

# Statement on Phthalates



Statement 29/03/2022

## Phthalate statement

The Medical Devices Directive and Medical Devices Regulation both include a requirement for the labelling of products, which contain phthalates of certain categories.

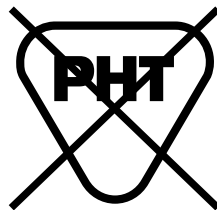
Products, which contain certain phthalates such as DEHP, will be labelled with a symbol on the packaging.



The Essential Requirements of the Medical Devices Directive and General Safety and Performance Requirements of the Medical Devices Regulation 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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The manufacturer Intersurgical Ltd is certified to ISO 9001:2015, ISO 13485:2016, ISO 14001:2015 and MDSAP

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