

Statement on Phthalates



Statement 06/03/2010

Phthalate statement

An amendment has been made to the Medical Devices Directive. This includes a requirement for the labelling of products, which contain phthalates of certain categories, as defined in the Dangerous Substances Directive. This amendment will apply to all medical device manufacturers and will become a legal requirement by 21 March 2010.

Products, which contain certain phthalates such as DEHP, will be labelled with an international symbol on the packaging.



The Essential Requirements of the Medical Devices Directive also require that all manufacturers must provide in the instructions for use, information about risks and cautions if products containing certain phthalates are to be used on children, or the children of pregnant or nursing women.

There is more concern about the effect on children than adults, because of their small body size and possible effects of phthalates on the development of children's reproductive tracts. Respiratory treatment is unlikely to pose a high risk of exposure to phthalates, except for multiple procedures on sick neonates due to repeated exposures and small body size.

We will also be indicating that some products do not contain phthalates and will be using the following symbol.



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