



ARAZY GROUP
Medical Device Consultants
Fact Sheet N° 5
August 2006



IMPLICATIONS OF THE ROHS DIRECTIVE (2002/95/EC)
IN THE MEDICAL DEVICES INDUSTRY

What does the RoHS Directive establish?

The RoHS Directive 2002/95/EC regulates the use of certain hazardous substances in electrical and electronic equipment (EEE) in the European Union. Examples of these hazardous substances are: lead, mercury, cadmium, chromium, etc. and they are used in several applications in the EEE. Medical Devices Industry is included within this category as defined in the WEEE Directive 2002/96/EC, therefore manufacturers of medical devices have an interest in knowing how their products are affected.

What is the purpose of WEEE Directive?

The main purpose of the Directive 2002/96/EC is the prevention of Waste Electrical and Electronic Equipment (WEEE), and in addition the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste. It also seeks to improve the environmental performance of all operators involved in the life cycle of electrical and electronic equipment. Electrical and electronic medical devices are classified in category 8 of the Annex IA of this directive. Also, the WEEE directive is referred by the RoHS Directive in the definition of its scope and exceptions.

Is the RoHS Directive applicable to EE Medical Devices?

The scope of the RoHS Directive 2002/95/EC as defined in Article 2 does not include the EE Medical Devices:

1. Without prejudice to Article 6, this Directive shall apply to electrical and electronic equipment falling under the categories 1, 2, 3, 4, 5, 6, 7 and 10 set out in Annex IA to Directive No 2002/96/EC (WEEE) and to electric light bulbs, and luminaries in households.

Hence, **MEDICAL DEVICES ARE CURRENTLY EXCLUDED FROM THE SCOPE OF THE ROHS DIRECTIVE.**

When will the RoHS Directive become applicable to EE Medical Devices?

At the present time, the applicability to EE Medical Devices is a matter yet to be defined. Article 6 of the RoHS Directive states that *"...the Commission shall review the measures provided for in this Directive to take into account, as necessary, new*

scientific evidence. In particular the Commission shall... present proposals for including in the scope of this Directive equipment which falls under categories 8 and 9 set out in Annex IA to Directive 2002/96/EC (WEEE)." This matter was studied during 2005, and early in 2006 a group of federations representing 98% of the European medical device industry recommended and justified exemptions to medical devices in the document *"Joint statement of the Medical Device Industry on the RoHS Directive (2002/95/EC)"*. Justifications for exemptions are based on the need to ensure the uninterrupted availability of many current and future innovative products to health care, until technological evolution allows the replacement of hazardous materials. This group of federations proposed that Medical Devices should not become part of the scope of the RoHS directive before 2012. The European Commission is studying this recommendation and others', and has appointed a Contractor to study the possible inclusion of categories 8 and 9 of the WEEE directive in the scope of the RoHS Directive, as well as the exemptions to it (more information is available at http://ec.europa.eu/environment/waste/pdf/era_tec hnology_study_12_2004.pdf). The final report on the "Adaptation to scientific and technical progress under Directive 2002/95/EC" will be published in September 2006.

Although medical devices are currently exempted, we must assume that in the future they will be included in the scope of the RoHS directive as manufacturers adapt their products to scientific and technical progress, and that several exemptions will stand. Manufacturers should put this issue in their surveillance procedures to avoid design un-updating in the future when the RoHS directive becomes mandatory for medical devices.

Where to find more information?

For more information see [http://ec.europa.eu/environment/waste/weee_index .htm](http://ec.europa.eu/environment/waste/weee_index.htm) , and the FAQs on RoHS and WEE at http://ec.europa.eu/environment/waste/pdf/faq_we ee.pdf

Mizpe Aviv, Industrial Park 13 - M.P. Misgav 20187 - Israel
Phone: +972 4994 7880 - Fax: +972 4994 4224
beinfo@arazygroup.com - www.arazygroup.com