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**LATEX ALLERGY**

Latex products and their use are regulated in various ways, nationally and internationally.

Medical Devices are regulated under the EU Medical Devices Directives (MDD's) (Directives 90/385, 93/42 and 98/79), transposed at national level in the U.K.'s Medical Devices Regulations 2003, and enforced by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Within the European Union, The Medical Device Directive requires that:

- Neither the clinical condition, nor the safety of the patient or user, must be compromised by the product or its use;
- Risks must be acceptable when balanced against benefits to patients; and
- Risks must be eliminated or reduced in accordance with the state of the art.

We work closely with our suppliers to ensure that we can comply with the Directives.

No part, nor component part, used in the SpO2 products has any Latex incorporated.

Each product grouping therefore has a Latex Free Certificate.