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** **Y Sensor**
Type:	Y-2217-31 Nellcor Y-2217-31M Nellcor Y-2217-9 Nellcor Y-2227 BCI Y-3225 EnviteC Y-3227 EnviteC
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:	Marcus Ostländer Managing Director