EC-Declaration of Conformity

Manufacturer:

Name	:	METKO Medikal ve Tıbbi Cihazlar Dış Ticaret Ltd. Şti.
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Authorized European Representative:

Name	:	Medset Medizintechnik GmbH
Address	:	Curslacker Neuer Deich 66 D-21029 Hamburg \ Germany
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Product: Pulse Oximetry (SpO2) Sensors

Reference Numbers:

Non- Sterile Reusable Pulse Oximetry (SpO2) Sensors; 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, 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-LM, 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, SPL-L, SW-L, TRS-L, TRT-L, UTS-L)
SENSORPLUS SP01XXXX, SP02XXXX, SP03XXXX, SP04XXXX, SP05XXXX. (XXXX variable: 0001 to 0089)
Sterile Disposable Pulse Oximetry (SpO2) Sensors; FMT-DAF/XXX, FMT-DPF/XXX, FMT-DIF/XXX, FMT-DNF/XXX, FMT-DVF/XXX (XXX variable: BCI, CSI, DTX, MEK, MSD, MSM, NKN, NLC, NLO, NON, NVM, OHM, OXN, OXY)
Non-Sterile Disposable Pulse Oximetry (SpO2) Sensors; SENSORPLUS SP06XXXX, SP07XXXX, SP08XXXX, SP09XXXX, SP10XXXX
(XXXX variable: 0010 to 0071)

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 conforms to the Medical Device Directive 93/42/EEC with Medical Device Directive 2007/47/EC.

Standards:

EN 60601-1:2006	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 4th 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 80601-2-61:2011	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
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-11:2010	Biological evaluation of medical devices - Part 11: Systemic toxicity tests
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
MDD 93/42/EEC	Council Directive 93/42/EEC of 14 June concerning medical devices
MDD 2007/47/EC	Council Directive 2007/47/EC of 5 September 2007 European Parliament concerning medical devices
RoHS 2011/65/EU	Council Directive 2011/65/EU of 8 June 2011 Restriction of the use of certain hazardous substances

Notified Body: **KIWA Certification Services Inc.**
ITOSB 9. Cadde No:15 Tepeören-Tuzla İstanbul / Turkey

EC-Mark: CE 1984

Number of Certificate: 1984-MDD-10-075
Start of EC Mark: 19.11.2004
Duration of Validity: 16.04.2019 – 20.11.2020
Date of issue: 16.04.2019

Signature:

Name: Filiz ERSOY
Position: Company Manager