pixel level. nSIGHT imaging incorporates the use of precision beamformer along with powerful massive parallel processing.	
EPIQ 7	EPIQ 7 features xMATRIX, the most leading-edge, versatile ultrasound transducer technology, that offers clear, full, thorough visuals, making exams faster and easier for both clinicians and patients. This technology enables quick and easy volume acquisition, supports multiple interrogation capabilities and provides views not possible with 2D imaging with remarkable image quality.	
HeartModel	a new Anatomically Intelligent Ultrasound (AIUS) application that automatically detects, segments and quantifies the left ventricle and left atrium volumes and ejection fraction, from the same, live 3D volume.	
Affiniti 70	Delivers the right balance of advanced ergonomic design and precision engineering. It offers a combination of performance and workflow for quick, confident diagnosis.	

# **News/ Key Developments**

Table 99
Koninklijke Philips N.V.: News/Key Developments, 2022-2024

Year	Strategy	Description	
2024	Innovation	Carilion Clinic further expands access to quality cardiac care with the latest Philips innovations at the new regional cardiovascular institute in Virginia, U.S.	
2024	Partnership	Philips and Dutch Isala Hospital renew long-term partnerships focused on innovation and affordable, sustainable healthcare.	
2024	Collaboration.	Bon Secours Mercy Health and Philips signed a multi-year strategic collaboration.	
2024	Product Launch	Philips launched the Duo Venous Stent System to treat symptomatic venous outflow obstruction.	
2024	Expansion	Philips aims to transform diagnostic cardiology by introducing a new Cardiac Workstation.	



Year	Strategy	Description
2024	Expansion	Philips and Dutch Franciscus Gasthuis & Vlietland signed a technology agreement for a new future-proof operating suite and intervention center.
2024	Partnership	Philips and smartQare partnered to automate and simplify continuous patient monitoring in and out of the hospital.
2024	Collaboration	Philips and AWS collaborated to scale digital pathology in the cloud, enhancing diagnostic capabilities and improving productivity.
2024	Product Launch	Philips launched the Zenition 90 Motorized, a high-power, fast-motorized mobile C-arm designed to help surgeons deliver high-quality care to patients.
2024	Product Launch	Philips launched a new Azurion neuro biplane system at the European Congress of Radiology 2024 to speed up and improve minimally invasive diagnosis and treatment of neurovascular patients.
2023	Product Launch	Philips launched HealthSuite Imaging, a cloud-based next-generation Vue PACS, with new AI-enabled clinical and operational workflows.
2023	Collaboration	Philips, County Durham and Darlington NHS Foundation Trust collaborated on a sustainability blueprint to reduce carbon emissions and waste.
2023	Innovation	Philips introduced a new contrast-enhanced ultrasound application to enhance diagnostic confidence for cancer patients.
2023	FDA Clearance	Philips receives FDA 510(k) clearance for the Ultrasound Compact system to optimize portability and performance.
2023	Innovation	Philips and Masimo introduced advanced monitoring capabilities to Philips high acuity patient monitors.
2023	Partnership	Philips and Northwell Health partnered to standardize and future-proof patient monitoring across the enterprise.
2023	Collaborations	Philips formed strategic collaborations with industry leaders to inspire action toward net-zero healthcare.
2023	Partnership	Philips and TriHealth announced the multi-year partnership at the heart of the new TriHealth Heart & Vascular Institute on the campus of Bethesda North Hospital.
2023	Partnership	Philips and Candid partnered to offer dental professionals a more effective and efficient orthodontic solution.
2022	FDA Clearance	Philips receives FDA clearance for the latest breakthrough high- performance MR 7700 system.
2022	Partnership	The company partnered with Prisma Health to innovate healthcare across the enterprise and unlock the power of patient data.
2022	Partnership	The company partnered with Oulu University Hospital Finland to deliver advanced image-guided specialist care.

# LIVANOVA PLC.

20 Eastbourne Terrace London, W2 6LG U.K.

Tel: +44-0-203-325-0660 Website: www.livanova.com



#### **Company Snapshot**

Table 100
LivaNova PLC.: Company Snapshot

Corporate Category	Information	
Ticker	NASDAQ: LIVN	
Year Founded/Incorporated	2015	
Global Headquarters	London, U.K.	
Revenue 2023 (\$ Millions)	1,153.5	
Number of Employees (2023)	2,900	
Key Business Regions	U.S., Europe and Rest of World	
Primary Region/Country for Business	U.S.	
Main Business Segment	Neuromodulation	
Entity Type	Public	
Ownership Type	Parent	

Source: Company website, annual reports, investor presentations and press releases

# **Company Overview**

LivaNiova, a U.K.-based medical technology company, offers innovative solutions for the head and heart. It designs, builds and commercializes novel medical technologies for better patient improvements. The company operates through three reportable segments: cardiopulmonary, neuromodulation and advanced circulatory support (ACS). It offers a wide range of product portfolios and pipelines, including cardiopulmonary, difficult-to-treat depression, drug-resistant epilepsy and obstructive sleep apnea.

It employs 2,900 employees and commercializes its medical devices in over 100 countries.

# **Key Financial Highlights**

 Neuromodulation net revenue increased 9.0% to \$519.7 million in 2023, showcasing growth across all regions, including new and replacement implants in the U.S.



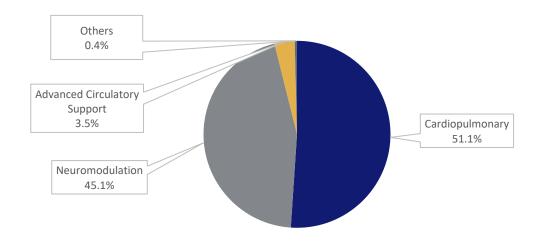
# **Company Financials**

Table 101
LivaNova PLC.: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	1,021.8	1,153.5
R &D	155.8	193.8
Operating Income	(76.8)	(68.5)
Net Income	(86.2)	17.5
Total Current Assets	886.1	988.2
Total Current Liabilities	297.4	335.0

Source: Company website; company annual report; and SEC filings

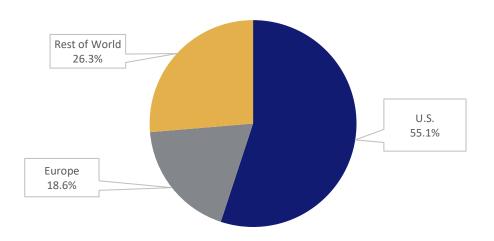
Figure 49
LivaNova PLC.: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; and SEC filings



Figure 50
LivaNova PLC.: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; and SEC filings

#### **Product Portfolio**

Table 102 LivaNova PLC.: Product Portfolio

Segment/Category	Description	
Cardiovascular Devices	<ul> <li>Sorin Heart Valves: A range of mechanical and biological heart valves designed for long-term durability and performance in heart surgery.</li> <li>Sorin Perfusion Systems: Comprehensive solutions for extracorporeal circulation during cardiac surgery, ensuring optimal blood flow and oxygenation.</li> <li>Sorin Cardiac Rhythm Management Devices: A range of devices designed to monitor and manage various cardiac arrhythmias, improving patient outcomes</li> </ul>	
Neuromodulation Devices	<ul> <li>Vagus Nerve Stimulation (VNS) Therapy: This device treats epilepsy and treatment-resistant depression by delivering electrical impulses to the vagus nerve, helping to regulate brain activity.</li> <li>SenTiva: A newer VNS device with an innovative design for ease of use and patient comfort, featuring programmable stimulation settings.</li> </ul>	
Heart-Lung Machines	Sorin C5 Heart-Lung Machine: A sophisticated system for cardiopulmonary bypass during cardiac surgery, offering advanced monitoring and control features.	

Source: Company website



# **MEDTRONIC**

20 On Hatch Lower Hatch Street Dublin 2 Ireland

Tel: +353-1-438-1700

Website: www.medtronic.com

#### **Company Snapshot**

Table 103 Medtronic: Company Snapshot

Corporate Category	Information	
Ticker	NYSE: MDT	
Year Founded/Incorporated	1949	
Global Headquarters	Dublin, Ireland	
Revenue 2023 (\$ Millions)	31,227.0	
Number of Employees (2023)	95,000	
Key Business Regions	U.S., Non-U.S. Developed Markets and Emerging Markets	
Primary Region/Country for Business	U.S.	
Main Business Segment	Cardiovascular	
Entity Type	Public	
Ownership Type	Parent	

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Medtronic is engaged in designing, manufacturing and commercializing medical devices. The company operates in four segments: Cardiovascular, Medical-Surgical, Neuroscience and Diabetes. Its product portfolio covers advanced surgical technology, cardiac rhythm, cardiovascular, diabetes, digestive and gastrointestinal, ear, nose and throat general surgery, gynecological, neurological, oral and maxillofacial, patient monitoring, renal care, respiratory, orthopedic, surgical navigation and imaging and urological. It has over 95,000 employees and operates in approximately 150 countries.

# **Key Financial Highlights**

 Our targeted product lies in their Cardiovascular segment, which experienced net sales for cardiovascular products in the fiscal year 2023, which amounted to \$11.6 billion, indicating a 1% rise from the previous year.



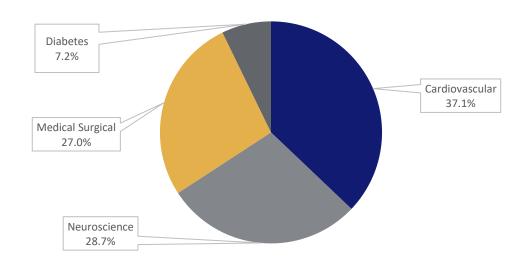
# **Company Financials**

Table 104
Medtronic: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	31,686.0	31,227.0
R&D	2,746.0	2,696.0
Operating Income	5,517	5,364
Net Income	5,062.0	3,784.0
Total Current Assets	23,059.0	21,675.0
Total Current Liabilities	12,394.0	9,051.0

Source: Company website; company annual report; and SEC filings

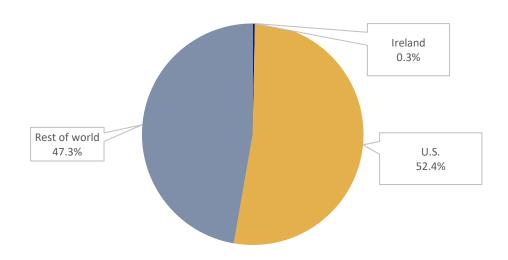
Figure 51
Medtronic: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; and SEC filings



Figure 52
Medtronic: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; and SEC filings

#### **Product Portfolio**

Table 105 Medtronic: Product Portfolio

Segment/Category	Description
Cardiac rhythm disease management (CRDM)	A portfolio of catheter-based ablation systems, implantable cardiac resynchronization therapy pacemakers and defibrillators, implantable pacing systems and remote monitoring systems for implantable cardiac devices.
Coronary	Stents, other guide wires, guide catheters and balloon catheters.
Diabetes care	FDA-approved, integrated diabetes management systems, including insulin pumps, a continuous glucose monitoring (CGM) system and therapy management software.
Endovascular	The aortic segment develops stent grafts and auxiliary technology and the peripheral segment develops stents and balloon catheters.
Neuromodulation	Neurostimulation systems and implantable drug delivery systems.
Spine	Artificial cervical discs, balloon kyphoplasty, biologic fusion systems and interspinous spacer products.
Structural heart	A portfolio of heart valve repair, mechanical valves, tissue valves and tissue stabilization systems.
Surgical Technologies	Products and procedural solutions for surgical applications.

Source: Company website



# Table 106 Medtronic: Patient Monitoring Device Product Portfolio

Device Type	Products
	BIS Complete 2-Channel Monitor
	BIS Complete 4-Channel Monitor
	BIS Quatro (4 Electrode) Sensor
Brain monitoring	BIS Bilateral Sensor
	BIS Pediatric Sensor
	BIS Extend (Extended-Use) Sensor
	BIS Brain Monitoring OEM Solutions
	Nellcor Bedside Respiratory Patient Monitoring System, PM1000N
	Nellcor Respiration Rate Software
	Nellcor Portable SpO₂ Patient Monitoring System, PM10N
	Nellcor Bedside SpO₂ Patient Monitoring System, PM100N
	Nellcor Bedside SpO₂ Patient Monitoring System
	Alarm Management System
	Nellcor N-85 Monitor with OxiMax Technology and Microstream Capnography
Pulse oximetry	Nellcor SpO₂ Forehead Sensor with OxiMax Technology
	Nellcor Flexible SpO₂ Reusable Sensor
	Nellcor SpO₂ Adhesive Sensors
	Nellcor SpO₂ Non-Adhesive Sensors
	Nellcor Reusable SpO₂ Sensors with OxiMax Technology
	Nellcor Two-Piece SpO₂ Sensors with OxiMax Technology
	Philips A04 SPM with OxiMax Technology
	Nellcor Remanufactured Sensors with OxiMax Technology
	Nellcor Pulse Oximetry OEM Solutions
OFNA magnitaring calutions	Microstream Capnography OEM Solutions
OEM monitoring solutions	INVOS Cerebral/Somatic Oximetry OEM Solutions
	BIS Brain Monitoring OEM Solutions
	Capnostream 35 Portable Respiratory Monitor
	Capnostream 20p Bedside Monitor with Apnea-Sat Alert Algorithm
	Microcap Handheld Capnographs
Capnography monitoring	FilterLine etCO₂ Sampling Lines
	Omnistream etCO₂ Sampling Lines
	Surestream CO₂ Sampling Lines
	Microstream Capnography OEM Solutions
	INVOS 5100C Cerebral/Somatic Oximeter
Corobral/comatic avimatry	INVOS Cerebral/Somatic Oximetry Adult Sensors
Cerebral/somatic oximetry	INVOS Cerebral/Somatic Oximetry Infant-Neonatal Sensors
	INVOS Cerebral/Somatic Oximetry OEM Solutions



Device Type	Products	
Health informatics and	Vital Sync Monitoring and Clinical Decision Support (CDS) Solution	
	Vital Sync Weaning Readiness and Spontaneous Breathing Trial (SBT) Monitoring App	
monitoring	Vital Sync Early Warning Score (EWS) App	
	Vital Sync Virtual Patient Monitoring Platform 2.6	

**News/ Key Developments** 

Table 107 Medtronic: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Partnership	Medtronic announced FDA approval of Simplera CGM and a global partnership with Abbott. The Simplera platform, featuring the company's newest CGM form factor, includes the Simplera CGM, designed to be used as part of a Smart MDI system with the InPen intelligent insulin pen and the Simplera Sync sensor, which is intended to be integrated with the MiniMed 780G system.
2024	FDA Approval	Medtronic received FDA approval for Inceptiv closed-loop spinal cord stimulator.
2024	FDA Approval	Medtronic announced FDA approval of the newest-generation Evolut TAVR system for the treatment of severe symptomatic aortic stenosis.
2024	FDA Approval	FDA approves Medtronic Percept RC neurostimulator with exclusive BrainSense technology.
2024	Innovation	Medtronic Diabetes announced the world's first approval for MiniMed 780G System with Simplera Sync disposable, all-in-one sensor.
2023	Collaboration	Medtronic will boost Al innovation with the introduction of a new platform.  Medtronic plc, Cosmo Pharmaceuticals (opens new window) and NVIDIA (opens new window) planned to integrate NVIDIA's Al technologies into the GI Genius intelligent endoscopy module (opens new window) the first FDA-cleared, Alassisted colonoscopy tool to help physicians detect polyps that can lead to colorectal cancer.
2023	FDA Approval	Medtronic received FDA approval for its next-generation Micra leadless pacing systems.
2023	Acquisition	Medtronic acquired wearable insulin patch maker EOFlow.
2023	FDA Approval	Medtronic announced FDA approval of a minimally invasive device to treat hypertension.
2023	FDA Approval	Medtronic received FDA approval for its novel PulseSelect Pulsed Field Ablation System to treat atrial fibrillation.
2022	Approval	The firm received U.S. FDA approval for the Vanta recharge-free neurostimulator and Intellis rechargeable neurostimulator to treat chronic pain associated with diabetic peripheral neuropathy.
2022	Approval	The firm announced that the National Medical Products Administration (NMPA) had approved the CoreValve Evolut PRO TAVR system.
2022	Acquisition	The firm agreed to acquire Affera Inc., a Boston-based, privately held medical technology company.



Year	Strategy	tegy Description	
2022	Approval	The company announced that its Freezor and Freezor Xtra Cardiac Cryoablation Focal Catheters are the only ablation catheters approved by the U.S. FDA to treat the growing prevalence of pediatric atrioventricular nodal reentrant tachycardia (AVNRT).	
2022	Launch	The company launched its NuVent Eustachian tube dilation balloon, which the U.S. FDA cleared to treat chronic, obstructive eustachian tube dysfunction.	
2022	Approval	The company received U.S. FDA approval for its Onyx Frontier drug-eluting stent (DES).	
2022	Acquisition	Medtronic plc acquired Intersect ENT, expanding the company's comprehensive ear, nose and throat (ENT) portfolio with innovative products used in sinus procedures to improve post-operative outcomes and to treat nasal polyps.	
2022	FDA Clearance	Medtronic received FDA clearance for a next-generation UNID Spine Analyzer with a predictive model for degenerative spine surgery.	
2022	Acquisition	Medtronic plc announced that it has completed the acquisition of Affera Inc.  This acquisition expanded the company's cardiac ablation portfolio to include its first-ever cardiac mapping and navigation platform, encompassing a differentiated, fully integrated diagnostic, focal pulsed field and radiofrequency ablation solution.	
2022	Partnership	Medtronic announced a partnership with BioIntelliSense to distribute a multi- parameter wearable for continuous remote patient monitoring from in-hospital to home exclusively in the U.S.	
2022	FDA Clearance	Medtronic received FDA clearance for an expanded indication of LINQ II insertable cardiac monitor for pediatric patients ages two and older.	
2022	FDA Clearance	Medtronic received FDA approval to pace the heart's natural conduction system.	
2022	Product Launch	The launch of Medtronic Neurovascular Co-Lab Platform to accelerate innovation in stroke treatment. The company aimed at advancing technological innovations with the most significant potential to benefit millions of stroke patients.	
2022	Product Launch	Medtronic launched the World's First and Only Infusion Set for Insulin Pumps that Doubles Wear Time up to 7 days in the U.S.	

# SIEMENS HEALTHINEERS AG

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Germany

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We b site: www.siemens-health in eers.com



#### **Company Snapshot:**

Table 108
Siemens Healthineers AG: Company Snapshot

Corporate Category	Information
Ticker	ETR: SHL
Year Founded/Incorporated	2015
Global Headquarters	Munich, Germany
Revenue 2023 (\$ Millions)	23,152.1
Number of Employees (2023)	71,000
Key Business Regions	Americas
Primary Region/Country for Business	Americas, Europe, C.I.S., Africa, Middle East (EMEA), Asia-Pacific
Main Business Segment	Imaging, Diagnostics
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Siemens Healthineers is a well-established company in the healthcare industry. It provides its products and services to many countries around the world. It has production sites in Germany, the U.S., China, India, Great Britain and Slovakia and a presence in more than 70 countries in the world and products are available in 180 plus countries. It has four business segments: Imaging, Diagnostics, Varian and Advanced Therapies.

Siemens Healthineers is a key player in diagnostic imaging, offering a wide range of technologies including MRI, CT, ultrasound and X-ray systems, used in hospitals and healthcare facilities worldwide. The company also has a strong foothold in laboratory diagnostics, particularly in in-vitro diagnostics, which covers a broad spectrum of testing, from routine blood work to advanced genetic testing. In recent years, Siemens Healthineers has expanded into precision medicine and digital healthcare solutions, incorporating Al-driven tools and robotics to enhance diagnostic accuracy and treatment outcomes. The company is committed to transforming healthcare delivery by improving diagnostic and therapeutic options, optimizing clinical workflows and enhancing patient outcomes.

#### **Key Financial Highlights**

- The company's total revenue increased by 1.2% over the previous year. There was growth in all the segments except the rapid COVID antigen test.
- There was an increase on the comparable basis of 10.9%, 14.8% and 7.8% in imaging, Varian and advanced therapy segments, respectively, over the year 2022. The growth was possible due to demand from various Asia-Pacific and North America.



#### **Financial Performance**

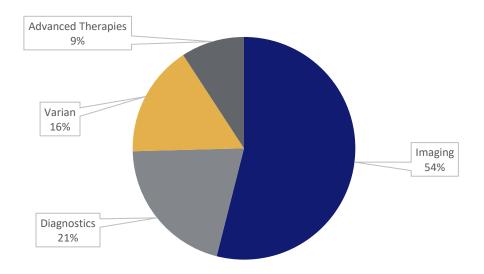
Table 109
Siemens Healthineers AG: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	23,541.1	23,152.1
R &D	(1,935.2)	(1,992.7)
Operating Income	3,173.3	2,280.0
Net Income	2,226.8	1,628.5
Total Current Assets	14,504.7	15,095.8
Total Current Liabilities	13,035.7	14,352.6

Conversion rate: 2022, 1.084143 and 2023 1.067901

Source: Company website; company annual report; and SEC filings

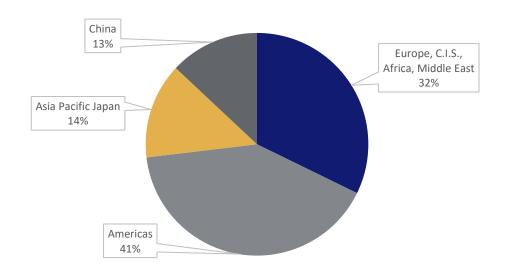
Figure 53
Siemens Healthineers AG: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; SEC filings



Figure 54
Siemens Healthineers AG: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; SEC filings

# **Product Portfolio**

Table 110
Siemens Healthineers AG: Product Portfolio

Segment/Category	Description	
ACUSON SC2000 PRIME	The ACUSON SC2000 PRIME is a cardiovascular ultrasound device that performs 2D and 3D transthoracic (TTE), transesophageal (TEE) and intracardiac echocardiography (ICE). It operates with 64 parallel beams (four times more than conventional technology).	
ACUSON X300 PE	The ACUSON X300 ultrasound system, premium edition (PE), provides exceptional imaging performance across a wide range of cardiac patients. The system includes applications such as stress echo, color M-mode, adult TEE and left ventricular opacification, as well as advanced imaging applications such as intracardiac echocardiography (ICE).	
ACUSON S1000	The ACUSON S1000 Ultrasound System (HELX Evolution with Touch Control) offers the workflow efficiency, imaging performance and sustainability associated with ultrasound technologies, such as elastography imaging, multimodality review and contrast-enhanced ultrasound.	
ACUSON X700	The ACUSON X700 Ultrasound system has built-in features that permit upgrades, like transducer compatibility, with the ACUSON X family of ultrasound transducers and the ACUSON S family of transducers.	
ACUSON X600	An ultrasound system with Dynamic TCE contrast enhancement technology.	



Segment/Category Description		
ACUSON X300 PE	The ACUSON X300 PE ultrasound system with ErgoDynamic Imaging has a fully adjustable, 18-inch-high resolution display, created to handle a wide variety of clinical applications with unmatched versatility and accessibility to the latest Siemens pioneering technologies.	
ACUSON X150	The ACUSON X150 ultrasound system provides superior 2D-mode imaging and pulsed wave Doppler functionality, providing high-quality audio and visual capabilities for spectral visualization and blood flow quantification.	
ACUSON AcuNav Ultrasound Catheter	For performing intra-cardiac echo during interventional procedures.	
ACUSON NX3	ACUSON NX3 ultrasound system has a portfolio of fully compatible and scalable transducers for advanced superficial imaging.	
ACUSON NX2	ACUSON NX2 ultrasound system offers premium imaging performance for efficient diagnostic imaging.	
Medical imaging	This segment offers a different type of medical imaging equipment including angiography equipment, computed tomography, fluoroscopy devices, imaging for radiation therapy, magnetic resonance imaging, mammography, mobile Carms, molecular imaging, radiography systems, refurbished systems, robotic X-ray systems, ultrasound machines and urology equipment.	
Laboratory diagnostics	This segment offers a broad spectrum of immunoassay, chemistry, hematology, molecular and urinalysis testing systems, in conjunction with automation, informatics and services. Some key products include the Attellica portfolio, laboratory automation systems, clinical chemistry analyzers, drug testing diagnostics, hematology analyzers, hemostats, immunoassays, integrated immunoassays, chemistry analyzers and urinalysis devices.	
Point-of-care testing	This segment offers blood gas products, cardiac systems, coagulation analyzers, urinalysis products and point of care testing products.	
Digital health solutions	Offers a wide range of digital health products and services.	
Services and consulting	This segment offers laboratory diagnostic services, customer services, enterprise services and value partners for healthcare consulting.	
Healthcare IT	Offers imaging IT and diagnostic IT devices and services.	

**News/ Key Developments** 

Table 111 Siemens Healthineers AG: News/Key Developments, 2022-2024

Year	Strategy	Description	
2024	Innovation	Siemens Healthineers announced New Cardiology Applications for Acuson Sequoia Ultrasound System.	
2024	Expansion	Expansion Siemens Healthineers announced £250m Oxford facility, the UK's first significant production site for new MRI cooling technology.	
2024	Innovation	Siemens Healthineers has developed an automated, self-driving C-arm system for intraoperative imaging in surgery.	
2024	FDA Clearance	Varian received FDA 510(k) Clearance for TrueBeam and Edge Radiotherapy Systems Featuring the HyperSight Imaging Solution.	



Year	Strategy	Description	
2024	Innovation	Siemens Healthineers Introduced Magnetom Flow for Greater Sustainability and Efficiency in Magnetic Resonance Imaging.	
2024	Partnership	Siemens Healthineers expanded its partnership with City Cancer Challenge. Through collaboration with local stakeholders, it aims to improve access to cancer care and health equity.	
2024	Partnership	Varian and Nova Scotia Health Form First Multi-Disciplinary Oncology Partnership to Catalyze Advancements in Cancer Care.	
2023	Expansion	Siemens Healthineers expanded its production site in Rudolstadt, Germany.	
2023	Innovation	Siemens Healthineers revealed the Acuson Origin premium cardiovascular ultrasound system, an Al-powered system designed to expedite patient diagnosis and reduce measurement variability.	
2023	Partnership	SSM Health, Siemens Healthineers partnered to advance health equity and empower workforce development in underserved communities.	
2023	Product Launch	Siemens Healthineers launched Atellica CI Analyzer, a compact testing system to tackle lab challenges.	
2023	Product Launch	Siemens Healthineers launched next-gen hematology analyzers and workflow barriers were removed to help patients get faster results.	
2023	Agreement	Siemens Healthineers entered an Agreement with Scopio Labs to Distribute Full-Field Digital Cell Morphology Technology.	
2023	Agreement	Siemens Healthineers and Sysmex signed a global agreement to supply hemostasis instruments and reagents as OEMs.	
2023	Strategic Partnership	Siemens Healthineers and Unilabs launched a strategic partnership for the latest diagnostic testing infrastructure to improve patients' care.	
2022	Expansion	Siemens Healthineers opened a new Ultrasound manufacturing facility in Košice, Slovakia.	
2022	Partnership	Siemens Healthineers and Atrium Health Entered a Multi-Year Value Partnership to Improve healthcare care Capabilities, Access and Equity.	
2022	Product Launch	Siemens Healthineers introduced a new mobile magnetic resonance imaging scanner, Magnetom Viato. Mobile.	
2022	Expansion	Varian manufactured Halcyon radiotherapy systems in Germany for the first time. Following Varian's successful integration, radiotherapy systems were produced at Siemens Healthineers' site in Kemnath.	
2022	Partnership	The company collaborated with the University of Miami Health System to advance technological advancements and standardize equipment at the health system while allowing the university to create educational and training programs for clinicians and technologists.	
2022	Launch	The company launched the Acuson family of ultrasound portfolios. The refreshed ultrasound portfolio is designed to offer even more clinical adaptability and address challenges across various clinical applications.	
2022	Launch	The company launched Mobilett Impact, its newest mobile X-ray system. the system combines all the benefits of a mobile X-ray system for imaging at the patient's bedside with full digital integration and an economical price.	
2022	Partnership	The company partnered with Ohio State University Wexner Medical Center to advance personalized medicine and improve access to high-quality, costeffective healthcare.	
2022	Launch	The company launched Symbia Pro.specta SPECT/CT scanner, a single photon emission computed tomography/computed tomography (SPECT/CT) system with CE mark and Food and Drug Administration (FDA) clearance that has advanced SPECT and CT imaging technologies.	
2022	Launch	The company launched the angiography system Artis iconic Ceiling for precise tumor embolization.	



Year	Strategy	Description
2022	Partnership Services to the most extensive private project in the healthcare sector Slovakia	
2022	Partnership	The company partnered with Oulu University Hospital to provide medical technology management and digital solutions, including research, innovation development, comprehensive training programs and consulting services for workflow improvements.
2022	Approval	Siemens Healthineers introduced Symbia Pro.specta, a single photon emission computed tomography/computed tomography (SPECT/CT) system with the CE mark and Food and Drug Administration (FDA) clearance that has advanced SPECT and CT imaging technologies.

# SMITH & NEPHEW PLC

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# **Company Snapshot**

Table 112 Smith & Nephew PLC: Company Snapshot

Corporate Category	Information
Ticker	LON: SN
Year Founded/Incorporated	1856
Global Headquarters	Hertfordshire, U.K.
Revenue 2023 (\$ Millions)	5,549
Number of Employees (2023)	18,000
Key Business Regions	U.S., Europe, Canada, Japan, Australia and New Zealand
Primary Region/Country for Business	U.S.
Main Business Segment	Orthopedics
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases



#### **Company Overview**

Smith+Nephew is a medical equipment company engaged in developing, manufacturing and marketing medical technology products and services. It offers innovative products for minimally invasive surgeries, specialized knee replacement procedures, hip joint reconstruction, sports medicine, trauma and extremities and arthroscopic procedures. The company operates in three reportable segments: Orthopedics, Sports Medicine & ENT and Advanced Wound Management.

The company offers drug-device combination products through its advanced wound management segment. The company operates in more than 100 countries. The company was Incorporated in 1856 and had a workforce of 18,000 (as of December 31, 2023). The company has a worldwide presence across America, Europe, Asia, the Middle East, Australia and New Zealand.

#### **Key Financial Highlights**

- Group revenue in 2023 was \$5,549 million (2022: \$5,215 million), an increase of 7.2% on an underlying basis.
- Orthopedics underlying growth up 5.7%, setting foundations for further improvement
- Advanced Wound Management delivered 6.4% underlying revenue growth, maintaining momentum from the prior year.

#### **Financial Performance**

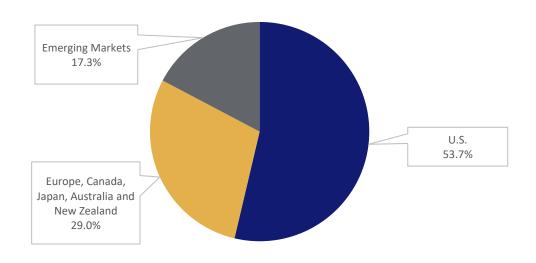
Table 113
Smith & Nephew PLC: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	5,215	5,549
R&D	(345)	(339)
Operating Income	235	290
Total Current Assets	3,856	4,030
Total Current Liabilities	1,715	2,271

Source: Company website; company annual report; and SEC filings

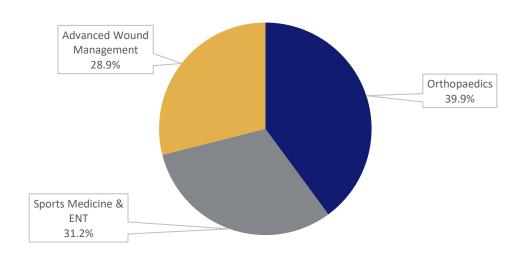


Figure 55
Smith & Nephew PLC: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; and SEC filings

Figure 56
Smith & Nephew PLC: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; and SEC filings



# **Product Portfolio**

Table 114
Smith & Nephew PLC: Product Portfolio

Segment/Category	Description	
PICO Negative Pressure Wound Therapy (NPWT) System	A portable, disposable device used for managing complex wounds. It uses negative pressure to help promote healing by removing exudate (fluids) and reducing infection risk.	
RAPID Resurfacing Implants	A type of orthopedic implant used in partial joint resurfacing procedures. It helps preserve healthy bone tissue while reducing joint pain, primarily for patients with osteoarthritis.	
VERSAJET Hydrosurgery System	A surgical device used for wound debridement. It delivers a precise stream of saline solution to remove dead tissue, debris and bacteria from wounds while preserving healthy tissue.	
ALLEVYN Wound Dressings	Advanced foam dressings are designed for managing exuding wounds. They provide optimal moisture balance to accelerate healing, help absorb excess fluid and reduce infection risk.	
REGENETEN Bioinductive Implant	A bioinductive implant is used in rotator cuff repair. It promotes the body's natural healing by stimulating new tendon-like tissue growth, which strengthens the rotator cuff tendon.	
TRUCLEAR Hysteroscopic Morcellator System	A surgical device used for removing intrauterine pathologies like fibroids and polyps. It provides real-time tissue removal while minimizing damage to the surrounding uterine tissue.	
HEALICOIL Suture Anchor	Used in soft tissue repairs such as shoulder or hip surgeries. These suture anchors are designed to secure soft tissues to bone, aiding in tendon or ligament repair.	
POLAR3 Total Hip Replacement System	A complete hip implant system designed to improve stability and range of motion for patients undergoing hip replacement surgery, offering reduced wear and extended implant longevity.	
Orthopedics, Sports medicine and Advanced Wound Management	<ul> <li>ACL reconstruction fixation device - Endobutton CL</li> <li>Fluid management system - Dyonics 25</li> <li>High-definition camera system - 560 Series, progressive scan surgical camera</li> <li>Hip-guide system - Crosstrac</li> <li>Meniscal repair system - Fast-Fix</li> <li>Monopolar ablation probes - Sculptor</li> <li>Shaver hand piece for arthroscopic surgery - Powermax</li> <li>Suture anchors - Bioraptor 2.3 PK, Footprint PK</li> </ul>	

Source: Company website



# **News/ Key Developments**

Table 115
Smith & Nephew PLC: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Product Launch	Smith+Nephew announced the launch of its TOTAL ANKLE Patient- Matched Guides, which give surgeons a predictable and efficient option for planning and performing total ankle replacement (TAR) procedures.
2024	Collaboration	Smith+Nephew announced an exclusive digital and advanced analytics collaboration with Healthcare Outcomes Performance Company (HOPCo) – the world's most extensive, fully integrated musculoskeletal (MSK) value-based care and outcomes management company.
2024	Product Launch	Smith+Nephew announced the launch of its new CORIOGRAPH Pre- Operative Planning and Modeling Services, providing an unparalleled, personalized solution for surgeons and patients across partial and total knee arthroplasty procedures.
2024	Product Launch	Smith+Nephew introduced the RENASYSO EDGE Negative Pressure Wound Therapy System, an exciting new option in home-based care for patients with chronic wounds.
2024	Agreement	Smith+Nephew announced that it has entered a Master Cooperative Research and Development Agreement (CRADA) with the U.S. Army Institute of Surgical Research (USAISR).
2024	Acquisition	Smith+Nephew announced that it had completed the acquisition of CartiHeal, developer of Agili-C, a novel sports medicine technology for cartilage regeneration in the knee.
2023	Acquisition	Smith+Nephew had entered into a definitive agreement to acquire CartiHeal, developer of Agili-C, a novel sports medicine technology for cartilage regeneration in the knee.
2023	Product Launch	Smith+Nephew launched a revolutionary REGENETENO Bioinductive Implant in Japan, providing an advanced healing option for patients with rotator cuff tears.
2023	Expansion	Smith+Nephew had announced the opening of the purpose-built Smith+Nephew Academy Munich, a new centre for surgical innovation and training.
2023	Product Launch	Smith+Nephew launched its OR3O Dual Mobility System in India for primary and revision hip arthroplasty.
2023	Product Launch	Smith+Nephew launched its REGENETEN Bioinductive Implant in India. Since its introduction, more than 100,000 procedures have been completed globally and the REGENETEN implant has had a transformative impact on how surgeons approach rotator cuff procedures.
2023	FDA Clearance	Smith+Nephew announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its AETOS Shoulder System.
2023	Innovation	Smith+Nephew announced that its PICO Single Use Negative Pressure Wound Therapy Systems have received an Innovative Technology contract from Vizient Inc., the nation's largest member-driven healthcare performance improvement company.



Year	Strategy	Description
2023	Innovation	Smith+Nephew introduced its new CORI♦ Digital Tensioner, a purpose-built device that allows surgeons to measure the ligament tension in a knee prior to cutting bone.
2023	Agreement	Smith+Nephew signed an exclusive distribution agreement to bring a unique NAVBIT SPRINT solution for accurate acetabular cup alignment to Japan.
2023	Innovation	Smith+Nephew Sports Medicine advanced procedural innovation by launching the QUADTRACO Quadriceps Tendon Harvest Guide System and expanding the ULTRABUTTONO Adjustable Fixation Devices family for ACL reconstruction.
2022	Product Launch	Smith+Nephew launched the OR3O Dual Mobility System in Japan for primary and revision hip arthroplasty use.
2022	Partnership	Smith+Nephew announced a partnership with Rods&Cones to provide customers with innovative surgery glasses and digital remote assistance.
2022	Expansion	Smith+Nephew announced a new UK R&D and manufacturing facility for Advanced Wound Management with \$100m+ investment near Hull.
2022	Product Launch	Smith+Nephew launched a next-generation Robotics system in Japan; the CORI Surgical system, designed to augment the surgical experience for high accuracy (1-4 *) and improve outcomes in knee arthroplasty (5**,6‡)
2022	Acquisition	Smith+Nephew announced the acquisition of Engage Surgical, owner of the only cementless unicompartmental (partial) knee system commercially available in the US.
2022	Expansion	Smith+Nephew had announced the grand opening of a new commercial hub to serve customers across the Nordic region better.

## **STRYKER**

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#### **Company Snapshot**

Table 116
Stryker: Company Snapshot

Parameter	Information
Ticker	NYSE: SYK
Year Founded/Incorporated	1941
Global Headquarters	Michigan, U.S.
Revenue 2023 (\$ Millions)	20,498
Number of Employees (2023)	52,000
Key Business Regions	U.S.
Primary Region/Country for Business	U.S., Europe, Middle East and Africa, Asia-Pacific
Main Business Segment	MedSurg and Neurotechnology
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations

#### **Company Overview**

Stryker produces orthopedic, medical, surgical, neurotechnology and spine products. Its primary offerings encompass orthopedic implants, surgical equipment, surgical navigation systems, patient handling equipment, emergency medical gear, disposable products for intensive care, endoscopic systems and communication systems. Additionally, Stryker provides neurosurgical equipment, neurovascular devices, spinal devices and medical devices for various conditions.

#### **Key Financial Highlights**

In FY23, Stryker witnessed a growth of 11.1% as compared to the previous year. The company generated \$20.5 billion in 2023 compared to \$18.5 billion in 2022. This is mainly due to the company's increased sales in the U.S.



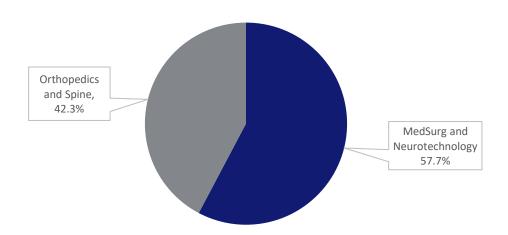
#### **Financial Performance**

Table 117
Stryker: Financial Performance, FY 2022 and 2023
(\$ Millions)

Financial Metric	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	18,449	20,498
R&D	1,454	1,388
Operating Income	2,841	3,888
Net Income	2,358	3,165
Total Current Assets	10,275	12,518
Total Current Liabilities	6,303	7,921

Source: Company website; company annual report; and SEC filings

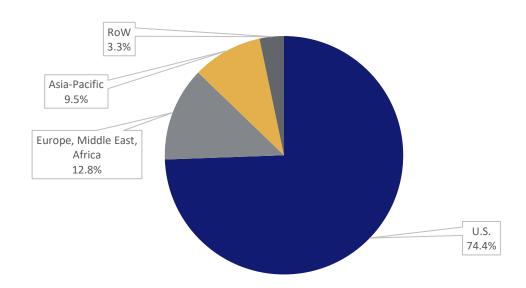
Figure 57
Stryker: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website, company annual report and SEC filings



Figure 58
Stryker: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website, annual reports, investor presentations



#### **Product Portfolio**

# Table 118 Stryker: Product Portfolio

Product/Segment	Description
Hip implants	<ul> <li>Accolade II</li> <li>Anato</li> <li>Anatomic Dual Mobility</li> <li>Mako Total Hip</li> <li>Modular Dual Mobility</li> <li>Secur-Fit Advanced</li> <li>Triathlon</li> <li>Triathlon Tritanium</li> <li>Trident</li> <li>X3</li> </ul>
Knee implants	<ul> <li>Accolade II</li> <li>Anato</li> <li>Anatomic Dual Mobility</li> <li>Mako Partial Knee</li> <li>Mako Total Knee</li> <li>Modular Dual Mobility</li> <li>Restoris MCK</li> <li>Secur-Fit Advanced</li> <li>Triathlon</li> <li>Triathlon Tritanium</li> <li>Trident</li> <li>X3</li> </ul>
Shoulder and elbow reconstruction	<ul> <li>AxSOS 3 Ti Proximal Humerus</li> <li>ReUnion RFX</li> <li>ReUnion TSA</li> <li>rHead</li> <li>rHead Lateral</li> <li>rHead Recon</li> <li>T2 Humeral</li> <li>T2 Proximal Humeral</li> <li>TrueSight</li> <li>UNI-Elbow</li> <li>VariAx 2 Clavicle</li> <li>VariAx 2 Elbow</li> </ul>
Trauma and extremities	<ul> <li>4Fusion</li> <li>AlloWrap DS</li> <li>Asnis III</li> <li>Asnis Micro</li> <li>AutoFix</li> <li>Avanta CMC</li> <li>AxSOS 3 Ti Compression</li> <li>dl femur</li> </ul>



Duadust/Cogmont	Description
Product/Segment	<ul> <li>Description</li> <li>AxSOS 3 Ti Distal Lateral Femur</li> </ul>
	AxSOS 3 Ti Distal Ederal Ferrital     AxSOS 3 Ti Distal Tibia
	AxSOS 3 Ti Pistai Tibia      AxSOS 3 Ti Proximal Humerus
	AxSOS 3 Ti Proximal Tibia  AxSOS 3 Ti Proximal Tibia
	• BIO <sup>4</sup>
	CableFix Xpress
	• DBM
	Diamond Carpal
	Endotrac ECTR
	• Gamma3
	Hoffmann 3
	Hoffmann LRF
	Hoffmann LRF Hexapod
	HydroSet
	• Imbibe
	KnifeLight
	Nerve repair
	Omega 3
	• PRO
	<ul> <li>ProLayer</li> </ul>
	• ReMotion
	ReUnion RFX
	ReUnion RSA
	ReUnion TSA
	• rHead
	rHead Lateral
	rHead Plating
	rHead Recon
	Silicone MCP, MCPX, PIP
	SR MCP and PIP
	• T2 Ankle Arthrodesis
	• T2 Femur a/R
	• T2 GTN
	• T2 Humeral
	• T2 Kids
	T2 Proximal Humeral     T3 Page 1999
	• T2 Recon
	• T2 SCN
	• T2 Tibia
	<ul><li>TrueSight</li><li>TwinFix</li></ul>
	<ul><li>uHead</li><li>UNI-Elbow</li></ul>
	VariAx 2 Distal Fibula
	VariAx 2 Clavicle
	VariAx 2 Compression
	VariAx 2 Distal Radius
	VariAx 2 Elbow
	VariAx 2 Foot
	VariAx 2 SpeedGuide
	VariAx 2 Wrist Fusion
	VariAx Hand



Product/Segment	Description
Product/Segment	Description
	• Vitoss
	Vitoss BA
	Vitoss BA2X
	Vitoss BBTrauma
	AlloWrap DS
	● BIO <sup>4</sup>
	• DBM
	HydroSet
	Imbibe
Biologics	Nerve repair
	ProLayer
	• Vitoss
	Vitoss BA
	Vitoss BA2X
	Vitoss BBTrauma
	• ACP-1
	Aero-AL
	• Aero-C
	Aero-LL
	AlloCraft CA
	AlloCraft CL
	AlloCraft CP
	AlloCraft CS
	Aviator
	AVS Anchor-C
	AVS Anchor-L
	AVS ARIA
	AVS AS
	AVS Navigator
	AVS TL     AVS TL
	AVS UniLIF     DIO AVIS CO
	BIO AVS C Open  BIO AVS C River  BI
Spine	BIO AVS C Plug     BIO AVS Usi Us
	<ul><li>BIO AVS UniLIF</li><li>BIO Chips</li></ul>
	BIO DBM
	BIO Shaft
	BIO Wedge
	BIO Wedge      BIOExpand
	BIO <sup>4</sup>
	Bone Mill
	• ES2
	Escalate
	• Giza
	IBD PEEK <sup>c</sup>
	Imbibe
	LITe Anterior Retractor
	LITe BIO Delivery System
	LITe Decompression
	LITe Midline Retractor System
	LITe Pedicle Access Solution



Product/Segment	Description
	LITe Pedicle Based Retractor (PBR) System
	LITe Plate System
1	• Luxor
1	Mantis
1	• OASYS
1	<ul> <li>Osteotomy</li> </ul>
1	Phantom Retractor
1	• Radius
1	Reflex Hybrid
1	• Serrato
1	• Tempus
1	• Trio+
1	Tritanium C
1	Tritanium PL
1	UniVise
1	<ul> <li>VBOSS</li> </ul>
1	• Vitoss
1	Vitoss BA
1	<ul> <li>Vitoss BA2X</li> </ul>
1	Vitoss BiModal
1	• VLIFT
1	• Xia 3
1	Xia 3 SUK DVR
	• Xia 4.5
	Xia CT (Cortical Trajectory)

#### **News/ Key Developments**

Table 119
Stryker: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Acquisition	Stryker completed acquisition of care.ai. The acquisition will strengthen Stryker's growing healthcare IT offering and wirelessly connected medical device portfolio.
2024	Acquisition	Stryker announces definitive agreement to acquire Vertos Medical Inc., expanding interventional pain management solutions
2022	Acquisition	The firm completed its acquisition of Vocera Communications Inc.

Source: Company website



#### SYSMEX CORP.

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Tel: +81-78-265-0500 Website: www.sysmex.co.jp

#### **Company Snapshot**

Table 120
Sysmex Corp.: Company Snapshot

Corporate Category	Information
Ticker	TYO: 6869
Year Founded/Incorporated	1968
Global Headquarters	Kobe, Japan
Revenue 2023 (\$ Millions)	3,037.7
Number of Employees (2023)	10,522
Key Business Regions	Japan, Americas, EMEA, China, Asia-Pacific
Primary Region/Country for Business	EMEA
Main Business Segment	Diagnostic
Entity Type	Public
Ownership Type	Parent

Note: JPY to USD converted by using the average exchange rate 0.0089 in 2022 and 0.0074 in 2023

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Established in 1968, Sysmex Corp. develops and provides clinical diagnostics, automation and information systems. The Company conducts business through the following divisions: hematology, urinalysis, immunochemistry, clinical chemistry, FCM, life science, others and medical robotics.

The Company is a global leader in the hematology market and has maintained its number-one ranking for the last 15 years. The Hematology division offers hematology analyzers, reagents, consumables and services to various healthcare end users. The Company has a significant alliance with Roche and Cellavision in hematology. The Company is expanding its market presence by introducing high-end models. Additionally, the Company is focused on designing sustainable products with reduced power consumption and fewer space requirements.

Sysmex Corp. provides solutions through various diagnostic products and services in hospitals, research institutes and medical institutions. The Company has a strong market in Asia-Pacific and has a market presence in more than 190 countries. It has seven instrument manufacturing bases and 14 location bases for reagent manufacturing. Further, the Company is strengthening its position by offering robust customer support.



#### **Key Financial Highlights**

Sales of hematology instruments rose in North America in the 2022 fiscal year, while the
expansion of the installed instrument base contributed to a rise in reagent sales in the urinalysis
field. The company strengthened its direct sales structure in Central and South America, where
hematology and urinalysis also saw strong remittance sales. Sales increased by 5.2% in local
currency.

#### **Financial Performance**

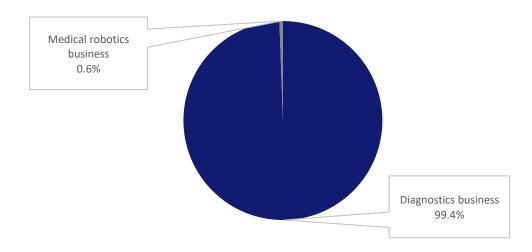
Table 121
Sysmex Corp.: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	3,035.3	3,197.8
R&D Expenses	229.7	217.6
Operating Income	508.1	516.9
Net Income	338.1	344.9
Total Current Assets	2,184.9	2,379.8
Total Current Liabilities	821.5	818.2

Note: JPY to USD converted by using the average exchange rate 0.007394 in 2022 and 0.006929 in 2023

Source: Company website; company annual report; and SEC filings

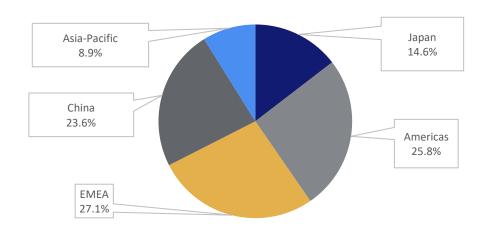
Figure 59
Sysmex Corp.: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; SEC filings



Figure 60
Sysmex Corp.: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; SEC filings

#### **Product Portfolio**

Table 122 Sysmex Corp.: Product Portfolio

Segment/Category	Description
XN-Series Hematology Analyzers	Advanced blood testing systems provide comprehensive diagnostic insights by analyzing red and white blood cells and platelets. They are commonly used to diagnose blood disorders such as anemia and leukemia.
UF-Series Urine Analyzers	This series is designed to automate urinalysis, providing fast and accurate results for urine samples. These devices detect urinary tract infections (UTIs) and kidney diseases and monitor overall renal health.
XT-Series Automated Hematology Analyzers	These analyzers offer reliable and scalable solutions for routine and specialized testing in hematology. The XT series focuses on delivering accurate and efficient blood cell counts, helping laboratories manage large volumes of tests.
Sysmex CS-Series Coagulation Analyzers	The CS-series devices measure blood clotting times and other coagulation parameters. They are essential in monitoring conditions such as hemophilia or in patients taking anticoagulant medications.
Sysmex XP-300 Hematology Analyzer	This compact hematology system is ideal for small to medium-sized labs. It provides 3-part differential results, offering essential hematology testing for clinics and smaller healthcare settings.
SP-50 Hematology Slide Preparation Unit	The SP-50 automates preparing and staining blood slides for microscopic review. This helps improve efficiency and reduces human error in labs handling large sample volumes.



Segment/Category	Description
Sysmex HISCL-Series Immunoassay Analyzers	These devices use chemiluminescence technology to precisely detect disease markers, including hormones, tumor markers and infectious diseases. They play a crucial role in diagnostics and patient monitoring.
Sysmex DI-60 Digital Morphology Analyzer	This device helps in the digital imaging of blood cells, providing enhanced visualization and aiding in identifying abnormal cell morphology. It supports diagnostics in hematological diseases.
XN-L Series Hematology Analyzers	Designed for smaller labs, the XN-L Series offers a 6-part differential analysis, helping detect diseases like anemia, leukemia and infections. It features compact designs and high accuracy for routine blood diagnostics.
XT-2000i Automated Hematology Analyzer	It provides advanced blood analysis, including reticulocyte counting, for more detailed diagnostic insights. It is often used in hospitals and large clinical labs.
Sysmex UN-Series Urine Analyzers	These devices provide fully automated urine testing with features for sediment analysis, chemical analysis and imaging, useful for diagnosing UTIs, kidney disease and metabolic disorders.
SNCS Laboratory Network System	A laboratory information system (LIS) that connects multiple Sysmex devices, allowing for seamless data integration, test results management and workflow optimization in laboratories.
HISCL-800 Automated Immunoassay Analyzer	A high-throughput analyzer for immunoassay testing, ideal for detecting biomarkers related to infectious diseases, cancers and other conditions with chemiluminescent detection.
Sysmex POCH-100i Hematology Analyzer	A small, easy-to-use hematology analyzer for point-of-care testing (POCT). This is often used in clinics or emergency settings for rapid blood analysis.
Sysmex CA-660 Coagulation Analyzer	A compact analyzer designed to perform blood coagulation tests, especially useful for small labs and clinics dealing with blood clotting disorders.

## **News/ Key Developments**

Table 123
Sysmex Corp.: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Agreement	Sysmex Corp.'s Strategic Alliance Agreement with QIAGEN N.V. to deepen their collaboration in genetic testing, including research and development, production, clinical development and sales marketing.
2024	Expansion	Sysmex Corp. announces the completion of construction of a new manufacturing base in India. This is the Group's first factory capable of producing both reagents and instruments.
2024	Brand expansion and Product Commercialization	Sysmex Begins Selling Hemostasis Instruments and Reagents Under the Sysmex Brand in the U.S. and EU Countries.
2024	Product Commercialization	Sysmex Begined Sales of Six Testing Parameters for the Immunoassay Panel Related to Gynecological and Gonadal Hormones in Japan. Contributing to the Diagnosis and Treatment of Gynecological Disorders and Infertility Treatment.



Year	Strategy	Description
2024	Collaboration	Sysmex and Hitachi High-Tech Agreed to Collaborate on Development of New Genetic Testing Systems.
2024	Business Expansion	Sysmex Corp. is to commence direct sales and service in Italy in hematology, urinalysis and hemostasis, as well as in life science and industrial flow cytometry.
2023	Partnership	Sysmex and Fujirebio expanded the CDMO Partnership into the Field of Neurodegenerative Diseases under their Immunoassay Collaboration.
2023	Acquisition	AlliedCel, a joint venture between Sysmex and JCR Pharmaceuticals, acquired a new pipeline to promote the early social implementation of regenerative medicine products.
2023	Innovation	Sysmex Corp. announced the establishment of the Innovation Healthcare Science Hub Tokyo (HCST), a new research and development hub, in Shinkiba (Koto-ku, Tokyo)
2023	Expansion	Sysmex Corp. announced an expansion of the Global Business Partnership Agreement ("GBPA") with Roche Diagnostics International Ltd., the diagnostic business unit of F. Hoffmann-La Roche Ltd, to address long-term issues in providing additional value to customers in laboratories and realizing a sustainable society.
2023	Product Launch	Sysmex launched the World's First Point-of-Care Testing System in Europe to Detect Antimicrobial Susceptibility within 30 Minutes.
2023	Product Launch	Sysmex launched the Clinical Flow Cytometry System in Japan, realizing higher efficiency and Standardization of Flow Cytometry (FCM) Testing.
2022	Product Launch	Sysmex Corp. launched the UF-1500 Fully Automated Urine Particle Analyzer (UF-1500), a new product for urine sediment testing.

## TERUMO CORP.

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Tel: +81-3-3374-8111 Website: www.terumo.com



#### **Company Snapshot**

Table 124
Terumo Corp.: Company Snapshot

Corporate Category	Information
Ticker	TSE: 4543
Year Founded/Incorporated	1921
Global Headquarters	Tokyo, Japan
Revenue 2023 (\$ Millions)	6,387.6
Number of Employees (2023)	30,207
Key Business Regions	Americas, Japan, Europe,
Primary Region/Country for Business	Americas
Main Business Segment	Cardiac and Vascular Company
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Terumo Corp. is a medical technology company founded in 1921 that manufactures and commercializes medical products and equipment. The company serves various healthcare sectors, including pharmaceuticals, nutritional food supplements, disposable medical devices, cardiovascular systems, blood glucose monitoring systems and electronic devices.

The company operates its business through its three reportable segments: Cardiac and Vascular Company, Medical Care Solutions Company and Blood and Cell Technologies Company. The company offers drug-device combination products through its Cardiac and Vascular Company. The company operates in over 160 countries and has around 30,000 employees globally as of December 31, 2023.



#### **Financial Performance**

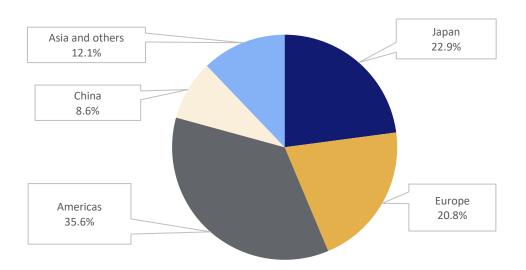
Table 125
Terumo Corp.: Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	6,064.6	6,387.6
Operating Income	858.7	975.8
Net Income	660.5	737.1
Total Current Assets	4,520.7	5,003.5
Total Current Liabilities	1,611.9	2,627.1

Note: Yen to USD converted in 2022 averages 0.007394 and 2023 averages 0.006929

Source: Company website; company annual report; and SEC filings

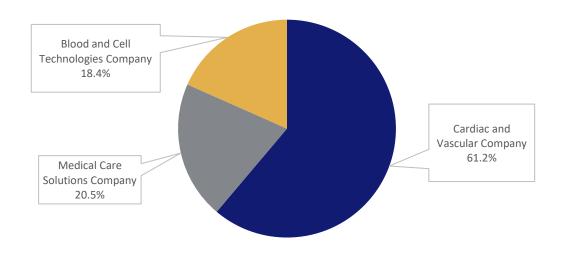
Figure 61
Terumo Corp.: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; and SEC filings



Figure 62
Terumo Corp.: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; and SEC filings

#### **Product Portfolio**

Table 126
Terumo Corp.: Product Portfolio

Product/Segment	Description
Terumo HeartMate 3 LVAD	A left ventricular assist device (LVAD) designed for advanced heart failure patients, providing long-term circulatory support.
CAPIOX Oxygenator	A cardiopulmonary oxygenator is used during open-heart surgeries to oxygenate and remove carbon dioxide from the blood outside the body.
Aquarius Hemodialysis System	A renal replacement therapy device for continuous and intermittent hemodialysis in critically ill patients with acute kidney injury.
Ultimaster Coronary Stent	A drug-eluting stent designed for treating coronary artery disease, offering superior vessel healing and restenosis prevention
Terumo SurGuard 3 Safety Hypodermic Needle	A safety-engineered needle system designed to reduce the risk of needlestick injuries with three modes of safety activation
Angio-Seal Vascular Closure Device	A hemostasis closure device is used to seal arterial puncture sites following catheter-based procedures, providing quick and secure closure.



Product/Segment	Description
Terumo Advanced Perfusion System 1	A heart-lung machine system is used during cardiopulmonary bypass, providing advanced monitoring and control of patient parameters during surgery.
Terumo Blood and Cell Processing Systems	Devices designed for blood management, including autotransfusion and apheresis systems, to ensure safe and efficient blood collection and processing.

**News/ Key Developments** 

Table 127
Terumo Corp.: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	FDA Clearance	Terumo Cardiovascular received FDA 510(K) Clearance for The CDI OneView Monitoring System. All-new modular, expandable design displays up to 22 vital patient parameters with real-time convenience.
2023	Product Launch	Terumo India launched an Insulin Syringe for Patients Requiring Daily Insulin Injections to Manage Diabetes.
2023	Expansion	Terumo Corp. is setting up Terumo South Africa (Pty) Ltd. (Terumo South Africa), its newest subsidiary in South Africa. This strategic move represents a significant milestone in the company's continued commitment to expanding its global footprint and strengthening its presence in critical growing markets.
2023	PMDA Approval	Terumo Aortic announced that the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) has granted approval for the Thoraflex Hybrid Frozen Elephant Trunk (FET) device for commercial sale in Japan for the treatment of patients with complex aortic arch disease.
2023	FDA Approval	Terumo Aortic received FDA Approval for Dissection and Transection Indication Expansion for the RELAY Pro Stent-graft System in the U.S
2023	Innovation	Terumo Aortic Announced First Implant of Innovative Custom-made Thoracoabdominal Hybrid Device in North America.
2022	Product Launch	Terumo announced the launch of a drug-device combination product codeveloped with Kyowa Kirin.
2022	Partnership	Terumo India Signed a New Strategic Commercial Distribution Partnership with Sensible Medical Innovations.
2022	Collaboration	Radboudumc and Terumo Europe N.V. signed a strategic collaboration agreement. The two partners will collaborate to improve existing treatments for cancer patients and develop new, personalized therapies.
2022	FDA Approval	Terumo Aortic received US FDA Approval for Thoraflex Hybrid Device.
2022	Product Launch	Terumo Aortic Announced First Commercial Implant of "Upon Request" RelayPro Endovascular Device in the U.S

Source: Company website



#### **WUXI APPTEC**

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Website: www.wuxiapptec.com

#### **Company Snapshot**

Table 128
WuXi AppTec: Company Snapshot

Corporate Category	Information
Ticker	SHA: 603259
Year Founded/Incorporated	2000
Global Headquarters	Shanghai, China
Revenue 2023 (\$ Millions)	5,700.2
Number of Employees (2023)	38,134
Key Business Regions	U.S., The People's Republic of China (PRC)
Primary Region/Country for Business	U.S.
Main Business Segment	WuXi Chemistry, WuXi Testing, WuXi Biology, WuXi ATU, WuXi DDSU and Others
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

WuXi AppTec is a contract research, development and manufacturing organization. It operates in six reportable segments: WuXi Chemistry, WuXi Testing, WuXi Biology, WuXi Advanced Therapies (ATU), WuXi DDSU and Others.

WuXi Chemistry provides contract research, development and manufacturing services for new drug development from discovery to commercial for all synthetic molecular modalities, including small molecules, oligonucleotides, peptides and complex conjugates. WuXi Testing Division offers testing services to support pharma companies across the full spectrum of their drug development efforts. WuXi Biology offers a full spectrum of biology services and solutions, from target discovery to candidate selection and into the clinic. WuXi ATU offers contract testing, development and manufacturing services for advanced therapies. WuXi DDSU provides drug discovery services to pharmaceutical and biotech customers operating in China.

WuXi AppTec operates in over 30 countries and regions through its 32 operating bases and subsidiaries worldwide.



#### **Key Financial Highlights**

In FY 2023, revenue increased 2.5% over FY 2022. WuXi Chemistry revenue grew 1.1%, WuXi Testing grew 14.4%, WuXi Biology revenue grew 3.1% and WuXi ATU grew 0.1% over the FY 2022. WuXi DDSU revenue declined 25.1% YoY due to business transition.

#### **Financial Performance**

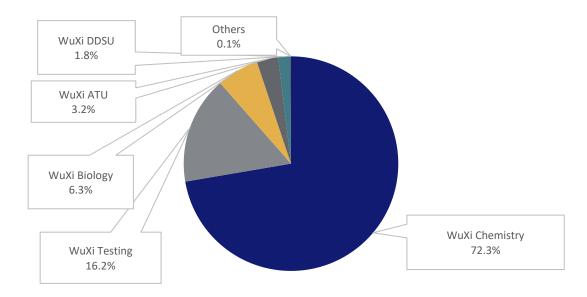
Table 129
WuXi AppTec Financial Performance, FY 2022 and 2023
(\$ Millions)

Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	5,856.0	5,700.2
R &D	(240.2)	(203.6)
Operating Income	1,610.7	1,863.9
Net Income	1,324.7	1,525.7
Total Current Assets	3,570.8	4,298.7
Total Current Liabilities	2,157.5	2,085.1

Note: Chinese yuan to USD conversion for 2022 was 0.1488 and for 2023 was 0.1413.

Source: Company website; company annual report; and SEC filings

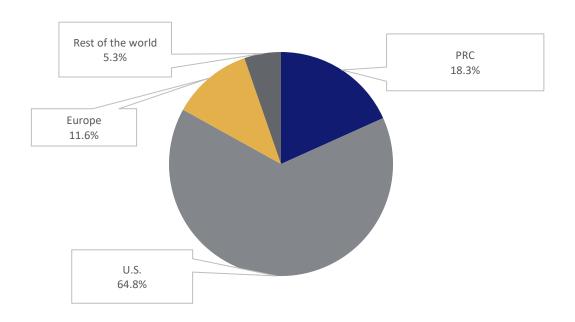
Figure 63
WuXi AppTec: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; and SEC filings



Figure 64
WuXi AppTec: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; and SEC filings

#### **Product Portfolio**

Table 130 WuXi AppTec: Product Portfolio

Product/Segment	Description
Diagnostic Devices	Wuxi AppTec aids in the development of in vitro diagnostic devices, providing services such as assay development and regulatory support to ensure compliance with industry standards.
Surgical Instruments	They assist in the manufacturing and quality control of surgical instruments, ensuring they meet safety and performance requirements for clinical use.
Biopharmaceutical Devices	This includes the development of devices used in administering biopharmaceuticals, such as injection systems and delivery mechanisms, focusing on patient safety and efficacy.

Source: Company website



## **News/ Key Developments**

Table 131
WuXi AppTec: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	FDA Approval	WuXi Advanced Therapies received FDA Approval to Manufacture Iovance's AMTAGVI for Advanced Melanoma.
2024	Expansion	WuXi AppTec Tripled Peptide Manufacturing Capacity and Launched the Expansion of the New Taixing API Manufacturing Site.
2022	Expansion	WuXi STA Opened a New Sterile Lipid Nanoparticle Formulation Facility to Enhance Global CRDMO Services for Customers.
2022	Expansion	WuXi AppTec, announced a plan to build a new R&D and manufacturing site in Singapore. Manufacturing services that enable the global pharmaceutical and healthcare industry.

Source: Company website

## **YPSOMED**

Brunnmattstrasse 6 3401 Burgdorf Switzerland

Tel: +41-34-424-41-11

Website: www.ypsomed.com



#### **Company Snapshot**

Table 132
YPSOMED: Company Snapshot

Corporate Category	Information
Ticker	SWX: YPSN
Year Founded/Incorporated	1984
Global Headquarters	Burgdorf, Switzerland
Revenue 2023 (\$ Millions)	619.3
Number of Employees (2023)	2,400
Key Business Regions	Switzerland, Europe, North America and Rest of the World
Primary Region/Country for Business	Europe
Main Business Segment	Delivery Systems
Entity Type	Public
Ownership Type	Parent

<sup>\*</sup>CHF to USD converted March 2023 average 1.0476.

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Founded in 1984 and headquartered in Burgdorf, Switzerland, Ypsomed AG is a medical technology company focused on developing, manufacturing and selling injection pens for global pharmaceutical and biotech companies. The company operates in two segments: Delivery Devices and Diabetes Direct Business.

- The Delivery Devices segment's products include pen systems, pen needles, infusion sets and other injection molding products sold globally by leading pharmaceutical and biotech companies under their brand names.
- The Diabetes Direct business sells and trades devices for self-monitoring blood glucose levels, infusion pumps, accessories and other day-to-day items for people with diabetes. It offers insulin pumps, injection systems and pen needles for treating diabetes, growth disorders, infertility and other therapeutic areas, as well as pen needles under the Mylife Diabetes Care brand. These products are marketed directly to diabetes patients, doctors, specialist personnel or health insurance providers.

Ypsomed AG markets its products through biotech and pharmaceutical partners, as well as through its distribution network and independent distributors. It lists nearly 2,200 global employees.

#### **Key Financial Highlights**

• The Ypsomed AG revenue for 2023 was \$521.2 million, an increase of 7.4% from the previous year.



• The Delivery Systems segment has shown strong growth in the market, with 18.8% compared to the previous year.

#### **Financial Performance**

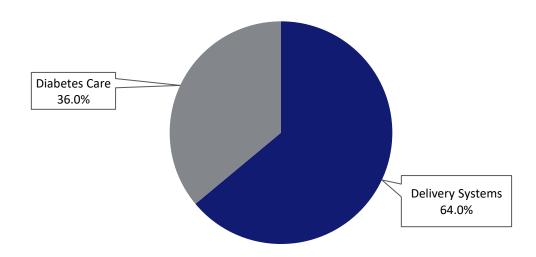
Table 133
YPSOMED: Financial Performance, FY 2022 and 2023
(\$ Millions)

Financials	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	521.1	619.3
Net Income	59.3	92.5
Operating Income	53.7	88.5
Total Current Assets	218.2	381.6
Total Current Liabilities	271.3	497.1

<sup>\*</sup>CHF to USD converted March 2023 average 1.0476 and March 2022 average 1.0885.

Source: Company website; company annual report; SEC filings

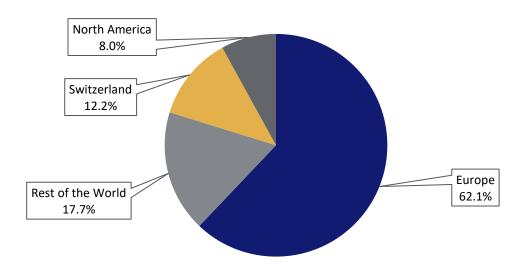
Figure 65
YPSOMED: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; SEC filings



Figure 66
YPSOMED: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; SEC filings

#### **Product Portfolio**

Table 134
YPSOMED: Product Portfolio

Product/Segment	Description
mylife YpsoPump	A compact, user-friendly insulin pump designed for people with diabetes. It offers intuitive touch-screen control, easy cartridge changes and Bluetooth connectivity for data integration with mobile apps.
mylife OmniPod	A tubeless, wearable insulin pump system that continuously delivers insulin without needing an infusion set. It offers a discreet and flexible solution for diabetes management.
mylife Clickfine Pen Needles	High-quality pen needles for insulin injection feature thin-wall technology for more effortless insulin flow. They are available in various lengths and ensure a smooth injection experience.
mylife Orbit Infusion Sets	Soft cannula infusion sets for insulin pumps offer a 360-degree rotating connection for increased comfort and flexibility. They are designed for easy handling and reliable insulin delivery.
YpsoMate Autoinjector Platform	A two-step, prefilled autoinjector designed for easy selfadministration of injectable drugs. It comes in both 1.0 mL and 2.25 mL versions and is highly customizable to meet the needs of various therapies.



Product/Segment	Description
YpsoMate Zero	A sustainable version of the YpsoMate autoinjector made from recyclable materials, designed to reduce environmental impact while providing the same ease of use and functionality.
YpsoPen – Variable and Fixed-Dose Pens	These reusable or disposable pens are designed to administer insulin, growth hormones, or other therapies. They feature easy-to-use dosing mechanisms and customizable designs to meet specific treatment needs.
YpsoDose – Large Volume Patch Injector	A prefilled and pre-assembled patch injector designed for the subcutaneous delivery of large-volume drugs (up to 10 mL). It is fully automated and intended for easy self-administration of biologics.
LyoTwist – Reconstitution Pen	A pen designed to reconstitute lyophilized drugs with a pre-filled cartridge. It allows for the simple mixing of drugs before injection, which is ideal for therapies requiring reconstitution.
ServoPen	A reusable pen injector is suitable for multi-dose drug delivery, customizable for different therapeutic areas such as diabetes or hormone therapies. It offers variable dosing and durability.
mylife Softlance	An ergonomic lancing device designed for pain-free blood sampling, with customizable depth settings for individual comfort.

**News/ Key Developments** 

Table 135
YPSOMED: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Collaboration	Ypsomed and Ten23 Health collaborated on the commercialization of the YpsoDose patch injector. This collaboration aims to advance the commercialization of the YpsoDose wearable injector for the subcutaneous self-injection of large-volume doses. ten23's expertise in drug development, filling and device assembly will significantly contribute to the product offering.
2023	Agreement	Ypsomed concluded a long-term supply agreement with Novo Nordisk for large quantities of autoinjectors. The autoinjectors will administer drugs for self-treatment in various metabolic indications.
2023	Partnership	Ypsomed expanded its offering of digital health solutions in the future with S3 Connected Health. S3 Connected Health, headquartered in Dublin, Ireland, is a specialist digital health partner for life science companies.
2023	Expansion	Ypsomed expanded its production facility in Schwerin.
2023	Expansion	Ypsomed's new production facility was built in the Changzhou National Hi-tech District. In the first phase, to efficiently serve the rapidly growing Chinese market for injection systems, Ypsomed is investing over CHF 35 million in the new manufacturing plant.
2023	Agreement	Ypsomed and Mediq have completed the sale of DiaExpert. The transaction strengthens Ypsomed's focus on developing, manufacturing



Year	Strategy	Description
		and distributing high-quality medical technology products for people with chronic conditions.
2022	Product Launch	Ypsomed and CamDiab launched the first system for automated insulin dosing with Abbott's FreeStyle Libre 3.
2022	Innovation	Ypsomed has developed a new autoinjector platform for liquid medications with volumes ranging from 1.5 to 5.5 ml.
2022	Partnership	Ypsomed partnered with leading digital therapeutics innovator Sidekick Health to improve therapy outcomes.
2022	Partnership	Ypsomed partnered with CamDiab Ltd to drive on smartphone-based adaptive automated insulin delivery (AID).

#### ZEISS AG

Carl-Zeiss-Strasse 22 73447 Oberkochen Germany

Tel: +49-7364-20-0 Website: www.zeiss.com

#### **Company Snapshot**

Table 136
Zeiss AG: Company Snapshot

Corporate Category	Information
Year Founded/Incorporated	1846
Global Headquarters	Oberkochen, Germany
Revenue 2023 (\$ Millions)	10,794.8
Number of Employees (2023)	42,992
Key Business Regions	Germany, EMEA (without Germany), Americas, APAC
Primary Region/Country for Business	EMEA (without Germany)
Main Business Segment	Industrial Quality & Research
Entity Type	Private
Ownership Type	Subsidiary

Source: Company website, annual reports, investor presentations and press releases

#### **Company Overview**

Zeiss AG develops, manufactures and sells products for diagnosing and treating eye diseases, including implants, consumables, visualization solutions for microsurgery and intraoperative radiotherapy products.



In eye care, the company provides cataract surgery tools, ophthalmic lasers and diagnostic equipment. A standout product is the Humphrey Field Analyzer (HFA), which has been the standard in glaucoma diagnostics and management for over 30 years.

The company is represented in over 50 countries, with around 60 sales and service companies, 30 production sites and 25 development facilities worldwide.

#### **Key Financial Highlights**

- The main markets of France, Spain and Italy contributed significantly to the growth of the EMEA region's revenue. The Americas region's sales growth was primarily driven by high US and Latin American market growth rates.
- With record revenue of \$10,795.3 million (previous year: \$9,493.7 million) and an EBIT margin of 17% (prior year: 18%), the ZEISS Group concluded its fiscal year 2022–2023.

#### **Financial Performance**

Table 137
Zeiss AG: Financial Performance, FY 2022 and 2023
(\$ Millions)

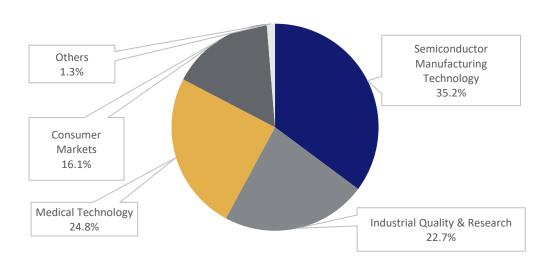
Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	9,491.0	10,794.8
R&D Expenses	-1,248.1	-1,649.4
Operating Income	1,721.7	1,800.6
Net Income	1,252.6	1,342.7
Total Current Assets	7,498.2	8,462.6
Total Current Liabilities	4,354.1	5,123.9

Note: Euro to USD converted by using the average exchange rate of 1.0841 in 2022 and 1.0679 in 2023

Source: Company website; company annual report; and SEC filings

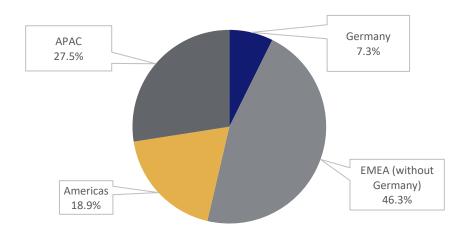


Figure 67
Zeiss AG: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website; company annual report; SEC filings

Figure 68
Zeiss AG: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website; company annual report; SEC filings



#### **Product Portfolio**

Table 138
Zeiss AG: Product Portfolio

Segment/Category	Description	
ZEISS ATLAS 500	The ATLAS 500 from ZEISS is a cutting-edge, multi-modality solution for the anterior eye segment that provides corneal topography. It also allows clinicians to conduct dry eye assessments from a single workstation, enhancing efficiency within a compact design.	
ZEISS Data Management Software	FORUM from ZEISS is the leading ophthalmic data management solution that can be customized to meet the needs of any practice or hospital setting.	
Humphrey Field Analyzer	A leading device for visual field testing, essential for glaucoma diagnosis and management.	
VisuMax	A femtosecond laser designed for advanced refractive eye surgery, offering precision and safety.	
OCT Angiography	A non-invasive imaging tool that evaluates retinal blood flow and vascular conditions.	
Keratometer	Used for measuring corneal curvature, necessary for contact lens fitting and surgical planning.	
SL-D4 Slit Lamp	An advanced slit lamp for comprehensive eye examinations, providing detailed views of ocular structures.	
OPMI VISU 160	A surgical microscope designed for ophthalmic procedures, enhancing visibility and precision during surgery.	
OPMI VARIO	A surgical microscope that provides exceptional optical performance and ergonomic design, suitable for various microsurgical applications.	
KINEVO 900	An innovative robotic-assisted surgical microscope that offers enhanced depth perception and 3D visualization, allowing surgeons to focus on complex procedures with greater accuracy.	
AxioCam	A high-resolution camera system that captures detailed images during microsurgical procedures, facilitating documentation and collaboration.	
MediSight	An advanced digital visualization system that integrates high-definition imaging and real-time data to improve surgical outcomes.	

Source: Company website



#### **News/ Key Developments**

Table 139
Zeiss AG: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Innovation	ZEISS Redefines Disease Management and Treatment within the ZEISS Retina Workflow. ZEISS highlights new surgical innovations and artificial intelligence (AI) tools for retinal patient care, helping doctors diagnose and treat patients efficiently and effectively.
2024	Innovation	ZEISS announced OCT technology enhancements to better support the growing era of data-driven patient care.
2024	Acquistion	Carl Zeiss Meditec AG completed the acquisition of the Dutch Ophthalmic Research Center (D.O.R.C.), a company united to shape the ophthalmology market.
2024	FDA Clearance	U.S. FDA Approved the VISUMAX 800 with SMILE pro software from ZEISS.
2023	Long-Term Strategic Collaboration	ZEISS and Boehringer Ingelheim joined to develop early detection of eye diseases and prevent vision loss.
2023	FDA Approval	ZEISS received U.S. FDA Approval for the CT LUCIA 621P Monofocal IOL, Offering the Unique ZEISS Optic to the U.S. Market.
2022	Strategic Partnership	ZEISS announced a partnership with the European Association of Neurosurgical Societies.
2022	FDA Clearance	ZEISS Received FDA Clearance for MTLawton, A New Generation of Bipolar Forceps for Electrosurgery.
2022	FDA Clearance	ZEISS Announced U.S. FDA Clearance of the QUATERA 700, a Revolution in Phaco Technology.
2022	Acquisition	Carl Zeiss Meditec announced the acquisition of two surgical instrument manufacturers (Kogent Surgical, LLC and Katalyst Surgical, LLC) to strengthen its positioning as a solution provider.

Source: Company website

#### ZIMMER BIOMET

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Website: www.zimmerbiomet.com



#### **Company Snapshot**

Table 140
Zimmer Biomet: Company Snapshot

Parameter	Information
Ticker	NYSE: ZBH
Year Founded/Incorporated	1927
Global Headquarters	Indiana, U.S.
Revenue 2023 (\$ Millions)	7,394.2
Number of Employees (2023)	18,000
Key Business Regions	U.S.
Primary Region/Country for Business	U.S.
Main Business Segment	Knees, Hips and S.E.T.
Entity Type	Public
Ownership Type	Parent

Source: Company website, annual reports, investor presentations

#### **Company Overview**

Zimmer Biomet is a medical device company specializing in musculoskeletal healthcare. The company designs and manufactures orthopedic reconstructive products, biologics, sports medicine, extremities, trauma products and a suite of integrated digital and robotic technologies. Additionally, it offers craniomaxillofacial and thoracic products, office-based technologies and associated surgical products. These products and solutions aid in the treatment of patients with bone, joint and soft tissue disorders or injuries. Zimmer Biomet serves orthopedic surgeons, neurosurgeons, specialists, stocking distributors, hospitals, healthcare dealers and purchasing organizations.

#### **Key Financial Highlights**

Annual net sales for FY2023 were \$7.4 billion, an increase of 6.5% and 7.5% when adjusted for constant currency fluctuations. This growth is mainly due to increased sales in the U.S. market and the increase in sales of its Knees, Hips and S.E.T segments in the U.S. and global markets.



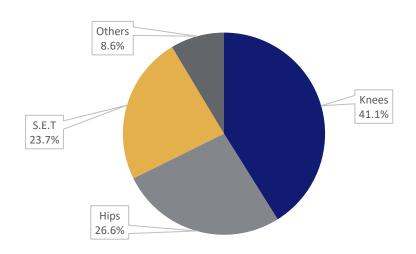
#### **Financial Performance**

Table 141
Zimmer Biomet: Financial Performance, FY 2022 and 2023
(\$ Millions)

Financial Parameter	2022 Value (\$ Millions)	2023 Value (\$ Millions)
Net Revenue	6,939.9	7,394.2
R&D	406.0	458.7
Operating Income	403.5	1,067.3
Net Income	231.4	1,024.0
Total Current Assets	4,427.3	4,609.5
Total Current Liabilities	2,358.2	2,857.4

Source: Company website, company annual report and SEC filings

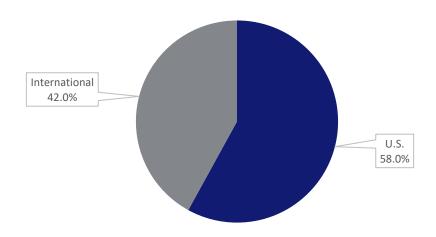
Figure 69
Zimmer Biomet: Revenue Share, by Business Unit, FY 2023
(%)



Source: Company website, annual reports, investor presentations



Figure 70
Zimmer Biomet: Revenue Share, by Country/Region, FY 2023
(%)



Source: Company website, annual reports, investor presentations

#### **Product Portfolio**

Table 142
Zimmer Biomet: Product Portfolio

Product/Segment	Description
Knee replacement	Persona, the Personalized Knee System, Oxford Partial Knee and Vanguard 360 Revision Knee System. The products are:  Oxford Partial Knee Gender Solutions Patello-Femoral Joint (PFJ) System Persona Partial Knee Persona the Personalized Knee Vanguard Knee System NexGen Complete Knee Solution Vanguard XP Total Knee System Vanguard ID Total Knee Vanguard 360 Revision Knee System NexGen Legacy Constrained Condylar Knee (LCCK) RexGen Rotating Hinge Knee Trabecular Metal Femoral and Tibial Cone Augments OsseoTi Tibial Sleeves iASSIST Knee OSS orthopedic Salvage System Compress Device OSS Modular Arthrodesis System OSS Side Access Expandable Device



Product/Segment	Description
Hip replacement	<ul> <li>Multi-Bearing G7 and Continuum Acetabular Systems, implant systems such as Arcos Modular Femoral Revision System and the Taperloc Complete Microplasty Stem. the products are:</li> <li>BioCUE Blood and Bone Marrow Aspirate (BBMA) Concentration System</li> <li>PerFuse Percutaneous Decompression System</li> <li>Trabecular Metal Technology</li> <li>JuggerKnot Soft Anchor-1.0 mm Mini</li> <li>Zimmer Natural Nail System</li> <li>Echo Hip System</li> <li>Avenir Hip System</li> <li>Echo Hip System</li> <li>M/L Taper Hip Prosthesis</li> <li>Taperloc Complete Hip System</li> <li>Trabecular Metal Primary Hip Prosthesis</li> <li>CPT 12/14 Femoral System</li> <li>Zimmer M/L Taper with Kinectiv Technology</li> <li>Fitmore Hip Stem</li> <li>Continuum Acetabular System</li> <li>G7 Acetabular System</li> <li>Trilogy Acetabular Hip System</li> <li>E1 Antioxidant Infused Polyethylene</li> <li>OsseoTi Porous Metal Technology</li> <li>Trabecular Metal Technology</li> <li>Vivacit-E Vitamin E Highly Crosslinked Polyethylene</li> </ul>
Shoulder	<ul> <li>Comprehensive Total Shoulder System</li> <li>Anatomical Shoulder Domelock System</li> <li>Zimmer Trabecular Metal Humeral Stem</li> <li>Zimmer Trabecular Metal Glenoid Fixation</li> <li>Comprehensive Fracture System</li> <li>Comprehensive Segmental Revision System</li> <li>Copeland Humeral Resurfacing Head</li> <li>Copeland EAS Humeral Resurfacing Head</li> <li>Sidus Stem-Free Shoulder</li> <li>Anatomical Shoulder Fracture System</li> <li>Bigliani/Flatow the Complete Shoulder Solution</li> <li>Anatomical Shoulder Combined System</li> <li>Anatomical Shoulder Inverse/Reverse System</li> <li>Trabecular Metal Reverse Shoulder System</li> <li>Comprehensive Reverse Shoulder System</li> <li>Comprehensive Reverse Shoulder System</li> </ul>
Foot and Ankle Solutions	<ul> <li>Unite3D Wedge</li> <li>OsseoTi Porous Metal Technology</li> <li>F.a.S.T. Guide Technology</li> <li>ZipLoop Technology</li> <li>Zimmer Biomet Trabecular Metal Total Ankle</li> <li>Arcus Staple System</li> <li>A.L.P.S. Total Foot System</li> <li>A.L.P.S. Small Fragment System</li> <li>A.L.P.S. Distal Tibia Plating System</li> <li>A.L.P.S. Fibula Plating System</li> </ul>



Product/Segment	Description
	<ul> <li>A.L.P.S. Minimally Invasive (MIS) and Mesh Calcaneus Plating System</li> <li>Cannulated Screw System</li> <li>F3 Fragment Plating System</li> <li>Periarticular Locking Plate System</li> <li>FRS Fusion and Reconstruction System</li> <li>Nextra Hammertoe Correction System</li> <li>Re+Line Bunion Correction System</li> <li>MSP Metatarsal Shortening System</li> <li>Zimmer Biomet Trabecular Metal Total Ankle</li> <li>Phoenix Ankle Arthrodesis Nail System</li> <li>Ankle Fix System 4.0</li> <li>JuggerKnot Soft Anchor Short Rigid</li> <li>JuggerKnot Soft Anchor 1.4mm Short</li> <li>JuggerKnot Soft Anchor 2.9mm with Needles</li> <li>JuggerKnot Soft Anchor Mini 1.0 mm</li> <li>ALLthread Suture Anchor</li> <li>ZipTight Ankle Fixation System</li> </ul>
Biologics	<ul> <li>BioCUE Blood and Bone Marrow Aspirate (BBMA) Concentration System</li> <li>GPS III Platelet Concentration System</li> <li>Clotalyst Autologous Activation Solution</li> <li>Plasmax Plasma Concentration System</li> <li>StaGraft DBM Putty and Plus</li> <li>CERAMENT   BONE VOID FILLER</li> <li>StaGraft Cancellous DBM Sponge and Strips</li> <li>Bonus CC Matrix – Bone Graft System</li> <li>FiberStack Demineralized Bone Matrix (DBM)</li> <li>DermaSpan Acellular Dermal Matrix</li> <li>PerFuse Percutaneous Decompression System</li> <li>Chondrofix Osteochondral Allograft</li> <li>DeNovo NT Natural Tissue Graft</li> </ul>
Spine	<ul> <li>TriCor Sacroiliac Joint Fusion System</li> <li>PathFinder NXT Minimally Invasive Pedicle Screw System</li> <li>Alpine XC Adjustable Fusion System</li> <li>Aspen MIS Fusion System</li> <li>Mobi-C Cervical Disc</li> <li>inViZia Anterior Cervical Plate System</li> <li>MaxAn Anterior Cervical Plate System</li> <li>Trinica Select Anterior Cervical Plate System</li> <li>Vista-S Fusion Device</li> <li>Puros-S and S-2 Cervical Interbody Allograft Implants</li> <li>TM-S Cervical Fusion Device</li> <li>Trinnect Anterior Cervical Spacer System</li> <li>Alta ACDF System</li> <li>Optio-C Anterior Cervical System</li> <li>ROI-C Cervical Cage</li> <li>Virage OCT Spinal Fixation System</li> <li>Lineum Occipito-Cervico-Thoracic (OCT) Spine System</li> <li>Timberline Lateral Fusion System</li> <li>Avenue L Lateral Lumbar Cage</li> </ul>



Product/Segment	Description
	<ul> <li>ROI-a ALIF Cage</li> <li>InFix Anterior Lumbar Device</li> <li>Durango ALIF System</li> <li>Puros-a and -P Allograft Systems</li> <li>Polaris Deformity System</li> <li>Universal Clamp Spinal Fixation System</li> <li>Vitality Spinal Fixation System</li> <li>Dynesys Dynamic Stabilization Product Family (LIS, Top-Loading and Zimmer DTO)</li> <li>Polaris 6.35 Spinal System</li> <li>Polaris 5.5 Spinal System</li> <li>Vital Spinal Fixation System</li> <li>TM Ardis Interbody System</li> <li>Zyston Straight and Curve Interbody Systems</li> <li>Avenue T TLIF Cage</li> <li>Cellentra Advanced Allograft</li> <li>CopiOs Bone Void Filler</li> <li>InterGro DBM</li> <li>PlatFORM CM Osteoconductive Collagen Mineral Bone Graft Matrix</li> <li>Pro Osteon Bone Graft Substitute</li> <li>Puros Demineralized Bone Matrix with Reverse Phase Medium</li> <li>Indux Cancellous Sponge and Strip + Indux Cortical Strip</li> <li>SpF Spinal Fusion Stimulator</li> </ul>
Trauma	<ul> <li>AFFIXUSHip Fracture Nail System</li> <li>Cable-Ready Cable Grip System</li> <li>NCB Periprosthetic Femur System</li> <li>NCB Polyaxial Locking Plate System</li> <li>N-Force Fixation System</li> <li>Zimmer Natural Nail System</li> <li>A.L.P.S. Proximal Tibia Plating System</li> <li>Phoenix Antegrade Femoral Nail System</li> <li>Phoenix Retrograde Femoral Nail System</li> <li>Phoenix Tibial Nail System</li> <li>Pediatric VHS (Vari-Angle Hip Screw) System</li> <li>Peanut Growth Control Plating System</li> <li>XtraFix External Fixation System</li> <li>ACE-Fischer External Fixation System</li> <li>ACE-Fischer External Fixation System</li> <li>Biomet Vision FootRing System</li> <li>ACE-Fischer External Fixation System</li> <li>Biomet Carbon Rail Deformity System</li> <li>Biomet Multi-Axial Correction (MAC) Fixation System</li> <li>FastFrame External Fixation System</li> <li>A.L.P.S. Elbow Fracture System</li> <li>A.L.P.S. Hand Fracture System</li> <li>A.L.P.S. Proximal Humerus Plating System</li> <li>DVR Crosslock Distal Radius Plating System</li> <li>DVR Volar Rim Plating System</li> <li>DVR Wrist Plating System</li> <li>DVR Wrist Plating System</li> <li>DVR Wrist Plating System</li> <li>MAX VPC Screw System</li> <li>Zimmer Periarticular Proximal Humerus Locking Plate System</li> <li>VersaNail Humeral, Proximal and Universal Nail System</li> </ul>



Product/Segment	Description
	<ul> <li>NCB Proximal Humerus Plating System</li> <li>OsteoGen Bone Growth Stimulator</li> <li>OsteoGen Dual Lead Bone Growth Stimulator</li> <li>OsteoGen-M Bone Growth Stimulator</li> </ul>

**News/ Key Developments** 

Table 143
Zimmer Biomet: News/Key Developments, 2022-2024

Year	Strategy	Description
2024	Acquisition	Zimmer Biomet Signed Definitive Agreement to Acquire OrthoGrid Systems Inc
2024	Agreement	Zimmer Biomet Entered a Distribution Agreement with THINK Surgical to Offer TMINI Miniature Handheld Robotic System for Total Knee Arthroplasty.
2024	FDA Clearance	Zimmer Biomet received FDA Clearance for the ROSA Shoulder System, the World's First Robotic Assistant for Shoulder Replacement Surgery.
2023	Acquisition	Zimmer Biomet Holdings Inc. announced that it has signed a definitive agreement to acquire Embody Inc.,
2022	Innovation	Zimmer Biomet introduced First-of-its-Kind Artificial Intelligence Capabilities for the Omni Suite Intelligent Operating Room.

Source: Company website



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