

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® plus medium

Type:

RM-2203-16plus Nihon Kohden	RM-3227plus EnviteC
RM-2412plus HP/Philips	RM-3227-18plus EnviteC
RM-2414-15plus HP/Philips	RM-3412plus Ohmeda
RM-2414-30plus HP/Philips	RM-3512-9plus Datex
RM-3012plus Nonin	RM-3512-20plus Datex
RM-3212-9plus Nellcor®	RM-3512-40plus Datex
RM-3212-31plus Nellcor®	RM-3513-30plus GE Datex-Ohmeda
RM-3213-9plus Mindray	RM-3513-40plus GE Datex-Ohmeda
RM-3222-12plus BCI	

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:

Marcus Ostländer
Managing Director