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** **Ear Sensor**

Type:

ES-2182-3 Minolta	ES-3003-9 FlexMon	ES-3222-12 BCI	ES-3512-20 Datex
ES-2203-16 Nihon Kohden	ES-3012 Nonin	ES-3225 EnviteC	ES-3512-40 Datex
ES-2412 HP/Philips	ES-3212-9 Nellcor	ES-3227 EnviteC	ES-3512-9 Datex
ES-2414-15 HP/Philips	ES-3217-9 GE Nellcor		
ES-2414-30 HP/Philips			

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**
Valid from:	2015-07-01
Valid until:	2018-06-30
Place, Date:	Wismar, 2015-07-01

Authorized Signature:

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