 Tecno Instruments (Pvt) Ltd.	<b>EU Declaration of Conformity (Monopolar &amp; Bipolar Cables)</b>	Document No.	EDOC-TE-4.1
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## EU DECLARATION OF CONFORMITY

We, Tecno Instruments (Pvt) Ltd., hereby under our sole responsibility declares that below mentioned medical device(s) manufactured by us have been classified according to the classification rules stated in the Chapter III of Annex –VIII and conform to the General Safety and Performance Requirements as laid out in the Annex-I of the (EU) 2017/745 as amended by 2020/561 and the CE marking may be affixed.

**Device(s) Name:**

Monopolar and Bipolar Cables (non-sterile & reusable).

**Device(s) Classification:**

Class I according to Rule 1 of Chapter III in Annex-VIII, (EU) 2017/745.

**Conformity Assessment procedure:**

Annex II, Annex III, Article 19 and Annex IV.

**Single Registration Number (SRN):**

(Will be achieved soon)

**Basic Unique Device(s) Identification (UDI-DI):**

8964001339190-EBC-EMCPU


**European Medical Device(s) Nomenclature (EMDN):**

EMDN Code	EMDN Description
K02010203	Monopolar and Bipolar Cables

**Product List:**

Sr. #	GMDN Code(s)	Product(s) name	Classification Rationale as per EU MDR 2017/745	Risk Class	Product Code / Catalogue #
1	47487	Monopolar and Bipolar Cables	Rule 1 of Chapter III in Annex-VIII, (EU) 2017/745	I	Appendix L

Tecno Ins. Code	Gima Code	italian description	English description
190-185	30315	CAVO BIPOLARE ETHICON SILICONE, 3 m , per 30310	ETHICON SILICONE BIPOLAR CABLE 3 m for 30310
190-180	30325	CAVO BIPOLARE SILICONE, 3 m , per 30320	SILICONE BIPOLAR ARTERY SEALER CABLE 3 m for 30320
190-250	30609	CAVO MONOPOLARE 4 mm - M-F	MONOPOLAR CABLE - 4 mm M-F for Laparoscopic electr
190-118	30617	CAVO BIPOLARE EU PER MB 80D-120D-160D	EU BIPOLAR CABLE FOR MB 80D-120D-160D
190-100	30618	CAVO BIPOLARE US 2pin per MB 240-380	US BIPOLAR CABLE FOR MB 240-380
190-110	30632	CAVO BIPOLARE EU PER MB 240-380	EU BIPOLAR CABLE FOR MB 240-380
190-170	30637	CAVO BIPOLARE ATTACCO US per MB 120F-200D/F-250-300D-400-400D	US BIPOLAR CABLE for MB 120F-200D/F-250-300D-400-4
190-140	30638	CAVO BIPOLARE PER ERBE	EU BIPOLAR CABLE for ERBE
190-120	30639	CAVO BIPOLARE PER MARTIN	EU BIPOLAR CABLE for MARTIN
190-160	30640	CAVO BIPOLARE ATTACCO EU per MB 120F-200D/F250-300D-400-400D	EU BIPOLAR CABLE for MB 120F-200D/F-250-300D-400-4
190-119	30643	CAVO BIPOLARE EU 2 pin per MB122-132-160-200-202	EU BIPOLAR CABLE 2 PINS for MB 122-132-160-200-202
190-109	30644	CAVO BIPOLARE US PER MB120D-160D	US BIPOLAR CABLE for MB 120D-160D

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**Intended Purpose(s):**

Monopolar and Bipolar Cables are designed to transfer HF electrical current from the output of ES generator to the instrument.

When combining with other electrosurgical device(s), ensure that the output parameters of the electrosurgical generator do not exceed the rated voltage of the cable. Use only with compatible electrosurgical generators and instruments. The connectivity depends on the specific types of

We have prepared and maintained technical documentation for each device(s) as required by Annex II & III of (EU) 2017/745 as amended by 2020/561. The records are maintained for 10 years.

**We have designated an EU Authorized Representative (EUAR):**

**CMC MEDICAL DEVICES & DRUGS, S.L**

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C. P 29006

Málaga-Spain

**Phone:** +34 951 214 054

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**Notified Body Details: Not Applicable**

**Signed for and on behalf of: TECNO INSTRUMENTS (PVT) LTD.**



Name: Haseeb Bhatti

Designation: Marketing Director

Place of Issue: 316-C, S.I.E., Sialkot - Pakistan

Date of Issue: March 01, 2023