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® medium**

Type:

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