ROHS 2 OBLIGATIONS FOR MEDICAL DEVICES AND IVDS

FREQUENTLY ASKED QUESTIONS

This Frequently Asked Questions (FAQ) paper has been developed by COCIR, EDMA and Eucomed on the basis of questions received from Members which are not otherwise addressed in previous Guidance Documents both from Industry and Institutions.

This document should be considered a live paper: additional questions will be added on a regular basis.

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SCOPE

1. What medical technologies and related products fall under which categories of annex I?

Category 8 'Medical Devices' includes EEE medical devices and in vitro diagnostic (IVD) medical devices as defined by their sectoral legislation (directives 93/42/EEC and 98/79/EC). It does not include active implantable medical devices (AIMD) as defined by their sectoral legislation, which are excluded from scope under RoHS Directive 2011/65/EU ("RoHS 2"), Art 2(h). All CE-marked medical devices excluding AIMD are therefore category 8. Medical devices (with the exception of AIMD) fall under the scope of RoHS2 from 22 July 2014 and IVDs from 22 July 2016.

For products which are not CE-marked as medical devices or IVDs but are similar (e.g. veterinary or forensic use) or are commonly used together with our products, other categories may be considered by manufacturers:

- Category 9 includes monitoring and control instruments including for industrial or professional use. Category 9 could therefore cover many non CE-marked devices which provide a monitoring or control function.

  Monitoring and control instruments fall under the scope of RoHS 2 from 22 July 2014 however **industrial** monitoring and control instruments only from 22 July 2017.

- Category 3 'IT and telecommunications equipment' may include IT equipment which is not CE-marked as a medical device.

  Products under Category 3 came into scope of Directive 2002/95/EC ("RoHS 1") in June 2006.

- Category 6 'Electronic and electrical tools' includes drills and equipment for separating or altering the physical form of materials, gases and liquids in some way.[1]

  Products under Category 6 came into scope of RoHS 1 in June 2006.

- Category 11 'Other EEE not covered by any of the categories above' may include devices similar to medical devices or accessories which do not fall under any other category of RoHS 2.

  All products under Category 11 will be subject to RoHS restrictions from 22 July 2019.

Given the variety of products on the market, manufacturers should judge the most

[1] *i.e. turning, milling, sanding, grinding, sawing, cutting, shearing, drilling, making holes, punching, folding, bending or similar processing of materials and spraying, spreading, dispersing or other treatment of liquid or gaseous substances. This description of products falling under category 6 comes from the first WEEE Directive 2002/96/EC which was linked to the first RoHS Directive 2002/95/EC. Although the second RoHS Directive 2011/65/EU no longer links to categories under WEEE legislation, the description may be taken as a helpful indicative list.*

appropriate category in which to include their product. For more information, see Q6.2 of the European Commission FAQ document on RoHS2.

2. In which category of annex I does training medical equipment fall?

The primary purpose of training medical equipment is to train health professionals or other users and will therefore fall under either Category 3, 6, 9 or 11.

3. In which category under annex I do IVD devices for performance evaluation fall?

IVD devices for performance evaluation which meet the definition of an in vitro diagnostic medical device (IVD) under Directive 98/79/EC are not CE-marked (this is an exception – all other IVDs are CE-marked). They are however IVDs and as such fall under Category 8 of annex I.

4. Do programmers used for active implantable medical devices (AIMD) fall under the scope of RoHS?

No, programmers used with AIMD medical devices do not fall under the scope of RoHS 2 as supported by the RoHS Directive and Medical Device Sector CE marking practices.

AIMDs are defined in Directive 90/385/EEC as:

> *'active implantable medical device' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;*

A 'programmer' is a device for communicating with the AIMD and consequently the level of 'risk' associated with the programmer is similar to that for the AIMD since a malfunction in the programmer may lead to a malfunction in the AIMD. Programmers are an example for products considered accessories to AIMDs. In MEDDEV 2. 1/2 rev2 Clause 2.2 states:.

> *"Accessories" to an active implantable medical device are by definition "active implantable medical devices" and therefore covered by the Directive 90/385/EEC. This does not presuppose that the attributes "active" and "implantable" must be necessarily met by a product called "accessory". It is sufficient that a product in its intended purpose is ancillary to the purpose of an active implantable medical device in such a way that it enables the device to be used in accordance with the intended device purpose or that it enhances the purpose of a device as intended by the device manufacturer. Following this a programmer or an external transmitter intended for activating or controlling the implantable part of the device is covered by the definition of "active implantable medical device"*

Since the rationale for exempting AIMDs from the RoHS Directive (patient safety) can also be applied to the programmer (as recognized by the MEDDEV) programmers are outside the scope of RoHS.

PLACING ON THE MARKET

5. At what point is a product considered 'placed on the market'?

The Interpretative document of the Commission Services from 16 December 2010, "Placing on the market of medical devices" gives a helpful interpretation citing the "Blue Guide":
"(10) The Guide to the implementation of directives based on the New Approach and the Global Approach states that the placing on the market takes place when the product is transferred from the stage of manufacture with the intention of distribution or use on the Community market... "
"(11) The transfer can consist in a physical hand-over and/or be based on a legal transaction. It can relate to the ownership, the possession or any other right transferred from the manufacturer to a distributor or to the end user. A transfer of a product is considered to have taken place, e.g., when it is sold, leased, given as a gift, rent out or hired. Where a manufacture operates an own distinct distribution chain, the transfer can also occur to that distribution chain
(12) According to the "Blue Guide", placing on the market is considered not to take place where a product, amongst others, is
– in the stocks of the manufacturer, or the authorised representative established in the Community, where the product is not yet made available, unless otherwise provided for in the applicable directives;…"

The question may arise at what point a product is placed on the market when it is transferred from the point of manufacture to a company's own distinct distribution chain. Depending on company procedures, 'release to inventory' with the intention of distribution may be considered sufficient. A documented transfer of physical or legal ownership should certainly be considered sufficient to satisfy the definition of 'placed on the market'. As procedures may vary from company to company, the interpretation is left to the individual company to decide.
Additional clarification may be provided by the European Commission in the revision of the Blue Guide. The new version will likely be available in 2014.

6. After July 2014 can non-RoHS compliant products be exported to extra-EU market?

The RoHS Directive applies only to products placed on the EU market. Products produced for exportation only, which are not intended to be placed on the EU market, can be non-RoHS compliant (but must be in compliance with the applicable legislation of the importing country).
That is also specified in the European Commission - Interpretative document of the Commission's Services "Placing on the market of medical devices"- (16 November 2010)

7. Can a company send a non-compliant product from a third country to the EU, for refurbishment or temporary holding past July 2014 if the intention is to sell the product in a non-EU market?

According to the European Commission - Interpretative document of the Commission's Services "Placing on the market of medical devices"- (16 November 2010), imported products must be at least released for free circulation on the EU market before they can be considered as placed on the market. Customs regulations determine when an

imported product is released for free circulation. Should the same criteria be applied to the imported product as to EU manufactured products, they can be considered as being placed on the market.
A custom procedure known as 'inward processing' allows imported raw materials or semi-manufactured goods to be processed for re-export within the Community by Community manufacturers without a requirement that the manufacturers have to pay customs duty and VAT on the goods being used. See relevant information under the European Commission DG Customs and Taxation website.

8. Can products newly in the scope of RoHS 2 which do not comply with RoHS 2 already placed on the market continue to be made available or put into service after 2019?

The Commission is addressing the issue raised by Article 2.2 regarding the making available of non-RoHS products after July 2019 in the context of the scope review of the RoHS Directive and it is expected to present a proposal by June 2014 in order to exclude Categories 8 and 9. See also the EC Roadmap for RoHS 2 at:
http://ec.europa.eu/governance/impact/planned_ia/docs/2012_env_009_legislative_proposal_on_rohs_scope.pdf.

NEW LEGISLATIVE FRAMEWORK

9. Do components require a CE marking according to RoHS requirements?

RoHS applies only to finished Electrical and Electronic Equipment (EEE) as listed in the categories of annex I. Components, spare parts or unfinished products, as far as they do not fall under the definition of EEE are not considered EEE. Thus they don't fall under the RoHS scope, and there are no legal obligations for the manufacturers to apply the CE marking to the component or to draw a Declaration of Conformity or the technical documentation according to RoHS.
Nonetheless components destined to be integrated/installed into equipment falling into RoHS scope have to comply with substance restrictions, independent of the fact whether they constitute an EEE or not.

Q7.3 of the European Commission FAQ document on RoHS 2 states:

Do components have to comply with RoHS 2?
RoHS 2 provides that EEE has to meet the requirements of the Directive. Since equipment consists of different components, the EEE itself can only meet the substance requirements if all its components and parts meet the substance restriction requirements of RoHS 2, including non-electronic or non-electric components like fasteners or the plastic case of a desktop computer. Therefore components being used in finished EEE or for repair or upgrade of used EEE, which is in the scope of RoHS 2 must meet the substance restrictions according to Art. 4 but do not need CE marking. ***Components sold as a stand-alone components*** *or if produced to be used in a product benefiting from an exclusion* ***do not have to be CE marked and do not have to comply with the substance requirements.***

RoHS 2 does not define components, but provides a definition of spare part which can be applied to components:

'spare part' means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part;

Components, if sold alone, do not fall under the scope of the RoHS Directive as they are not finished EEE. In case such components are required by other Directives to be CE marked, reference to RoHS 2 should not be added to the DoC or to the technical file (as the CE marking means that the product complies with applicable Directives).

10. Are there minimum requirements for suppliers' declarations?

The EN 50581 standard "*Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances*" considers supplier declarations / supplier's declarations of conformity as a valid tool (documents) to prepare the technical documentation for products falling under RoHS.

Note: Supplier's declarations of conformity should not to be confused with the manufacturer EU declaration of conformity.

With reference to EN 50581, examples of supplier declarations could be:

- Declarations confirming that the restricted substance content of the material, part, or sub-assembly is within the permitted levels and identifying any exemptions that have been applied;
- Signed contracts confirming that the manufacturer's specification for the maximum content of restricted substances in a material, part, or sub-assembly is fulfilled.

Supplier's declarations can also be collected electronically using IT platforms (sometimes called material declaration tool). In such a case, the supplier's and material declarations are generated out of the platform (e.g. as a PDF document). It is also important for the supplier's declaration to specify if exemptions (and which ones) have been used to determine the compliance with RoHS requirements.

Such declarations or agreements shall cover a specific material, part and/or subassembly, or a specific range of materials, parts and/or sub-assemblies.

RoHS and the EN 50581 standard do not set specific minimum requirements for suppliers' declarations to ensure a sufficient quality of the documentation.

The reference to standard ISO/IEC 17050-1 "Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements" could provide useful guidance to companies.

From the EN ISO/IEC 17050-1 standard:

"Supplier's declaration of conformity" is a "declaration" as defined in EN ISO/IEC 17000, i.e. first-party attestation.
"4 Purpose of the declaration of conformity
The purpose of the declaration is to give assurance of conformity of the identified object to specified requirements to which the declaration refers, and to make clear who is responsible for that conformity and declaration.
A supplier's declaration of conformity may be used alone or in conjunction with another conformity assessment procedure for regulatory or non-regulatory purposes."

From EN ISO/IEC 17050-1 Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements

*"**As a minimum, the declaration of conformity shall contain the following:***
a) unique identification of the declaration of conformity;
b) the name and contact address of the issuer of the declaration of conformity;
c) the identification of the object of the declaration of conformity (e.g. name, type, date of production or model number of a product, description of a process, management system, person or body, and/or other relevant supplementary information);
d) the statement of conformity;
e) a complete and clear list of standards or other specified requirements, as well as the selected options, if any;
f) the date and place of issue of the declaration of conformity;
g) the signature (or equivalent sign of validation), name and function of the authorized person(s) acting on behalf of the issuer;
h) any limitation on the validity of the declaration of conformity."

RoHS 2 Article 7 refers to Decision No 768/2008/EC ("Member States shall ensure that:…. manufacturers draw up the required technical documentation and carry out the internal production control procedure in line with module A of Annex II to Decision No 768/2008/EC or have it carried out") and EN ISO/IEC 17050-1 is an harmonized standard to Decision No 768/2008/EU. See also:
http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/new-legislative-framework-and-emas/index_en.htm

11. Is RoHS setting obligations for manufacturers to withdraw or recall non-RoHS compliant products from the market?

Medical devices and IVDs placed on the market from 22 July 2014 and 22 July 2016 respectively must be compliant with RoHS Directive 2011/65/EU. Products which are placed on the market before these dates are however not subject to RoHS obligations. They may furthermore continue to be made available until 22 July 2019 (see FAQ 8).
A medical device or an IVD cannot be placed on the market after 22 July 2014 and 22 July 2016 respectively unless it is in compliance with RoHS.

RoHS 2, Art. 7 (i) states:

"manufacturers who consider or have reason to believe that EEE which they have placed on the market is not in conformity with this Directive immediately take the necessary corrective measures to bring that EEE into conformity, to withdraw it or recall it, if appropriate, and immediately inform the competent national authorities of the Member States in which they made the EEE available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken"

Manufacturers must also keep a register of non-conforming EEE and product recalls, and keep distributors informed.

The same obligations are applied to importers (Art. 9 f) and distributors (Art. 10 (d). Distributors must ensure corrective actions are taken but are not required to keep a registry of non-conforming EEE.

DISCLAIMER

This document reflects the best knowledge of industry experts across Europe and the state-of-the-art at the moment of publication. COCIR, EDMA and Eucomed cannot be held responsible of any damage caused by the interpretations provided in this guide. Valid interpretation of Community legislation is the exclusive competence of the European Court of Justice. COCIR, EDMA and Eucomed also recommend to manufacturers when applying this document and its principles to always refer to the national legislation of the Member State in question.

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COCIR is the voice of the European Radiological, Electromedical and Healthcare IT Industry. COCIR is a non-profit trade association, founded in 1959, representing the medical technology industry in Europe. COCIR's members play a driving role in developing the future of healthcare in Europe and worldwide. The global market for medical equipment is worth €80 billion with around €28 billion in Europe, and of this €20 billion for COCIR member companies. With an annual growth rate of 5% and investments in R&D representing up to 8% of sales volume, medical imaging and health ICTs are among the most innovative and dynamic industry sectors in Europe and globally. For more information visit www.cocir.org.

About EDMA

Committed to raising awareness of the important role of diagnostics in the entire healthcare equation, the European Diagnostic Manufacturers Association (EDMA) provides services and activities to members engaged in the research, development, manufacturing or distribution of in vitro diagnostic (IVD) products in Europe. Founded in 1979, EDMA advocates for an appropriate regulatory system and a realistic economic environment for healthcare in Europe. For more information visit www.edma-ivd.eu.

About Eucomed

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