Honeywell
Healthcare Solutions GmbH

# EU Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer in accordance with Regulation 2017/745/EU Article 120 and Directive 93/42/EEC in its currently valid version.

Product: **Reusable Pulse Oximetry Sensors SoftTip® small**

Basic UDI-DI: 4036616RSpO2S5J

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: (Annex VIII) **Class IIb**

CE Mark: CE 0123

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

Conformity Assessment Process: Annex II, section 3 of Directive 93/42/EEC.

Particular product standard applied: ISO 80601-2-61

Issued by:

**Honeywell Healthcare Solutions GmbH**
**Eudamed-SRN: DE-MF-000004924**
**Alter Holzhafen 18**
**D-23966 Wismar**
**Germany**

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Place, Date: Wismar, 01.08.2023

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