

 Tecno Instruments (Pvt) Ltd.	<b>EU Declaration of Conformity</b>	Document No.	EDOC-TE-4.1
		Revision No.	02
		Page	1 of 2
		Date	March 08, 2024

## EU DECLARATION OF CONFORMITY

We,  
**TECNO INSTRUMENT (PVT) LTD.**

**316-C, S.I.E. Sialkot - Pakistan**

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 MDR 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 MDR 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 MDR 2017/745	I	Appendix L

Tecno Ins.Code	Gima Code	Italian Description	English Description
190-185	30315	CAVO BIPOLAR ETHICON SILICON, 3m, per 30310	ETHICON SILICON BIPOLAR CABLE 3m for 30310
190-180	30325	CAVO BIPOLAR SILICONE,3m, per 30320	SILICON BIPOLAR ARTERY SEALER CABLE 3m for 30320
190-250	30609	CAVO MONOPOLAR 4mm-M-F	MONOPOLAR CABLE-4MM m-f For Laparoscopic electr
190-118	30617	CAVO BIPOLAR EU PER MB 80D-120D-160D	EU BIPOLAR CABLE FOR MB 80D-120D-160D
190-100	30618	CAVO BIPOLAR US 2pin per MB 240-380	US BIPOLAR CABLE FOR MB 240-380
190-110	30632	CAVO BIPOLAR EU PER MB 240-380	EU BIPOLAR CABLE FOR MB 240-380
190-170	30637	CAVO BIPOLAR ATTACCO US per MB 120F-200D/F-250-300D-400-400D	EU BIPOLAR CABLE for MB 120F-200D/F-250-300D-400-4
190-140	30638	CAVO BIPOLAR PER ERBE	EU BIPOLAR CABLE for ERBE
190-120	30639	CAVO BIPOLAR PER MARTIN	EU BIPOLAR CABLE for MARTIN
190-160	30640	CAVO BIPOLAR ATTACCO EU per MB 120F-200D/F250-300D-400-400D	EU BIPOLAR CABLE for MB 120F-200D/F-250-300D-400-4

Tecno Instruments (Pvt) Ltd.  
316-C, Small Industrial Estate  
Sialkot-51340 ( Pakistan )

Tel: +92 52 3552723  
+92 52 3552681

Fax: +92 52 3552396  
+92 52 4588135

Email: info@tecno.com.pk  
Website: www.tecno.com.pk



 Tecno Instruments (Pvt) Ltd.	<b>EU Declaration of Conformity</b>	Document No.	EDOC-TE-4.1
		Revision No.	02
		Page	2 of 2
		Date	March 08, 2024

190-119	30643	CAVO BIPOLAR EU 2 pin MB1122-132-160-200-202	EU BIPOLAR CABLE 2 PINS for MB 122-132-160-200-202
190-109	30644	CAVO BIPOLAR US PER MB120D-160D	US BIPOLAR CABLE for MB 120D-160D
190-260	30610	CAVO MONOPOLARE PER MB	Monopolar cable 4mm - banana plug- L= 3m

#### 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 connectors, both on the generator side and the instrument side.

We have prepared and maintained technical documentation for each device(s) as required by Annex II & III of EU MDR 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

C/ Horacio Lengon18

C. P 29006

Málaga-Spain

Phone: +34 951 214 054

Email: [info@cmcmmedicaldevices.com](mailto:info@cmcmmedicaldevices.com)

#### Notified Body Details: Not Applicable

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



Name: Haseeb Bhatti

Designation: Marketing Director

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

Date of Issue: March 08, 2024