

EC-Declaration of Conformity

Manufacturer:

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Product: Adaptor & Extension Cable for Pulse Oximetry (SpO2) Sensors, (GMDN Code: 37808)
Adaptor & Extension Cable for Medical Temperature Probes, (GMDN Code: 37340)
Adaptor & Extension Cable for Nebulizer and Flow Sensor, (GMDN Code: 37340)
Adaptor & Extension Cable for Disposable IBP Transducers, (GMDN Code: 36550)

Reference Numbers:

AEC-51XX, AEC-52XX Pulse Oximetry (SpO2) Sensor Adaptor & Extension Cables, (XX variables: 00-99)
FMT400/AEC-XX, FMT400/AEC/Z, FMT400/AEC/Z-E, FMT400/AEC/Z-R, FMT400/AEC/Z-P, FMT400/AEC3-XX,
FMT400/AEC3/Z and FMT400/AEC3/Z-E, FMT400/AEC3/Z-R Temperature Probe Adaptor & Extension Cables,
(XX variables: --, BL, E, EBL, ES, EGE, EGE2, EHP, ESW, EMN, GE, HP, S, SPL, SW, MN, NKN, THT, THT2, MTR, RMMM,
R, RHP, RS, RSW, RGE, RMN, RBL, P, PHP, PS, PSW, PGE, PMN, PBL)
Nebulizer and Flow Sensor Adaptor & Extension Cables AEC-ARG, AEC-ARG/GE, AEC-SLE, AEC-GEEC, AEC-FAB
IBP-YY/ZXX IBP Transducer Adaptor & Extension Cables, (YY variables: 01-10, Z variables: 0-3, XX variables: 01-50)
IBP-ADP/XXX IBP Transducer Adaptor & Extension Cables, (XXX variables: 000-100)

Classification: Class I Medical Device, Annex IX Rule 1

Conformity Assessment Procedure: Annex VII

We herewith declare that the above mentioned products meet the Essential requirements and conforms to the Medical Device Directive 93/42/EEC.

Standards:

EN 60601-1:2006	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
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 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 9001:2015	Quality management systems-Requirements
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes

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Signature:



Name: Filiz ERSOY
Position: Company Manager