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®plus large

Type:

R-2203-16plus Nihon Kohden	R-3222-12plus BCI
R-2412plus HP/Philips	R-3227plus EnviteC
R-2414-30plus HP/Philips	R-3227-18plus EnviteC
R-3012plus Nonin	R-3412plus Ohmeda
R-3212-9plus Nellcor®	R-3512-20plus Datex
R-3212-31plus Nellcor®	R-3512-40plus Datex
R-3213-9plus Mindray	R-3513-30plus GE Datex-Ohmeda
R-3217-9plus GE Nellcor	R-3513-40plus GE Datex-Ohmeda

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
Alter Holzhafen 18
D-23966 Wismar
Germany

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Authorized Signature:

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