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 medium**
Type:	RM-2203-16plus Nihon Kohden RM-2412plus HP/Philips RM-2414-15plus HP/Philips RM-2414-30plus HP/Philips RM-3012plus Nonin RM-3212-9plus Nellcor® RM-3212-31plus Nellcor® RM-3213-9plus Mindray RM-3222-12plus BCI RM-3227plus EnviteC RM-3227-18plus EnviteC RM-3412plus Ohmeda RM-3512-9plus Datex RM-3512-20plus Datex RM-3512-40plus Datex RM-3513-30plus GE Datex-Ohmeda RM-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