July 22nd, 2014 : Enter in force of the RoHS 2 Directive, What impact for the US Manufacturers of medical devices ?

Starting July 22nd, 2014, if US Manufacturers of medical devices do not to fully comply with the RoHS 2 Directive, they will have to stop all their shipments in EU. In fact, their products should be already into the EU distribution chain, e.g. already placed on the market at this date. Then, they could be sold to end users until July 29th, 2019.

The most common questions concerned the ROHS documentation, certification and the Declaration of conformity to this directive.

Do you need to be inspected or certified by a third party? Answer: **NO** or do we self- certify that we conform to the RoHS requirements? Answer: **YES** as per 7.1. CONFORMITY ASSESSMENT AND TECHNICAL DOCUMENTATION :
The Article 7 references Module A of Annex II to Decision 768/2008/EC, "internal production control" **under the sole responsibility of the manufacturer, without the involvement of any third party**.
This procedure requires the manufacturer to issue a Declaration of conformity (DoC) and to draw up a technical documentation that should contain, wherever applicable:
- general description of the product
- conceptual design and manufacturing drawings and schemes, with necessary explanations
- harmonized standards applied and/or relevant technical specifications
- test reports

The above mentioned documentation should allow control authorities to verify the conformity of the product to RoHS II requirements.
In general it can be said that the detail level of the technical documentation depends on the risk presented by the restricted substances to be contained in certain materials or components. **In most cases the declarations collected from suppliers or contractual agreements/technical specifications would be sufficient.**
Chemical tests and test reports are normally not required unless for components/parts/material for which a high risk of non-conformity is involved, due to the nature of the product, or the low reliability of the supplier or other considerations.

Regarding the declaration of conformity, you have the choice to issue a single combined Declaration of Conformity adding after the last paragraph of your current DoC a paragraph such as:

"In addition, we also insure and declare under our sole responsibility and for an undetermined period of time that the Electrical and Electronic Equipments included into the attached list of medical devices to which this declaration relates are also in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment."

or to issue a separate declaration based on the model provided in Annex VI of the EEE Directive:

EU DECLARATION OF CONFORMITY

1. No … (unique identification of the EEE):

2. Name and address of the manufacturer or his authorized representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):

4. Object of the declaration (identification of EEE allowing traceability. It may include a photograph, where appropriate):

5. The object of the declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (*):

6. Where applicable, references to the relevant harmonized standards used or references to the technical specifications in relation to which conformity is declared:

7. Additional information:

Signed for and on behalf of:
.....
.....
(place and date of issue):
(name, function) (signature):