Changes of the RoHS Directive (2002/95/EC) and its implication for medical device manufacturers

What does the RoHS Directive mean?

"The restriction of the use of certain hazardous substances in electrical and electronic equipment" is regulated by the RoHS Directive (2002/95/EC). Since July 1st, 2006, this directive controls the content of chemicals in new electrical and electronic equipment. Equipment containing more than the agreed level of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants won't be permitted to enter the European market.

The RoHS directive and medical devices

Initially, medical devices were not affected by the directive on Restriction of Hazardous Substances (RoHS). As from June 8, 2011, medical devices have been enclosed in the directive as they may be classified as electrical or electronic equipment. However, there is still an exception for active implantable medical devices. They remain completely outside the scope of the legislation. Additionally, an Annex is dedicated to specific cases for medical devices.

Upcoming Changes

July 22, 2014: Medical devices and monitoring and control instruments have to meet RoHS requirements.

July 22, 2016: The RoHS directive will become effective for in vitro diagnostic medical devices.

To date, the RoHS directive regulates the content of the chemicals lead, mercury, cadmium, hexavalent chromium, PBB and PBDE in electrical and electronic equipment. Ongoing debates might lead to a wider range of included substances considered to be hazardous to human health and/or the environment.

Implications for medical device manufacturers

- Detailed understanding of the directive is inevitable to meet its requirements.
- Medical device manufacturers need to review their product portfolio in terms of products which might be affected by the regulations determined in the directive.
- The selection and evaluation of materials used for manufacturing becomes more important in respect to chemicals banned by the RoHS directive.

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