EC-Declaration of Conformity

Manufacturer:

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

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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 Disposable IBP Transducers, (GMDN Code: 35946)

Models: AEC-51XX, AEC-52XX Pulse Oximetry (SpO2) Sensor Adaptor & Extension Cables,(XX variables: 00-99)
FMT400/AEC-XX, FMT400/AEC/Z and FMT400/AEC/Z-E
Temperature Probe Adaptor & Extension Cables,
(XX variables:--, BL, E, EBL, ES, EGE, EGE2, EHP, ESW, EMN, GE, HP, S, SPL, SW, MN, NKN,THT)
IBP-YY/XXX IBP Transducer Adaptor & Extension Cables, (YY variables: 01-10, XXX variables: 001-030)
IBP-ADP/XXX IBP Transducer Adaptor & Extension Cables,(XXX variables: 000-999)

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 with Medical Device Directive 2007/47/EC.

Standards:

EN 60601-1-1:2001	Medical electrical equipment, Part 1: General requirements for safety, 1. Collateral standard safety requirements for medical electrical systems
EN ISO 15223-1:2012	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2012	Medical Devices – Application Of Risk Management To Medical Devices
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN ISO 9001:2008	Quality management systems-Requirements
EN ISO 13485:2003	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 Directive2011/65/EU of 8 June 2011 Restriction of the use of certain hazardous substances

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Signature: [redacted]

Name: Filiz ERSOY
Position: Company Manager