**MDR (MEDICAL DEVICE REGULATION)**

Medical Device Regulation (MDR) refers to the rules and guidelines established by regulatory authorities to ensure that medical devices are safe, effective, and of high quality before they reach the market. MDR applies to all medical devices, including diagnostic equipment, implants, surgical instruments, and software used in healthcare.

**Diagnostic Equipment**:

Devices used to detect and diagnose diseases or medical conditions. Helps in early detection, diagnosis, and monitoring of diseases. MRI, CT scan, X-ray machines, Ultrasound.

**Therapeutic Equipment**:

Devices used to treat, manage, or correct medical conditions. Helps in treatment, prevention, or management of medical conditions. Blood warmer, Dialysis machine, Ventilator, Defibrillator, Pacemaker.

**Non-invasive devices**:

Do not penetrate the body (e.g., stethoscopes, X-ray machines).

**Invasive devices**:

Enter the body, either through an opening (e.g., endoscopes) or by penetrating tissue (e.g., needles, implants).

**Active Medical Devices**:

Require an external energy source to function (e.g., blood warmers, ventilators).

**Non-Active Medical Devices**:

Function without an external power source (e.g., surgical instruments).

**Implants**:

Medical devices placed inside the body for therapeutic or reconstructive purposes. Provides long-term medical support, replacement, or enhancement of body functions. Pacemakers, Artificial joints, Stents, Dental implants, Cochlear implants.

**Healthcare Software**:

Software used for medical diagnosis, treatment planning, or monitoring. Assists in medical decision-making, patient monitoring, and workflow automation.

Different countries have their own regulatory authorities for medical device approval:

* **India** – **CDSCO** (Central Drugs Standard Control Organization) under **MDR 2017**.
* **USA** – **FDA** (Food and Drug Administration) under the **FD&C Act**.
* **Europe** – **EMA** (European Medicines Agency) & Notified Bodies under **EU MDR 2017/745**.
* **Canada** – **Health Canada** under the **Medical Devices Regulations (SOR/98-282)**.

**Indian Medical Device Regulation (MDR 2017):**

In India, medical devices are regulated under the Medical Device Rules, 2017 (MDR 2017), which is enforced by the Central Drugs Standard Control Organization (CDSCO) under the Drugs and Cosmetics Act, 1940.

**Classification of Medical Devices in India:**

Medical devices are classified into four risk categories based on intended use and risk level.

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| **Class** | **Risk level** | **Example** | **Approval Authority** |
| Class A | Low risk | Tongue depressor, Surgical dressings | SLA |
| Class B | Low -Moderate risk | Blood pressure monitors, Nebulizers | SLA |
| Class C | Moderate -High risk | Blood Warmers, Ventilators, Infusion pumps | CDSCO |
| Class D | High risk | Heart valves, Pacemakers, Blood bags | CDSCO |

**Class A & B devices** – Approved by the State Licensing Authority (SLA).

**Class C & D devices** – Require (CDSCO) Central Drugs Standard Control Organization approval and more stringent testing.

**APPROVAL PROCESS:**

**1.Determine the Device Classification**: Based on the risk level it is classified into Class A, B, C and D.

**2.** **Registration & Licensing on CDSCO SUGAM Portal**: The manufacturer/importer must register on the CDSCO SUGAM Portal (<https://cdsco.gov.in>) and submit the required documents.

**3.** **Apply for License Based on Device Class**:

* **Application for class A and B**: Manufacturer applies for a Manufacturing License (Form MD-3 & MD-5).

Approval Authority: State Drug Controller (SDC).

**Location**: Maharashtra SLA is in Mumbai, Tamil Nadu SLA is in Chennai.

Timeline: Approx. 3-6 months for approval.

* **Application for class C and D**: Manufacturer applies for a Manufacturing License (Form MD-7 & MD-9).

Additional Requirements: Requires clinical trials, performance studies, and review.

Approval Authority: CDSCO (Central Licensing Authority).

**Location:** FDA Bhawan, Kotla Road, New Delhi, India.

Timeline: Approx. 6-12 months for approval.

**4.** **Import License (If Device is Imported)**: Importers must apply for an Import License (Form MD-14 & MD-15). Required for imported Class A-D devices before sale in India.

**5. Post-Market Surveillance & Compliance**: Market Authorization is granted after approval. Ongoing monitoring & quality compliance is required. Manufacturers must follow ISO 13485 (Quality Management System).

\***Fees**\*- ₹5,000 - ₹50,000 depending on class.

**American Medical Device Regulation:**

The U.S. Food and Drug Administration (FDA) which comes under the regulatory body of Food, Drug, and Cosmetic Act (FD&C Act),classifies medical devices into three risk-based classes (Class I, II, and III) based on the level of risk to patients and users.

**FDA Device Classification System:**

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| **Class** | **Risk level** | **Example** |
| Class I | Low risk | Tongue depressors, bandages, stethoscopes. |
| Class II | Moderate risk | Blood warmers, infusion pumps, powered wheelchairs. |
| Class III | High risk | Pacemakers, heart valves, deep brain stimulators. |

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| **APPROVAL PROCESS:**   1. **Determine Device Classification & Regulatory Pathway**: Based on the risk level it is classified into Class I, II and III. 2. **Prepare and Submit Required Pre-Market Application**: The approval process depends on the device classification   **Class I Devices**:Most Class I devices are exempt from pre-market submission but must comply with General Controls (21 CFR 820).  **Class II Devices (510(k) Pre-market Notification)**: Manufacturers must submit a 510(k) application to prove that the device is substantially equivalent (SE) to a predicate device (previously FDA-approved device).  **Class III Devices (PMA – Pre-Market Approval)**: Class III devices require extensive clinical trials to prove safety & effectiveness. Manufacturers must submit a Pre-Market Approval (PMA) application with clinical data.   1. **FDA Review & Market Authorization**:   **Class I (exempt devices):** No FDA approval required.  **Class II (510(k) devices):** FDA review within 90 days.  **Class III (PMA devices):** FDA review within 180+ days.   1. **Register Establishment & List Device with FDA**: All manufacturers must register their facility with the FDA under the Establishment Registration & Device Listing rule.   \* Annual renewal is required.   1. **Post-Market Surveillance & Compliance**: Monitor & report adverse events (MDR - Medical Device Reporting). Maintain compliance with QSR (21 CFR Part 820).   \***Fees**\*- $5,000 - $300,000 based on device class.  **Location**: Silver Spring, Maryland, USA  **FDA Regulatory Pathways:**  • 510(k) Notification (class II): Proves that a device is substantially equivalent to an existing FDA-approved device, Timeline :3-6 months.  • Premarket Approval (PMA) (class III): Requires clinical trials and scientific data to demonstrate safety & efficacy, Timeline:12-18 months.  • De Novo Pathway (class I &II): Used for new devices with no existing predicate but are still considered low/moderate risk.  • Exempt Devices (class I& some class II): Some Class I and a few Class II devices are exempt from 510(k) submission. |

**European Medical Device Regulation:**

The European Union Medical Device Regulation (EU MDR 2017/745) classifies medical devices based on their risk level, intended use, and duration of contact with the body. Devices are divided into four classes: I, IIa, IIb, and III.

**Classification of Medical Device under EU-MDR:**

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| **Class** | **Risk level** | **Examples** |
| Class I | Low risk | Bandages, Tongue Depressors, Thermometers, Stethoscopes. |
| Class IIA | Medium risk | Dental Fillings, Contact Lenses, Blood Pressure Monitors. |
| Class IIB | High risk | Blood Warmers, Infusion Pumps, Ventilators, Surgical Lasers. |
| Class III | Highest risk | Pacemakers, Heart Valves, Implantable Defibrillators, Artificial Organs. |

**Duration of Contact with the Human Body:**

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| **Duration** | **Description** | **Example** |
| Transient | Contact less than 60 minutes. | Syringes, tongue depressors |
| Short term | Contact between 60 minutes and 30 days. | Catheters, dressings |
| Long term | Contact more than 30 days. | Implants, pacemakers |

**Annexes in EU MDR 2017/745:**

The EU Medical Device Regulation (MDR 2017/745) consists of 17 Annexes, each outlining specific regulatory requirements for medical devices. These annexes cover everything from technical documentation to clinical evaluation and conformity assessment.

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| **Annex** | **Title** | **Purpose** |
| Annex  I | General Safety and Performance Requirements | Defines essential safety and performance standards for medical devices. |
| Annex  II | Technical Documentation | Specifies what manufacturers must include in the technical file (design, risk assessment, labeling, etc.). |
| Annex  III | Technical Documentation on Post-Market Surveillance | Describes requirements for post-market surveillance plans and reports. |
| Annex  IV | EU Declaration of Conformity | Defines the format and content for the EU Declaration of Conformity. |
| Annex  V | CE Marking of Conformity | Specifies how the CE marking should be affixed and displayed on medical devices. |
| Annex  VI | Information on UDI System | Provides details on the Unique Device Identification (UDI) system requirements. |
| Annex VII | Requirements for Notified Bodies | Outlines the role, responsibilities, and assessment process for Notified Bodies. |
| Annex VIII | Classification Rules | Defines the classification system (Class I, IIa, IIb, III) based on risk and intended use. |
| Annex  IX | Conformity Assessment – Quality Management System | Explains how manufacturers can demonstrate compliance via QMS (ISO 13485). |
| Annex  X | Conformity Assessment – Type Examination | Describes the evaluation of a medical device's design by a Notified Body. |
| Annex  XI | Conformity Assessment – Product Conformity Verification | Defines procedures for verifying product compliance before market approval. |
| Annex XII | |  | | --- | | Certificates Issued by Notified Bodies |  |  | | --- | |  | | Lists the types of certificates Notified Bodies can issue (EC Certificates, QMS Certificates, etc.). |
| Annex XIII | Custom-Made Devices | Details the regulatory requirements for custom-made medical devices. |
| Annex XIV | Clinical Evaluation and PMCF (Post-Market Clinical Follow-up) | Describes clinical evaluation processes and post-market follow-up requirements. |
| Annex XV | Clinical Investigations | Specifies how to conduct clinical trials for medical devices under EU MDR. |
| Annex XVI | Devices Without an Intended Medical Purpose | Lists non-medical devices regulated under MDR, such as cosmetic implants and contact lenses. |
| Annex XVII | Correlation Table | Provides a reference between EU MDR 2017/745 and the previous MDD 93/42/EEC. |

**Classification Rules (Annex VIII) in EU MDR 2017/745:**

The classification follows Annex VIII, which defines 22 rules that apply to all medical devices.

1. Non-invasive devices (Rules 1–4)

2. Invasive devices (Rules 5–8)

3. Active devices (Rules 9–13)

4. Special rules (Rules 14–22)

**Non-Invasive Devices (Rules 1–4):**

**Rule 1-** Non-invasive devices that do not touch the patient or interact with the body (e.g., hospital beds, stethoscopes).class I

**Rule 2 -** Devices that channel or store substances for later delivery into the body (e.g., syringes, IV tubing). **Class** IIa

**Rule 3 -** Devices modifying body fluids or intended for filtration (e.g., dialysis filters, blood warmers). **Class** IIa OR IIb

**Rule 4 -** Devices in contact with injured skin or wounds (e.g., wound dressings). **Class** IIa,IIb or III

**Invasive Devices (Rules 5-8):**

**Rule 5 -** Devices inserted into body openings (e.g., catheters, contact lenses). **Class** I or II a

**Rule 6** - Surgically invasive devices used for less than 30 days (e.g., surgical instruments, temporary pacemakers). **Class** IIa or IIb

**Rule 7** - Surgically invasive devices used for more than 30 days (e.g., orthopedic implants). **Class** IIb or III

**Rule 8** - Implantable devices and life-supporting devices (e.g., heart valves, pacemakers). **Class** III

**Active Devices (Rules 9–13):**

**Rule 9 -** Active therapeutic devices that provide energy to the body (e.g., blood warmers, ventilators). **Class** IIa or IIb

**Rule 10 -** Active diagnostic devices (e.g., MRI, ECG machines). **Class** IIa or IIb

**Rule 11 -** Software and medical apps affecting patient management (e.g., AI diagnostic tools). **Class** IIa ,IIb or III

**Rule 12-** Devices supplying energy to the body (e.g., defibrillators). **Class** IIb or III

**Rule 13**- Devices incorporating medicines (e.g., drug-eluting stents). **Class** III

**Special Devices (Rules 14–22):**

**Rule 14-** Devices containing or administering medicinal products (e.g., insulin pens). **Class** III

**Rule 15**- Contraceptive or fertility devices (e.g., IUDs) **Class** IIa or III

**Rule 16**- Devices for disinfecting or sterilizing medical devices (e.g., sterilizers). **Class** IIa or IIb

**Rule 17-** Devices incorporating animal or human tissues (e.g., biological implants). **Class** III

**Rule 18-** Blood bags and blood-handling devices. **Class** III

**Rule 19-** Devices using nanomaterials. **Class** III

**Rule 20-** Devices used for gene therapy. **Class** III

**Rule 21-** Devices that introduce or remove substances from the body via infusion, extraction, etc. **Class** IIb or III

**Rule 22**- Devices designed for capturing diagnostic data from the body. **Class** IIa,IIb or III

**APPROVAL PROCESS:**

1. **Classify the Medical Device**: Identify if the device falls under Class I, IIA, IIB, or III based on risk.
2. **Implement a Quality Management System (QMS)** -ISO 13485:2016 certification is mandatory for Class IIa, IIb, and III devices.
3. **Conduct a Conformity Assessment**: Depending on the risk class, conformity assessment procedures vary.

**Class I Devices** (except sterile/measuring): Self-certification by the manufacturer.

**Class IIa, IIb, and III Devices**: Assessment by a Notified Body (NB).

**Class III Devices**: Require clinical trials and detailed risk analysis.

1. **Clinical Evaluation**:Class III & High-Risk Class IIb Devices require ClinicalInvestigation to prove safety & effectiveness. Clinical data must comply with ISO 14155 (Good Clinical Practice for Medical Devices).
2. **CE Marking & Market Access**: Once approved, the CE Mark can be affixed to the product. The device can now be legally sold in the European Economic Area (EEA).
3. **Post-Market Surveillance & Compliance**:Monitor device safety & effectiveness.Report adverse events & incidents (Vigilance Reporting - MDR Article 87). Conduct Post-Market Clinical Follow-up (PMCF) (Annex XIV, Part B).

\* **Renew CE** Certification every 5 years.

European Commission (EC) **Headquarters**: Brussels, Belgium

European Medicines Agency (EMA) **Headquarters**: Amsterdam, Netherlands

**EU MDR Regulatory Pathways:**

• Self-Certification - Class I (low risk, non-sterile): Manufacturer declares compliance without a Notified Body.

• Notified Body Certification - Class I (sterile/measuring), IIa, IIb, III: External assessment by an EU Notified Body.

Timeline:12-24 months.

• Clinical Evaluation - Class IIb & III: Requires clinical trials & scientific data for approval.

• CE Marking - All Classes: Required for market access in the EU.

\***Fees**\*- €10,000 - €150,000 based on device classes.

**Canada Medical Device Regulation:**

In Canada, medical devices are regulated by Health Canada under the Medical Devices Regulations (SOR/98-282), part of the Food and Drugs Act. Manufacturers must obtain Medical Device Licenses (MDL) or a Medical Device Establishment License (MDEL) before selling in Canada.

**Classification of Medical Device under Health Canada:**

Medical devices are classified into four risk categories based on intended use and risk level.

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| **Class** | **Risk level** | **Example** | **Approval Authority** |
| Class I | Low risk | Stethoscope, Bandages | No License, Only Establishment Registration |
| Class II | Low -Moderate risk | Blood Pressure Monitors, Syringes | Medical Device License (MDL) |
| Class III | Moderate -High risk | Blood Warmers, Ventilators | MDL + Quality System Requirements |
| Class IV | High risk | Heart valves, Pacemaker | MDL + Clinical Data Required |

**Class I** devices do not require a Medical Device License (MDL) but need an Establishment License (MDEL).

**Class II-IV** devices must get an MDL from Health Canada.

**APPROVAL PROCESS:**

1. **Determine Device Classification**: Identify if the device falls under Class I, II, III, or IV based on risk.
2. **Apply for a Medical Device Establishment License (MDEL)**: Required for Class I Devices & Importers/Distributors. The application must apply in Health Canada Medical Devices E-Licensing System.
3. **Apply for a Medical Device Licence (MDL)**: Required for Class II-IV Devices.

**Class II Devices:** Safety & effectiveness summary.

**Class III Devices:** Pre-clinical & clinical data, risk assessment.

**Class IV Devices:** Extensive clinical data, risk analysis, post-market plans.

Timeline-6-12 months.

1. **Quality Management System (QMS) Requirements**: ISO 13485:2016 certification is mandatory for Class II-IV devices. MDSAP (Medical Device Single Audit Program) is required for manufacturers selling in Canada. The QMS must include design controls, risk management, and post-market surveillance.
2. **Obtain Health Canada Approval & Market Authorization**: Once approved, the device is listed in the Health Canada Medical Devices Active License Listing (MDALL) database. The device can now be legally sold in Canada.
3. **Post-Market Surveillance & Compliance**:Monitor device performance and report any adverse events to Health Canada. Ensure proper labeling (English & French). Renew licenses annually (MDEL renewal by April 1st).

**\*Fees**\*- CAD 500 – 5,000 depending on class.

**Location:** Ottawa, Ontario, Canada.