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 small**
Type:	RS-2203-16plus Nihon Kohden RS-2412plus HP/Philips RS-2414-15plus HP/Philips RS-2414-30plus HP/Philips RS-3012plus Nonin RS-3212-9plus Nellcor® RS-3212-31plus Nellcor® RS-3213-9plus Mindray RS-3222-12plus BCI RS-3227plus EnviteC RS-3412plus Ohmeda RS-3513-30plus GE Datex-Ohmeda RS-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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Place, Date:	Wismar, 2015-07-01
Authorized Signature:	Marcus Ostländer Managing Director