Title	Company Standard – Material-Compliance
Revision	*
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Company Standard Material-Compliance

Inhalt

1. Purpose

The Dornier MedTech GmbH company standard – Material-Compliance has the purpose to ensure that the legal requirements pertaining substance restriction are implemented in the company. This is to ensure the safe handling of substances and products within the company and for subsequent users in order to protect the human health and the environment.

This company standard describes the requirements of Dornier MedTech GmbH regarding all known and relevant substance restrictions.

The requirements of the company standard – Material-Compliance are equal to the other product requirements.

The company standard – Material-Compliance is a compilation of the legal requirements. Should further legal requirements or legal changes not be included in this company standard, this does not release the supplier from the obligation to comply with them. Suppliers are obliged to gather current laws, guidelines and standards themselves.

Products and raw materials whose origin and/or composition are unknown, or those for which insufficient material data is available, may not be used.

The supplier is obliged to transmit, free of charge, material information which serves to check compliance with the legal requirements and this guideline.

Dornier MedTech GmbH makes the company standard available via its Internet presence.

It is the duty of the supplier to check whether the works standard is available in an updated form. A new version of the works standard shall replace the previous version with immediate effect.

2. Scope

This document applies to all articles delivered to the Dornier MedTech GmbH, which are incorporated into devices by the Dornier MedTech GmbH or are intended for installation, as well as to all production auxiliary materials and operating supplies. Furthermore, this works standard applies to all products manufactured by Dornier MedTech GmbH.

3. Definitions

Abbreviation	Definition
Intentionally added	The term "intentionally added" is used to distinguish it from (unavoidable) technical impurities. In most cases, the concentration limit above which an intentional addition is assumed is 0.1%.
CAS Number	The CAS Number is an international standard for chemical substance identification.
Declarable Substances	Substances which are classified as declarable substances are not prohibited in principle, but they must be declared as soon as a threshold value is reached. This declaration obligation extends to every product, component, material and substance preparation, auxiliary or operating material. The threshold limits for the substances can be found in the relevant directives and regulations. Below the specified threshold values, the obligation to declare is not applicable.
Article	Object, which during production is given a specific shape, surface or design which determines its function to a greater extent than the chemical composition.
Homogenous Material	Material of uniform composition throughout or a material consisting of different materials which cannot be broken down or separated into individual materials by mechanical processes such as unscrewing, cutting, crushing, grinding and polishing.
Substance	A substance is a chemical element and its compounds in the

Abbreviation	Definition
	natural state or the result of a manufacturing process. In a manufacturing process, a chemical reaction is usually needed to form a substance.
Intentionally added	The term "intentionally added" is used to distinguish it from (unavoidable) technical impurities. In most cases, the concentration limit above which an intentional addition is assumed is 0.1%.

4. Obligations

4.1. Supplier Obligations

The supplier is obliged to comply with the substance restrictions listed in chapter 5 for all products, parts, assemblies, components, materials and packaging delivered to the Dornier MedTech GmbH. Furthermore, the supplier is obliged to ensure compliance with the substance restrictions and to communicate relevant information on substance regulations free of charge in the supply chain

4.2. Obligations of the Dornier MedTech GmbH

The following regulations must be carried out in the departments of Dornier MedTech GmbH:

- Current and upcoming substance prohibitions must be taken into account in product development.
- No prohibited substances may be demanded.
- Compliance with the company standard – Material-Compliance must be demanded in the documents supply contracts, purchasing conditions, the quality assurance agreement and the supplier contracts.
- The company standard – Material-Compliance must always be available in its most current form on the Dornier MedTech website.

5. List of regulated Substances

5.1. Substance regulations and bans - Relevant for all products

Regulation (EC) No 1907/2006 REACh - Annex XIV - List of substances subject to authorisation

Substances that are adopted from the list of substances of very high concern, into the Annex XIV of the REACh Regulation, undergo a procedure after which the substance is subject to authorisation. After a transitional period, the use of the substance is prohibited or only permitted with a special authorisation.

Articles to which substances from appendix XIV of the REACh regulation have been intentionally added, may not be delivered to Dornier MedTech GmbH, unless a valid exception exists. Dornier MedTech GmbH must be notified of the application of this exception.

The Regulation (EC) No. 1907/2006 can be accessed using the following link

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20140410&from=EN

The current Annex XIV of the REACh Regulation can be downloaded from the following link

https://echa.europa.eu/de/authorisation-list

Regulation (EC) No 1907/2006 REACh - Annex XVII - List of restricted substances

Annex XVII of the REACh Regulation regulates or bans certain applications for particular substances. Articles, to which substances from Annex XVII have been intentionally added, and which may not be used for medical applications, must be communicated with Dornier MedTech GmbH. Dornier MedTech GmbH is then obliged to decide, whether the article is prohibited in its specified application and in this case, not to use the article.

Annex XVII of the REACh regulation can be accessed via the following link

https://echa.europa.eu/de/substances-restricted-under-REACh

Regulation (EC) No 1272/2008 (CLP) - CLP

The CLP Regulation is an EU chemicals regulation. The CLP Regulation puts into practice the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). CLP stands for Classification, Labelling and Packaging of substances and mixtures.

The CLP Regulation aims to ensure a high level of protection for human health and the environment when handling mixtures and articles, by requiring manufacturers, importers or downstream users to classify, label and package their products properly, before placing them on the market. For deliveries to Dornier MedTech GmbH, all suppliers are obliged to comply with the specifications for classification, labelling and packaging.

The law can be found under the following link

https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX:32008R1272

Regulation (EU) 2019/1021- persistent organic pollutants (POPs)

This Regulation implements as European law the Stockholm Convention on Persistent Organic pollutants. The Regulation contains detailed requirements for the production, placing on the market, use and release of persistent organic pollutants. Persistent organic pollutants remain in the environment for a long time, accumulate in the food chain, can be transported over long distances in the environment and can be harmful to human health and the environment.

No products or materials to which persistent organic pollutants have been intentionally added may be delivered to Dornier MedTech GmbH.

The regulation can be reached under the following link

https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=uriserv:OJ.L_.2019.169.01.0045.01.DEU

Directive 94/62/EC - Packaging Directive

The EU Directive on packaging and packaging waste aims to harmonise the different measures of the Member States in the field of packaging and packaging waste management and to ensure a high level of environmental protection. The Directive aims primarily to prevent waste from packaging, to recover unavoidable waste and, as a consequence, to reduce the disposal of packaging waste. The Directive limits the cumulative concentration of lead, cadmium, mercury and chromium VI in packaging or packaging components to 100 ppm. Packaging and outer packaging for articles delivered to Dornier MedTech GmbH must comply with the requirements of the Packaging Directive.

The directive can be downloaded under the following link

https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31994L0062

5.2. Substance regulations and bans - relevant for products in different scopes

The substance regulations in this section only apply to certain products and applications of these products. Should a supplier not independently know the installation and application location of the product he has supplied, he should consult Dornier MedTech GmbH.

Directive 2011/65/EU - RoHS 2 Directive

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment aims to remove problematic components from electronic waste. This was additionally extended on 31 March 2015 by the delegated directive (EU) 2015/863. The delegated directive (EU) 2015/863 is sometimes referred to as RoHS 3, but is only a supplement to the RoHS 2 directive and does not override it. Declarations of conformity for articles delivered to Dornier MedTech GmbH must therefore continue to refer to the RoHS 2 directive. The RoHS 2 directive is valid for all installation regulations at Dornier MedTech GmbH and therefore conformity must be guaranteed for all articles used or intended for installation.

The RoHS 2 Directive can be downloaded from the following link

https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32011L0065

The delegated directive (EU) 2015/863 can be downloaded from the following link

https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32015L0863

The substance restrictions in RoHS 2 are related to maximum concentrations in the homogeneous material of an article. The definition of a homogeneous material can be found in paragraph 3 of this company standard.

Table 1 Substance regulations of the RoHS 2 Directive

Substance group	Maximum concentration in homogeneous material
Lead and lead compounds	0.10%
Mercury and mercury compounds	0.10%
Cadmium and cadmium compounds	0.01%
Hexavalent chromium	0.10%
Polybrominated biphenyls	0.10%
Polybrominated diphenyl ethers	0.10%
Addition from 31.03.2015	
Bis(2-ethylhexyl) phthalate (DEHP)	0.10%
Butyl benzyl phthalate (BBP)	0.10%
Dibutyl phthalate (DBP)	0.10%
Diisobutyl phthalate (DIBP)	0.10%

(EU) No. 528/2012 - Biocides Regulation

Regulation (EU) No 528/2012 regulates the supply and use of biocidal products in the EU. Every supplier is obliged to fulfil the requirements for biocidal products and treated goods. Materials treated with biocides, materials and components, must meet the requirements of the EU Biocide Regulation.

The delegated directive (EU) No. 528/2012 - Biocide Regulation can be downloaded under the following link

https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32012R0528

Directive 2006/66/EC - Battery Directive - Battery Act

Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators aims at restricting mercury and cadmium in batteries and accumulators. The Directive was transposed into German law by the Battery Act on 25 June 2009. All batteries or accumulators delivered to Dornier MedTech GmbH for installation or use, including those installed in components, must comply with the Battery Act.

Table 2 Substance regulations from the battery directive

Substance	Maximum concentration in articles	Application restriction
Mercury and mercury compounds	0,0005%	Batteries and rechargeable batteries
Cadmium and cadmium compounds	0,002%	Portable batteries and rechargeable batteries

The Battery Act can be found under the following link

https://www.gesetze-im-internet.de/battg/BJNR158210009.html

The Battery directive is available under the following link

https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32006L0066

5.3. Production auxiliaries and operating materials

Production auxiliaries are resources which are transformed into a product during production, but which do not essentially determine the final properties of the product. Operating supplies are materials that are consumed during the production process of a product. However, as residues of these substances may remain on or in products, these must also be delivered to Dornier MedTech GmbH in accordance with the legal regulations here. Often a safety data sheet is also required for these substances.

Safety data sheets (SDS)

Safety data sheets are used for communication in the supply chain for hazardous substances and mixtures. The following information must be available in the safety data sheet:

The REACh Regulation (EC) No. 1907/2006 in Article 31 and Annex II defines requirements for the content and format of safety data sheets. The Regulation (EC) No. 1907/2006 can be accessed using the following link

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20140410&from=EN

Suppliers of a substance/mixture are responsible for the technical correctness and completeness of the safety data sheet. The safety data sheet must be made available to Dornier MedTech GmbH in electronic form or as a download no later than the day of the first delivery.

5.4. Declarable Substances

Regulation (EC) No 1907/2006 REACh - List of Substances of Very High Concern (SVHC)

Regulation (EC) No 1907/2006 REACh - List of Substances of Very High Concern (SVHC)

The listing of a substance as a substance of very high concern is the first step in the authorisation and restriction of chemicals. Substances on the SVHC list are subject to special information obligations within the supply chain.

The list of substances of very high concern (SVHC) that are candidates for authorisation can be accessed via the following link https://echa.europa.eu/de/candidate-list-table

According to article 33 of the REACh regulation, every supplier is obliged to do the following:

(1) Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

This provision applies to components, spare parts, accessories and packaging. If a delivered article contains a substance on the SVHC candidate list in a concentration of more than 0.1% by weight, the supplier is obliged to provide all information in accordance with Art. 33 Para. 1 of Regulation 1907/2006/EC without being requested to do so. This information obligation also exists if the substance is included in the SVHC candidate list during an existing supply relationship.

As soon as a SVHC candidate in a delivered article exceeds the concentration limit of 0.1%, the name and concentration of the substance must be communicated to the Dornier MedTech GmbH.

In case of inquiries from customers regarding SVHC candidates in products, the necessary information must be provided by the Dornier MedTech GmbH, free of charge, within 45 days after receiving the request.

Use of natural rubber - in-house regulation

Natural rubber, colloquially often called latex, which is obtained from the rubber trees of the Hevea brasiliensis variety, can cause severe allergic reactions in humans, which in individual cases can lead to death. In addition, people can react allergically to residues of cross-linking agents or cross-linking accelerators used in the processing of natural rubber products.

A latex allergy often develops in people who regularly come into contact with natural rubber. Between 4% and 17% of doctors and nurses have a latex allergy and between 0.8% and 8.2% of the general population.

In order to protect patients and medical professionals, Dornier MedTech wants to avoid exposure to natural rubber. Therefore, by means of this company standard and the conditions of purchase, Dornier obliges its suppliers to report the presence of natural rubber in articles delivered to Dornier MedTech.