MDR-Practical Guide

Implementation of Regulation EU 2017/745 (MDR)

Requirements for Suppliers of Medical Devices and Materials used to Manufacture Medical Devices

All manufacturers* of medical devices are required to comply with the stringent legal requirements of the new Medical Device Regulation (MDR), the latest European Regulation on Medical Devices which will apply as of May 26, 2020. eurocom e.V. created this practical guide to help minimize the administrative burden in implementing the MDR.

The central objective of the MDR is to ensure the highest possible level of patient safety thanks to high-quality medical products, which requires the supervision of supply chains between manufacturers* and suppliers**. With this in mind, eurocom establishes common definitions and terms in line with the provisions of the MDR which will provide a framework for future collaboration along the supply chain.

The MDR imposes clear responsibilities on manufacturers*, in particular with regard to liability for products placed on the market. Therefore, the procured (preliminary) products which are processed or incorporated into the product as raw material, intermediate products, accessories or commodities must comply with the requirements to the extent that the manufacturer can declare that the finished medical device complies with the general safety and performance requirements.

The requirements are grouped into:

A) Material-related requirements
- Intentional / unintentional use
- Nanomaterials
- Hazardous substances
- Biocompatible materials
- Drug-free, non-DEHP, latex-free materials
- Materials of animal origin

B) Obligations
- Information obligation (Change)
- Reporting obligation (Vigilance)
- Traceability
- Consent to external audits
- Personnel qualification
- Liability

Definitions:

***** The **Manufacturer** is the company indicated on the ready-for-sale medical device, which assumes the obligations of the manufacturer pursuant to Article 10 MDR.

****** The **Supplier** provides the manufacturer with medical devices or materials required for the production of such devices. The supplier's obligations and responsibilities are set out in this confirmation, supply and purchasing agreements, contracts and statutory provisions.

The following pages offer detailed information on definitions, sources and the resulting requirements.

Berlin, October 16, 2019

A) Material Requirements

Intentional or unintentional use / Freedom	
Definition	**'Freedom'** is used as an umbrella term to describe materials that are free of certain substances. From a chemical point of view, hardly any material is entirely “free” of certain substances. Consequently, it has either to be proven that these substances were not used intentionally or unintentionally along the production chain or that the measured values do not exceed the corresponding limit values (see descriptions of materials on the following pages). **'Intentional use'** is defined as the targeted use of substances. This includes e.g. substances that are absolutely necessary for the production process or the product and are thus deliberately used. An **'unintentional use'** occurs if the materials used or produced contain substances that were not used knowingly or on purpose. If the question “Can it be ruled out that this material does not contain a certain substance?” can be answered in the negative, this could indicate that a substance was unintentionally used. Examples may be: - Migration of substances from packaging to the product - Operating fluids knowingly used in machinery during the production process that unintentionally migrate into the product when brought into contact.
Legal basis, source	The terms “freedom”, “intentional use” or “unintentional use” are not clearly defined by legislation or standards. However, the intentional or unintentional use of substances has an impact on: - evidence of the biological safety of the product (Regulation (EC) No 2017/745 (MDR), Annex I - General safety and performance requirements), - the grouping into risk classes (classification rules set out in Regulation (EC) No 2017/745 (MDR), Annex VIII) or - the labeling requirements (requirements regarding the information supplied with the product set out in Chapter III of Regulation (EC) No 2017/745 (MDR), Annex I).
Requirements	The supplier is obligated to provide information about an intentional use or any planned changes to the materials listed on the following pages (see below). To minimize the unintentional use of substances or materials, it is recommended that the supplier provides the certificate of compliance with STANDARD 100 by OEKO-TEX and/or technical or safety data sheets. Among other things, this facilitates assessing the risk of possible interactions and the use of critical substances can be avoided. In case of doubt, a biocompatibility test in accordance with ISO 10993 ff must be performed.

Hazardous Substances	
Definition	**'Hazardous substances'** are defined as substances or mixtures that may be harmful to human health or to the environment during production and use. (CLP: Regulation (EC) No 1272/2008 on the classification, labeling and packaging of substances and mixtures). Regulation (EC) No 2017/745 (MDR) explicitly lists (hazardous) substances having carcinogenic, mutagenic or reprotoxic properties ("CMR substances").
Legal basis	CLP: Regulation (EC) No 1272/2008 on the classification, labeling and packaging of substances and mixtures. Regulation (EC) No 2017/745 on Medical Devices (MDR), Annex I, Chapter I, Point 1: Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. Chapter II - Requirements regarding design and manufacture, Point 10 - Chemical, physical and biological properties, particularly Point 10.4.1. - Design and manufacture of devices: Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Devices, or those parts thereof or those materials used therein that […] come into direct contact with the human body […] shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2 [justification regarding the presence of […] substances): a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council […].
Requirements	The supplier is obligated to provide information about an intentional use of hazardous substances or in the event of any planned changes (see below). To minimize the unintentional use of substances or materials, it is recommended that the supplier provides the certificate of compliance with STANDARD 100 by OEKO-TEX and/or technical or safety data sheets. Among other things, this facilitates assessing the risk of possible interactions and the use of critical substances can be avoided. In case of doubt, a biocompatibility test in accordance with ISO 10993 ff must be performed. For further information about hazardous substances please visit www.echa.europa.eu: - Authorization list - List of substances requiring authorization - Substances restricted under reach - List of restrictions - Candidate list table - Candidate list of substances of very high concern for authorization

Biocompatibility	
Definition	**'Biocompatibility'** is defined as the capacity of a product to perform its intended function in or as a medical device without eliciting any undesirable local or systemic effects in the host Leachable substances causing an adverse biological reaction may lead to health problems. The ISO 10993 series of standards describes all associated requirements, including inspection specifications. DIN EN ISO 10993-1:2017-04 (draft) Point 3.1 “Biocompatibility” Capacity of a medical device or material to induce an appropriate host reaction in a specific application. Note on the term: This can be demonstrated by means of biological tests as well as an assessment of the effects of leachable chemicals and/or morphological characteristics (e.g. bonded chemicals, topological properties) of the medical device or material as well as by assessing product performance (e.g. maintenance of mechanical integrity), which may affect biological reaction. Point 3.2 “Biological Risk” Probability of health problems caused by a medical device or interactions between the materials.
Legal basis	Regulation (EC) No 2017/745 on Medical Devices (MDR): Annex I: General safety and performance requirements; requirements regarding design and manufacture Annex II: Technical documentation; pre-clinical and clinical evaluations.
Requirements	Evidence of the biological safety of a medical device Providing this evidence is facilitated if biocompatible (raw) materials are used. The proof is considered valid if a **certificate of biocompatibility according to ISO 10993 ff** by a certified test laboratory can be provided for the material in question. In addition, technical or safety data sheets, certificates of compliance with STANDARD 100 by OEKO-TEX or other evidence of the human ecological safety are to be considered. The manufacturer of medical devices is to be informed in advance of any changes to the production of the material, e.g. the use of different auxiliary materials, a change of sub-suppliers, etc., as the biological safety of the material or medical device has to be reassessed.

Medicinal products	
Definition	**'Medicinal products'** are defined as substances or preparations made from substances which are intended for use on or in the human or animal body and are intended for use as remedies with properties for the curing, alleviating or preventing of human or animal diseases or disease symptoms or can be used in or on the human […] body or can be administered to a human being […] to restore, correct or influence the physiological functions through a pharmacological, immunological or metabolic effect […]. (Medicinal products are covered by Directive 2001/83/EC, implemented in national law through the German Medicines Act (Arzneimittelgesetz - AMG) in the version published on December 12, 2005 (Federal Law Gazette I, page 3394), last amended by Article 1 of the Act of July 18, 2017 (Federal Law Gazette I, page 2757); Section 2 “The term ‘medicinal product’”).
Legal basis, source	The intentional use of medicinal products in combination with medical devices to produce an effect on the human body or to release medicinal products results in a higher classification of the medical devices in accordance with Regulation (EC) No 2017/745 (MDR), Annex VIII - Classification Rules, Chapter III, Rule 6 to 8 and 12 / 14 or 20.
Requirements	The supplier is obligated to provide information about an intentional use of medicinal products or in the event of any planned changes (see below). To minimize the unintentional use of substances or materials, it is recommended that the supplier provides the certificate of compliance with STANDARD 100 by OEKO-TEX and/or technical or safety data sheets. Among other things, this facilitates assessing the risk of possible interactions and the use of critical substances can be avoided. In case of doubt, a biocompatibility test in accordance with ISO 10993 ff must be performed.

Latex	
Definition	**'Latex'**, natural rubber or dry natural rubber latex, is used as a structural material in medical devices or in the packaging of medical devices. Synthetic rubber does not fall under this definition. Latex (i.e. the proteins contained therein) has an allergenic potential. Therefore, the name of this substance must appear on the label of the medical device.
Legal basis, source	DIN EN ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements; 5.4.5 Latex Federal Institute for Medicinal products and Medical Devices (BfArM), reference no. 923/0499 “Risks presented by natural rubber latex medical gloves: In view of the analytical variability near the detection limit as well as potential errors in the analytical test procedure, the BfArM believes that the protein content of medical gloves made of natural rubber latex can be considered to be minimal if it is less than three times the analytical detection limit, i.e. less than 30 µg protein/g per glove, which is the recommended reference value. This threshold value can also be applied to medical devices that come “into contact with intact skin”. Regulation (EC) No 2017/745 (MDR), Annex VI, Part B, 20. containing latex (labeling requirements) Part C, 3.9. g) critical warnings […] e.g. containing latex
Requirements	The supplier is obligated to provide information about an intentional use of latex or in the event of any planned changes (see below). To minimize the unintentional use of substances or materials, it is recommended that the supplier provides the certificate of compliance with STANDARD 100 by OEKO-TEX and/or technical or safety data sheets. Among other things, this facilitates assessing the risk of possible interactions and the use of critical substances can be avoided. In case of doubt, a biocompatibility test in accordance with ISO 10993 ff must be performed.

Phthalates (DEHP)	
Definition	**'DEHP'** (diethylhexyl **phthalate**) is mainly used as a plasticizer in PVC products. Phthalates can have endocrine effects.
Legal basis, source	Federal Institute for Medicinal products and Medical Devices (BfArM), reference no. 9211/0506 “DEHP as a plasticizer in medical devices made of PVC”. Harmonized EN 15986 “Symbol for use in the labeling of medical devices - Requirements for labeling of medical devices containing phthalates” as last amended by directive 2007/47/EG 2007/47/EG. Regulation (EC) No 2017/745 on Medical Devices (MDR), Annex I, Chapter I, Point 1: Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. Chapter II - Requirements regarding design and manufacture: Point 10 - Chemical, physical and biological properties, particularly Point 10.4.1. - Design and manufacture of devices: Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. 10.4.3 Guidelines on phthalates Annex VI, Part C, 3.9. g) critical warnings […] e.g. containing […] DEHP.
Requirements	The supplier is obligated to provide information about an intentional use of phthalates or in the event of any planned changes (see below). To minimize the unintentional use of substances or materials, it is recommended that the supplier provides the certificate of compliance with STANDARD 100 by OEKO-TEX and/or technical or safety data sheets. Among other things, this facilitates assessing the risk of possible interactions and the use of critical substances can be avoided. In case of doubt, a biocompatibility test in accordance with ISO 10993 ff must be performed.

Products of Biological Origin	
Definition	**'Derivative'** means a “non-cellular substance” extracted from human or animal tissue or cells through a manufacturing process. The final substance used for manufacturing of the device in this case does not contain any cells or tissues.
Legal basis	Regulation (EC) No 2017/745 on Medical Devices (MDR) Chapter I: Scope and definitions Annex I: General safety and performance requirements; requirements regarding design and manufacture Annex II: Technical documentation Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells Directive 2002/98/EC on setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components Regulation (EU) No 722/2012 concerning particular requirements […] with respect to active implantable medical devices and medical devices manufactured utilizing tissues of animal origin.
Requirements	Special regulations apply to products of biological origin to establish the compliance of medical devices with the essential safety requirements. Apart from the Regulation on Medical Devices, other European legal norms are applicable (see above). Suppliers must therefore inform their customers if products of biological origin are used and provide certificates to enable the manufacturer of medical devices to comply with the essential safety requirements. Such information must be provided prior to any planned changes.

Nanomaterials	
Definition	'**Nanomaterials**' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm-100nm. Fullerenes, graphene flakes and single-walled carbon nanotubes with diameters of less than 1nm are also considered as nanomaterials.
Legal basis	Regulation (EC) No 2017/745 on Medical Devices (MDR): Chapter I: Article 2 - Definitions Annex I: General safety and performance requirements; requirements regarding design and manufacture
Requirements	The risks and benefits of using nanomaterials in products have **not** yet been scientifically clarified. In order to ensure a high level of health protection, free movement of goods and legal certainty for manufacturers, manufacturers of medical devices using nanomaterials in the design and manufacture of the products in question are required to take special precautions. Suppliers must therefore inform their customers if nanomaterials are used. Such information must be provided prior to any planned changes. However, it has to be differentiated between – **Intentional use** of nanomaterials (e.g. absolutely necessary for the production process) and **unintentional use** (e.g. contamination due to inappropriate packaging).

B) Obligations

Information obligation	
Definition	**'Information obligation'** means that suppliers must inform their customers of any changes prior to the implementation pursuant to the requirements listed below.
Legal basis, source	Regulation (EC) No 2017/745 (MDR), Chapter II, Article 10, Sentence (9): Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics […] shall be adequately taken into account in a timely manner […]. The quality management system shall address at least the following aspects: (a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system; Pursuant to Annex VII, Point 4.9, the notified body shall have documented procedures and contractual arrangements with manufacturers in place relating to the manufacturers' information obligations and the assessment of changes to: – the approved quality management system or systems or to the product-range covered, – the approved design of a device, – the intended use of or claims made for the device, – the approved type of a device, and – any substance incorporated in or utilized for the manufacturing of a device and being subject to the specific procedures in accordance with Section 4.5.6. [materials of animal origin – for further details, refer to Section 4.5.6.]. Pursuant to Point 4.11, […] those procedures shall require the manufacturer in question to submit a summary of changes and scientific findings for the device, including: (a) all changes to the originally approved device, including changes not yet notified, (b) experience gained from post-market surveillance, (c) experience from risk management, (d) experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I, (e) experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF, (f) changes to the requirements, to components of the device or to the scientific or regulatory environment, (g) changes to applied or new harmonized standards, CS or equivalent documents, and (h) changes in medical, scientific and technical knowledge, such as: – new scientific findings on materials and components, including findings on their biocompatibility […] ISO 13485:2016: 7.4.2 Purchasing information Purchasing information must include, where appropriate, a written agreement stating that the supplier will notify the organization before implementing any changes to the product procured. This applies to changes which may affect the ability of the product procured to fulfill the specified procurement requirements.

Requirements	As changes at the supplier's facility can directly affect the product quality, customers must be notified promptly in writing prior to any - changes to the product - changes to the manufacturing process - changes to the sub-suppliers - changes to outsourced processes - changes to materials/primary materials or raw and auxiliary materials - changes to test certificates - changes to the supplier's certification status and the customer needs to approve these changes. The customer has to verify whether these changes will affect the conformity of the product.

Reporting Obligation	
Definition	**'Reporting obligation'** means the supplier's obligation to forward all relevant information from the market to the customer to enable a systematic collection and evaluation (in accordance with Article 83, MDR)
Legal basis, source	Regulation (EC) No 2017/745 (MDR), Chapter VII, Section 1+2, Articles 83 to 92 Detailed description of the surveillance measures required, reporting of serious incidents and field safety corrective actions.
Requirements	The customer must be informed immediately in the event of any serious incidents in connection with identical or similar products (within 15 days), in the event of a death or serious deterioration in the state of health of a patient or user (within 10 days), or in the event of a risk to public health (within 2 days). If there is urgent need for action, a preliminary message must be sent immediately. If the supplier is uncertain whether or not an incident is reportable, the customer must be notified in any case.

Traceability	
Definition	ISO 9001:2015: Traceability - The ability to trace the history, application, or location of a product. With respect to products or services, traceability may involve: - Sources of raw materials and components; - The history of processing; - The distribution and location of products or services after their delivery.
Legal basis, source	Regulation (EC) No 2017/745 (MDR), Chapter III, Article 25 Identification within the supply chain 1. Distributors and importers shall co-operate with manufacturers or authorized representatives to achieve an appropriate level of traceability of devices. 2. Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8): (a) any economic operator to whom they have directly supplied a device; (b) any economic operator who has directly supplied them with a device; (c) any health institution or healthcare professional to which they have directly supplied a device. ISO 13485:2016: 7.5.1 Control of Production and Service Provision The organization shall establish and maintain a record for each medical device or batch of medical devices that provides traceability to the extent specified in in 7.5.9 and identifies the amount manufactured as well as the amount approved for distribution. 7.5.9 Traceability The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained.
Requirements	The supplier shall ensure the traceability of the goods supplied to the customer. In the event of product defects and the ensuing recalls, it must be ensured that the affected batches can be identified and selected irrespective of whether they are still stocked or already put on the market. All related procedures must be documented. It has to be traceable when, where, how and how much of a product was produced, which raw materials were used, which employees were involved, what equipment was used and where the product was delivered to. • Examples of labeling types: Lot/serial/batch/version or order number, product ID • Examples of labeling procedures: Stickers/labels, laser engravings, barcodes, RFID

External Audits	
Definition	ISO 9000:2015: Audit - systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. External audits include audits generally known as second-party or third-party audits. Second-party audits are carried out by parties interested in an organization, such as customers or other persons acting on their behalf. Third-party audits are carried out by independent external organizations, e.g. those offering registration or certification of conformity, or by state authorities.
Legal basis, source	Pursuant to Regulation (EC) No 2017/745 on Medical Devices (MDR), the following provisions apply to medical devices classified in a risk class higher than I (conformity assessment procedure requires the intervention of a Notified Body): Annex VII - 4.5.2. b) Based on the audit program it has drawn up, the notified body shall, in accordance with its documented procedures: - […] audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers. Annex IX - Chapter I: 2.3 The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes. In general, the following requirements of ISO 13485:2016 apply to organizations involved in the life-cycle of medical devices (including suppliers of e.g. raw materials, components, sub-assemblies, medical devices, providers of sterilization services, calibration services, distribution services, and maintenance services): 7.4.1 Purchasing Process The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be: a) based on the supplier's ability to provide product that meets the organization's requirements; b) based on the performance of the supplier; c) based on the effect of the purchased product on the quality of the medical device; d) proportionate to the risk associated with the medical device. The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process.
Requirements	Consent to external audits on the supplier’s premises to obtain objective evidence (e.g. insight into the manufacturing process and the quality-related test documents) to determine whether the supplier is suitable with regard to the items delivered and to be delivered.

Personnel	
Definition	**'Personnel'** means all employees in an organization's area of responsibility involved in the product development process and capable of affecting the parameters of the product.
Legal basis, source	ISO 13485:2016, 6.2 Human Resources: Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel. The organization shall: a) determine the necessary competence for personnel performing work affecting conformity to product requirement; b) provide training or take other actions to achieve the necessary competence; c) evaluate the effectiveness of the actions taken; d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; e) Maintain appropriate records of education, training, skills and experience. 6.4 Work environment and contamination control: The organization shall: a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance; b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person. Procured products 7.4.2 Purchasing information: c) Requirements for qualification of supplier's personnel […]
Requirements	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The process(es) for establishing competence, providing needed training, and ensuring awareness of personnel shall be documented. The supplier shall determine the level of competence and, if necessary, take actions (e.g. provide training) to achieve or maintain the necessary competence, evaluate the effectiveness of the actions taken, ensure that its personnel are aware of the importance of their activities and how they contribute to the achievement of the quality objectives, and maintain appropriate records of these activities. The supplier shall document requirements for health, cleanliness and clothing of personnel if this could affect product quality.

Liability	
Definition	**'Liability'** means the obligation to compensate for damages in the event of a culpable breach of duty – the obligation for damage compensation. Liability arises from personal injury, property damage or financial loss. Liability may also arise from the failure to take necessary action. However, there are also cases of strict liability (without fault), e.g. product liability.
Legal basis, source	MDR 2017/745 Article 10 - General obligations of manufacturers Paragraph 16 “Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law.” 85/374/EEC Article 1 [Liability of the author] The producer shall be liable for damage caused by a defect in his product. Article 3 [Producer] (1) 'Producer' means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part […]
Requirements	MDR Article 10 - General obligations of manufacturers Paragraph 16 “Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.”

About eurocom

eurocom e.V. is the European manufacturers federation for compression therapy and orthopaedic devices. We consider ourselves as a contributor and partner in the healthcare market and we are committed to spreading the knowlegde about the medical benefits, efficiency and cost-effectiveness of compression therapy and orthopaedic devices. In addition, eurocom creates concepts for ensuring the current and the future supply of assistive devices. Almost all European companies for compression therapy and orthopedic devices operating in the German market belong to our association.

Liability for content

The practical guide does not claim to be completed and cannot replace the legal advice of a lawyer.

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