



Care & Cure Surgico

“Our Creation Is For Your Health”

EC DECLARATION OF CONFORMITY
(MDD 93/42/EEC)

We,

CARE & CURE SURGICO (SRN: PK-MF-000031203)

Adress: Roras Road, Sialkot, 51310, Pakistan

Phone : 0092 345 8420345

Email: info@carecuresurgico.com

Hereby under sole responsibility declares that below mentioned medical devices manufactured by us have been classified according to the classification rules stated in the Annex – IX and conform to the Essential Safety and Performance as laid out in the Annex-I of the Council Directive 93/42/EEC as updated by 2007/47/EC.

Device Name:

Surgical Instruments

Device Classification: Class I Reusable Surgical Instruments

Product List:

Sr. #	Product name	Classification rationale per MDD	Class
1.	Chisel, Gouges & Osteotomes	Rule 6	I
2.	Curettes	Rule 6	I
3.	Elevators	Rule 6	I
4.	Needle Holder	Rule 6	I
5.	Tweezer	Rule 6	I
6.	Forceps	Rule 6	I
7.	Retractor	Rule 6	I
8.	Extracting Forceps	Rule 6	I
9.	Surgical Scissors	Rule 6	I
10.	Bone Cutting Instruments	Rule 6	I
11.	Scalpel Handles & Knives	Rule 6	I
12.	Wires and Saws	Rule 6	I
13.	Suture Needles	Rule 6	I
14.	Suction Tube	Rule 6	I

CARE & CURE SURGICO,
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CE ISO 9001: 2008
ISO 13485: 2003





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Conformity Assessment procedure:

Annex I and VII

Applicable Harmonized Standards:

To which this declaration related is in conformity with the following standard(s) or other normative document(s)

Applicable Standards: EN ISO 13485, EN ISO/IEC 17050-1, EN ISO 14971, EN ISO 15223-1, EN ISO 15223-2, EN ISO 10993-1, EN ISO 10993-18, EN ISO 7153-1, EN ISO 13402, EN ISO 17665-1, EN ISO 17664-1.

We have prepared and maintained technical documentation. The records are maintained for 10 years. We have also designated EU AUTHORIZED REPRESENTATIVE (EUAR):

EU Representative Information:

CMC MEDICAL DEVICES & DRUGS, S.L.

C/ Horacio Lengo n18

C. P 29006

Málaga-Spain

Tel: +34 951 214 054

Email: info@cmcmedicaldevices.com



Signed for and on behalf of: Care & Cure Surgico

Name: Mr. Tahir Ashfaq

Designation: CEO

Place of Issue: Roras Road, Sialkot, 51310, Pakistan

Date of Issue: May 21, 2020

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