



**VIAMED Ltd.**

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## **LATEX FREE PRODUCT CERTIFICATION**

### **PRODUCT:**

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 all of our suppliers to ensure that we can comply with the Directives.

Therefore, working within the above-mentioned Directives, the above product is certified as being 100% Latex Free.

For and on behalf of  
Viamed Limited

Kevin Rush  
Regulatory Affairs

	<b>VIAMED Ltd.</b> 15 Station Road, Cross Hills, Keighley, West Yorkshire, BD20 7DT, UK. Website: <a href="http://www.viamed.co.uk">www.viamed.co.uk</a> . Email: <a href="mailto:info@viamed.co.uk">info@viamed.co.uk</a> . Tel: +44 (0)1535 634542. Fax: +44 (0)1535 635582.
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## **LATEX ALLERGY and VIAMED PRODUCTS**

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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.

Therefore, working within the above-mentioned Directives, all Viamed products are 100% Latex Free. This Includes:

- Teledyne Sensors and Monitors
- Pulse Oximeter Monitors and Probes – Disposable and Re-usable
- Plastic Products e.g. Headbox, Light Shield
- Medical Instruments e.g. Billimed, Patient Monitors, Microstim
- Baby Warmers and Associated Accessories
- Disposable Products e.g. "Tee" Pieces, Adaptors
- Infant Resuscitation Devices and Patient Circuits
- Temperature Probes and ECG Cables

For and on behalf of  
Viamed Limited

John S.Lamb  
Managing Director  
March 14<sup>th</sup> 2006