

EU Medical Device Regulation 2017/745 Declaration of Conformity

Manufacturer:

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SRN : TR-MF-000022486

Product Name: Electrosurgery Cables & Accessories

Electrosurgery High Frequency Bipolar Cables, (GMDN Code: 35041)
Electrosurgery High Frequency Monopolar Cables, (GMDN Code: 61876)
Electrosurgery Dispersive Cables, (GMDN Code: 35041)
Electrosurgery Bipolar Adaptors, (GMDN Code: 35041)
Electrosurgery Reusable Grounding Pads, (GMDN Code: 42551)
Electrosurgery Reusable Connection Cable for Universal Patient Return Electrodes, (GMDN Code: 35041)

Reference Numbers/Product Code:

ESU-BP/XXY Series, ESU-BP/CONA, ESU-BP/OWE, ESU-BP/FWE, ESU-BP/BWE, ESU-BP/LWE, ESU-BP/GYR,
ESU-BP/GYRL (XX variables: AA to ZZ; Y variables: -, L, T, TL)
ESU-MP/XXY Series (XX variables: AA to ZZ; Y variables: -, L)
RDC-XXY Series (X variables: A to Z; Y variables: 3, 5, 3A and 5A)
ESU-ADP/XX Series (XX variables: 01 to 10)
RGPC-XX Series (XX variables: 00 to 99)
FMT-RGPX Series (X variable: B, M)
FMT-MDX/YY (X variables: 1 to 9, YY variables: -, 24, 44)

Intended Purpose: FMT electrosurgical cables, adaptors and accessories are used to connect electrosurgical instruments/ accessories to HF generators and cables.

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: 86988703ESUCABLEACCESSTT

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, EN 60601-1-2:2015, EN IEC 60601-2-2:2018, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 17664-1:2021, EN ISO 14155:2020, EN ISO 14971:2019/A11:2021, ISO 24971:2020, EN 62366-1:2015/A1:2020, EN ISO 9001:2015, EN ISO 13485:2016/A11:2021

Signed by / Signature: Filiz ERSOY



Position: Company Manager

Place and Date of issue: Ankara / Türkiye, 26.01.2024