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Medical Devices: Sources of Regulation (Germany)

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A Practice Note explaining the regulatory regimes that apply to medical devices and their components in Germany. It covers both regulatory regimes specific to medical devices and general regulatory regimes that apply to a range of products including medical devices.

Medical devices are used extensively in healthcare systems globally to treat patients and, increasingly, to improve consumer health. There is normally a degree of risk associated with the use or misuse of medical devices. For this reason, most nations control and monitor the supply and use of medical devices. Additionally, due to the international nature of the medical device industry, many countries have formed relationships to facilitate cross-border trade in medical devices. This includes, for example, mutual recognition of conformity assessments and regulatory documents.

In Germany, medical devices are subject to product-specific regulation. They are also subject to general product regulation that may apply to all product types or a subset of products, including medical devices or their components. This Note explains the regulatory regimes that may apply (depending on the exact nature of the medical device or component in question), what they seek to control, and the key legislation and sources of authoritative guidance.

Medical Devices

As a preliminary matter in relation to medical device instructions, practitioners should consider whether the medical device in question qualifies as a regulated medical device under the applicable product-specific regulatory regime.

The regulatory framework for medical devices in Germany is to a significant extent governed by EU legislation. The respective Regulations are Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), which are accompanied by numerous delegated and implementing acts.

These regulations notably:

- Provide rules on the classification and conformity assessment of medical devices and in vitro diagnostics.
- Define different economic operators and their respective duties.
- Set up requirements regarding post market surveillance and vigilance, for example.

Generally, medical devices can only be placed on the market if they have undergone a conformity assessment procedure allowing them to bear a CE mark.

Assistance in applying MDR and IVDR is provided by the EU Medical Device Coordination Group (MDCG), which has published a range of documents and guidance.

After the EU regulations entered into force, the German Medical Devices Act (Medizinproduktegesetz – MPG), which transposed the previous Medical Device Directive 93/42/EEC and In Vitro Diagnostic Directive 98/79/EC into German law, was mainly repealed. However, there are still several relevant national provisions complementing and clarifying the EU legislation. This includes the Medical Device Law Implementation Act, 2020 (Medizinprodukterecht-Durchführungsgesetz – MPDG), which followed the MPG, as well as further ordinances and administrative rules, such as the Medical Devices Operation Ordinance, 1998 (Medizinproduktebetreiberverordnung - MPBetreibV) and the Medical Devices Supply Ordinance, 2014 (Medizinprodukteabgabeverordnung – MPAV).

The MPDG specifies and complements certain provisions of the MDR and IVDR, for example, regarding clinical evaluations and clinical investigations of medical devices. The MPDG also determines which tasks are performed on federal and state levels respectively. The MPDG further provides several notification obligations in addition to registration in the European database on medical devices (Eudamed) according to the MDR and IVDR. At the time of writing, Eudamed is not yet fully operational. It is expected to be fully operational by the fourth quarter (Q4) of 2024. Until then, the registration obligation on a national level under the MPG remains in force. Accordingly, medical device manufacturers and European representatives must register with the German Medical Device Information and Database System (Deutsches Medizinprodukte-Informations- und Datenbanksystem – DMIDS) provided by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte – BfArM). The MPDG also defines criminal and administrative offences for violations of European and German medical device law, for example, placing medical devices on the market before completion of a conformity assessment procedure qualifies as a criminal offence in the case of intent, and as an administrative offence in the case of negligence according to sections 93 and 94 of the MPDG. The MPBetreibV establishes several requirements for the operation and use of medical devices to ensure the safety of patients. Duties arising from the MPBetreibV include certain instruction or documentation requirements and the presence of a Medical Device Safety Officer in health institutions with more than 20 employees (section 6, MPBetreibV). The MPAV regulates conditions for the sale of medical devices.

Chemicals

In Germany, the most relevant pieces of legislation applicable to chemicals are EU Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) and Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation). The Federal Act on the Protection from Hazardous Substances, 1980 (Gesetz zum Schutz vor gefährlichen Stoffen – Chemikaliengesetz, Chemicals Act) regulates the surveillance and enforcement of those EU regulations.

The REACH Regulation imposes on producers and importers of a substance in amounts of one tonne or more per year the obligation to register with the European Chemicals Agency (ECHA) (Article 6, paragraph 1, REACH Regulation). It further imposes certain obligations in relation to the manufacture and import of "articles" (Article 7, REACH Regulation). They are objects which during production have been given a special shape, surface, or design which determines their function to a greater degree than their chemical composition (see Article 3, no. 3, REACH Regulation). Registration obligations apply with respect to articles containing substances in quantities totalling over one tonne per producer or importer per year, if those substances are intended to be released under reasonably foreseeable conditions of use (such as in the case of a pantyhose with lotion). An obligation to notify the ECHA may apply where articles contain substances included in the "Candidate List of Substances of Very High Concern Opens in a new window" according to Article 59, paragraph 10 (published on ECHA's webpage), for example, melamine, in quantities totalling over one tonne per producer or importer per year, provided the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w). In addition, regardless of whether the threshold of one tonne is reached, the producers and importers of such articles must submit information on their articles to the so-called "SCIP database", operated by the ECHA.
The REACH Regulation imposes restrictions on the use of certain substances for certain purposes (see Annex XVII, REACH Regulation) and makes the placing on the market and use of Substances of Very High Concern subject to authorisation (see Annex XIV, REACH Regulation). Further information obligations apply along the supply chain, such as the provision of a safety data sheet according to Article 31 of REACH Regulation.

The CLP Regulation harmonises the criteria for the classification of substances and mixtures and the rules on labelling and packaging for hazardous substances and mixtures throughout the EU.

The Federal Chemicals Act (and by extension the REACH Regulation and the CLP Regulation) are given further effect by several ordinances, namely:

– The Federal Ordinance on Prohibitions and Restrictions of the Placing on the Market and the Supply of Certain Substances, Mixtures, and Articles under the Chemicals Act, 2017 (Verordnung über Verbote und Beschränkungen des Inverkehrbringens und über die Abgabe bestimmter Stoffe, Gemische und Erzeugnisse nach dem Chemikaliengesetz – Chemikalien-Verbotsverordnung), which contains some prohibitions on placing substances on the market beyond the REACH Regulation and contains some exemptions from the REACH Regulation.

– The Federal Ordinance on Sanctions in relation to European Regulations on Chemicals Safety, 2013 (Verordnung zur Sanktionsbewehrung gemeinschafts- oder unionsrechtlicher Verordnungen auf dem Gebiet der Chemikaliensicherheit – Chemikalien-Sanktionsverordnung), which in particular regulates the criminal and administrative sanctions that may be imposed if the REACH or CLP Regulations are infringed.

The REACH Regulation applies to medical devices, with few exemptions. This means, particularly, that manufacturers of medical devices must verify whether the substances they use are subject to authorisation or restriction under the REACH Regulation. In some cases, the REACH Regulation provides for exemptions from authorisation or restriction requirements, or for extended transitional periods for the use of a substance in medical devices, for example:

– Where a substance is subject to authorisation only due to its hazards for human health and is used in a medical device, no authorisation must be applied for, as risks for human health are assessed during the conformity assessment procedure under the MDR (see Article 60 (2) and Article 62 (6), REACH Regulation).

– An exemption regarding information obligations in the supply chain applies to medical devices which are invasive or used in direct physical contact with the human body if in the finished state and intended for the final user (see Article 2 (6) (c), REACH Regulation).

– The MDR contains specific restrictions regarding the use of certain substances which are carcinogenic, mutagenic, or toxic to reproduction and of certain endocrine disruptors (see Annex I, Chapter II, section 10.4, MDR).

The CLP Regulation does not apply to medical devices which are invasive or used in direct physical contact with the human body, if in the finished state and intended for the final user, or to in-vitro diagnostics (see Article 1 (5) (d), CLP). However, as far as a medical device is a substance or a mixture under the CLP Regulation, it is subject to classification, labelling, and packaging under the CLP Regulation, which is applicable in addition to the labelling and packaging requirements of the MDR.

Radioactive Material

In Germany, radiation protection is regulated by the Federal Radiation Protection Act, 2017 (Strahlenschutzgesetz) and the Federal Radiation Protection Ordinance, 2018 (Strahlenschutzverordnung). These regulations aim to protect human beings from the negative effects of ionising radiation and have a comprehensive scope, covering exposure to ionising radiation in the professional context, in a medical context, and any other exposure scenarios for the population (excluding cosmic and natural radiation). Section 12 of the Federal Radiation Protection Act requires, particularly, a notification or permit prior to handling radioactive substances and prior to operating equipment generating ionising radiation.

Section 23 of the Federal Radiation Protection Act specifies that product-related requirements applicable to ionising substances or equipment using ionising radiation that qualify as medical devices are provided in the MDR. In this context, Annex I, Chapter II, section 16 of the MDR is particularly relevant. When designing their products, manufacturers of medical devices using ionising radiation must therefore observe the MDR, while the manufacturing process may require permits for the handling of radioactive substances under German national law. The operation of medical devices using ionising radiation may also trigger notification or permit requirements.

Advanced Therapies, Tissues, and Cells

Modern medicine involves the use of cutting-edge combinations of medical devices with pharmaceuticals, tissues, cells, and other materials. These products may fall under a particular regulatory regime or be subject to multiple regulatory regimes that apply to their different components.

Drug-Device Combinations

There is no specific regulation or law governing combinations of medical devices and medicinal products. Therefore, either the MDR or the rules on medicinal products (including Regulation (EC) No 2004/726, Directive 2001/83/EC, and the German Medicinal Products Act, 1976 (Arzneimittelgesetz – AMG) apply. Drug-device combinations are classified on a case-by-case basis which largely depends on the primary mode of action of the product. MDCG Guidance 2022-5 provides guidance on borderline cases. Even if a drug-device combination falls under the regulatory regime for medicinal products, it still must fulfil the General Safety and Performance Requirements under Annex I of the MDR.

Advanced Therapy Medicinal Products

Advanced Therapy Medicinal Products (ATMPs) are medicinal products based on gene therapy, somatic cell therapy, or tissue-engineered products. They fall under the ATMP Regulation (EC) 1394/2007. If an ATMP incorporates a medical device as an integral part, leading to a combined advanced therapy medicinal product, the ATMP Regulation applies to this combined ATMP. However, the medical device must also fulfil certain specific requirements laid down in Annex I to Directive 93/42/EEC (essential requirements for medical devices) and Annex I to Directive 90/385/EEC (essential requirements for active implantable medical devices).

Tissues and Cells

If they are not part of an ATMP, tissues and cells are governed by Directive 2004/23/EC (Tissues and Cells Directive), which was implemented in Germany, inter alia, in the German Medicinal Products Act. Borderline products, which contain a medical device component and a non-viable tissue or cell component, might fall under the scope of the Tissues and Cells Directive or the MDR. The distinction is based on the primary mode of action. If the tissue or cell component only serves an ancillary purpose, the MDR applies.

Machinery and Specific Types of Equipment

Within the general description of medical devices, there are numerous types of laboratory and clinical equipment. Some equipment is regulated as a medical device under the applicable product-specific regime, and some may be regulated under separate equipment regulatory regimes. Alternatively, both types of regulatory regime may apply.

The product regulations governing medical devices in Germany are either German regulations implementing EU Directives or directly applicable EU Regulations. Medical devices are not only subject to regulations specifically regarding medical devices, but also to more general EU product regulations. In some cases, the MDR explicitly excludes the application of other regulations (for example, Article 1 (11), MDR excludes the application of Directive 2014/30/EU on electromagnetic compatibility), or other product regulations specify that they do not apply to medical equipment (for example, Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits). Where there are no exempting rules, medical devices must, generally, comply with the requirements of all applicable regulations. Only where two or more product regulations cover the same hazard or impact, may there be an issue of overlap. This might be resolved by giving preference to the more specific regulation. The more specific regulation can be identified by carrying out a risk analysis of the product, or sometimes an analysis of the intended purpose of the product.

Machinery

Machinery is governed by Directive 2006/42/EC on machinery (Machinery Directive), transposed into German law by the First Ordinance under the Federal Product Safety Act, 2016 (1. Produktsicherheitsverordnung). Medical devices that are also machinery within the meaning of the Machinery Directive must, where a hazard relevant under the Machinery Directive exists, also meet the essential health and safety requirements set out in the Machinery Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in the MDR (Article 1 (12), MDR). Directive 2006/42/EC will be replaced by Regulation (EU) No 2023/1230 on machinery, which will largely apply as of 14 January 2027.

Electrical Equipment

Electrical equipment is governed by the following Directives:

– Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive), which generally applies to medical devices with some exemptions (for example, for active implantable medical devices or medical devices qualifying as “large-scale fixed installations”), transposed into German law by the Federal Ordinance on Substances in Electrical and Electronic Equipment, 2013 (Elektrostoffverordnung).

– Directive 2012/19/EU on waste electrical and electronic equipment (WEEE Directive), which generally applies to medical devices, although with some exemptions (such as for medical devices and in vitro diagnostic medical devices, where these devices are expected to be infective prior to end of the device’s life cycle, active implantable medical devices, or medical devices qualifying as “large-scale fixed installations”), transposed into German law by the Federal Act on Electrical and Electronic Equipment, 2015 (Elektro- und Elektronikgerätegesetz).

– Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment, transposed into German law by the Federal Radio Equipment Act, 2017 (Funkanlagengesetz).

– Directive 2006/66/EC on batteries and accumulators and waste batteries and waste accumulators (Batteries Directive), which may need to be observed where medical devices are operated with batteries or accumulators, transposed into German law by the Federal Batteries Act, 2009 (Batteriegesetz). The Batteries Directive will be replaced gradually by Regulation (EU) 2023/1542 concerning batteries and waste batteries, which applies from February 2024.

Measuring Devices

Measuring devices are subject to Directive 2014/31/EU on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments, transposed into German law by the Federal Measuring and Calibration Act, 2013 (Mess- und Eichgesetz)and the Federal Measuring and Calibration Ordinance, 2014 (Mess- und Eichverordnung).

Personal Protective Equipment

Personal protective equipment falls under Regulation (EU) No 2016/425 on personal protective equipment (PPE Regulation) and the Federal Act on the Enforcement of Regulation (EU) No 2016/425, 2019 (PSA-Durchführungsgesetz). Certain products may qualify as PPE and as a medical device (“dual use”), for example, gloves or face masks, and therefore fall within the scope of both the PPE Regulation and the MDR.

Consumer Protection, General Safety, and Product Liability

Consumer Protection

Consumer protection laws in Germany are largely based on EU law and have been implemented in the German Civil Code (Bürgerliches Gesetzbuch – BGB). For example, section 312 to section 312m BGB apply to contracts between consumers and traders and provide information and revocation rights in case of contracts entered into, for example, online or off-premises. The purchase of goods by consumers from traders is regulated in section 474 to section 479 BGB and is characterised by stricter warranties and a deviating burden of proof for the defectiveness of a sold good in favour of the consumer.

For manufacturers of medical devices, these regimes generally only apply directly if the manufacturer enters into contracts directly with consumers rather than selling to other entrepreneurs as intermediaries. However, consumer protection laws might also influence the recourse of an intermediary against the manufacturer.

General Safety

Medical devices must comply with the general safety requirements set out in Article 5 (2) and Annex I, MDR. These requirements apply to all medical devices in the EU and include, the safety and effectiveness of the device, the establishment and maintenance of a risk management system, and the minimisation of risks (for patients and users) and undesirable effects. Annex I, MDR further stipulates specific provisions depending on the nature of the device, for example, for devices incorporating materials of biological origin, devices connected to or equipped with an energy source, or devices intended for self-testing or near-patient testing.

Compliance with the requirements is supervised by the competent national authorities as described in the MPDG, which are equipped with the powers set out in Article 93, MDR and can require documentation to be made available, inspect premises, and potentially demand the device to be brought into compliance or restrict its availability.

A unique German feature is the medical device advisor (Medizinprodukteberater), who professionally informs and instructs healthcare professionals in the use of (certain) medical devices. A person acting as a medical device advisor requires sufficient qualifications and experience (section 83, MPDG).

Violations of safety requirements can be sanctioned under Article 113, MDR and sections 92 to 95, MPDG, which define criminal and administrative offences for certain violations of the MDR and MPDG.

Product Liability

While the MDR and MPDG do not contain specific provisions on civil liability, claims for damages can arise under contractual liability, product liability law, or tort law.

In case of contractual relationships, any culpable breach of a contractual duty can lead to claims for damages under section 280 of the BGB. The exact contractual obligations need to be determined on a case-by-case basis, but non-compliance with the provisions of the MDR might constitute a breach.

Even without a contractual relationship and irrespective of culpability, the manufacturer is also liable for damages caused by a defective product under section 1 of the German Product Liability Act, 1989 (Produkthaftungsgesetz – ProdHaftG). The provision explicitly targets the manufacturer of a product. However, it also applies to anyone importing the product into the EEA, as well as to providers of raw materials or suppliers of components. The Product Liability Act only covers a person's death, bodily harm, damage to health, and damage to property. The manufacturer is not liable in certain situations, for example, if they can prove that they did not place the product on the market or that the defect could not be detected according to the state of scientific and technical knowledge at the time they placed the product on the market. A draft by the European Commission submitted in September 2022 suggests amending the underlying EU Product Liability Directive 85/374/EEC , which inter alia, might further shift the burden of proof to the manufacturers (for example, in the case of insufficient documentation).

Section 823 of the BGB can also give rise to tort liability. Compared to liability under the ProdHaftG, tort liability is directed at everyone (not limited to manufacturers) and not restricted to damages caused by defects of a product, but rather requires culpability (intent or negligence). A breach of the relevant provisions of the MDR may constitute negligence under section 823 (1), BGB on the part of the manufacturer. Liability due to violations of the MDR can further arise under section 823(2), BGB, as the MDR is regarded as a protective law (Schutzgesetz) which at least also serves to protect the legal interests of individuals.

Health Systems and Public Procurement

Dispensation

The Medical Device Dispensation Ordinance (Medizinprodukteabgabeverordnung – MPAV) governs the sale of medical devices. The applicable rules are less strict than those for medicinal products, with a prescription requirement (Verschreibungspflicht) and a restriction to "pharmacy-only" sale (Apothekenpflicht) applying only in a limited number of special cases.

A prescription by a medical professional is only required if either:

– The device is intended to be used directly by a patient and contains a prescription-only medicinal product according to the Medicinal Products Prescription Ordinance, 2005 (Arzneimittelverschreibungsverordnung – AMVV).

– The device is listed in Annex 1 to the MPAV.

The restriction of the sale in pharmacies only applies if a prescription is required or the device is listed in Annex 2 to the MPAV, which currently only covers haemodialysis concentrates.

While there are some further provisions on the storage of the medical devices and the consultation of patients about them, medical devices falling under neither requirement of the MPAV can generally be sold freely under the same conditions as any other product.

Reimbursement

Medical devices might be reimbursed by statutory health insurance (Gesetzliche Krankenversicherung) or private health insurance (Private Krankenversicherung) in in-patient as well as out-patient settings.

In the in-patient sector, investments to acquire large-scale devices (such as CT systems) might be borne by the respective federal state under the Hospital Funding Act, 1972 (Krankenhausfinanzierungsgesetz – KHG). The running costs for consumable medical devices (such as disposable syringes, cannulas, and gloves) are covered as part of the Diagnosis Related Groups (DRGs), which define flat-rate payments under health insurance based on factors such as diagnosis, treatment, and duration of stay.

In the out-patient sector, expenses for medical devices are generally included in compensation for treatments defined by the Uniform Value Scale (Einheitlicher Bewertungsmaßstab – EBM) for the statutory health insurance and the Physician's Fee Schedule (Gebührenordnung für Ärzte – GOÄ) for private health insurance. A physician might also receive compensation from statutory health insurance for medical devices which they regularly keep in stock and use for a larger number of patients as "practice supplies" (Sprechstundenbedarf).

Health insurance also covers the patient's costs for medical aids (Hilfsmittel) listed in the Medical Aids Register (Hilfsmittelverzeichnis) according to the German Social Security Code Book V (SGB V). This includes for example, hearing aids, mobility aids, or prostheses. Therefore, according to section 127, SGB V, medical aid contracts are now concluded through individual agreements between statutory health insurers and manufacturers.

Since 2020, medical devices qualifying as digital health apps (Digitale Gesundheitsanwendungen – DiGAs) can be reimbursed by statutory health insurance, if they fulfil certain requirements and are listed in the DiGA directory (DiGA-Verzeichnis) run by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte – BfArM). Digital health apps can for example assist a patient in documenting their symptoms and behaviours (for example, diabetes diaries, or medication plans) or even have diagnostic functions (such as birthmark-screening apps).

Dual Use and Export Restrictions

It is possible that medical devices or their components or incorporated technology may be used for illicit purposes such as terrorism, warfare, illegal surveillance, or cyber-attacks. For this reason, some nations may have a system designed to prevent undesired use of materials contrary to that nation's security interests.

In Germany, export restrictions are mainly laid down in the Foreign Trade and Payments Act, 2013 (Außenwirtschaftsgesetz), the Foreign Trade and Payments Ordinance, 2013 (Außenwirtschaftsverordnung) and the directly applicable Regulation (EU) 2021/821 setting up a Union regime for the control of exports, brokering, technical assistance, transit, and transfer of dual-use items (Dual-Use Regulation). Sanction regulations, with respect to both specific countries and specific persons and entities, must be considered as well. These sanctions are mostly imposed by directly applicable EU regulations.

Medical devices may, in certain cases, qualify as dual-use items. For instance, detection systems, specially designed or modified for detection or identification of biological agents, qualify as dual-use items. Where a medical device qualifies as a dual-use item, an authorisation is required for export to non-EU countries and under certain circumstances even for intra-EU transfers to a recipient in another EU member state. The competent authority for the grant of these authorisations is the Federal Office for Economic Affairs and Export Control (Bundesamt für Wirtschaft und Ausfuhrkontrolle – BAFA). On request, the BAFA can also issue a binding confirmation that it does not consider a certain product a dual-use item.

Software, Systems, Networks, and Cybersecurity

Many medical devices contain software and networking hardware and are linked to networks so they can be monitored and controlled remotely, which may include the transfer of data concerning the patient or consumer.

While the MDR contains some basic requirements for electronic programmable systems (see Annex 1, no. 17, MDR), at the point of intersection between medical devices and digital products and services several other legislative acts can become relevant.

Data Protection

Data protection is primarily governed by the General Data Protection Regulation, Regulation (EU) 2016/679 (GDPR), which establishes the principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, privacy by design, and privacy by default to which any data processor must adhere. Consumers are also equipped with information and erasure rights.

On a national level, the German Federal Data Protection Act, 2017 (Bundesdatenschutzgesetz – BDSG) complements and expands on the GDPR where the latter does not apply or contains opening clauses, for example in the field of employee data protection and regarding the German supervisory authorities.

Cybersecurity

There is no comprehensive set of rules on cybersecurity in Germany or the EU, but only sector specific provisions, for example targeting network and information systems and critical infrastructure, such as the Act on the Federal Office for Information Security, 2009 (BSI Act – BSIG)and the BSI Kritis Ordinance (BSI-KritisV) implementing NIS 2 Directive 2022/2555 and complementing Regulation (EU) 2019/881. The EU is currently working on the Cyber Resilience Act, a regulation on products with digital elements, which will establish obligations to implement cybersecurity measures depending on the criticality of a product and the obligation to close security gaps throughout the whole lifecycle of a product.

Cybersecurity is also addressed in MDCG guidance 2019-16 Rev. 1 and a position paper by the European Association of Medical Devices Notified Bodies. Standards ISO 14971:2019 and IEC 81001-5-1 can assist manufacturers in meeting existing requirements.

Digital Health Applications

More specific requirements regarding data protection and cybersecurity can apply to digital health apps (DiGAs). To be listed in the DiGA directory (and therefore be entitled to reimbursement by statutory health insurance), specific data protection requirements stipulated by the BfArM and specific cybersecurity requirements provided by the Federal Office for Information Security (Bundesamt für Sicherheit in der Informationstechnik – BSI) must be fulfilled, for example, the establishment of an information security management system and the implementation of safe authentication methods.

Artificial Intelligence

With artificial intelligence (AI) becoming increasingly available and important, the EU has started the process of adopting an AI-Regulation, which might enter into force in 2024 and is intended to establish, inter alia, obligations for providers to conduct a conformity assessment of high-risk AI and further duties for importers, distributors, and non-professional users. A proposed AI-Directive is intended to regulate liability for damages incurred by AI.

Packaging and Labelling

Packaging and labelling of medical devices are governed by the general provisions of the German Packaging Act, 2017 (Verpackungsgesetz – VerpackG) and specific requirements of the MDR.

The VerpackG regulates the placing on the market, collection, and recycling of packaging. It basically imposes an obligation on producers of packaging to register with the packaging register “LUCID” of the Central Agency Packaging Register (Zentrale Stelle Verpackungsregister – ZSVR) and to report data on the amount of packaging placed on the market to ZSVR at regular intervals. In relation to packaging targeted at private consumers, producers must fulfil their obligation to collect and recycle packaging by entering into an agreement with an authorised collection scheme, which will then arrange for the collection and recycling of the waste packaging against the payment of a fee by the producer.

Medical devices need to provide, either on the product itself or on its packaging, the information set out in Annex I, Chapter III, MDR. This includes the name of the product, the manufacturer, the unique ID of the medical device, its serial number, usage instructions, and potentially relevant warnings which must be indicated. Additionally, the CE mark must be printed on the device or the packaging (Article 20, MDR).

Advertising and Promotion

The advertising and promotion of medical devices are addressed in the MDR, IVDR, the Act on Advertising in the Field of Health, 1965 (Heilmittelwerbegesetz – HWG) and the general provisions of the Act against Unfair Competition, 2004 (Gesetz gegen den unlauteren Wettbewerb – UWG). According to the broad definition of the term, "advertising" includes all product-related claims which are intended to promote the sale of the advertised product.

In addition to Article 7 of the MDR and IVDR, which prohibits the use of certain claims for medical devices or in-vitro diagnostics, the HWG and UWG generally prohibit misleading advertising. Therefore, any statement must be accurate and may not cause assumptions the medical device cannot meet. Subject to rather strict interpretation, this requires the manufacturer to be able to prove any claims regarding the functions and effects of the device. The UWG also prohibits certain kinds of comparative advertisements, for example, comparisons with products intended for different purposes are not allowed (section 6, UWG).

The HWG imposes several general restrictions on advertising as well as specific restrictions for direct-to-consumer (DTC) advertising. Accordingly, several provisions do not apply to advertising directed at healthcare professionals. The HWG, inter alia, restricts offering or granting gifts, using certain claims, and advertising medical devices intended for the diagnosis or treatment of certain diseases, such as infectious diseases or addictions.

Competitors might pursue violations of the relevant provisions as unfair commercial practice by warning letters, preliminary injunctions, or trial proceedings. These violations can also constitute criminal or administrative offences.

Waste and Environmental

Used medical devices and the by-products of their manufacture may qualify as regulated types of waste and may pose risks to the environment and human health.

In general, German waste management is governed by the Federal Circular Economy Act, 2012 (Kreislaufwirtschaftsgesetz) and further ordinances. The Federal Circular Economy Act distinguishes between hazardous and non-hazardous waste. Stricter requirements for disposal apply to hazardous waste. The Federal Ordinance on a European Waste, 2001 (Abfallverzeichnis-Verordnung) provides when waste qualifies as hazardous or non-hazardous. There is specific official guidance from the Working Group between the Federation and the Federal States on Waste (Bund/Länder-Arbeitgemeinschaft Abfall – LAGA) on the disposal of waste from medical institutions (see: Vollzugshilfe zur Entsorgung von Abfällen aus Einrichtungen des Gesundheitsdienstes). Although not binding, the guidance plays an important role in practice. It states, inter alia, how medical sharps and infectious waste should be disposed of.

Medical devices qualifying as electrical and electronic equipment may be subject to Directive 2012/19/EU on waste electrical and electronic equipment (WEEE Directive), transposed into German law by the Federal Act on Electrical and Electronic Equipment" (Elektro- und Elektronikgerätegesetz). In this case, medical devices should be designed in a way that considers their environmental impact across their whole lifecycle. The applicable legislation imposes extended producer responsibility on the producers of electrical and electronic equipment, meaning that the producer remains responsible for the product throughout its lifecycle and must ensure its proper collection, treatment, and recovery. Extended producer responsibility may also apply where medical devices including batteries or accumulators are placed on the market.

Packaging waste is governed by Directive 94/62/EC on packaging and packaging waste, transposed into German law by the Federal Packaging Act, 2017 (Verpackungsgesetz)Opens in a new window. The Federal Packaging Act provides for extended producer responsibility, which basically means that market actors placing packaged goods on the market must ensure the proper collection, treatment, and recovery of the packaging.

Radioactive waste must, as a general rule, be provided to specific collection points established by the German Federal States (Landessammelstellen).

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