

Revision of Medical Devices Directive 93/42/EEC Essential Requirement 7.5 – Carcinogenic, Mutagenic and Reprotoxic Substances (e.g. DEHP)

Introduction

The EU Council of Ministers and the European Parliament reached an agreement on the issue on 6 March 2007 that in line with the essential requirements of the MDD, manufacturers should avoid the use of substances that may possibly compromise the health of patients – in particular substances which are carcinogenic, mutagenic or toxic to reproduction (CMR).

To whom is this Med-Info relevant?

This Med-Info is relevant to all manufacturers of medical devices, but especially to those producing devices that contain phthalates.

Revised essential requirement 7.5 (2007/47/EC)

Essential requirement 7.5 states, “The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

If parts of a device (or a device itself) intended to administer and/or remove medicines, body fluids or other substances to or from the body, or if devices intended for transport and storage of such body fluids or substances contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled as a device containing phthalates on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging.

If the intended use of such devices includes the treatment of children or the treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, give information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.”

Which substances are covered?

Annex I to Directive 67/548/EEC refers to Directive 2006/121/EC commonly known as the REACH Directive; Appendices 1–6 of this Directive give a detailed list of different categories of CMR substances.

What needs to be considered?

- What substances are present in raw materials and finished devices?
- Can these substances leak from the device?
- Are these substances listed in category 1 of the REACH Directive or are they phthalates of category 1 or 2?
- Is the device intended to administer and/or remove medicines, body fluids or other substances to or from the body, or is it intended for transport and storage of such body fluids and substances?
- Is the device intended for use with children, pregnant or nursing women?

What are you expected to do?

- Review specifications for materials used in the device itself (or during its manufacture) and talk to your suppliers.
- Identify substances present that could leak from the device during its intended use. The identification should refer to the CAS number, index number or EC number.
- Devices containing phthalates of either category 1 or 2 (as well as having an intended use as specified above) must be labelled to inform the user that it contains phthalates.
- If the device contains a substance that can leak from the device and is of category 1,

CMR risks must be considered within the risk analysis. This should include the amount of substance that could leak during use of the device.

- If the device is intended to be used on children or nursing/pregnant women, a justification for the use must be prepared and additional information must be provided with the devices.

When do you need to be ready?

The revised requirements of the Medical Device Directive come into force on 21 March 2010. Manufacturers should start analyzing the impact of these changes now. Planning activities including risk management should consider how best to identify the substances contained within the devices as well as any necessary changes to labels and instructions for use.

Where can you find further information?

<http://www.fda.gov/cdrh/ost/dehp-pvc.pdf>

<http://www.phthalates.com/ras>

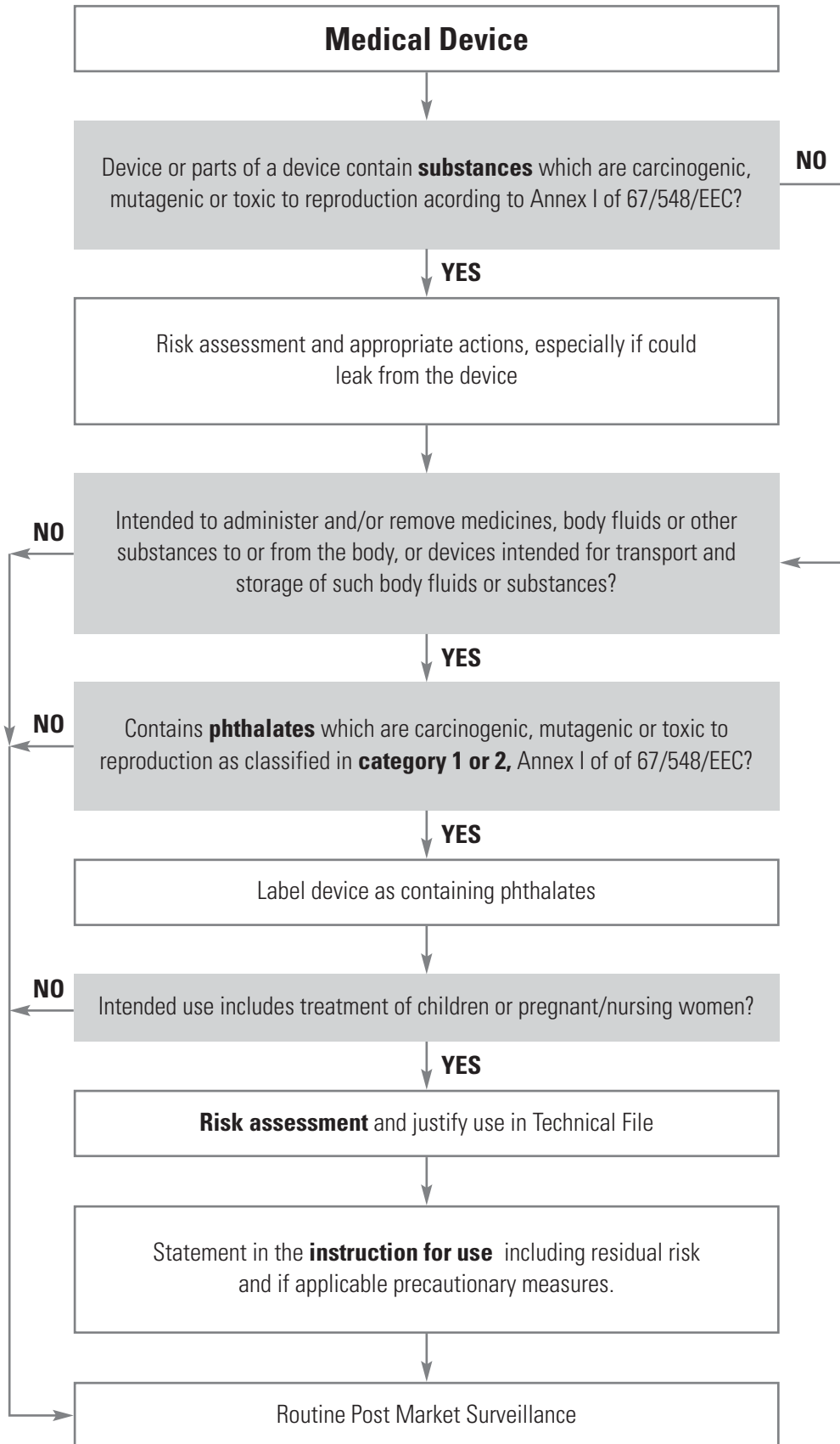
ISO 10993-17: Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances

prEN 15986: Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates

Directive 67/548/EEC:

http://ec.europa.eu/environment/chemicals/dansub/main67_548/index_en.htm

<http://ecb.jrc.ec.europa.eu/classification-labelling/search-classlab/>





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