Eucomed
Medical Technology

Guidance document
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Delineation between the Conformity Assessment requirements of the Medical Devices and the RoHS 2 Directives

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RoHS CE Marking of Medical Devices

Scope

This paper is intended to provide clarification regarding the Conformity Assessment requirements of the Medical Devices and the RoHS 2 Directives. In particular it addresses the extent of the Notified Body review of a manufacturer's technical documentation according to the Medical Devices Directive when their medical device also falls within the scope of the Recast Directive on the Restriction of Hazardous Substances in Electrical and Electronic Equipment 2011/65/EU (RoHS 2).

Eucomed is not aware of any other Industry, Authority or Notified Body position paper or guidance on this subject. This paper reflects the current interpretation by Eucomed of the requirements under RoHS 2 with respect to CE Marking and is intended to achieve mutual understanding between affected stakeholders in this regard.

Subject for Clarification

Confusion may arise as to the scope of the assessment of the technical documentation carried out by a Notified Body under the Medical Devices Directive when the manufacturer of a medical device, that also falls within the scope of RoHS 2, has chosen to create a single technical documentation. Additional confusion may arise when the Declaration of Conformity is a single declaration stating compliance to both the Medical Devices and RoHS 2 Directives.

Under the Medical Devices Directive, manufacturers are responsible for ensuring that their product complies with the relevant Essential Requirements of the Directive. With the exception of low risk class I devices, the conformity assessment performed by the manufacturer requires the involvement of a Notified Body. Upon certification by the Notified Body, the manufacturer may draw up an EC Declaration of Conformity and affix the CE Marking.

Similarly, as RoHS 2 is now a CE Marking Directive, manufacturers must draw up the required technical documentation, carry out an internal production control procedure, draw up an EC Declaration of Conformity and affix the 'CE' mark to their product. However, RoHS 2 outlines surveillance responsibilities of Member States but does not contain a mandate for Notified Body assessment of compliance with the RoHS 2 provisions.

Position

- Notified Body audits under the Medical Devices Directive should not include a review of technical documentation or Quality System documents and procedures related to RoHS 2 conformity. Ensuring compliance to the RoHS 2 Directive remains the responsibility of the Member State (see Article 4 Paragraph 1 of Directive 2011/65/EU).

  Justification: RoHS 2 outlines surveillance responsibilities of Member States but does not contain a mandate for Notified Body assessment of compliance with the RoHS 2 provisions. In

contrast, under the Medical Devices Directive, Notified Bodies are designated by the Competent Authorities to carry out conformity assessment activities under the appropriate Directive for medium and high risk devices. To ease administrative burden, RoHS 2 Article 7 (c) offers the option of drawing up one set of technical documentation demonstrating compliance with the requirements of applicable Directives. In other words, a manufacturer may choose to incorporate the RoHS 2 technical documentation within the medical device technical documentation (or design dossier for class III devices) so that only one single file needs to be maintained.

- Under the Medical Devices Directive, a Notified Body reviewing the technical documentation of a manufacturer with a Declaration of Conformity demonstrating compliance to several Union Acts should limit the scope of their conformity assessment activities to those requirements of the Union Acts for which their involvement is required. Technical documentations according to RoHS 2 are subject to surveillance by authorities of the Member States.

  Justification: According to Article 5 of Decision 768/2008/EC of the European Parliament and of the Council a manufacturer's Declaration of Conformity may address compliance with the Medical Devices Directive as well as with other relevant Union Acts such as RoHS 2. Since this Decision has still to be implemented in the EU Medical Device Legislation, separate Declaration of Conformity documents referring to the Medical Devices Directive and RoHS 2 compliance are still legally possible. Nevertheless, in all cases when addressing compliance to RoHS 2, the Declaration of Conformity must contain a disclaimer stating that it is issued under the sole responsibility of the manufacturer underlining the manufacturer's responsibility for compliance with the referenced Union Acts. In the event that compliance with several Union Acts is declared in one Declaration of Conformity the name, address and identification number of the Notified Body involved per Act should be specifically declared.

Background

RoHS 2 represents a recast of Directive 2002/95/EC (RoHS), making it a CE Marking Directive. It broadens the scope of RoHS to electrical and electronic medical devices from 22 July 2014. Accordingly, electrical and electronic medical devices shall comply with the RoHS 2 provisions on hazardous substances and CE Marking, when placed on the EU market for the first time as from that date.

In order to ensure and demonstrate compliance with Directive 2011/65/EC, Art. 7 requires manufacturers to draw up the required technical documentation, carry out an internal production control procedure in line with 'Module A' of Annex II to Decision No 768/2008/EC (comparable to Annex VII of Directive 93/42/EC), draw up an EC Declaration of Conformity and affix the 'CE' mark to the finished product.

In addition Art. 4(5) of the Medical Devices Directive requires that with the "one" CE-mark, compliance with all applicable Directives is claimed.

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About Eucomed

Eucomed is the European medical technology industry association. Its mission is to make modern, innovative and reliable medical technology available to more people. Eucomed represents directly and indirectly 22,500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability. Small and medium sized companies make up more than 80% of this sector. The European medical technology industry generates annual sales of €95 billion, invests some €7.5 billion in R&D and employs around 500,000 highly skilled workers. For more information, visit www.eucomed.org.

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