ENVITEC
by Honeywell

EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer in accordance with the Council Directive 93/42/EEC in its currently valid version (Annex I) concerning medical devices.

Product: **Reusable Pulse Oximetry Sensor SoftTip® large**

Type:

R-2182-3 Minolta	R-3013 Nonin	R-3225 EnviteC	R-3512-20 Datex
R-2203-16 Nihon Kohden	R-3013-30 Nonin	R-3226 EnviteC	R-3512-40 Datex
R-2412 HP/Philips?	R-3212-31 Nellcor	R-3227 EnviteC	R-3512-9 Datex
R-2414-15 HP/Philips	R-3212-9 Nellcor	R-3227-18 EnviteC	R-3513-30 GE Datex-Ohmeda
R-2414-30 HP/Philips	R-3213-9 Mindray	R-3412 Ohmeda	R-3513-40 GE Datex-Ohmeda
R-3003-9 FlexMon	R-3214-12 Nellcor	R-3412-10 Ohmeda	
R-3012 Nonin	R-3222-12 BCI	R-3412-9 Ohmeda	
R-3012-30 Nonin			

Classification: (RL 93/42/EEC, Annex IX): **Class IIb**

CE mark: CE 0123

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany

Conformity Assessment Process: Annex II, section 3 of the Directive 93/42/EEC

Particular product standard applied: ISO 80601-2-61

Issued by:

EnviteC-Wismar GmbH
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Germany

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Authorized Signature:

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