

## 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® medium

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

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

**Class IIb**

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:

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