

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-2227 BCI
Y-2217-31M Nellcor	Y-3225 EnviteC
Y-2217-9 Nellcor	Y-3227 EnviteC

Classification: **Class IIb**
(RL 93/42/EEC,
Annex IX)

CE mark:



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

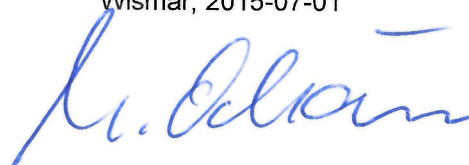
Particular product standard applied: ISO 80601-2-61

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