

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® small**

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

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:

2021-04-21

Valid until:

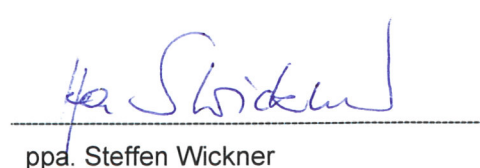
2024-05-26

Place, Date:

Wismar, 2021-04-21

Authorized Signature:


ppa. Marko Sprössel


ppa. Steffen Wickner