

Regulatory Compliance

In general, **compliance** means conforming to a rule, such as a specification, policy, standard, or law. At Ortofon A/S and Ortofon Microtech A/S, we aspire to comply with all regulations and directives applicable to the products that we manufacture and sell in the EU regarding health, safety, performance, and environmental requirements:

1. CE mark

The CE mark means that Ortofon A/S, as **the manufacturer takes responsibility for the compliance of a product with all applicable European health, safety, performance, and environmental requirements**. CE stands for "Conformité Européenne", the French for European conformity.

The document certifying compliance with CE marking directives is the Declaration of Conformity. The Declaration of Conformity is our acknowledgment that we are responsible for the compliance of our products with the applicable directives.

In the section Declaration of Conformity, you will find the declarations for our cartridges.

2. RoHS

RoHS compliance is the main driver for the CE mark requirement.

RoHS (Reduction of Hazardous Substances, Directive 2011/65/EU)

- The RoHS directive aims to restrict the use of hazardous substances in **Electrical and Electronic Equipment (EEE)** and promote the *collection and recycling of such equipment*. The legislation also *requires certain hazardous substances to be **substituted** by safer alternatives*.

3. REACH

REACH (Registration Evaluation Authorisation of Chemicals, regulation (EC) No 1907/2006)

- The REACH regulation is a comprehensive regulation concerning most companies. As a company, we are aware of our obligations in connection with REACH as well as *the potential risk* that some chemicals, substances, mixtures, or articles will be removed/banned from the European market.
- In the REACH regulation, a list of [Substances of Very High Concern](#) (SVHC-candidate list) is constantly observed as it is updated every six months.
- If any of the components in our products contain any of the SVHC chemicals in a concentration of more than 0,1%, it is our duty to notify the articles in the EU [SCIP database](#).
- SCIP is the database for information on **Substances of Concern** in articles as such or in complex objects (**P**roducts) established under the Waste Framework Directive (WFD). Companies supplying articles containing substances of very high concern (SVHCs) on the Candidate List in a concentration above 0.1% weight by weight (w/w) on the EU market must submit information on these articles to ECHA as from 5 January 2021. *The SCIP database ensures that the information on articles containing Candidate List substances is available throughout the whole lifecycle of products and materials, including at the waste stage. The information in the database is then made available to waste operators and consumers.*

4. POP

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POP (Persistent Organic Pollutants, [Regulation \(EU\) No. 2019/1021](#))

- The POP regulation aims to protect human health and the environment with a specific control. Products ***are not allowed to be placed on the European market*** if they contain any of the substances and are above the limit given in Annex I of the POP regulation.

Ortofon A/S hereby declares that none of our products contain substances given in Annex I of the POP regulation.

5. The European Conflict Minerals Regulation (Regulation EU/2017/821)

- In politically unstable areas, armed groups often use *forced labor to mine minerals*. They then sell those minerals to fund their activities, such as buying weapons. The EU Conflict minerals regulation aims to stop:
 - conflict minerals and metals from being exported to the EU;
 - global and EU smelters and refiners from using conflict minerals, and;
 - mine workers from being abused.
- The minerals are:
 - tin
 - tantalum
 - tungsten
 - gold.

Ortofon A/S hereby declares that none of our products contain substances or materials mentioned in Regulation EU/2017/821.