

Medical Devices – Compliance with RoHS (Restricted Hazardous Substances)

EU Directives restrict the use of hazardous substances in electrical and electronic equipment (EEE)

EU Directives have restricted the use of certain hazardous substances in electrical and electronic equipment for more than a decade. RoHS Directive (2002/95/EC) issued in 2002 restricted the use of the six chemicals: lead, cadmium, mercury, and hexavalent chromium, as well as flame retardants polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs). Manufacturers are required to replace these chemicals in their products with less hazardous alternatives.

In May 2011, the European Union adopted new legislation concerning the RoHS in Electrical and Electronic Equipment, RoHS II (2011/65/EU). This Directive replaces the previous RoHS Directive (2002/95/EC). Under RoHS II, medical devices will be subject to restrictions regarding the use of hazardous substances as of 22 July 2014, and in vitro diagnostic medical devices will be required to comply with hazardous substances restrictions as of 22 July 2016. For now, active implantable medical devices remain outside the scope of RoHS requirements, but are subject to future review by the EU Commission.

Manufacturers are required to comply with RoHS requirements not only in their technical documentation, but also on the EU Declaration of Conformity. RoHS II compliance must be demonstrated. The technical documentation must include among other things a conformity assessment, the use of standards, supplier declaration(s) of compliance, materials declarations, and results of any supplier audits as well as possible test results.

Medical device manufacturers are advised to review the conformity assessment procedures applicable to their device to avoid delays in the product review and approval process.

Medical device manufactures may be subject to other EU directives and regulations addressing the use of hazardous substances and the control of electrical and electronic waste (e.g. Directive 2012/19/EC - WEEE II, EU regulation No 1907/2006 - REACH, EU directives on the disposal of batteries, and on product packaging and packaging waste.

Overview of banned substances (RoHS II):

- Lead (0.1%)
- Mercury (0.1%)
- Cadmium (0.01%)
- Hexavalent chromium (0.1%)
- Polybrominated biphenyls (PBB) (0.1%)
- Polybrominated diphenyl ethers (PBDE) (0.1%)