

EC-Declaration of Conformity

Manufacturer:

Name : METKO Medikal ve Tıbbi Cihazlar Dış Ticaret Ltd. Şti.
Address : İvedik O. S. B. Ağaç İşleri Sanayi Sitesi 1354 Cad. 1358 Sok. No:9
06378 Yenimahalle - Ankara \ Turkey
Tel : + 90 312 387 12 46 (pbx)
Fax : + 90 312 387 12 51
E-mail : metko@metkold.com
Web : www.metkold.com

Authorized European Representative:

Name : Medset Medizintechnik GmbH
Address : Curslackener Neuer Deich 66 D-21029 Hamburg \ Germany
Tel : 0049 40 725 822- 0
Fax : 0049 40 725 822-11
E-mail : info@medset.com
Web : www.medset.com

Product:

ECG – EKG Cables & Leadwires
ECG Suction & Clamp Electrodes
ECG Adaptors for Cables and Leadwires

Reference Numbers:

E100/XYZ/I, E101/XYZ/I, E103/XYZ/I, E104/XYZ/I, E105/XYZ/I, E106/XYZ/I, E107/XYZ/I, 100/XYZ/A, E101/XYZ/A, E103/XYZ/A, E104/XYZ/A, E105/XYZ/A, E106/XYZ/A and E107/XYZ/A Series **Diagnostic EKG Cables** (X: A to Z; Y: N, R; Z: O, B, G, P and S); E100/MDR/GI, E100/MDR/GA, E100/MDR/SI and E100/MDR/SA **Diagnostic EKG Cables**; E200-YXXX/Z, E201-YXXX/Z, E202-YXXX/Z, E204-YXXX/Z, E205-YXXX/Z, E206-YXXX/Z, E207-YXXX/Z, E208-YXXX/Z and E209-YXXX/Z Series **ECG Cables** (Y: 3, 4, 5, 6; XXX: (000-999); Z: SA, SI, GA, GI, VA, VI, OA, OI); E21-XX, E22-XX, E23-XX, E31-XX, E32-XX, E33-XX, E40-XX, E41-XX, E42-XX, E43-XX, E51-XX, E52-XX, E53-XX, E61-XX, E62-XX, E63-XX, E71-XX, E72-XX, E73-XX, E80-XX, E81-XX, E82-XX, E83-XX, E91-XX, E92-XX and E93-XX Series **ECG Leadwires set** (XX: 3A, 3I, 5A, 5I, 6A, 6I, 3IT, 3AT, 5IT, 5AT, 3AN, 3IN, 5AN, 5IN, 3AM and 3IM); MT32X, MT52X, MT62X Series **ECG Leadwires set** (X: I, A); E21-XX, E22-XX, E23-XX, E31-XX, E32-XX, E33-XX, E41-XX, E42-XX, E43-XX, E51-XX, E52-XX, E53-XX, E61-XX, E62-XX, E63-XX, E71-XX, E72-XX, E73-XX, E81-XX, E82-XX, E83-XX, E91-XX, E92-XX and E93-XX Series **ECG Leadwires** (XX: 0C, 0L, 0R, 0N, 0F, 0V, LA, RA, RL and LL); E32-XX-OR **ECG Leadwires set** (XX: 3I, 3A, 5I, 5A, 3IM, 3AM); E82-XX-OR **ECG Leadwires set** (XX: 3I, 3A); E101XX/10, E102XX/10, E103XX/10, E104XX/10, E105XX/10, E112XX/10, E117XX/10, E118XX/10, E119XX/10, E120XX/10 and E121XX/10 Series **Diagnostic EKG Leadwires set** (XX: BI, SI, GI, PI, BA, SA, GA and PA); E101XX/YY, E102XX/YY, E103XX/YY, E104XX/YY, E105XX/YY, E112XX/YY, E117XX/YY, E118XX/YY, E119XX/YY, E120XX/YY and E121XX/YY Series **Diagnostic EKG Leadwires** (XX: BI, SI, GI, PI, BA, SA, GA and PA), (YY: R, N, F, L, C1, C2, C3, C4, C5, C6, RA, RL, LA, LL, V1, V2, V3, V4, V5, V6, 3A, 3B, 5A, 5B); E106XX/5, E107XX/5, E108XX/5, E109XX/5, E110XX/5, E111XX/5, E113XX/4, E114XX/6 and E122XX/6 Series **Diagnostic EKG Leadwires set** (XX: BI, SI, GI, PI, BA, SA, GA and PA); E110GX/5-OR and E111GX/5-OR **Diagnostic EKG Leadwires set** (X: I, A); HLXXZ-YYZ Series **ECG Holter Leadwires** (XX: 01-20; Z: A, B, C, D, E or empty; YY: 01-20 or empty); SE1, SE2 **ECG Suction Electrode set**, CEAI1, CEAI2, CEAA1, CEAA2 **ECG Clamp Electrodes**, MTM/01 **Multi Parameter Cable**, BS3, BS4, BG3, BG4, BA4 **ECG Adaptors**

Classification: Class I Medical Device, Annex IX Rule 1

Conformity Assessment Procedure: Annex VII

GMDN Code: 35562

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
ANSI/AAMI EC53:2013	ECG Trunk cables and leadwires
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

Date of issue: 05.02.2020

Signature:

Name: Filiz ERSOY
Position: Company Manager