EU Medical Device Regulation 2017/745 Declaration of Conformity

Manufacturer:
Name : Metko Medikal ve Tıbbi Cihazlar Dış Ticaret Sanayi A.Ş.
Address : İvedik O. S. B. Ağaç İşleri Sanayi Sitesi 1354 Cad. 1358 Sok. No:9
06378 Yenimahalle - Ankara / Türkiye
Tel : + 90 312 387 12 46 (pbx)
Fax : + 90 312 387 12 51
E-mail : metko@metkoltd.com
Web : www.metkoltd.com
SRN : TR-MF-000022486

Product Name: ECG – EKG Cables & Leadwires (GMDN Code: 35562)
ECG Suction & Clamp Electrodes (GMDN Code: 35562)
ECG Adaptors for Cables and Leadwires (GMDN Code: 35562)

Reference Numbers/Product Code:
E100/XYZ/I, E101/XYZ/I, E103/XYZ/I, E104/XYZ/I, E105/XYZ/I, E106/XYZ/I, E107/XYZ/I, E100/XYZ/A, E101/XYZ/A, E103/XYZ/A, E104/XYZ/A, E105/XYZ/A, E106/XYZ/A and E107/XYZ/A Series **FMT Diagnostic EKG Cables** (X: A to Z; Y: N, R; Z: 0, B, G, P and S); E100/MDR/GI, E100/MDR/GA, E100/MDR/SI and E100/MDR/SA **FMT 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 **FMT ECG Cables** (Y: 3, 4, 5, 6; XXX: (000-999); Z: SA, SI, GA, GI, VA, VI, 0A, 0I); 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 **FMT 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 **FMT 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 **FMT ECG Leadwires** (XX: 0C, 0L, 0R, 0N, 0F, 0V, LA, RA, RL and LL); E32-XX-OR **FMT ECG Leadwires set** (XX: 3I, 3A, 5I, 5A, 3IM, 3AM); E82-XX-OR **FMT 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 **FMT 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 **FMT 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 **FMT Diagnostic EKG Leadwires set** (XX: BI, SI, GI, PI, BA, SA, GA and PA); E110GX/5-OR and E111GX/5-OR **FMT Diagnostic EKG Leadwires set** (X: I, A); HLXXZ-YYZ Series **FMT ECG Holter Leadwires** (XX: 01-20; Z: A, B, C, D, E or empty; YY: 01-20 or empty); SE1, SE2 **FMT ECG Suction Electrode set**, CEAI1, CEAI2, CEAA1, CEAA2 **FMT ECG Clamp Electrodes**, MTM/01 **FMT Multi Parameter Cable**, BS3, BS4, BG3I/10, BG3A/10, BG4/10, BA4 **FMT ECG Adaptors**, AXXXXXX Series **SensorPlus Diagnostic EKG Cables** (X: 0-9), BXXXXXX Series **SensorPlus ECG Cables** (X: 0-9), LXXXX Series **SensorPlus ECG Leadwires set** (X: 0-9)

Intended Purpose: EKG/ECG cables, leadwires and accessories are used to convey electrocardiographic signals of a patient to the related medical equipment.
Classification Rule: Class I Medical Device, Annex VIII, Chapter 3, Rule 1
Conformity Assessment Procedure: Section II Article 52 (7) of Regulation (EU) 2017/745
Basic UDI-DI: 86988703ECGEKGCABLEADPXV

As Metko Medikal ve Tıbbi Cihazlar Dış Ticaret Sanayi A.Ş. company, we declare under our sole responsibility that the devices covered by this declaration comply with the Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices and that the requirements specified in the Regulation are fulfilled for these devices. The declaration of conformity has been prepared in accordance with Annex IV of MDR 2017/745.

Common Specifications / Standards:

EN 60601-1:2006/A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
ANSI/AAMI EC53:2013	ECG Trunk cables and leadwires
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO 24971:2020	Medical devices - Guidance on the application of ISO 14971
EN 62366-1:2015/A1:2020	Medical devices - Part 1: 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

Signed by / Signature: Filiz ERSOY

Position: Company Manager

Place and Date of issue: Ankara / Türkiye, 27.02.2023