

## 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  
Fingerclip**

Typ:	F-2182-3 Minolta	F-3212-9 Nellcor	F-3226 EnviteC	F-3512-20 Datex
	F-2203-16 Nihon Kohden	F-3212-31 Nellcor	F-3226-20 EnviteC	F-3512-40 Datex
	F-2412 HP/Philips	F-3212-31 M Nellcor	F-3227 EnviteC	F-3512-9 Datex
	F-2414-15 HP/Philips	F-3213-30 Mindray	F-3412 Ohmeda	F-3513-30 GE Datex-O hmeda
	F-3003-9 FlexMon	F-3213-9 Mindray	F-3412-10 Ohmeda	
	F-3012 Nonin	F-3222-12 BCI	F-3412-9 Ohmeda	
	F-3012-30 Nonin	F-3222-24 BCI		
	F-3013-30 Nonin	F-3222-30 BCI		
	F-3015-30 Nonin			

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

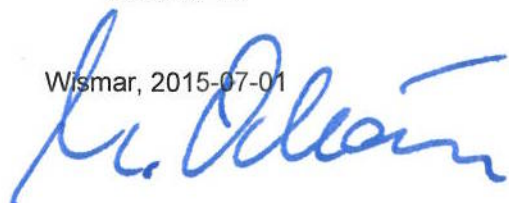
Particular product standard applied: ISO 80601-2-61

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