MDR-Practical Guide

Implementation of Regulation EU 2017/745 (MDR)

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

As manufacturer of medical devices, we 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. We created this questionnaire and the attached practical guide in cooperation with eurocom e.V. to meet the requirements of the MDR as well as related standards and regulations.

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, we establish common definitions and points 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 product, 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 divided into:

A) Material-related requirements

1. Hazardous substances
2. Biocompatible materials
3. Drug-free, non-DEHP, latex-free materials
4. Materials of animal origin
5. Nanomaterials

B) Obligations

1. Information obligation (Change)
2. Reporting obligation (Vigilance)
3. Traceability
4. Consent to external audits
5. Personnel qualification
6. Liability

Please refer to the attached practical guide for an explanation of the terms used and a summary of the legal requirements.

Ideally, all questions are answered with "yes". If you answer a question with "no", please enclose the relevant documents for further evaluation.

Date: 10/16/2019

We purchase the following items from your company – **please specify**:

	Material number Manufacturer Supplier	Description	Ingredients	Data sheet available? If yes, please enclose.	Safety data sheet available? If yes, please enclose.
1.				Yes ☐ No ☐	Yes ☐ No ☐
2.				Yes ☐ No ☐	Yes ☐ No ☐
3.				Yes ☐ No ☐	Yes ☐ No ☐
4.				Yes ☐ No ☐	Yes ☐ No ☐
5.				Yes ☐ No ☐	Yes ☐ No ☐
6.				Yes ☐ No ☐	Yes ☐ No ☐
7.				Yes ☐ No ☐	Yes ☐ No ☐
8.				Yes ☐ No ☐	Yes ☐ No ☐
9.				Yes ☐ No ☐	Yes ☐ No ☐
10.				Yes ☐ No ☐	Yes ☐ No ☐
11.				Yes ☐ No ☐	Yes ☐ No ☐
12.				Yes ☐ No ☐	Yes ☐ No ☐
13.				Yes ☐ No ☐	Yes ☐ No ☐
14.				Yes ☐ No ☐	Yes ☐ No ☐
15.				Yes ☐ No ☐	Yes ☐ No ☐
16.				Yes ☐ No ☐	Yes ☐ No ☐

Should the questions below with regard to different materials require different answers, please fill in the questionnaire multiple times and clearly mark each questionnaire.

Questionnaire for all materials ☐ / for material number_____

Question A1 - Hazardous Substances

a)

We do not intentionally use hazardous substances according to CLP: Regulation (EC) No 1272/2008 on the classification, labeling and packaging of substances and mixtures or CMR substances (hazardous substances having carcinogenic, mutagenic or reprotoxic properties) as defined in Regulation (EC) No 2017/745 on medical devices (Medical Device Regulation).

Yes ☐ No ☐

We (the supplier) acknowledge that we are obligated to provide information about an intentional use of hazardous substances or in the event of any planned changes.

Acknowledged ☐

b)

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.

Are there certificates for the items supplied?

Yes ☐ No ☐

If yes, please enclose.

Question A2 - Biocompatibility

Can you provide certificates of a biocompatibility test in accordance with ISO 10993 ff by a certified test laboratory for the items supplied?

Yes ☐ No ☐

If yes, please enclose.

Question A3 - Material is free from
a) Medicinal products

We do not intentionally use medicinal products.

Yes ☐ No ☐

We (the supplier) acknowledge that we are obligated to provide information about an intentional use of medicinal products or in the event of any planned changes.

Acknowledged ☐

b) Latex

We do not intentionally use latex.

Yes ☐ No ☐

We (the supplier) acknowledge that we are obligated to provide information about an intentional use of latex or in the event of any planned changes.

Acknowledged ☐

c) DEHP

We do not intentionally use phthalates.

Yes ☐ No ☐

We (the supplier) acknowledge that we are obligated to provide information about an intentional use of DEHP or in the event of any planned changes.

Acknowledged ☐

Question A4 - Freedom from Products of Biological Origin

We do not intentionally use products of biological origin.

Yes ☐ No ☐

We (the supplier) acknowledge that we are obligated to provide information about an intentional use of products of biological origin or in the event of any planned changes.

Acknowledged ☐

Question A5 - Freedom from Nanomaterials

We do not intentionally use nanomaterials.

Yes ☐ No ☐

We (the supplier) acknowledge that we are obligated to provide information about an intentional use of nanomaterials or in the event of any planned changes.

Acknowledged ☐

Question B1 - Information Obligation

We (the supplier) answered the above questions with regard to the material-related requirements to comply with the information obligation.

We (the supplier) undertake to inform the customer about all changes to the product, the substances contained therein or used in its manufacturing, the manufacturing process, potential sub-suppliers or outsourced processes, test certificates, the management system and its certification status before these changes are implemented.

Acknowledged ☐

We (the supplier) have a management system.

Yes ☐ No ☐

If yes and certification exists, please enclose the certificate.

Question B2 - Reporting Obligation

We (the supplier) undertake to forward all relevant information from the market to the customer to enable a systematic collection and evaluation.

Yes ☐ No ☐

Question B3 - Traceability

We (the supplier) undertake to keep and maintain records of the origin of materials and parts as well as the sequence of processing steps over a period of 10 years. The extent of traceability is to be set jointly to achieve an appropriate level.

Acknowledged ☐

Question B4 - Consent to External Audits

We (the supplier) agree that external audits are conducted on our business 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.

Yes ☐ No ☐

Question B5 - Personnel Qualification

Our (the supplier‘s) personnel involved in activities affecting product quality is competent on the basis of appropriate education, training, skills and experience. The qualifications are documented.

Yes ☐ No ☐

We (the supplier) shall document requirements for health, cleanliness and clothing of personnel if this could affect product quality.

Acknowledged ☐

Question B6 - Liability

Pursuant to the Medical Device Regulation, 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.
According to this Directive, suppliers of raw materials or component parts are subject to the same liability as the manufacturer.
To assess the risk, we need information about your product liability insurance.

We (the supplier) have a product liability insurance.

Yes ☐ No ☐

If yes, please fill in the sum insured per case and enclose the insurance certificate.

Sum insured per case: _____€

I acknowledge that I shall report to the following contact to fulfill my information obligation:

The information must be forwarded as quickly as possible.

I confirm that the above information is true and complete to the best of my knowledge and belief.

_____	_____	_____
Name	Position	Date

_____	_____
Signature	Stamp

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.

Contact

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