

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
WRAP**

Type: W-2203-16 Nihon Kohden W-3012 Nonin
W-2412 HP/Philips W-3212-9 Nellcor
W-2414-15 HP/Philips W-3227 EnviteC

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
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Authorized Signature: 

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