

## 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 small**

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

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

CE mark:    **CE** 0123

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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