



Tecno Instruments (Pvt) Ltd.

## EU Declaration of Conformity

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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 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.

Tecno Ins. Code	Gima Code	italian description	English description
415-110-07	30300	PINZA JEWELER MONOUSO 11,5 cm con cavo 3 metri - punta 0,5 mm	DISPOSABLE JEWELER FORCEPS 11.5 cm with 3 m cable
415-140-10	30302	PINZA RETTA MONOUSO 20 cm con cavo 3 metri - punta 1,0 mm	DISPOSABLE STRAIGHT FORCEPS 20 cm with 3 m cable -
415-122-10	30304	PINZA RETTA MONOUSO 15 cm con cavo 3 metri - punta angolata 1,0 mm	DISPOSABLE STRAIGHT FORCEPS 15 cm with 3 m cable -
415-180-10	30306	PINZA A BAIONETTA MONOUSO 20 cm con cavo 3 metri - punta 1,0 mm	DISPOSABLE BAYONET FORCEPS 20 cm with 3 m cable -
110-815-18	30310	FORBICI BIPOLARI MONOUSO 18 cm - curve	BIPOLAR SCISSORS 18 cm - curved
110-750	30320	PINZA BIPOLARE SALDATURE 26 cm	BIPOLAR ARTERY SEALER 26 cm
170-120-05	30370	ELETTRODO AD AGO IN TUNGSTENO 5 cm - dritto - monouso	TUNGSTEN NEEDLE ELECTRODE 5 cm - straight - dispos
170-122-05	30371	ELETTRODO AD AGO IN TUNGSTENO 5 cm - angolato - monouso	TUNGSTEN NEEDLE ELECTRODE 5 cm - angled - disposab
170-120-06	30372	ELETTRODO AD AGO IN TUNGSTENO 6 cm - dritto - monouso	TUNGSTEN NEEDLE ELECTRODE 6 cm - straight - dispos
170-122-06	30373	ELETTRODO AD AGO IN TUNGSTENO 6 cm - angolato - monouso	TUNGSTEN NEEDLE ELECTRODE 6 cm - angled - disposab
170-120-07	30374	ELETTRODO AD AGO IN TUNGSTENO 7 cm - dritto - monouso	TUNGSTEN NEEDLE ELECTRODE 7 cm - straight - dispos
170-122-07	30375	ELETTRODO AD AGO IN TUNGSTENO 7 cm - angolato - monouso	TUNGSTEN NEEDLE ELECTRODE 7 cm - angled - disposab
150-110-07 NS	30420	ELETTRODO NON-STICK A LAMA - 7 cm - sterile	NON-STICK BLADE ELECTRODE - 7 cm - sterile
151-110-10 NS	30422	ELETTRODO NON-STICK A LAMA - 10 cm - sterile	NON-STICK BLADE ELECTRODE - 10 cm - sterile
151-120-10 NS	30425	ELETTRODO NON-STICK AD AGO - 10 cm - sterile	NON-STICK NEEDLE ELECTRODE - 10 cm - sterile
151-160-13 NS	30429	ELETTRODO NON-STICK A SFERA - 13 cm - sterile	NON-STICK BALL ELECTRODE - 13 cm - sterile
310-120-10NS	30460	PINZA "NON STICK" RETTA - 15 cm - punte 1 mm	EU NON-STICK STRAIGHT FORCEPS 15 cm - 1 mm point
310-130-10NS	30461	PINZA "NON STICK" RETTA - 18 cm - punte 1 mm	EU NON-STICK STRAIGHT FORCEPS 18 cm - 1 mm point
310-140-10NS	30462	PINZA "NON STICK" RETTA - 20 cm - punte 1 mm	EU NON-STICK STRAIGHT FORCEPS 20 cm - 1 mm point
310-132-10NS	30464	PINZA "NON STICK" RETTA - 18 cm - punte angolate 1 mm	EU NON-STICK STRAIGHT FORCEPS 18 cm - angled 1 mm
310-142-10NS	30465	PINZA "NON STICK" RETTA - 20 cm - punte angolate 1 mm	EU NON-STICK STRAIGHT FORCEPS 20 cm - angled 1 mm
310-170-10NS	30468	PINZA "NON STICK" BAIONETTA - 18 cm - punte 1 mm	EU NON-STICK BAYONET FORCEPS 18 cm - 1 mm point
310-180-10NS	30469	PINZA "NON STICK" BAIONETTA - 20 cm - punte 1 mm	EU NON-STICK BAYONET FORCEPS 20 cm - 1 mm point
310-110-07NS	30472	PINZA "NON STICK" JEWELLER - 11,5 cm - punte 0,7 mm	EU NON-STICK JEWELLER FORCEPS 11.5 cm - 0.7 mm poi
310-112-07NS	30473	PINZA "NON STICK" JEWELLER - 11,5 cm - punte angolate 0,7 mm	EU NON-STICK JEWELLER FORCEPS 11.5 cm - angled 0.7
310-300-10NS	30474	PINZA "NON STICK" ADSON - 12,1 cm - punte 1 mm	EU NON-STICK ADSON FORCEPS 12.1 cm - 1 mm point
150-100	30553	MANIPOLO MB MONOUSO	GIMA SINGLE USE MB HANDLE - sterile
150-200-36	30605	ELETTRODO LAPAROSCOPIA UNCINO L - 36 cm	L-HOOK LAPAROSCOPIC ELECTRODE - 36 cm
150-210-36	30606	ELETTRODO LAPAROSCOPIA UNCINO J - 36 cm	J-HOOK LAPAROSCOPIC ELECTRODE - 36 cm
150-230-36	30607	ELETTRODO LAPAROSCOPIA SPATULA - 36 cm	SPATULA LAPAROSCOPIC ELECTRODE - 36 cm
330-110-10	30611	PINZA MONOPOLARE RETTA - 15 cm	STRAIGHT MONOPOLAR FORCEPS - 19 cm
330-154-20	30612	PINZA MONOPOLARE A BAIONETTA - 21 cm	LONG-NOSE MONOPOLAR FORCEPS - 21 cm
330-220	30613	FORBICE MONOPOLARE - 18 cm	MONOPOLAR SCISSORS - 18 cm
330-200	30614	FORBICE MONOPOLARE METZENBAUM retta - 18 cm	METZENBAUM MONOPOLAR SCISSORS - straight - 18 cm
330-202	30615	FORBICE MONOPOLARE METZENBAUM curva - 18 cm	METZENBAUM MONOPOLAR SCISSORS - curved - 18 cm
110-200-10	30620	PINZA BIPOLARE ADSON - 12,1 cm	US ADSON FORCEPS 12,1 cm
110-220-05	30621	PINZA BIPOLARE SEMKIN - 14 cm	US SEMKIN FORCEPS 14 cm
110-230-10	30622	PINZA BIPOLARE CUSHING - 15,9 cm	US CUSHING FORCEPS 15.9 cm
110-360-10	30623	PINZA BIPOLARE JANSEN BAYONET - 17,8 cm	US JANSEN BAYONET FORCEPS 17.8 cm



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310-560	30645	PINZA BIPOLARE BINNER - 22cm angolata	EU BINNER FORCEPS 22 cm - angled
310-500	30646	PINZA BIPOLARE BINNER RETTA - 18 cm	EU BINNER FORCEPS 18 cm - straight
310-540	30647	PINZA BIPOLARE BINNER ANGOLATA - 18 cm	EU BINNER FORCEPS 18 cm - angled
310-590	30648	PINZA BIPOLARE BINNER ANGOLATA 45° - 19 cm	EU BINNER FORCEPS 19 cm - angled 45°
	30649	DISPONIBILI SU RICHIESTA ALTRI MODELLI DI PINZA BIPOLARI (minimo 25 pe)	OTHER MODELS OF EU/US BIPOLAR FORCEPS AVAILABLE ON
310-130-10	30650	PINZA BIPOLARE RETTA 18 cm - punte 1 mm	EU STRAIGHT FORCEPS 18 cm - 1 mm point
310-140-10	30651	PINZA BIPOLARE RETTA 20 cm - punte 1 mm	EU STRAIGHT FORCEPS 20 cm - 1 mm point
310-132-10	30652	PINZA BIPOLARE CURVA 18 cm - punte 1 mm	EU STRAIGHT FORCEPS 18 cm - angled 1 mm point
310-142-10	30653	PINZA BIPOLARE CURVA 20 cm - punte 1 mm	EU STRAIGHT FORCEPS 20 cm - angled 1 mm point
310-170-10	30654	PINZA BIPOLARE BAIONETTA 18 cm - punte 1 mm	EU BAYONET FORCEPS 18 cm - 1 mm point
310-180-10	30655	PINZA BIPOLARE BAIONETTA 20 cm - punte 1 mm	EU BAYONET FORCEPS 20 cm - 1 mm point
310-130-10IR	30656	PINZA BIPOLARE RETTA 18 cm - irrigazione	EU STRAIGHT FORCEPS 18 cm - irrigation
310-160-10	30657	PINZA BIPOLARE BAIONETTA 16,5 cm - punte 1 mm	EU BAYONET FORCEPS 16.5 cm - 1 mm point
310-140-20	30658	PINZA BIPOLARE RETTA 20 cm - 2 mm	EU STRAIGHT FORCEPS 20 cm - 2 mm point
310-190-10	30659	PINZA BIPOLARE BAIONETTA 22 cm - punte 1 mm	EU BAYONET FORCEPS 22 cm - 1 mm point
310-132-03	30660	PINZA BIPOLARE CURVA 18 cm - punte 0,3 mm	EU STRAIGHT FORCEPS 18 cm - angled 0.3 mm point
310-130-03	30661	PINZA BIPOLARE RETTA 18 cm - punte 0,3 mm	EU STRAIGHT FORCEPS 18 cm - 0.3 mm point
310-140-03	30662	PINZA BIPOLARE RETTA 20 cm - punte 0,3 mm	EU STRAIGHT FORCEPS 20 cm - 0.3 mm point
310-200-10	30663	PINZA BIPOLARE BAIONETTA 24 cm - punte 1 mm	EU BAYONET FORCEPS 24 cm - 1 mm point
310-300-10	30664	PINZA ADSON 12,1 cm	EU ADSON FORCEPS 12.1 cm
310-110-03	30665	PINZA BIPOLARE RETTA 11,50 cm - punte 0,25 mm	EU JEWELER FORCEPS 11.5 cm - straight 0.25 mm poin
310-112-03	30666	PINZA BIPOLARE CURVA 11,50 cm - punte 0,25 mm	EU JEWELER FORCEPS 11.5 cm - angled 0.25 mm point
310-120-05	30667	PINZA BIPOLARE RETTA 15 cm - punte rette 0,5 mm	EU STRAIGHT FORCEPS 15 cm - straight 0.5 mm point
310-122-03	30668	PINZA BIPOLARE RETTA 15 cm - punte curve 0,5 mm	EU STRAIGHT FORCEPS 15 cm - angled 0.5 mm point
310-100-05	30669	PINZA MC-PHERSON 10,2 cm	EU MC-PHERSON FORCEPS 10,2 cm - straight 0.5 mm po
150-170-08	30677	ELETTRODO LOOP QUADRATO 10 x 8 - monouso sterile	SQUARE LOOP ELECTRODE 10 x 8 mm - disposable - ste
150-180-08	30678	ELETTRODO LOOP 15 x 8 - monouso sterile	LOOP ELECTRODE 15 x 8 mm - disposable - sterile
150-190-10	30679	ELETTRODO LOOP 20 x 10 - monouso sterile	LOOP ELECTRODE 20 x 10 mm - disposable - sterile
152-170-08	30686	ELETTRODO LOOP QUADRATO 10 x 8 - autoclavabile	SQUARE LOOP ELECTRODE 10 x 8 mm - autoclavable
152-180-08	30687	ELETTRODO LOOP 15 x 8 mm - autoclavabile	LOOP ELECTRODE 15 x 8 mm - autoclavable
152-190-10	30688	ELETTRODO LOOP 20 x 10 mm - autoclavabile	LOOP ELECTRODE 20 x 10 mm - autoclavable

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**Classification of Device(s):** Class IIb

**Intended Use:** The devices are intended for cutting and coagulation of tissues by use of high-frequency electrical current.

The products declared in above are in compliance to applicable standards and common specifications that are harmonized by Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

The conformity assessment procedure as per Annex II of MDD 93/42/EEC as amended by Directive 2007/47/EC and EN ISO 13485:2016 are performed and certificated by “Notified Body SGS Belgium NV, Notified Body 1639, SGS House Noorderlaan 87 2030 Antwerp Belgium” and “SGS United Kingdom Ltd, certification body UKAS accredited, Rossmore Business Park Ellesmere Port Cheshire CH65 3 EN UK” respectively.

<b>Conformity Assessment Procedure</b>	Annex II – Excluding design
<b>Certificates:</b> CE Certificate	PK19/818842627 valid till 24 May 2024
EN ISO 13485:2016	PK00/51863 valid till 13 March, 2024

This declaration is effective for products placed on the market as of the date of issue. Any modifications of the medical device not authorized by Tecno Instruments Pvt (Ltd.) will invalidate this declaration.

<p><b>Manufacturer:</b>  <b>Tecno Instruments (Pvt) Ltd.</b>  <b>Address:</b> 316-C Small Industrial Estate          Sialkot-51340, Pakistan.          Tel: + 92 52 355 2723          Email: <a href="mailto:info@tecno.com.pk">info@tecno.com.pk</a></p>
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<p><b>Authorized EU Representative:</b>  <b>Obelis s.a</b>  <b>Address:</b> Bd. General Wahis 53          B- 1030, Brussels (BELGIUM),          Tel: +32(0)2 7325954</p>
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Best Regards,



Haseeb A. Bhatti  
(Marketing Director)

Date & Place of Issue: Jan. 20, 2023. Sialkot, Pakistan.