An Overview of Medical Device Law in Germany

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Introduction
There is hardly a medical or nursing activity today that could be carried out without medical devices. Despite this and in contrast to the term "medicinal product", the meaning of "medical device" is not immediately obvious to the user.

According to the basic definition of terms in § 3 No. 1 German Medical Device Act (Medizinproduktegesetz, hereinafter MPG), medical devices are intended for use on humans for the following purposes:

• diagnosing, preventing, monitoring, treating or alleviating illnesses;
• diagnosing, preventing, monitoring, treating, alleviating or compensating injuries or disabilities;
• testing, replacing or altering anatomical structure or a physiological process;
• contraception.

Medical devices achieve their purpose primarily by physical means. In contrast, medicinal products act mainly in a pharmacological or immunological way and/or stimulate metabolic processes.

When distinguishing between medical devices and medicinal products, the primary intended effect is decisive. Thus, a medical device does not lose its character if the physical effect is supported by a pharmacological, immunological or metabolic effect (e.g. antibiotic bone cement).

Overview

Product groups that fall within the term “Medical Device”

Auxiliary products as defined in the Part 5 of the German Social Security Code (SGB V) are, for example

• Visual aids (spectacle lenses, contact lenses, magnifying spectacles, electronic magnifying lenses) hearing aids,
• Prosthetics (e.g. prosthetic arms or legs, the purpose of which is to compensate a physical disability),
• Orthopaedic aids (e.g. orthopaedic shoes, orthotics, supports of all kinds),
• Other aids (e.g. wheelchairs, invalid carriages and other mobility aids),
• Aids for the hygiene sector, aids for dressing and undressing, reading and speaking and aids for communication

as well as bandages (§ 31 SGB V).

Active implantable devices,
e.g. pace-makers, medication pumps or inner-ear prosthetics

Electromedical devices,
e.g. respirators

Technical medical instruments and products,

1 Ministerialrat, manager of the “Medical Devices” Department at the Federal Ministry of Health
e.g. operating instruments or needles

**Dental Products**

**In-vitro diagnostics:**
Reagents and technical medical analytical instruments for examining bodily fluids and tissue taken from the human body

**Legal Basis – the European Level**

The CE-marking is an essential legal requirement for placing a medical device on the market or starting to operate it. Through this the manufacturer certifies that his product has successfully passed through a testing procedure (conformity assessment procedure, see below) and fulfils the basic requirements set forth in the relevant directives.

The CE marking must be obvious, legible and permanently affixed to more than just medical devices; computers, monitors, toys, lifts, etc. must also feature a corresponding marking.

The CE marking system is governed by European law. As a rule, directives determine the requirements which the CE-marked products have to fulfil. The EC Harmonising Directives for the area of Medical Devices have followed the “new approach” since the decision of the European Council of 7 May 1985.

The central elements of the “new approach” are:

- The sphere of application is defined according to the product or the risks involved;
- The determination of the basic safety and information requirements with which the products must in each case comply when being placed on the market for the first time;
- The detailed regulation of the basic technical requirements through “harmonised norms”, the application of which, however, remains voluntary;
- Guaranteeing free movement of goods on the part of the Member States, if the products are properly labelled with the CE-marking;
- Determination of a community procedure for monitoring compliance with safety requirements (safeguards procedures).

This “new approach” is supplemented by the “global approach” dating from the year 1993. The determination of suitable conformity assessment procedures is at the forefront here. The object of this procedure is to enable the competent supervisory bodies to monitor whether the products placed on the market correspond with the requisite standards.

Which conformity assessment procedure to carry out and to what extent an independent testing and certifying body (designated body) has to be involved, depends on the potential risk of the products. While active implantable medical devices are not divided according to risk factors, Directive 93/42 EEC provides for the division of products into four categories (I, IIa, IIb, III). Products are classified according to the criteria defined in Annex IX to the Directive.

**EU Directives**

Directive on active implantable medical devices 90/385 EEC

Directive concerning medical devices 93/42/EEC

Directive on in-vitro diagnostic medical devices 98/79/EC

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2 OJ EC C 136/1 of 4 June 1985
3 OJ L 220/23 of 30 August 1993


In-vitro diagnostics are also divided into various categories for the purposes of determining which conformity assessment procedure to use (products pursuant to Annex II, List A of Directive 98/79/EC; products pursuant to Annex II, list B; products for personal use; other in-vitro diagnostics).

The conformity assessment procedure for active implantable medical devices, medical devices in categories IIa, IIb and III, class I medical devices put onto the market sterile, class I medical devices with measuring function, in-vitro diagnostics pursuant to Annex II of Directive 98/79/EG as well as in-vitro diagnostics for personal use, must be carried out by a “designated body”.

The application of the CE marking follows completion of the (successful) assessment procedure.

The manufacturer is solely responsible for compliance with all legal requirements and the CE-marking. On the basis of the “new approach”, the state has withdrawn from the area of licensing medical devices. It influences the accreditation and appointment of testing laboratories and market supervision (by the member states).

Legal basis – the national level

The implementation of the European requirements is governed in Germany by the Medical Device Act, the Ordinance on Medical Devices (Verordnung über Medizinprodukte, MPV), the Medical Device Safety Plan Ordinance (Medizinprodukte-Sicherheitsplanverordnung, MPSV) and the Ordinance on data-bank-based information system for medical devices of the German Institute for medical documentation and information (DIMDI Ordinance).

In addition to the European requirements, there are other rules that fall within the sphere of national regulatory competence and which have no basis in European law, e.g. provisions

• for the operation, use and maintenance of medical devices
• on the prescription requirement and pharmacy-only requirement for medical devices
• on the “in-house manufacture” of medical devices
• on processing medical devices
• on medical device reps

In addition, there are provisions in national medical device law on the performance of clinical trials or supervision by the competent authorities, which, while these render the European requirements in a more concrete form, are valid only in Germany.

Finally, attention must be drawn to the “Breast-implant Ordinance”, which transposed a Directive dealing exclusively with the higher classification of breast implants.
The Medical Device Operators Ordinance and the Medical Device Safety Plan Ordinance are of particular importance for operators and users of medical devices. The risk-free use of medical devices requires that the minimum requirements set out in these ordinances are observed.

**Medical Devices Operators Ordinance (MPBetreibV)**

The obligations for operators and users of medical devices are many-sided. From the patient’s point of view, it would not be conducive to the desired aim if stringent requirements had to be observed at the time medical devices are placed on the market, but damage could later be caused through incorrect use.

Therefore, medical devices may only be constructed, operated or serviced by persons with the requisite training, knowledge or experience. These requirements as to the factual (technical) qualifications include, *inter alia*, product-specific training, as well as well-founded knowledge of the implementation of safety and measuring tests. The staff employed to service the medical devices (§ 4 MPBetreibV) must also have such knowledge and capabilities.

In this connection, the subject of reprocessing of medical devices, particularly the reprocessing of “single-use” medical devices, is regularly the focus of public debate. In general, the processing of medical devices is a critical process in which, in the view of the Federal Health Ministry, preventative patient protection is paramount.

In 2002, the requirements with regard to the reprocessing procedure were made stricter. With the “2nd Act to Amend the MPG” a whole bundle of amendments and supplements to the MPG and the MPBetreibV, as well as other, non-statutory regulations entered into force. The requirements regarding processing of medical devices have been made more stringent.

The standards for processing are set forth in the “Recommendations of the Commission for Hospital Hygiene and the Prevention of Infection at the Robert Koch Institute and the Federal Ministry for Drugs and Medical Devices concerning hygiene requirements when reprocessing Medical Devices”, regardless of whether these are “single use” or “multi-use products”.

The existing statutory provisions with their concrete requirements facilitate safe processing of these medical devices. Monitoring of the processors (e.g. hospitals, medical practices and external processors) by the competent authorities is therefore very important. In future, the Länder will be more active in this area.

**Medical Device Safety Plan Ordinance (MPSV)**

There are a multitude of possible reasons why a product does not work in line with the instructions. Efficient risk management (recording, evaluation, if necessary removing or minimising risks of the medical device on the market or in use) requires the notification of as many events as possible.

**National legal Ordinances concerning the Medical Devices Act**

Ordinance on Medical Devices
Medical Device Safety Ordinance
Medical Device Operators Ordinance
DIMDI Ordinance
Ordinance on the Cost of Medical Devices
Ordinance on the Prescription Requirement

Ordinance on Distribution Routes

Ordinance on Breast Implants

Ordinance on Basic Requirements for Medical Device to protect against TSE

As a result, in addition to the manufacturers and other persons placing medical devices on the market, operators and users are also included in the medical device monitoring and notification system. All participants in the system must communicate any ‘notifiable events’ that occur when using medical devices to the competent supreme federal authority\(^4\).

Pursuant to the legal definition in § 2 no.1 MPSV, a notifiable event is a product defect in the broad sense (malfunction, breakdown, changes in the characteristics or performance, incorrect labelling or instructions), which has at least a possible (also indirect) causal connection with the death or serious deterioration of a patient’s health, or that of a user or another person.

A serious deterioration of health is to be assumed in the case of

- a life-threatening illness or injury
- a permanent limitation of a bodily function or a lasting bodily injury

Explanation of “event”

Product Defect
(i.e. malfunction, breakdown, changes in the characteristics or performance, incorrect labelling or instructions)

possible causal connection
(even indirect)

Serious medical consequences
(i.e. death or serious deterioration of health, even potential)

- A condition requiring medical or surgical intervention in order to prevent permanent restriction of a bodily function or prevent lasting bodily injury.

This is not, however, an exhaustive list, meaning that there has to be an evaluation in each individual case as to whether there is indeed a serious deterioration of a patient’s health, taking into account the treatment objective.

Suitable organisation of the notification procedure is the responsibility of the healthcare system. Instead of individual notifications by medical or medical-technical staff who observed the event, at least in larger institutions, a centralised process makes sense. This necessitates the appointment of a responsible person (e.g. the person responsible for quality assurance). The notification system must be reliably verified in each case. In the course of the routine monitoring of operators and users of medical devices this structural requirement will in the future also be subject to tests by the competent regional authorities.

Experience has shown that, as the proportion of user notifications in the total number of events notified to the BfArM has for many years been around 25\%, it can be assumed that operators/users comply with their general obligation to notify events pursuant to § 3 para. 2 MPSV only to a limited extent. There is a need for this process to be optimised.

\(^4\) The Federal Institute for Drugs and Medical Devices (BfArM) or the Paul-Ehrlich Institute (High-risk IVD)
Outlook

At both the European and the national level there are legislative activities, which were only referred to briefly here. The focus is currently centred around the suggestion of a “Directive of the European Parliament and the Council of […] to amend Council Directives 90/385 EEC and 93/42 EEC and Council and Parliament Directive 98/8/EC” regarding the review of the Directives on medical devices. The consultations of the Council Working Group on Medicinal Products and Medical Devices have progressed such that, at least one political agreement seems possible during the current Finnish presidency. The European Parliament has also submitted its opinion. It would appear that a short-term compromise is possible.

This year, the cabinet will decide the Act to Amend medical device law and other provisions at the national level. Furthermore, ‘Directive 2005/50/EC of the European Commission of 11 August 2005 on the reclassification of replacement joints for hips, knees and shoulders’ has to be implemented in the course of Directive 93/42/EC concerning medical devices. This will be done by way of an amendment to the Ordinance on Medical Devices. This will also be used as an opportunity to include the regulatory content of the breast implant ordinance in the medical devices ordinance so that the former can be revoked. Furthermore, an amendment to the Medical Devices Operators Ordinance is in preparation and will be sent to the groups involved for review during the first quarter of 2007.

Further reading

Rainer Hill, Joachim M. Schmitt and Dierk Meyer-Lüerßen: Medizinprodukterecht (WiKo), Loose-leaf collection including CD. Cologne, last issue May 2006
Wolfgang Rehmann and Susanne Wagner: Medizinprodukteregest, Munich 2005
Ehrhard Anhalt und Peter Diener: Handbuch des Medizinprodukterechts. Munich 2003