80 YEARS: QUALITY
MADE IN GERMANY

HEINE POLICY MATERIAL COMPLIANCE

Requirements for HEINE Products

Version 09/26

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Content

1 Introduction

1.1 General

HEINE Optotechnik GmbH & Co KG (hereafter HEINE) is a manufacturer of medical devices trusted by patients and users around the world.

The HEINE Material Compliance Policy describes the most important requirements from national and international laws, directives and regulations that apply to HEINE products at the time this version was created.

These requirements include bans, restrictions or declaration obligations for certain substances, which are regulated, for example, in the REACH Regulation EC No. 1907/2006, the RoHS Directive 2011/65/EU and the Medical Device Regulation 2017/745 (MDR), which has been in force since May 2021.

To ensure safe and environmentally friendly handling of HEINE products for patients and users, it is necessary that all products sold by HEINE comply with all applicable regulations. This means that all parts, materials and components that are parts or accessories of HEINE products must also meet these requirements.

1.2 Scope of application

This policy is the internal basis for the selection of materials for the development and manufacture of HEINE products as well as for the procurement of substances, mixtures and all products, which are part/component/accessory of a HEINE product.

This policy therefore applies to HEINE suppliers and their products supplied to HEINE as well as the HEINE specialist departments involved.

2 Duties

2.1 Duties of HEINE

HEINE specialist departments are obliged to observe the following points:

- Development: Current and future substance bans must be taken into account in product development.
- Procurement: Compliance with the HEINE Material Compliance Policy is to be required by means of a corresponding note on the framework supply contracts, orders or other supplier contracts.
- Production: Auxiliary and operating materials that are used in the production process and may remain in the end product are also subject to the requirements of this directive.

2.2 Obligations of the supplier

The supplier undertakes to comply with all regulatory requirements listed below under 4. for the products supplied to HEINE and to provide HEINE with the corresponding declarations where required.

The HEINE Material Compliance requirements are equivalent to the other product requirements.
This policy supplements the HEINE Terms and Conditions of Purchase as well as the other agreements that are binding for HEINE suppliers (main contract, quality assurance agreement, etc.) and is therefore the subject matter of every delivery.

If any changes to the law are not yet reflected in this policy, this does not release the supplier from the obligation to take current changes into account in order to comply with the applicable legal requirements.

The supplier's obligation to comply with legal requirements is not affected by this policy.

The supplier is obliged to obtain the information on the respective legislation on its own responsibility and to regularly check whether the HEINE Material Compliance Policy is available in an updated version. HEINE will not actively notify the supplier. The policy can be accessed via the HEINE website in the purchasing conditions section.

Products and raw materials of unknown origin and/or composition must not be used.

Details of the material specification (supplier declarations) relating to the delivered product must be submitted to HEINE on request free of charge. These must meet the following criteria:

- Up-to-dateness
- Traceability of which delivered product the specification refers to
- Reference to the current version of the regulation, which states
- If applicable, indication of the exemption used*
- Signature with contact details of the contact person

*Should the supplier make use of exemptions from a law, a regulation, etc., HEINE must be informed of this, in particular if modifications to the delivered product result from changes to legal requirements and expiry of deadlines.

HEINE reserves the right to carry out tests and laboratory examinations on materials.

3 Regulatory requirements

3.1 Relevance in different areas

The regulatory requirements fall into different areas:

1. Relevant for **all** products that become part of a HEINE product, are a HEINE product or are accessories of a HEINE product (REACH Regulation).

2. Relevant for all products that become part of a **HEINE electrical device** (including the live components) or are an electrical device. The scope of application also includes cables and spare parts (RoHS Directive).

3. Relevant for products that contain or are batteries and accumulators (Regulation (EU) 2023/1542 on batteries and waste batteries).

4. Relevant for products that **come into contact with the human body** as part of an **invasively used HEINE product** (directly or indirectly via introduced gases). This also applies to packaging materials or auxiliary and operating materials that can be transferred to these products through abrasion or contamination (MDR Regulation).

5. Relevant for products containing **tin, tantalum, gold and tungsten**, so-called "conflict minerals".

6. Relevant for **packaging** (regulated under Regulation (EU) 2025/40 on packaging and packaging waste, PPWR).

As the supplier does not always have information on which regulatory material-specific requirements apply to the product it supplies to HEINE (see e.g. MDR), HEINE provides this information during the ordering process or the supplier asks HEINE Purchasing for this information.

The most important regulatory requirements are presented below in an overview matrix:

4 Excerpt of the most relevant applicable regulatory requirements

Title	Legal basis	Application area	Explanation	Supplier obligations
REACH Regulation EC No. 1907/2006	European regulation, directly applicable in all EU member states	Relevant for **all** products that become part of a HEINE product, are a HEINE product or are accessories of a HEINE product	European chemicals legislation (registration, evaluation and authorization of chemicals). This regulation affects all participants in the supply chain who either manufacture or place a substance or mixture on the market or **process it in a product,** at least through an information obligation within the supply chain (Art. 33), if a substance of very high concern (SVHC - see definition) listed on the **candidate list** is present in a concentration of more than 0.1% by mass in the product (in relation to the individual article and not the composite article). The substances on the candidate list are the substances of very high concern that are eligible for authorization. **This list is updated twice a year**; the inclusion of a substance on the list entails an immediate obligation to provide information in accordance with Article 33. Candidate list see here https://echa.europa.eu/de/candidate-list-table After a transitional period, **substances subject to authorization (Annex XIV)** may only be used with an authorization or their use will be completely banned. If a substance is included in **Annex XVII**, the manufacture, placing on the market and use of these substances in individual applications are **restricted or prohibited** Further information on the REACH Regulation can be found on the website of the ECHA, the European Chemicals Agency. **https://echa.europa.eu/de/regulations/reach/understanding-reach**	The supplier shall provide HEINE with information without delay as part of its duty to inform in accordance with Article 33 if a product supplied by it contains a substance on the candidate list in a higher mass concentration than 0.1%. The same applies if the supplier uses a substance subject to authorization according to Annex XIV in his articles or a substance listed in Annex XVII. Here too, information must be provided on which indicated use the supplier is referring to. Suppliers of substances and mixtures shall provide HEINE with up-to-date safety data sheets for hazardous substances and mixtures in accordance with Article 31 and Annex II of the REACH Regulation. The supplier shall provide HEINE with a REACH supplier declaration on request.
RoHS Directive 2011/65/EU	European Directive, transposition into national law of the EU member states	Relevant for all products that become part of a **HEINE electrical**	This directive restricts the use of certain hazardous substances in electrical and electronic equipment (including cables and spare parts).	The substance restrictions must be observed.

<table>
<tr><th>Title</th><th>Legal basis</th><th>Application area</th><th>Explanation</th><th>Supplier obligations</th></tr>
<tr>
<td></td>
<td>(in Germany ElektrostoffV)</td>
<td>device (including the current-carrying components) or are an electrical device. The scope of application also includes cables and spare parts.</td>
<td>
Annex II lists the restricted substances and their maximum permitted concentrations. Annex II was amended by Directive EU 2015/863 and 4 additional substances were added. The transitional period for medical devices ends 07/2021.
The substance bans always refer to the homogeneous material (see definition) of an article. Overview of regulated substances
<table>
<tr><th>Substances</th><th>Maximum concentration in homogeneous material in %</th></tr>
<tr><td>Cadmium and cadmium compounds</td><td>0,01%</td></tr>
<tr><td>Hexavalent chromium (Cr6+) and Cr6+ compounds</td><td rowspan="9">0,10%</td></tr>
<tr><td>Lead and lead compounds</td></tr>
<tr><td>Mercury and mercury compounds</td></tr>
<tr><td>Polybrominated diphenyl ethers (PBDE)</td></tr>
<tr><td>Polybrominated biphenyls (PBB)</td></tr>
<tr><td>Di(2-ethylhexyl)phthalate (DEHP)</td></tr>
<tr><td>Butyl benzyl phthalate (BBP)</td></tr>
<tr><td>Dibutyl phthalate (DBP)</td></tr>
<tr><td>Diisobutyl phthalate (DIBP)</td></tr>
</table>
Annex III lists applications that are exempt from the restriction (these are limited in time). Directive EU 2018/740 amended Annex III with regard to the exemption of lead as an alloying element in aluminum.

Link to the European Directive 2011/65/EU
https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32011L0065&qid=1623222107252&from=EN

Adaptation 2015/863
https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32015L0863&qid=1623222239110&from=EN

Adaptation 2018/740
</td>
<td>
If the Supplier relies on an exemption in accordance with Annex III, HEINE must be informed of which exemption is involved and when this exemption expires.

This information is particularly important if the fact that the exemption expires results in modifications that affect the properties of the product supplied to HEINE.

The supplier shall provide HEINE with a RoHS supplier declaration for the RoHS Directive on request.
</td>
</tr>
</table>

Title	Legal basis	Application area	Explanation	Supplier obligations
			https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32018L0740&qid=1623222285005&from=EN Transposition into national law D, ElektrostoffV http://www.gesetze-im-internet.de/elektrostoffv/index.html	
Medical Device Regulation EU 2017/745 (in force since 26.05.2021)	European regulation, directly applicable in all EU member states	Products that come into contact with the human body as part of an invasively used HEINE product (directly or indirectly, e.g. via gases), or packaging, or auxiliary and operating materials remain on these products due to abrasion/cleaning	This regulation, known as the Medical Device Regulation or European Medical Device Regulation, places higher requirements on products containing hazardous substances than the Medical Device Directive it replaced. The following is regulated under 10.4./Substances in the MDR: Carcinogenic, mutagenic and reprotoxic substances (CMR substances) of category 1A or 1B in accordance with Part 3 of Annex VI of CLP Regulation 1272/2008 (this chemicals regulation governs the classification, labelling and packaging of substances and mixtures) and substances with endocrine-disrupting properties may only be contained in invasively applied product components that come into direct contact with the human body at a concentration above 0.1% weight by weight (w/w) if there is a justification for the presence of these substances. In addition to the justification, the products concerned must be labelled with an indication of the substance. Special attention must also be paid to nanomaterials. The substances with endocrine-disrupting properties in question here are on the candidate list of the REACH Regulation as of 10/2021; see: https://echa.europa.eu/de/candidate-list-table and also on this list https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu?page=0 The CMR substances from the CLP Regulation can be found here ECHA Website Link to the European Medical Device Regulation EU 2017/745 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745&qid=1623222804913	HEINE shall inform the supplier whether the product supplied by him falls within the scope of the material declaration obligation of the MDR. The supplier shall then provide HEINE with an MDR substance supplier declaration. HEINE must also be informed if a product contains nanomaterials.
Regulation (EU) 2023/1542 on batteries and waste batteries	European regulation, directly applicable in all EU member states. European regulation, transposition into	Products that contain or are batteries and accumulators	It should be noted that the current Battery Act (BattG) in Germany will be replaced by the Battery Law Implementation Act (BattDG) on August 18, 2025. According to §3 BattG, it is prohibited to place batteries containing more than 0.0005% mercury by mass on the market. It is also prohibited to place portable batteries containing more than 0.002% cadmium by mass on the market.	The substance restrictions must be complied with and the batteries supplied must be labeled in accordance with the requirements of the BattG and from August 18, 2025 with the requirements of the BattDG.

Title	Legal basis	Application area	Explanation	Supplier obligations
	national law of the EU member states (in Germany, the Act on the Placing on the Market, Return and Environmentally Sound Disposal of Batteries and Accumulators)		The manufacturer is obliged to mark batteries that contain more than 0.0005% by mass of mercury, more than 0.002% by mass of cadmium or more than 0.004% by mass of lead with the chemical symbols of the metals (Hg, Cd, Pb) for which the limit value is exceeded before placing them on the market for the first time. Link to the European Regulation (EU) 2023/1542 **https://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=CELEX:32023R1542** Link to the German Battery Law https://www.gesetze-im-internet.de/battg/index.html	
POP (Persistent Organic Pollutants) Regulation EU 2019/1021	European regulation, directly applicable in all EU member states	Products containing organic substances	This ordinance regulates the handling of persistent organic pollutants and sets out detailed requirements regarding the manufacture, placing on the market, use and release of persistent organic pollutants. The aim is to protect human health and the environment from POPs (persistent organic pollutants) in accordance with the precautionary principle. The ordinance also restricts the release of these substances and lays down provisions for the disposal of waste. The POP Regulation and the REACH Regulation are independent legal regulations that must be observed in parallel. The stricter regulation applies in each case. The POPs Regulation implements the Stockholm Convention, which aims to end or restrict the production, use and release of POPs. Link to the European Regulation EU 2019/1021 https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32019R1021&qid=1623145772504&from=EN	The substance bans must be observed. HEINE must be informed if a substance is used due to an exception.
Biocide Regulation EU 528/2012	European regulation, directly applicable in all EU member states	Products that come into contact with the human body	This regulation governs the authorization of biocides in the European Union and standardizes the provision and use of biocidal products on the European market. Link to the European regulation https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32012R0528	The specifications and obligations for biocidal products and products treated with them that are delivered to HEINE must be fulfilled. Furthermore, the information obligations must be complied with as soon as a delivered product has been treated with a biocide for which corresponding labeling is

Title	Legal basis	Application area	Explanation	Supplier obligations
				required according to the regulation.
Regulation (EU) 2025/40 (also known as PPWR for Packaging and Packaging Waste Regulation)	European regulation, directly applicable in all EU member states	Packaging, as defined under the PPWR.	With the introduction of the EU Packaging and Packaging Waste Regulation (PPWR), uniform requirements for packaging are established across Europe. The objective is to reduce packaging waste, strengthen the circular economy, and minimize the environmental impact of packaging throughout its entire life cycle. To this end, the PPWR contains requirements regarding the sustainability and recyclability of packaging as well as provisions on specific substances. The requirements of the PPWR apply progressively in accordance with the application and transitional deadlines set out in the Regulation. Insofar as individual obligations are not yet applicable, suppliers are required to provide, upon request, the information necessary for assessing future PPWR requirements. Link to the European Regulation: **https://eur-lex.europa.eu/eli/reg/2025/40/oj/eng**	Information required for conformity assessment under the PPWR must be provided to HEINE upon request. This includes: - Proof of compliance with applicable substance restrictions - Information on material composition - Information for assessing recyclability - Immediate notification of relevant changes to material, composition, or regulatory status - Where the supplier acts as a manufacturer within the meaning of the PPWR, the supplier must provide the corresponding EU declaration of conformity and the documentation required for this purpose.
Dodd-Frank-Act	USA legislation	Products containing gold, tin, tungsten and tantalum.	The minerals gold, tin, tungsten and tantalum are classified as conflict minerals, as they are mined in some African countries on the basis of massive human rights violations and the proceeds are used to finance armed conflicts. Listed companies in the USA are obliged to provide evidence that the minerals they purchase are mined without conflict.	Even if HEINE is not directly affected by the German legislation (< 3000 employees), the requirements cascade through the entire supply chain. We are increasingly receiving inquiries about conflict minerals.
Ordinance on conflict minerals	*European regulation, directly applicable in all EU member states*		*This regulation only affects EU importers of these substances. The regulation has been in force since June 2017 and the due diligence obligation will apply from January 1, 2021. The law ensures greater transparency within the supply chain.*	

Title	Legal basis	Application area	Explanation	Supplier obligations
EU 2017/821 (only applies to importers)				We therefore require information from our suppliers on request, whether its contractual products contain the raw materials tantalum, tin, gold and tungsten (hereinafter referred to as "conflict minerals"). All minerals should be DRC-free, i.e. they should not contain minerals that directly or indirectly finance or benefit armed groups in the Democratic Republic of Congo (DRC) or an adjoining country. In the event that the contractual products contain conflict minerals, the Supplier shall name these products to HEINE and disclose at least the country of origin and the name of the industrial processor (smelter) for each mineral contained and, if possible, the smelter identification number and the source of the smelter identification number.
EU supply chain law being implemented	*D already implemented: Law on corporate due diligence obligations to prevent human rights violations in the supply chain* 19/28649		The German Supply Chain Act strengthens the protection of human rights. Companies must ensure that human rights are respected throughout the supply chain. Among other things, they must set up complaints mechanisms and report on their activities. This will apply from 2023 for companies with 3,000 employees, and later from 1,000 employees. Link to the German law http://www.gesetze-im-internet.de/lksg/LkSG.pdf	
California Proposition 65	USA - California law	All products distributed in California.	California's Safe Drinking Water and Toxic Enforcement Act is often referred to simply as California Proposition 65, or CP65 for short. The essence of this regulation is: "No person shall knowingly and intentionally expose an individual to a chemical known to the State of California to be a carcinogen or reproductive toxicant in the course of business without first providing that individual with a clear and reasonable warning." Specifically, this affects around 900 substances listed by the OEHHA that are carcinogenic, cause birth defects or are otherwise toxic to reproduction.	HEINE will inform the supplier whether the product supplied by the supplier falls within the scope of California Proposition 65. If substances in the delivered product that are contained in the CP-65 list exceed the safe

Title	Legal basis	Application area	Explanation	Supplier obligations
			A warning must be issued if one of the substances is contained in the product and consumer exposure may occur. There is therefore no need to warn about gallium arsenide in the semiconductors of a smartphone, but there is a warning about DEHP in a USB cable. The CP65 list contains so-called "safe harbor levels" for around 250 substances, i.e. exposure limits below which no harm is to be expected. If the exposure limit value is undershot, no warning to the consumer is required. Link to the California Proposition 65 list https://oehha.ca.gov/proposition-65/proposition-65-list	harbor level and the consumer (HEINE user and patient) is exposed, HEINE must be informed of the substance and the specific exposure value.

5 HEINE specific substances to be declared

Title	Legal basis	Application area	Explanation	Supplier obligations
Guideline on Medical Devices / here Latex, MDR	MDR/HEINE requirement	Products containing latex	Latex can cause allergies and should therefore not be used in HEINE products.	The supplier shall inform HEINE if the delivered products contain latex.
Materials of animal origin (MDR)	MDR/HEINE requirement	Products containing materials of animal origin	The Medical Device Regulation includes a declaration obligation for materials of animal origin, therefore materials of animal origin should not become part of a HEINE product.	The supplier shall inform HEINE if the delivered products contain materials of animal origin.

6. Definitions

Regulatory definitions can be found in the context of the respective law/regulation.

Term	Definition
Product	Product is everything that is made available to HEINE as a delivery item as well as everything that is manufactured by HEINE itself and remains on/in a product that is placed on the market by HEINE. Examples: • Complete product, including merchandise • Part, component • Spare part • Preparation or mixture • Fabric
ECHA	European Chemicals Agency, based in Helsinki
Substance bans	Prohibited substances are substances for which a general ban has been issued in accordance with the applicable regulations or for which a ban has been imposed due to other requirements (restriction of use, authorization requirement, etc.). Prohibited substances may not be contained in products, components, materials or auxiliary and operating materials above the limit values specified in the applicable regulations. The substances may only be contained as naturally occurring impurities; they may not be added intentionally. The impurities must be specified in qualitative terms.
Declarable substances	Declarable substances are all substances for which a declaration obligation exists according to the applicable regulations. Substances classified as declarable must be declared above the specified limit values.
Restricted substances	Restricted substances are subject to conditions for the manufacture, use or placing on the market or a ban on these activities. Substances whose manufacture, marketing or use entail an unacceptable risk to human health or the environment may be subject to restriction or even a ban (REACH Regulation).
Placing on the market	Supply to third parties against payment or free of charge or making available to third parties. Importing is deemed to be placing on the market.
SVHC (Substance of Very High Concern)	A substance of very high concern is a chemical substance that has been identified under the REACH Regulation as having particularly hazardous properties and may have serious effects on human health or the environment. This includes substances with the following properties: • CMR = carcinogenic, mutagenic or toxic to reproduction (carcinogenic, germ cell mutagenic or toxic to reproduction) • PBT = persistent, bioaccumulative and toxic (persistent, bioaccumulative and toxic) • Endocrine disruptors (substances that disrupt the hormone system) • Neurotoxic substances (substances that have a damaging effect on the nervous system)
List of candidates/ Authorization requirement	The status as a substance of very high concern is officially confirmed by the ECHA by publishing the substance in the candidate list on its website (updated every six months). The Candidate List is the selection list for substances subject to authorization. At least every 2 years, the Agency makes recommendations for the inclusion of a substance in Annex XIV of the REACH Regulation, after which the substance may only be used with authorization after the transitional periods have expired, unless the use has been exempted (research, regulation by other directives/regulations).

Term	Definition
Authorization requirement	The authorization requirement is a prohibition subject to authorization, i.e. the use of a substance listed in Annex XIV of the REACH Regulation is generally prohibited unless an authorization has been granted (see e.g. chromium trioxide).
Regulation	Law, regulation
Homogeneous	RoHS relevance: Definition of "homogeneous material": a homogeneous material means a material of uniform composition throughout or a material consisting of different materials that cannot be broken down or separated into individual materials by mechanical processes such as unscrewing, cutting, crushing, grinding and sanding. Example: a non-homogeneous component such as a painted metal part contains 3 homogeneous materials - the metal, the primer and the paint.
Battery and accumulator	A source of electrical energy consisting of one or more (non-rechargeable) primary cells or one or more (rechargeable) secondary cells obtained by direct conversion of chemical energy.
Biocide	Biocides are used to kill or repel harmful organisms. They work, for example, by paralyzing the nervous system or impairing the ability of harmful organisms to reproduce. This also makes them potentially dangerous for humans and the environment.
Article	Article 3, REACH: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.
Packaging	'Packaging' means an item, irrespective of the materials from which it is made, that is intended to be used by an economic operator for the containment, protection, handling, delivery or presentation of products to another economic operator or to an end-user. The concept of packaging also includes, in particular, components of packaging and ancillary elements integrated into packaging, service packaging and certain single-use items, provided that they fulfil a packaging function.
Manufacturer	Any natural or legal person that manufactures packaging or a packaged product or has packaging or a packaged product designed or manufactured, and markets that packaging or packaged product under its own name or trademark.