April 2012

INFORMATION ON TERUMO MEDICAL DEVICES AND PHTHALATES (DEHP, DBP, BBP)

Phthalates of Concerns and the Medical Device Directive 93/42/EEC
last amended by Directive 2007/47/EC

Annex I, section 7.5 requires by 21 March 2010 specific labelling where phthalates are an integral part of the medical device material formulation (i.e. not including contaminants/residues) and these phthalates are classified as carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1 or 2, in accordance with Annex I of Directive 67/548/EEC (*), and parts of the medical device (or the medical device itself) are intended to administer and/or remove medicines, body fluids or other substances to or from the body or the medical device is intended for transport and storage of such body fluids or substances.

Furthermore, when intended use includes treatment of children, pregnant or nursing women, a justification for use of such phthalates is required within the technical documentation and information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures is required within the instructions for use.

Note: This specific labelling requirement does not apply to active implantable medical devices and in vitro diagnostic medical devices.

(*) Directive 67/548/EEC is being repealed by Regulation 1272/2008

The only phthalate classified as carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1 or 2, in accordance with Annex I of Directive 67/548/EEC and that can be applied in some of the Terumo medical devices is DEHP (Bis(2-ethylhexyl)phthalate).
Based on the above conditions, the intended use of the medical device and its respective risk management, Terumo has taken action either by replacing DEHP with a non CMR plasticizer, or by labelling the medical device for the presence of DEHP and by including in its instructions for use the related risk sentence.
All of these actions have been timely implemented to assure that concerned devices are compliant when placed on the EEA market as of 21 March 2010.

Terumo has used the following symbol (proposed by EN 15986:2011) on the unit packaging and/or on the sales packaging. This symbol consists of the generic “contains PHT” symbol accompanied by the name of the phthalate classified as CMR 1 or 2 (in Terumo’s case DEHP).

Until the symbol is harmonized, this symbol requires explanation in the instructions for use.

The related warning sentences appearing in the instructions for use or on the product labeling are:
This device contains DEHP.
Based on animal studies, significant exposure to DEHP may interfere with the normal development of the male reproductive tract.
For children, pregnant and nursing women, alternative devices may be appropriate.

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References:

- *Medical Device Directive 93/42/EEC latest amended by Directive 2007/47/EC*
- *Terumo product related risk management documents*
- *EN 15986:2011 – Symbol for use in the labelling of medical devices – Requirements for labelling of medical devices containing phthalates*
- *Eucomed – Labelling of medical devices containing phthalates, 7 July, 2009*
- *Eucomed - Guidance concerning the labelling of medical devices containing phthalates, 30 October, 2009*
- *European Commission, Directorate-General for Health & Consumers, SCENHIR, Opinion on the safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk, 6 February, 2008*