

	<b>Company Name: Cosil Instruments Company</b>	<b>Doc. # TFER-01-02/02</b>	<b>Issue 03</b>	
	EC Declaration of Conformity: Sterile/Non Sterile Single Use and Non Sterile Reusable Electrosurgical Bipolar Forceps with/without cable			
	Review Date: 21, May, 2021	Page 1 of 1 (Revised / Prepared by: QA Manager: NT)		
	<b>Revision History</b>		<b>Revision History</b>	
	Revision Level 01 – Change of Notified Body Number	Revision Level 03 - CPFD Series Added (Irrigation BF)		
Revision Level 02 – Product variants added in <b>Annex A-I</b>				

### European Communities Council Directive 93/42/EEC Concerning Medical Devices

The undersigned declares that the product named in this document meets the Essential requirements of Council Directive provisions that apply to it and the CE Mark may be affixed.

<b>Device Name:</b>	Sterile/Non Sterile Single Use and Non Sterile Reusable Electrosurgical Bipolar Forceps with/without cable
<b>MDD Classification</b>	Class: IIb and Rule: 09 according to annexure IX of MDD 93/42/EEC All active therapeutic devices intended to administer or exchange energy are in Class IIb (Electrical Energy), Electrosurgical Devices.
<b>Applicable Standards</b>	ISO 13485:2016, ISO14971:2019, EN 980:2008, EN ISO15223-1:2016, EN 1041:2008+A1:2013, BS EN 60601-1-11: 2015, IEC 60601-1-2:2014, IEC 60601-2-2:2017, ISO 11135:2014, BS EN ISO 11138-2:2017, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-7:2008, BS EN ISO 14644-1:2015, EN ISO 11607-1:2020, ISO EN 14644-1:2015
<b>Notified Body:</b>	<b>SGS</b> Belgium NV, SGS House Noorderlaan 87 2030 Country : Belgium Phone : +32 (0)3 545-48-48 Fax : +32 (0)3 545-48-49 Website: www.sgs.com
<b>Assessment Route:</b>	MDD Annex II (Fully Quality Assurance) Declaration Conformity
<b>Biocompatibility:</b>	Stainless Steel and Polymers used are biocompatible as per the requirement of table 1 of the ISO 10993-1:2009.
<b>GMDN Code:</b>	<b>56296</b> A device covered with a sheath of electrical insulation, except at the distal working tips, designed for use in open surgery for the coagulation of vessels or tissue bundles to prevent bleeding. It is connected to either an electrosurgical diathermy or an electrocautery generator which provides the bipolar electrical current to the device. It is typically constructed as: 1) a long, tweezers-like instrument with tapered, flat, blades which are closed by the surgeon applying pressure to the conjoined legs; or 2) a scissors-like instrument with long, curved, clamp-like blades. It is made of metal and synthetic materials in a variety of shapes and sizes.
<b>SGS MDD Certificate #:</b>	PK19/818842624.02



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### Annex-A-I

S/N	Product Codes	Product Description
1.	CEFM101X - CEFM124X	Bipolar Forceps – European Patron
2.	CEFM200X - CEFM214X	Irrigation Bipolar Forceps – European Patron
3.	CPFM116X - CPFM193X	Non-Stick Bipolar Forceps Special Feature Forceps Black
4.	CPFM212X - CPFM278X	Premium Bipolar Forceps Special Feature Nonstick Orange
5.	CEFM133X - CEFM184X	Bipolar Forceps - American Patron
6.	CPFD101D-3M - CPFD199D-3M	Single Use Irrigation Bipolar Forceps with/without Cable
7.	CSUB100X – CSUB299X	SU Sterile Bipolar Forceps with Cable
8.	CSUP281X – CSUP499X	SU Sterile Nonstick Bipolar Forceps with Cable
9.		

<b>Name:</b> Amir Gul Shahzad	<b>Designation:</b> CEO	<b>Signature:</b>
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