

## 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  
SoftTip® large**

Type:	R-2182-3 Minolta	R-3013 Nonin	R-3225 EnviteC	R-3512-20 Datex
	R-2203-16 Nihon Kohden	R-3013-30 Nonin	R-3226 EnviteC	R-3512-40 Datex
	R-2412 HP/Philips?	R-3212-31 Nellcor	R-3227 EnviteC	R-3512-9 Datex
	R-2414-15 HP/Philips	R-3212-9 Nellcor	R-3227-18 EnviteC	R-3513-30 GE Datex-Ohmeda
	R-2414-30 HP/Philips	R-3213-9 Mindray	R-3412 Ohmeda	R-3513-40 GE Datex-Ohmeda
	R-3003-9 FlexMon	R-3214-12 Nellcor	R-3412-10 Ohmeda	
	R-3012 Nonin	R-3222-12 BCI	R-3412-9 Ohmeda	
	R-3012-30 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

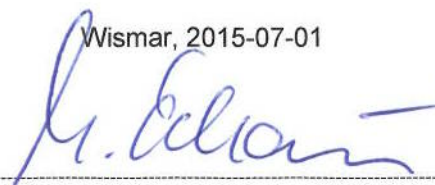
Issued by: **EnviteC-Wismar GmbH  
Alter Holzhafen 18  
D-23966 Wismar  
Germany**

Valid from: 2015-07-01

Valid until: 2018-06-30

Place, Date: Wismar, 2015-07-01

Authorized Signature:



Marcus Ostländer  
Managing Director