

## 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: **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

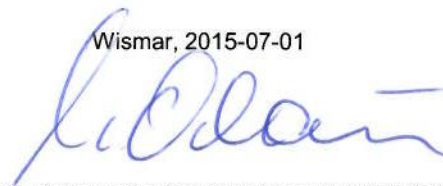
Particular product standard applied: ISO 80601-2-61

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  
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