

Directive

Legal and Compliance

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Global Compliance

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Target group

This Directive is addressed to all Siemens Healthineers employees and managers worldwide. If not specifically distinguished between, “employees” as mentioned herein also covers “managers”.

Purpose

The purpose of this Directive is to provide guidance to employees regarding applicable laws, codes of conduct of industry associations and internal regulations as compliance with these is the responsibility of all employees.

Compliance violations not only put our company’s reputation at risk but may also lead to severe risks for the company, its management, and employees. It is part of the management’s duties to prevent and mitigate these risks.

The basis of Siemens Healthineers’ internal regulations are the [Business Conduct Guidelines](#) (BCG). Together with this Directive they form the framework of the Siemens Healthineers Compliance System. This Directive contains:

- all company-wide regulations specifying the BCG provisions in the areas of anti-corruption, antitrust, antimoney laundering, human rights, collective action, data privacy¹, export control and customs² as well as
- specific regulations with respect to interactions with healthcare professionals and healthcare organizations.

Despite not mentioning Varian Ethical Compliance any further, this Directive merges Compliance Systems into one Global Compliance Directive.

¹ For details concerning Data Privacy please refer to Directive [1_D_71](#)

² For details concerning Export Control and Customs please refer to Directive [1_D_70](#)

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1 Glossary

Specific roles

Compliance Office	The department on global or Unit level responsible for Compliance matters
Compliance Officer	Head of Compliance for the respective Unit
Human Rights Officer	The Human Rights Officer (the Responsible person pursuant § 4 (3) LkSG) monitors the implementation and execution of the LkSG risk management at Siemens Healthineers and Controlled Companies. The Head of Compliance has been appointed as Human Rights Officer for Siemens Healthineers.

Specific terms

Antitrust	Antitrust laws prohibit behavior, which restricts or hinders fair competition in the market.
Business Conduct Guidelines	Business Conduct Guidelines of Siemens Healthineers are a set of basic internal rules which define the framework of ethical and legal behavior for Siemens Healthineers worldwide.
Collective Action	Collective Action is a joint effort of different stakeholders like competitors, customers, non-governmental organizations and authorities to fight against Corruption.
Compliance	Compliance means respecting the law, codes of conduct of industry associations and internal rules.
Compliance Approval	The process of obtaining documented approval from Compliance (if available, in an identified tool (e.g., SpoDoM, Compliance Approval Process (CAP), Needs Assessment, Healthcare Giving Portal (HGP)) for an activity in which it is required.
Compliance General Release	Compliance General Release shall mean a standing approval by Compliance for a type or several types of activities provided that certain criteria are met.
Conflict of Interest	Conflict of Interest appears if business decisions are mainly based on personal interests but not in the interest of Siemens Healthineers.

Corruption	Corruption is dishonest or illegal behavior, especially by people in power, typically involving bribery. Bribery is the act of offering, promising, or giving money, gifts, or other Benefits to a Public Official or private employee with the aim of receiving improper advantages. For the purpose of this Directive the term “Corruption” also includes passive Corruption (receiving a bribe or something in value in return for solicit, demand, accept, obtain or promise an improper advantage).
Healthcare Organization (HCO)	Any entity that provides health services to patients and may have meaningful influence on the prescription, recommendation, purchase, order, supply, utilization, sale or lease of medical technologies or related services, and/or (for the U.S. only “and”) is eligible to receive remuneration for such services from a government or other insurer, as determined by local law. For this purpose, a patient is generally limited to human beings unless local law provides otherwise. If an entity has direct influence over the purchasing decisions of a Healthcare Professional (HCP) or HCO, they could be considered to be an HCO for purposes of this Directive, subject to Legal and Compliance locally determining otherwise. Generally, “HCO” is limited to hospitals, clinics and laboratories (in each case dedicated to the treatment or evaluation of humans) but may also include other health service providers (e.g., nursing homes) as determined by local law.
Healthcare Professionals (HCP)	Any person who provides health services to patients and may purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services, and/or (for the U.S. only “and”) is eligible to receive remuneration for such services from a government or other insurer, as determined by local law, independent if their employment is with public or private sector. For this purpose, a patient is generally a human unless local law provides otherwise. If an individual has direct influence over the purchasing decisions of an HCP or Healthcare Organization (HCO), they could be an HCP for purposes of this Directive, subject to Legal and Compliance locally determining otherwise. Generally, “HCP” is limited to clinicians and physicians (in each case dedicated to the treatment or evaluation of humans) but may also include other health service providers (e.g., nurses, technicians, medical students, or laboratory scientists) as determined by applicable local law.
Investigation	An internal Compliance Investigation is a clearly defined process of fact finding and legal assessment in order to find out if there has been a violation of law, codes of conduct of industry association or internal rules.
Let us Know	“Let us Know” is the name of Siemens Healthineers confidential channel by which employees or third parties ³ can report any potential violations in which they become aware of. Anonymity of the person reporting is assured if this is required.
Money Laundering	Money Laundering means any transaction, which helps funds derived from criminal or illegal acts appear to be from legitimate sources.

³ Third Parties are non-Siemens Healthineers employees such as HCPs, HCOs, Public Officials, Business Partners, suppliers, public and private employees of other companies

Ombudswoman	The Ombudswoman has been appointed by Siemens Healthineers as an independent third party to allow employees or third parties to raise concerns about potential Compliance violations in a confidential way which includes anonymity if required by the person reporting the concern.
Policy Statement	With the Policy Statement, the Managing Board positions itself in support of the human rights strategy and expresses the self-commitment and commitment to respect human rights and environment-related obligations.
Public Official	<p>The term “Public Official” covers any person employed by or mandated by a public authority. This includes all government officials, which means anyone working at or on behalf of a government entity (including a government-controlled company) or public international organization, as well as any candidate for political office, political party official or employee, or a political party. It also includes officers, directors, or employees of a non-governmental institution whose employees are regarded, because of their status or other reasons, as Public Officials in accordance with applicable law.</p> <p>Examples of Public Officials are employees of public hospitals, public utilities or other public-sector companies; law enforcement officers; members of the military; customs officials; officials of the World Health Organization, the European Council, the World Bank or the United Nations; candidates for the office of mayor; members of parliament; judges, public prosecutors or judicial staff; or otherwise defined by local law.</p>
Supply Chain Due Diligence Act (“LkSG”)	The German law regulates global corporate responsibility for the observance of human rights and environmental obligations in the business activities of companies and in worldwide supply chains. This includes, for example, protection against child labor, the right to fair wages and environmental protection. The term “Supply chain” for the purposes of LkSG covers upstream activities provided by suppliers and sub-suppliers which fall under the Procurement process.
Transparency Laws	These laws require medical device and pharmaceutical companies to capture and report financial transactions (e.g., meals, consulting fees, speaker fees, research funding, travel costs, etc.) with HCPs and/or HCOs to their governments. Some governments publicly disclose this information on the internet for public view to provide transparency (sunshine) into each company’s interactions with HCPs/HCOs.
Unit	The term “Unit” covers Business Areas, Horizontals, Technology Units, Business Lines, Functions, Zones, Regions as well as legal entities (e.g. in the countries).
Value Based Care	A health care delivery model in which contributors to care are paid based on individual patient health outcomes, population health outcomes, increasing access to healthcare for underserved populations, managing costs, and/or improving efficiency.

2 Procedure/Requirements

2.1 Roles and Responsibilities

2.1.1 Management Responsibility

Managers must ensure that there are no violations of laws, codes of conduct of industry associations and internal regulations within their area of responsibility that proper supervision could have prevented. They remain accountable, even if they delegate particular tasks.

As part of our common purpose and values, managers must act and lead with integrity and ensure that employees feel safe to speak up concerning compliance and ethical risks.

Overall responsibility for Compliance lies with the CEO and the Heads of the Units⁴. They must act as role models in matters of Compliance, ethical behavior and integrity and ensure, through the right tone from the top and the middle, that all employees act accordingly.

In fulfilling these obligations, the CEO and Heads of the Units are supported by the members of the Compliance organization bearing responsibility for operating the Compliance system and providing appropriate guidance for managers to fulfill their duties.

2.1.2 Employee's responsibilities

Employees must ensure that they do not violate applicable law, applicable codes of conduct of industry associations and internal regulations during the execution of their professional duties. It is part of each employee's responsibility to participate in Compliance trainings when offered to the employee. In case of doubt employees shall seek advice from their manager, Compliance or Legal before acting or taking decisions. Siemens Healthineers expects its employees to report potential violations through a reporting channel ("[Let us Know](#)" or [Ombudswoman](#)) or directly to Compliance or Legal.

2.1.3 The Compliance Organization

The [Compliance organization](#) has global governance responsibility, acts as trusted partner for management and employees, drives integrity culture and ethical behavior and also operates systematic processes and tools to support the effective mitigation of Compliance risks.

2.1.4 Roles within Compliance

The Head of Compliance reports to the General Counsel of Siemens Healthineers AG. At the same time, the Head of Compliance reports to the Siemens Healthineers CEO in functional matters, has direct access to the Managing Board and the Audit Committee of the Supervisory Board, and reports to them on a regular and on an ad hoc basis.

The members of the Compliance organization are responsible for implementing the Compliance System in all Units of Siemens Healthineers. All Heads of Compliance of these Units ultimately report to the Head of Compliance of Siemens Healthineers.

The Head of Data Privacy / Group Data Privacy Officer of Siemens Healthineers reports to the General Counsel of Siemens Healthineers; at the same time, the Head of Data Privacy / Group Data Privacy Officer reports to the Siemens Healthineers CEO in functional matters and has direct access to the Managing Board. The Head of Export Controls and Customs reports to the General Counsel of Siemens Healthineers.

⁴ The term "Unit" is used for all units of Siemens Healthineers which are Business Areas, Business Horizontals, Technology Excellence Units, Business Lines, Functions, Zones, Regions as well as legal entities (e.g. in the countries)

2.2 General Aspects of the Compliance System

2.2.1 The Siemens Healthineers Business Conduct Guidelines

The Business Conduct Guidelines (BCG) provide the ethical and legal framework for Siemens Healthineers on a global basis. They contain the basic principles and rules for the conduct within the company, as well as the company's conduct in relation to its employees, managers, external partners, and the public. The BCGs outline the company's purpose and values and represent the core of Siemens Healthineers' Compliance rules. They are binding for the Managing Board, all managers, and employees worldwide.

2.2.2 Industry specific regulations and requirements of Third Parties

The medical technology industry is subject to national and supranational laws which govern many aspects of business operations. The relationship between the industry and Healthcare Professionals and Healthcare Organizations is therefore highly regulated and subject to additional regulations:

- Codes of Conduct due to participation in industry associations

Any Unit which intends to accept the code of conduct of an industry association shall get prior written approval from the Head of Compliance Rules & Procedures. The approval is also necessary in case a code of conduct of an association, where a Siemens Healthineers Unit is already a member of, will be significantly revised by the respective association. The process for obtaining approval is available on the [Compliance intranet](#).

- Compliance requirements of Third Parties and Declaration of Integrity

Often, third parties require Siemens Healthineers to accept their respective code of conduct or other document containing ethical standards before entering a business transaction.

This can only be accepted with the approval of Procurement for requests from suppliers and Compliance Office for requests from customers and other partners.

In case customers request a Declaration of Integrity, e.g., during a public tender, the respective Unit must address this with the Compliance Office in charge of the respective Unit.

2.2.3 Agreements with Healthcare Professionals (HCPs)

Any agreement with HCPs who will provide services for Siemens Healthineers, such as speaker, consultancy, or advisory board engagements, require prior Compliance Approval⁵. Preferably, the agreement should be concluded with the employer organization of the HCP. In case the agreement should be concluded directly with the HCP, the HCP should disclose the agreement to his/her employer organization (if not self-employed) before performing the service activity. Depending on local requirements the disclosure needs to be part of the agreement. The agreement draft and a Fair Market Value calculation shall be provided to the responsible Compliance Office; in cross border transactions, the Unit concluding the agreement shall get a release on the Fair Market Value and the draft agreement from the Legal and Compliance Office of the country where the HCP resides and/or where the event takes place as well. Tax implications must be considered.

HCPs shall be selected because of his/her specific qualification and required expertise. The selection of the HCP shall not be made based on volume or value of business (potentially) generated by the HCP or by his/her employer organization. Country-specific Compliance requirements and reporting obligations based on Transparency Laws can be found on the [Compliance World Map](#) or the [Compliance intranet](#).

⁵ See Glossary Term „Compliance Approval“. Use appropriate tool for Compliance Approval: Contact local CO for more information.

Travel, accommodation, and meals expenses for HCPs in the course of e.g., speakers and advisory board engagements must be included in the written agreement which requires Compliance Approval⁶.

The employee responsible for the speaker engagement shall ensure that Quality Management and Regulatory Affairs has reviewed the presentation materials prior to the event.

2.2.4 Agreements with Healthcare Organizations

Agreements with Healthcare Organizations are required for various types of activities. Main types within the company are often described as “collaborations” or “investigator-initiated trials”. Such projects (e.g., research, clinical trials, post market evaluation studies, investigator-initiated trials etc.) are strategic tools and an integral part of the business strategy with the purpose to advance the performance and usability of products and services, to extend access to markets and to drive forward new innovations and technologies. Such agreements shall not be used to influence procurement decisions of the partner directly or indirectly. Thus, the agreement needs to state clearly the legitimate business interest, e.g., the purpose of the engagement, a detailed description of milestones and expected deliverables. Such agreements with Healthcare Organizations are subject to Compliance Approval⁶, unless a Compliance General Release has been issued; further information can be found in Directive [1_D_103 Stipulations for Collaborations](#).

Other types of HCO agreements are such as Reference Site-Agreements and Fellowship-Agreements. These types do not fall under Directive [1_D_103 Stipulations for Collaborations](#) however, they have to be handled similarly to all other agreements with HCOs including Fair Market Value assessment and Compliance Approval⁷.

2.2.5 Value Based Care

Arrangements to advance value-based care (also referred to as results-based, outcomes-based, or performance-based payment arrangements) are designed to increase shared accountability among stakeholders for quality of, access to, and/or the total cost of care. These arrangements often condition payment or modify pricing for health care items or services based upon clinical, economic, and/or patient-experience outcomes, and may include payor-driven reimbursement arrangements for providers, arrangements between providers, and arrangements between providers and manufacturers or other participants in the health care system.

Value Based Arrangements must be aligned with and reviewed by Legal and the Compliance Office.

2.2.6 New Business Models

As part of its global business, Siemens Healthineers drives and establishes new business models such as operation of labs, radiology departments, public-private-partnerships, or hospitals. Such business models are different from the core business activities of Siemens Healthineers and require a specific compliance risk management. Any Unit establishing such models is responsible to develop a risk-based compliance framework to be aligned with and reviewed by Legal and the Compliance Office.

2.2.7 Compliance General Release

A Unit's Compliance Office can issue a Compliance General Release for various types of activities such as invitations of HCPs, speaker activities, collaborations and other activities based on risk criteria for the respective

⁶ See Glossary Term „Compliance Approval“. Contact local CO for more information.

⁷ See Glossary Term „Compliance Approval“. Contact local CO for more information.

country, local laws, and codes of conduct of industry associations. This Compliance General Release must be approved by the Head of Compliance and is documented and accessible in the [Compliance World Map](#).

2.2.8 Contract Lifecycle Management

All agreements need to be archived in accordance with [Directive 1_D_85](#) Contract Lifecycle Management.

2.3 Pillars of the Compliance System: “Prevent”, “Detect” and “Respond”

The key focus is the prevention of Compliance related violations. In addition, the company has put processes and tools in place to detect violations. The company will respond in appropriate form to any violation with disciplinary measures and remediation actions.

2.3.1 Prevent

2.3.1.1 Anti-Corruption

Siemens Healthineers does not tolerate any form of Corruption in its business interactions anywhere in the world. Any kind of Benefits provided to or received by third parties must be justified by a genuine business purpose and must avoid the appearance of improper influence or Corruption.

Benefits, General Criteria and Transparency Requirements

A Benefit is any economic and non-economic advantage for the recipient.

An economic Benefit could be money or values, which can be traded or exchanged in money or tangible non-monetary Benefits such as gifts, meals, hospitality, or coverage of expenses for travel and accommodation or entrance fees.

A non-economic Benefit is any other advantage; this may include an offer of employment or for internship to the recipient or the recipient's related parties, the granting of a permit or an introduction to certain influential individuals.

Before providing any Benefit, the Compliance risks must be evaluated:

- Benefits must be permitted by applicable law as well as by applicable codes of conduct of industry associations. The internal rules of the recipient's organization also need to be considered.
- Benefits shall not be offered to improperly influence a decision of the recipient or to obtain any other inappropriate advantage.
- Benefits must not be given in the form of cash or cash equivalents (e.g., vouchers, gift cards), unless exceptionally approved by the Compliance Office.
- Benefits should not be provided if this creates the appearance of improper influence.
- The nature, value, and frequency of the Benefit must be appropriate to the occasion on which it is given and to the position of the recipient and all other circumstances.
- The Benefit must be provided and received in a transparent manner.

Before accepting any Benefit, the following topics should be considered:

- Occasional gifts of purely symbolic value may be accepted; employees may also accept meals or entertainment reasonable in value that are consistent with local customs, locally binding thresholds might apply.
Employees must check and comply with any tax implications and documentation needs under local law. Benefits might be taxable as a wage component. For further information, the Human Resource (HR) organization can be contacted.

Benefits also may be prohibited or may be subject to reporting or approval obligations based on country specific transparency laws (see [Attachment 1](#) and [2](#)) or codes of conduct of industry associations.

More information can be found on the [Compliance World Map](#) and on the [Compliance intranet](#).

Invitations to Business Meals

Siemens Healthineers may pay for occasional, modest meals when employees meet with third parties to discuss business. Such business meals do not need Compliance Approval if the above-mentioned general criteria for providing Benefits are met, including that the individual(s) in attendance have a veritable business need to be present at the discussion. Country-specific Compliance requirements can be found on the [Compliance World Map](#).

Invitations to Company Events

Siemens Healthineers may invite third parties to company events (e.g., educational and scientific events, plant tours, acceptance visits, training) and may pay for travel⁸, accommodation and meals. These Benefits need to be in line with the above-mentioned general criteria for providing Benefits and require prior Compliance Approval⁶. In addition, these invitations need to be disclosed to the recipient's employer unless the recipient is self-employed. Further details can be found in [Attachment 3](#) and the [Compliance World Map](#).

Each country Compliance Office can issue a General Compliance Release for such invitations based on risk criteria for the respective country, local laws, and codes of conduct of industry associations. See Section 2.2.7. for more details on Compliance General Release.

For travel, accommodation, meals and other costs in sales agreements, details to be found in [Attachment 3](#).

Invitations to Third Party Educational Events and Ban of Direct Sponsorship

Almost all codes of conduct of industry associations prohibit direct sponsorships (i.e., paying) for individual HCPs regarding their attendance at third party educational events (including tradeshow). Instead, support of educational and scientific matters can only be granted to HCOs or a Third-Party organizer in the form of educational grants. Such educational grants must be documented in a written agreement and the HCO/Third-Party organizer is responsible for the selection of the final grantee(s). Travel arrangements and potential entrance fees must be organized by the HCO/Third-Party organizer. In addition, certain countries as well as industry associations require disclosure of such educational grants.

⁸ Travel includes flights, trains and other kinds of ground transportation

Educational grants need Compliance Approval⁹ prior to granting them to an HCO. Further information is available on the [Compliance](#) and [SpoDoM intranet](#).

Sponsoring, Donations, Charitable Contributions, Educational Grants and Other Contributions without Consideration

Each sponsoring, donation, charitable contribution, and educational grant must follow certain principles and undergo approval processes as defined in Directive [1_D_47 SpoDoM](#). Further information is available on the [SpoDoM intranet](#).

When the intended beneficiary/requesting organization is a U.S.-based organization, and only if the Unit (ARE) covering the cost is located in the U.S., that organization must request the donation, educational grant, or sponsoring via the U.S. [Healthcare Giving Portal](#). Further information is available there.

In case the contribution is not a sponsoring, donation, charitable contribution or an educational grant, it may fall in the category of "Other Contributions without Consideration". Such category includes any voluntary contribution in money or in kind without consideration that has a commercial background, such as an existing business relationship with the recipient, but that does not meet the prerequisites for a classification as a sponsoring or a donation / charitable contribution as set forth under Directive [1_D_47 SpoDoM](#). A contribution is still considered "without consideration" if Siemens Healthineers is offered a consideration in return that is of no or little value to Siemens Healthineers. Other Contributions without Consideration must fulfill the general requirements as defined in Section 2.2 of Directive [1_D_47 SpoDoM](#) and shall undergo the same approval and booking processes as defined therein.

All contributions must be documented in a written agreement and if the contribution is asked for by an employee of a customer or a member of the public sector (Public Official), the agreement needs to be disclosed to the respective employer of the requestor.

2.3.1.2 Antitrust

Behavior or arrangements which restrict or hinder fair competition (so called "hardcore" antitrust violations) are strictly prohibited. Such behavior or arrangements are e.g., cartel arrangements between competitors, the fixing of prices or other terms of trade, the allocation of markets or customers, aligned production or sales quota, bid rigging, limiting production or production capacities, limiting technical development, limiting recruitment, as well as agreements between manufacturers and their distributors about minimum resale prices or restrictions of reimports. To this end, all employees are asked to be very careful in their contacts with competitors and not to discuss or exchange any competitively sensitive information.

Legal and Compliance shall be contacted to assess the following company cooperation projects and business models that may restrict competition:

Consortia, rebate schemes, dealing with third parties re interoperability, dealing with third parties (incl so called independent service organizations) in the service business, joint research and development, joint sales and marketing agreements, specialization / joint production, standardization, exclusive purchasing, market information systems / benchmarking, exclusivity and non-compete arrangements and territorial restrictions in distribution and licensing agreements.

⁹ See Glossary Term „Compliance Approval“. Use appropriate tool for Compliance Approval. Contact local CO for more information.

Employees who are aware of any potential violation of Antitrust or competition law are expected to report this through a reporting channel ("[Let us Know](#)" or [Ombudswoman](#)) or directly to Legal and Compliance. More details can be found in the Antitrust Quick Guide and on the [Compliance intranet](#) and [Legal intranet](#).

2.3.1.3 Anti-Money Laundering (AML)

Goods-traders like Siemens Healthineers are required by law in Europe and many other countries to implement processes to avoid involvement in Money Laundering and financing of terrorism.

Therefore, the Units must conduct business only with reputable counterparts who are involved in lawful business activities and derive funds from legitimate sources. These counterparts must comply with the transparency requirements defined in the applicable Anti-Money Laundering legislations and Siemens Healthineers internal regulations.

Employees are expected to pay attention to potential AML Alert Signs and report them immediately to the Compliance Organization. These Alert Signs can be related to:

- Counterpart, its representatives and ultimate beneficial owners
e. g.: complex/in transparent company structure; company is a letterbox company or is owned by a letterbox company; ultimate beneficial owner not identifiable/avoids personal contact; financial background does not fit planned business transaction; (bad) reputation in general
- financial transactions and payment
e. g.: payments from unknown third parties; in-transparent source of funds; unusually high upfront payments; overpayments of amount due and request to have the balance transferred to a different account
- business model/relationship and its commercial, technical, and other parameters
e. g.: unnecessarily complex business model; business "lacks economic sense"; is questionable from technical, logistic or other perspective.

More information can be found here: [Attachment 4](#) and on the [Compliance intranet](#).

2.3.1.4 Business Partners

Cooperating with Business Partners (e.g., distributors, sales agents, customs clearing agents, consultants, consortium partners and resellers) is part of Siemens Healthineers business. Their integrity is an essential factor in protecting Siemens Healthineers from liability and reputational risks.

Therefore, the Unit entering a relationship with a Business Partner must follow certain steps to ensure that the relationship is responsibly evaluated, managed and monitored over the course of the relationship.

Instructions for cooperating with Business Partners are detailed in [Attachment 5](#) and the [BPC Web-Book](#).

Marketing & Sales (M&S) is the Governance Owner for Business Partner Management concerning distributors and agents and provides detailed information on the [M&S intranet](#).

2.3.1.5 Procurement

Identifying and mitigating all procurement related risks (including concerns regarding human rights and environmental issues according to the German Supply Chain Act) at an early stage is one of the goals of the supplier qualification and auditing processes. Siemens Healthineers also expects its suppliers to share Siemens Healthineers' values and comply with all applicable laws as established in the "[Code of Conduct for Suppliers and Third Party Intermediaries](#)".

In case that a newly registered supplier is acting as a Business Partner (e.g. as customs agent, business consultant) a Business Partner Compliance due diligence has to be executed by the requesting Unit in close cooperation with Procurement in the Business Partner Compliance Tool.

More information is provided in Directive [1_D_84 Principles of correct purchasing](#) and the [Procurement intranet](#).

2.3.1.6 Human Rights and implementation of the German Supply Chain Due Diligence Act ("LkSG")

Within its sphere of influence, Siemens Healthineers embraces and supports the set of core values for human rights, labor standards, the environment, and Anti-Corruption in the [United Nations Global Compact](#)¹⁰ ("UNGC") as an integral part of its business strategy and operations. Therefore, human rights risk assessment must be implemented in processes such as Procurement, Project Business and Human Resources; regular audits and certifications, if required by local law, have to be conducted accordingly.

The Code of Conduct for Suppliers and Third-Party Intermediaries requires that Business Partners and suppliers adhere to the human rights' minimum standards as anchored in the Code.

Involvement of Siemens Healthineers in any infringements of human rights or other adverse human rights impacts within or outside the company must be avoided and shall be addressed to the Compliance Office, the Human Rights Officer or through the reporting channels "Let Us Know" and the Ombudswoman immediately.

Implementation of the German Supply Chain Due Diligence Act (Lieferkettensorgfaltspflichtengesetz, "LkSG")

Applicable to Germany-based companies with more than 1,000 employees the LkSG imposes due diligence obligations related to human rights and environmental protection in the companies' business activities and in their supply chains. The term "companies' business activities" also refers to Controlled Companies and is therefore applicable to Siemens Healthineers throughout the world.

The LkSG contains the following prohibitions:

- child labour;
- slavery and forced labour;
- the disregard of occupational health and safety;
- unequal treatment in employment;
- the withholding of an adequate wage;
- the disregard of the right to form trade unions or employee representatives;
- serious human rights violations in the use of security forces;
- destruction of the natural basis of life through environmental pollution;
- the denial of access to food and water;
- as well as the unlawful deprivation of land and livelihoods or violations against International Minamata, Basler and POP Conventions.

¹⁰ As well as the violation of rules laid down in the framework agreement of the International Metalworkers' Federation (IMF), as applicable.

Furthermore, the LkSG imposes the following due diligence requirements on Siemens Healthineers:

- Implementation of a risk management system with the aim to reduce the risk of violating the protected legal positions stated above. In particular, the risk management system requires to define internal responsibilities and conduct a risk analysis on a regular basis and in some instances on an ad-hoc basis;
- Publishing, maintaining and communicating a policy statement on procedures, risks and expectations to the employees and suppliers;
- Ensure internal reporting of potential violations of the protected legal positions (anywhere within Siemens Healthineers or at suppliers or sub-suppliers of the company) and initiation of remedial actions to end or mitigate violations;
- Establishing a standardized complaint procedure;
- Documentation of fulfilment of the due diligence obligations;
- Preparation and publication of an annual report to the German Federal Office for Economic Affairs and Export Control (BAFA).

Implementation of requirements:

- The Managing Board has appointed the Head of Compliance as Human Rights Officer, having the overarching responsibility and governance for implementing the requirements of the LkSG. In addition to Compliance, the Functions Strategic Procurement, Human Resources, Environmental Protection, Health Management and Safety, Security, Assurance, Real Estate Management and Sustainability have respective responsibilities and are mandated to fulfill the requirements of the LkSG. The specific allocation of responsibilities and scope of activities of the Functions is defined in Attachment 5a.
- The process for conducting the annual LkSG risk assessment or - where required by the LkSG - an additional ad-hoc risk assessment is further described in Attachment 5a. To cover the business activities of Siemens Healthineers, a risk-based selection of Controlled Companies is initiated with the purpose to do deep-dives into potential risk areas and to initiate remedial actions, if required. To cover the supply chain of Siemens Healthineers, Strategic Procurement is conducting a respective risk-based assessment on the suppliers. All findings as well as other relevant factors (complaints, other available information etc.) are consolidated in an overall risk assessment for Siemens Healthineers. The Human Rights Officer is reporting on the results to the Managing Board.
- Siemens Healthineers issued a [Policy statement](#) describing the human rights strategy and fulfilment of the environmental protection-related obligations of Siemens Healthineers. This Policy statement is available in both German and English on the [corporate Siemens Healthineers website](#).
- All employees of Siemens Healthineers are encouraged to report potential violations of the LkSG requirements via the existing reporting channels, see Chapter 2.3.2. Siemens Healthineers has published a [Complaints Procedure](#) outlining the company's handling of incoming complaints.

More information can be found in [Attachment 5a](#) and on the [Compliance intranet](#).

2.3.1.7 Data Privacy

Processing of personal data – whether by Siemens Healthineers itself or by service providers used by Siemens Healthineers – must comply with all applicable legal data privacy requirements and internal company regulations, as stipulated by the certified Data Privacy and Cybersecurity Management System (CYSMS). Data Privacy requirements, including the handling of health data, are laid out in Directive [1_D_71 Data Privacy](#) (and Directive [1_D_19](#) for Cybersecurity specifics). Further guiding material and instructions are linked at the [Data Privacy intranet page](#), which also includes the link to the [Let Us Know Data Privacy tool](#) for reporting potential data breaches or submitting data subject requests.

2.3.1.8 Export Control and Customs

Siemens Healthineers is obliged to comply worldwide with the legal requirements for Export Control and Customs and to ensure their proper and efficient implementation. Further information can be found in [Directive 1_D_70 Export Control and Customs](#) and in the [Internal Control Program \(ICP\)](#).

2.3.1.9 Free of Charge Items, Refunds

Any performance of services or provision of equipment, instruments, reagents, or software free of charge to the customer may constitute a potential Compliance risk. If the following conditions are met, Compliance Approval however is not necessary:

- a) the recipient has a legal claim and the respective Legal department has confirmed the claim; scenarios are e.g. bridging of delivery difficulties in the case of a binding order or for refunds in case of unintentional overpayment, liability for warranty or other deficiencies in performance
- b) the delivery is intended to compensate the recipient for an unsatisfactory performance even though the compensation is not required by contract (within locally defined thresholds) and the unsatisfactory performance as well as the reasons for the decision, including the decision maker (taking into account the 4-eyes-principle), are well-documented
- c) the delivery is required by law and the respective Legal department has confirmed this
- d) it is a temporary replacement of defective customer devices as part of maintenance contracts or it is for (pre-purchase) evaluation purposes:

Multiple-Use (e.g. instruments, equipment, software; also called "Loaned Products") as well as Single-Use Products (e.g. reagents) may be provided to allow HCPs and HCOs to assess and test the appropriate use and functionality of the product in clinical practice.

Multiple-Use Products may be provided for a limited period of time not to exceed the length of time reasonably necessary for the adequate evaluation of the product. Single-Use Products should not exceed the amount reasonably necessary for the adequate evaluation of the product. Further information can be found in [Attachment 6](#).

2.3.1.10 Facilitation payments and payments under duress

A facilitation payment is the payment of a relatively small amount of money or the granting of any other Benefit to usually low-ranking Public Officials, for their own personal Benefit, with the aim of speeding up the performance of a legitimate official act (e.g., granting a business visa).

Facilitation payments are generally prohibited; however, no employee is expected to risk life, limb, or liberty in the course of performing his/her duties. Unjustified payments under duress will not be punished with disciplinary action. They are expected to be reported immediately in accordance with and as detailed in [Attachment 7](#).

2.3.1.11 Mergers and Acquisitions

Prior to the investment into or divestment of the whole or a part of a company, Directive [1_D_34 Mergers & Acquisitions](#) ensures to evaluate the potential Compliance, Data Privacy and ECC risks for Siemens Healthineers and to mitigate them by taking appropriate action. After any acquisition appropriate Compliance standards shall be established during the integration.

2.3.1.12 Project Business

Project Business as well as Real Estate projects are exposed to unique risks, e.g., liability, regulatory and Compliance risks. Therefore, a Compliance Risk Evaluation (Limits of Authority (LoA) CRE) concerning Corruption, Money Laundering and potential violations of human rights shall be performed within the approval process for Siemens Healthineers' customer projects according to Directive [1_D_78 Stipulations for LoA-process](#) and the [LoA Tool](#).

Real Estate projects shall be handled in accordance with [Attachment 8](#).

2.3.1.13 Communication

The Heads of all Units must ensure that employees are informed about all relevant laws, regulations, processes, and tools in the area of Compliance and that this information is kept up to date. The Heads of these Units are also responsible for establishing continuous and adequate communication with appropriate outreach at all organizational levels through the tone from the top and the tone from the middle.

The Compliance organization provides the relevant content and support.

The responsibility of Communications (CC) for relations with external media on Compliance topics in alignment with Compliance remains unaffected.

2.3.1.14 Training

The Compliance organization shall train employees, no matter if part time or full time, on Compliance and ethical topics customized to their function through web-based or in-person trainings on a regular basis.

Self-training material is provided on the [Compliance intranet](#); however, the Compliance organization can always be approached and can provide additional trainings whenever necessary.

Managers must ensure that employees participate in mandatory trainings in time which includes reminding and promoting compliance trainings.

2.3.1.15 Compliance Risk Assessment and Antitrust Risk Exposure Assessment

The Compliance Risk Assessment (CRA) ensures the bottom-up identification of risks, including ethical risks, in individual Siemens Healthineers Units worldwide. The Head of Compliance determines which Units must perform the CRA.

The Head of any such Unit is responsible for performing the CRA workshop and for defining mitigation measures. The Compliance Office of the respective Unit is responsible for coordinating and preparing the workshop, and for monitoring the timely implementation of defined mitigation measures. Relevant risks shall be reported to the Enterprise Risk Management (ERM) by the Head of Compliance responsible for the Unit.

The Antitrust Risk Exposure Assessment (AREA) shall be performed throughout the year for countries or Units selected on a risk-based approach by the Head of Compliance responsible for the respective Zone of the selected country or for the Unit. The Head of Compliance determines each financial year which countries or Units shall be subject of the AREA.

Further details are contained in the CRA and AREA Charter on the [Compliance intranet](#).

2.3.1.16 Compliance Checks integrated into Human Resources Processes

Compliance checks are a global standard procedure for all employees who are selected for promotion, transfer (including side-steps) or rehiring in certain sensitive functions defined by management, Human Resources (HR) and Compliance. The affected employees must be checked internally with respect to their legally compliant behavior and integrity by HR in close cooperation with the Compliance organization.

Compliance checks have also to be performed in case of potential conflicts of interests. Such conflicts of interest could occur if an employee moves to public service, or an employee of the public service moves to Siemens Healthineers as such transfers can be perceived as inappropriate.

Further information can be found on the [HR intranet](#).

2.3.1.17 Collective Action

Collective Action is a joint effort of different stakeholders like competitors, customers, non-governmental organizations, and authorities to fight against Corruption. The Head of Compliance responsible for the CRA or the Compliance Review Board (CRB) shall discuss within the process of the CRA or during the CRB with the Management on potential Collective Action projects. The management shall provide support during the implementation of a Collective Action project.

Further information and guidance are available on the [Compliance intranet](#).

2.3.1.18 Lobbying Activities

In some jurisdictions, organizations or companies like Siemens Healthineers shall follow specific laws and requirements when engaging external lobbyists. These lobbying activities are managed by the regionally responsible Governmental Affairs; any such activity needs to be approved by regionally responsible Governmental Affairs. Generally, external lobbyists are defined as Business Partners and require a Compliance due diligence via the [Business Partner Compliance Tool](#).

In some countries, activities initiated by Siemens Healthineers employees, including governmental affairs, sales, and marketing employees, toward Public Officials can also be considered as lobbying and as such may have strict requirements (e.g., registering as lobbyists, gift rules and reporting requirements). These lobbying activities are managed and monitored by the regionally responsible Governmental Affairs, unless locally determined otherwise (for EMEA Governmental Affairs please check Instruction [13_I_2 "Lobbying"](#)).

Specific Compliance requirements can be found on the [Compliance World Map](#) and the [BPC Web-Book](#).

2.3.1.19 Conflict of Interest

Business decisions must be taken in the best interest of Siemens Healthineers and should not be influenced by personal interests and /or personal benefits. Each employee is expected to inform the management about a potential Conflict of Interest that might exist in connection with the performance of employee's duties. More information on conflict of interest can be found in the Business Conduct Guidelines. If a tool for the declaration of conflicts of interest is locally available, such tool must be used.

2.3.2 Detect

2.3.2.1 Reporting of potential Compliance Cases and internal Compliance Investigations

Siemens Healthineers expects its employees to report all information they may have regarding impending or existing Compliance cases¹¹ without delay either

- to their supervisors who shall advise their team member on how to further report to Legal and Compliance or, alternatively, to reporting channels (Compliance Let Us Know/Ombudswoman) and/or
- the relevant Compliance Offices or directly to the Head of Compliance or
- any other member of the Legal and Compliance organization.

Employees¹² may also use the following protected reporting channels:

- Compliance "[Let Us Know](#)"
- [Ombudswoman](#)

When reporting Compliance cases, individuals may remain anonymous if legally permissible under local law. Retaliation of any kind against individuals who have reported Compliance cases in good faith will not be tolerated.

All Compliance cases reported to the Compliance organization will either be handled by the Compliance organization itself or forwarded to the relevant specialist department for further action.

All complaints must be handled by a formalized process. The objective of this process is to fully investigate all facts. This includes the analysis of company data and the conduct of confidential interviews with those individuals concerned. Following the completion of the fact-finding process, an Investigation report must be prepared and issued to the relevant stakeholders. The report must include recommendations for the implementation of appropriate and proportionate remediation measures.

Further information can be found in [Attachment 9](#) and on the [Compliance intranet](#).

2.3.2.2 Compliance Control Program

The Compliance Control Program (CCP) as part of the Risk and Internal Control (RIC) framework defines compliance-related control requirements. These control requirements can be found in the "Policy & Control Masterbook" (PCMB).

The responsible Control Requirements Contacts (CRCs) and Deputies are determined at the beginning of the "RIC year". The Head of each Siemens Healthineers company shall ensure together with RIC that the respective controls of the "Compliance Control Program" (CCP) are properly executed.

In the case of CCP controls which Compliance does not carry out itself, the Compliance Office can provide support.

2.3.2.3 Compliance Review Board

It is management's responsibility to review and evaluate the effectiveness of the Compliance System on a regular basis. This is done in a systematic form by the Compliance Review Board meeting.

¹¹ Potential violations are for example: corruption, bribery, conflict of interest

¹² The reporting channels are also available to external stakeholders (such as suppliers, customers, Business Partners etc.). All reported information is treated equally.

The Compliance Review Board (CRB) shall be established on corporate level for Siemens Healthineers AG as well as for every Zone and shall meet each quarter of the company's fiscal year. The CRB shall be governed by a CRB Charter and be held in the form of an in-person meeting/virtual meeting with the mandatory participants.

Mandatory participants are

- On corporate level: The members of the Managing Board, the Head of Legal and Head of Compliance.
- On Zone level: The Head of Zone, Head of Finance of Zone, Head of Legal and Head of Compliance of the Zone.

The CRB Charter may determine further mandatory participants.

The CRB shall cover the following mandatory topics: Compliance cases, Data Privacy, Export Control and Customs cases and risks, Business Partners, status of mitigation for identified risks during the CRA, CCP deficiency remediation, Compliance training measures, Compliance communication. Further topics are recommended to be dealt with in appropriate form.

2.3.2.4 Compliance Audits

Compliance audits such as those for Business Partners, suppliers or collaborations are performed by Siemens Healthineers Audit.

The Compliance organization will provide support in performing such audit activities.

2.3.3 Respond

2.3.3.1 Disciplinary consequences

Employees who violate the laws and/or internal regulations, including the Business Conduct Guidelines, are subject to appropriate disciplinary consequences¹³. Disciplinary consequences, depending on the nature of misconduct and level of the employee will be evaluated and determined either by the Central Disciplinary Committee, respective Regional Disciplinary Committees or on a country level. The Compliance organization has introduced basic principles and evaluation criteria to ensure consistency in the disciplinary process. Further information can be found in [Attachment 10](#) and on the [Compliance intranet](#).

Zero tolerance for misconduct – this is the guiding principle. However, considering all circumstances of the individual case, Siemens Healthineers may refrain from these actions against an employee who has committed a Compliance offense or who is suspected of such. This is particularly the case if,

- Siemens Healthineers is dependent on the active participation of suspicious employees for the clarification of Compliance-relevant facts with serious material or immaterial effects, and if such participation can only be obtained in this way, and
- the employee shows understanding and convincingly communicates that he will abstain from future misconduct and act as a role model for integrity.

Co-determination rights of the employee representatives (if and where applicable) shall be respected throughout the applicable processes.

¹³ Disciplinary consequences can be an oral warning, formal warning, termination but also Compliance training (list not exhaustive)

2.3.3.2 Remediation

Management must ensure that all identified Compliance matters such as findings from Compliance Investigations or audits or RIC deficiencies are followed up and implemented accordingly in due course. This process is called “remediation”.

- Remediation related to Compliance Investigations

The purpose of the remediation process is to ensure that weaknesses, deficiencies, and Compliance violations identified because of a Compliance Investigation are corrected. All Units affected by a Compliance Investigation must therefore implement the remediation measures recommended in the corresponding Investigation report.

The Compliance organization is responsible for the successful implementation and monitoring of recommended remediation measures.

- Other Remediation Matters

All deficiencies identified by the Risk and Internal Control Framework should be remediated prior to the fiscal year end where possible. All Units therefore have an obligation to organize, track and close measures, regardless of which Siemens Healthineers Unit defined them.

The remediation of audit related Compliance findings is handled as outlined in the respective audit report.

If a measure is not addressed directly to the Compliance organization but is related to a Compliance topic, the Compliance organization nevertheless will support the remediation process and monitor its status.

3 Implementation notes

The revision of this Directive including the integration of several other regulations does not cause changes in the underlying and already implemented processes.

The Compliance organization is responsible for communication and training and to support the Executive Management and all managers in their obligation to ensure Compliance with the stipulations of this Directive.

Siemens Healthineers Units shall only issue specific regulations in the scope of this Directive if required by law or to mitigate business-specific risks. All such regulations have to undergo the [Compliance Portfolio Management](#) process. Stricter standards shall prevail and need to be observed by all employees.

Specific tasks for ARE-Managing Directors / Finance Directors:¹⁴

Task	MD/ ARE-CEO	FD / ARE-CFO		account- able	respon- sible
Overall responsibility for Compliance lies with the MD and the Heads of the units. They must act as role models in matters of Compliance, ethical behavior and integrity and ensure, through the right tone from the top and the middle, that all employees act accordingly.	■	n/a		n/a	■
Ensure that there are no violations of laws, codes of conduct of industry associations and internal regulations within his area of responsibility that proper supervision could have prevented. He remains accountable, even if he delegates particular tasks.	■	■		n/a	■
To act as role model in matters of Compliance and integrity and ensure, through the right tone from the top, that all employees act accordingly.	■	■		n/a	■
Ensure that employees feel safe to speak up concerning compliance risks.	■	■		n/a	■

n/a: not applicable

¹⁴ Condensed summary of the immediate tasks for the executive management of an ARE resulting from this Directive. The management is in general jointly responsible in the external relationship; this is only concretized in those cases where the task specified in the Directive is explicitly assigned to only one member. "Accountability" to be understood as: being in charge, but no need to do him-/herself. The task can be delegated // "Responsibility" to be understood as: this needs to be done by that person.
The fact that no explicit task is mentioned here does not mean at all that this Directive is not applicable or not relevant; all Directives are binding and must be complied with within the Healthineers Group. The absence of mention of an explicit task therefore means (only) that there is no immediate need for action to be taken by the above-mentioned persons as a result of this Directive.

4 Risk and Internal Control (RIC) requirements

Compliance with the Control Requirements is to be ensured by the Management of the respective ARE (Managing Director/ARE-CEO, Finance Director/ARE-CFO) through the implementation of appropriate processes and controls. The assessment approach defined by the Governance Owner must be implemented analogously in accordance with the IC system.

The Control Requirements resulting from this Regulation are:

PCMB-Ref.	4.1.1.2-5	that an adequate Compliance System and Compliance organization is defined from a Governance perspective, reviewed on a regular basis (e.g. to reflect relevant legislation changes) and that the status of the implementation and its effectiveness is centrally monitored
	4.1.1.2-1	that the centrally defined Compliance System is implemented including local legal requirements and that a suitable monitoring is used to enforce and monitor the status of the implementation and its effectiveness.
	4.1.1.5-1	that a comprehensive Compliance Due Diligence is approved for a specific Business Partner and compliance provisions are included in the contract as defined in the respective regulations
	4.1.1.5-6	that for all relationships with third parties which fulfill the criteria of a Business Partner a Compliance Due Diligence has been approved as defined in the respective regulations.
	4.1.1.5-8	that every new sales-related Business Partner in Mainland China goes through a robust Onboarding and Monitoring Process that addresses the key risks in Mainland China.
	4.1.1.7-1	that payment of travel & lodging costs to third parties are assessed and approved accordingly.
	4.1.2-2	that all employees in the relevant target group receive information relating to the Business Conduct Guidelines (BCGs) and confirm that they comply with the BCGs.
	4.3.1-1	that the interpretations and developments of relevant laws and regulations are monitored by suitably qualified members of staff utilizing recognized local sources of law to be able to appropriately communicate changes and impact of relevant laws and regulations, if significant, to management.
	4.3.1-12	that the Compliance function implements the required information & reporting rules, methods, and procedures required to publish a report every year on how the due diligence obligations of the German Supply Chain Due Diligence Act ("SCDDA") have been fulfilled.
	4.4.1-1	that an effective Antitrust Compliance Program is operated, reviewed and continually updated.

Appendix

a) Document Release

Role	Name, First Name	OrgCode
Governance Owner	Mundani, Dagmar	LC
Content Owner	Knothe, Benedikt	LC CO
Author	Buettner, Andreas	LC CO RP

b) Change history

Revision	Changes	Date	Author
v3.2	Chapter 2.3.1.6 added: Implementation of the German Supply Chain Due Diligence Act ("LkSG") , Attachment 5a added	2023-09-19	Buettner, Andreas
v3.3	Formatting, typos/clarifications, embedded links, correction of references Chapter 2.3.1.1. Ban of cash or cash-equivalent regarding Benefits being provided; potential introduction of local thresholds regarding Benefits being accepted; clarification regarding use of Healthcare Giving Portal Chapter 2.3.1.9: documentation requirement regarding free-of-charge items Chapter 2.3.1.14: clarification training scope and manager responsibility Chapter 2.3.2.3: extension to virtual CRBs	2024-09-19	Buettner, Andreas

c) Reference documents

- [Business Conduct Guidelines](#)
- [Directive 1_D_19 "Cybersecurity"](#)
- [Directive 1_D_34 "Mergers & Acquisitions"](#)
- [Directive 1_D_47 "Principles for Sponsoring Activities, Donations, Charitable Contributions, Educational Grants and Memberships"](#)
- [Directive 1_D_70 „Export Control and Customs"](#)
- [Directive 1_D_71 „Data Privacy"](#)
- [Directive 1_D_78 "Stipulations for LoA-process"](#)
- [Directive 1_D_84 "Principles of correct purchasing"](#)
- [Directive 1_D_85 "Contract Lifecycle Management"](#)
- [Directive 1_D_103 "Stipulations for Research Cooperations"](#)

d) List of attachments

- [Attachment 1: Disclosure Requirements USA](#) (former MOR 3.3/01 IN06)
- [Attachment 2: Disclosure Requirements France](#) (former MOR 3.3/01 IN 07)
- [Attachment 3: Benefits](#)
- [Attachment 4: Anti-Money Laundering](#)
- [Attachment 5: Business Partners](#)
- [Attachment 5a: Implementation of the German Supply Chain Due Diligence Act \("LkSG\)](#)
- [Attachment 6: Multiple-use and Single-use Products](#)
- [Attachment 7: Facilitation Payments](#)
- [Attachment 8: Real Estate](#)
- [Attachment 9: Internal Investigations](#)
- [Attachment 10: Disciplinary Measures](#)
- [Illustration of changes from v2.1 to v3.0](#)