

EC DECLARATION OF CONFORMITY

Tecno Instruments (Pvt) Ltd. declares that the medical devices range described hereafter include Electrosurgical Instruments & accessories as mentioned in CE Certificate Nr. PK19/818842627 valid until 13 March, 2023

Gima code	Tecno code	Description
30553	150-100	Single use PENCIL-FINGER SWITCH-STERILE
		MONOPOLAR FORCEPS
30611	330-110	STRAIGHT Mc Indoe 15cm
30612	330-154-20	BAYONET 19cm
30613	330-220	MONOPOLAR SCISSORS 17,8cm
30614	330-200	MONOPOLAR SCISSORS METZEMBAUM STRAIGHT 17,8cm
30615	330-202	MONOPOLAR SCISSORS METZEMBAUM CURVED 17,8cm
		BIPOLAR CABLES
30617	190-119	BIP. CABLES WITH ADAPTOR GIMA-PLUG 3MT. EU-new connec.
30618	190-100	BIP. CABLE US - BANANA (old model / 2 pins)
30637	190-170	BIP. CABLE US - BANANA -PLUG- new connec.
30638	190-140	BIP. CABLE EU – TYPE ERBE
30639	190-120	BIP. CABLE EU – TYPE MARTIN
30640	190-160	BIP. CABLE -BANANA- PLUG 3 MT. EU- new connec.
30632	190-110	BIP. CABLE -BANANA- (old model / 2 pins) 3 MT. EU
30643	190-119	BIP. CABLE with Gima adaptor EU (old model / 2 pins)
30644	190-109	BIP. CABLE with Gima adaptor -PLUG 3MT. US-new connec.
30609	190-250	MONOPOLAR CABLE endoscopic 4mm female for x laparo/electrode + diatermo
		BIPOLAR FORCEPS
30620	110-200-10	ADSON 12,1 cm - punta 1 mm - US connector
30621	110-220-05	SEMKIN 14 cm - punta 0.5 mm - US connector
30622	110-230-10	CUSHING 15.9 CM - punta 1 mm - US connector
30623	110-360-10	JANSEN BAYONET 17.8 cm - punta 1mm - US connector
30645	310-560	BIPOLAR ELECTRODE BINNER ANGLED 22cm
30646	310-500	BIPOLAR ELECTRODE BINNER STRAIGHT 18cm
30647	310-540	BIPOLAR ELECTRODE BINNER ANGLED 18cm
30648	310-590	BIPOLAR ELECTRODE BINNER ANGLED 45° 19cm
30650	310-130-10	STRAIGHT-18 cm. Round tips 1mm - EU connector
30651	310-140-10	STRAIGHT 20 cm. Round tips 1mm - EU connector
30652	310-132-10	CURVED 18 cm. Round tips 1mm - EU connector
30653	310-142-10	CURVED 20 cm round tips 1mm - EU connector
30654	310-170-10	BAYONET 18 cm round tips 1 mm - EU connector
30655	310-180-10	BAYONET 20 cm round tips 1 mm - EU connector
30656	310-130-10IR	STRAIGHT with irrigation 18 cm – straight tips 1 mm - EU connector
30657	310-160-10	BAYONET 16,5cm – TIPS 1mm - EU connector
30658	310-140-20	STRAIGHT 20 cm – TIPS 2 mm (customzied) - EU connector
30659	310-190-10	BAYONET 22cm-TIPS 1mm - EU connector

30660	310-132-03	CURVED 18 cm sharp tips 0,3 mm - EU connector
30661	310-130-03	STRAIGHT 18 cm. Sharp tips 0,3 mm. - EU connector
30662	310-140-03	STRAIGHT 20 cm sharp tips 0,3 mm. - EU connector
30663	310-200-10	BAYONET 24cm – tips 1 mm -EU connector
30664	310-300-10	ADSON 12,1cm – tips 1mm - EU connector
30665	310-110-03	STRAIGHT 11,5 cm sharp tips 0,25 mm. Jeweler #5 - EU conn.
30666	310-112-03	CURVED 11,5 cm sharp tips 0,25 mm. Jeweler #5 - EU conn.
30667	310-120-05	STRAIGHT 15 cm sharp tips 0,5 mm. - EU connector
30668	310-122-05	CURVED 15 cm sharp tips 0,5 mm. - EU connector
30669	310-100-05	MC PHERSON STRAIGHT 10.2cm – straight tips 0,5 cm - EU conn.
		NON-STICK BIPOLAR FORCEPS - EU connector
30460	310-120-01 NS	STRAIGHT 15 cm. 1mm.
30461	310-130-10 NS	STRAIGHT 18 cm. 1mm.
30462	310-140-10 NS	STRAIGHT 20 cm. 1mm.
30464	310-132-10 NS	STRAIGHT (angled tips) 18 cm. 1mm.
30465	310-142-10 NS	STRAIGHT (angled tips) 20 cm. 1mm.
30468	310-170-10 NS	BAYONET 18cm. 1mm.
30469	310-180-10 NS	BAYONET 20cm. 1mm.
30472	310-110-07 NS	JEWELER #5 11,5cm. 0,7mm.
30473	310-112-07 NS	JEWELER #5 (angled tips) 11,5cm. 0,7mm.
30474	310-300-10 NS	ADSON 12,1 cm. 1mm.
		ELETTRODI
30605	150-200	LAPAROSCOPIC ELECTRODE - HOOK L 36cm
30606	150-210	LAPAROSCOPIC ELECTRODE - HOOK J 36cm
30607	150-230	LAPAROSCOPIC ELECTRODE – SPATULA 36cm
30678	150-180-08	LOOP ELECTRODE disposable 15x8mm sterile-box 10 pcs
		Loop electrode reusable (NON STERILI)- 20 CYCLES at 134°C
30686	152-170-08	SQUARE LOOP 10x8mm –L=13 cm.
30687	152-180-08	LOOP 15x8mm – L=13 cm.
30688	152-190-10	LOOP 20x10mm – L= 13 cm.
		NON STICK ELECTRODE Ø 2,4mm – DISPOSABLE (STERILE)
30420	150-110-07 NS	BLADE ELECTRODE 7cm
30422	151-110-10 NS	BLADE ELECTRODE 10cm
30425	151-120-10 NS	NEEDLE ELECTRODE 10cm
30429	151-160-13 NS	BALL ELECTRODE 13cm

Have been classified as Class IIb (Annex IX, Rule 9) and are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC

And are in conformity with the national standards transposing harmonized standards, EN ISO 13485:2016, EN ISO 11135:2014, EN ISO 15223-1:2016 & EN 1041:2008 +A1:2013.

And are subject to the procedure set out in the Annex II of the Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of Notified Body Number 1639, SGS Belgium NV, SGS House Noorderlaan 87, 2030 Antwerp, Belgium.

CE Certificate # PK19/818842627



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Best Regards,

A handwritten signature in black ink, reading 'Haseeb A. Bhatti', is written over a circular blue stamp. The stamp contains the text 'INSTRUMENTS (PVT) LTD.', 'SIALKOT', and '51340'.

Haseeb A. Bhatti
Sialkot (Pakistan)
Date: June 30, 2020