

# EC-Declaration of Conformity

## Manufacturer:

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## Authorized European Representative:

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**Product:** Pulse Oximetry (SpO2) Sensor

## Reference Numbers:

Non- Sterile Reusable Pulse Oximetry (SpO2) Sensor: FMT-RAF/XXX, FMT-RAFB/XXX, FMT-RPF/XXX, FMT-RYS/XXX, FMT-RAS/XXX, FMT-RASB/XXX, FMT-REC/XXX, FMT-RPS/XXX, FMT-RIS/XXX, FMT-RNS/XXX, FMT-RWS/XXX (XXX variable: ADC-L, AT-L, BCI, BCI-L, BCI-LR, BLT, BLT-LC, BLT-LR, BLT-LV, BNT-L, BNT-LD, BRC-L, BYS-L, CHC-LR, CMN-LR, CNC-LR, CRD-L, CRT, CRT-L, CRT-LL, CSI, DGC-L, DLP, DLW-L, DTS, DTS-L, DTX, DTX-L, DXT, DXT-L, EDN-LR, EMT-LD, EMT-LO, GLD-LL, GLD-LR, GOX-L, GTG-LR, HPB-L, HPS-L, IFM-L, INV-L, KNT-L, LHM, MEK, MEK-L, MEK-LD, MEK-LH, MEM-L, MMH-L, MND-L, MND-LO, MNM-L, MRQ-L, MRQ-LM, MRQ-LO, MSD, MSM-L, MTN-L, MTN-LO, NKN, NKN-L, NKN-LC, NKN-LO, NKN-LR, NLC, NLC-L, NLC-LN, NLO, NLO-L, NLO-LO, NON, NON-L, NTG, NTG-L, NTG-LR, NVM, NVM-L, OHM-L, OHM-S, OXN, OXY, PLC, PLC-L, PLM-LR, PLS, PLS-L, PRN-LR, PTS-L, RGB-LR, RSD-L, SHA-L, SIE-L, SIE-LD, SPL-L, SPL-LB, SPL-LC, SW-L, TRS-L, TRT-L, UTS-L)  
SENSORPLUS SP010XXX, SP020XXX, SP030XXX, SP040XXX, SP050XXX (XXX variable: 001 to 089)

Sterile Disposable Pulse Oximetry (SpO2) Sensor: FMT-DAF/XXX-Y, FMT-DPF/XXX-Y, FMT-DIF/XXX-Y, FMT-DNF/XXX-Y, FMT-DVF/XXX (XXX variable: BCI, CSI, DTX, MEK, MSD, MSM, NKN, NLC, NLO, NON, NVM, OHM, OXN, OXY; Y variable: F or M)

Non-Sterile Disposable Pulse Oximetry (SpO2) Sensor: SENSORPLUS SP06XXX, SP07XXX, SP08XXX, SP09XXX, SP10XXX (XXX variable: 001 to 007; Y variable: 0 or 1)

**Classification:** Class II b Medical Device, Annex IX Rule 10

**GMDN Codes:** 37808, 31658

**Conformity Assessment Procedure:** Annex II-3

*We herewith declare that the above mentioned products meet the Essential requirements and conform to the Medical Device Directive 93/42/EEC with 2007/47/EC amendment.*

## Standards:

EN 60601-1-2:2006/A1:2013	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014 4 <sup>th</sup> Ed.)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 80601-2-61:2019	Medical electrical equipment-Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14971:2012	Medical Devices - Application of risk management to medical devices
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
EN 14698-2:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments - Part 2: Specifications for monitoring and periodic testing to provide continued compliance with ISO 14644-1
EN ISO 14644-3:2005	Cleanrooms and associated controlled environments - Part 3: Test methods
EN ISO 14644-4:2001	Cleanrooms and associated controlled environments - Part 4: Design, construction and start up
ISO 14644-5:2004	Cleanrooms and associated controlled environments - Part 5: Operations
AAMI/ISO 11135:2014	Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 9001:2015	Quality management systems-Requirements
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes

## Notified Body:

Name: KIWA Belgelendirme Hizmetleri A.Ş.  
Address: İTOSB 9. Cadde No:15 Tepeören-Tuzla İstanbul / Turkey  
Identification Number: 1984

**Number of Certificate:** 1984-MDD-10-075

**Start of EC Mark:** 19.11.2004

**Duration of Validity:** 29.05.2020 – 27.05.2024

**Revision Date:** 29.05.2020

## Signature:



**Name:** Filiz ERSOY  
**Position:** Company Manager

Expiry date of declaration is expiry date of CE certificate.