



Care & Cure Surgico

"Our Creation Is For Your Health"

EU DECLARATION OF CONFORMITY

We,

Manufacturer's Name: Care & Cure Surgico

Address: Roras Road, Sialkot-Pakistan

Email ID: info@carecuresurgico.com

Hereby under sole responsibility declares that below mentioned medical devices manufactured by us have been classified as Class I according to the classification rules stated in the Chapter III of Annex – IX and conform to the Essential Requirements as laid out in the Annex-I of the EU MDR 93/42/EEC as amended by 2007/47/EC and the CE marking may be affixed.

Conformity Assessment procedure:

Annex I and Annex VII of EU MDR 93/42/EEC as updated by 2007/47/EC.

Medical Device Name:

Non-sterile, reusable, non-active Surgical Instruments, Dental Instruments, hollowware and hospital furniture

List of Products:

➤ **See List of Instruments (EUAR Agreement)**

This declaration related is in conformity with the following standard(s) used or other normative document(s) / guideline(s)

ISO 9001

Quality Management Systems

ISO 13485

Medical Devices – Quality Management Systems – Requirements for Regulatory Purpose



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MDR 93/42/EEC as amended 2007/47/EC

ISO 14971

ISO 17664

ISO 15223-1

cGMP

ASTM-F899

ISO 7153-1

ISO 21850-1

Council Directive for Medical Devices

Medical Devices–Application of Risk Management to Medical Devices

Sterilization of Medical Devices – Information to be provided by the manufacturer for the processing of re-sterilizable medical devices

Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied part-1 – general requirements

Medical Devices – Current Good Manufacturing Practices

Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments

Surgical Instruments – Metallic Materials – Part 1: Stainless Steel

Dentistry – Materials for dental instruments – part 1: Stainless Steel

We prepare and maintain technical documentation for each device as requires by applicable classification rules and Annex-VII of the regulation. Records are maintained for 10 years.

We have appointed the EU Authorized Representative as below:

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: ALI HASSAAN

Designation: DIRECTOR

Place of Issue: Roras Road, Sialkot-Pakistan

Date of Issue: 22-05-2021



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Annex I – Agreement 240822/216

Non-sterile, Reusable, Non-Measuring, Non-Implantable, Non-Active Instruments	
Sr#	Descriptions
Class I Dental Instruments List	
1.	Dental osteotomes
2.	Dental excavators
3.	Dental knives
4.	Dental rongeurs
5.	Retractors
6.	Root elevators
7.	Tooth extraction forceps
8.	Periotomes
9.	Dental files / rasp
10.	Elevators
11.	Scalpel handles
12.	Scalpels
13.	Dental surgical scissors
14.	Needle holders
15.	Skin hook



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Class I Surgical Instruments List



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1.	Scalpels & Knives
2.	Probes
3.	Scissors
4.	Forceps
5.	Needle Holders
6.	Chisels, Gouges
7.	Osteotomes
8.	Bone Curettes
9.	Bone Cutters
10.	Hand Drills
11.	Bone Levers/elevator
12.	Bone Holding Forceps
13.	Orthopaedic Rongeurs
14.	Bone Cutting Forceps
15.	Intestinal grasping forceps
16.	Intestinal Clamps
17.	Abdominal Retractors
18.	Hooks
19.	Self-Retaining Retractor
20.	Kidney Stone Forceps
21.	Gall Stone forceps
22.	Uterine Curettes
23.	Uterine Scoops
24.	Uterine tenaculum Forceps
25.	Biopsy Forceps
26.	Umbilical cord scissors
27.	Crocodile forceps



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28.	Scalpels & Knives
29.	Probes
30.	Scissors
31.	Forceps
32.	Needle Holders
33.	Chisels, Gouges
34.	Osteotomes
35.	Bone Curettes
36.	Bone Cutters
37.	Hand Drills
38.	Bone Levers/elevator
39.	Bone Holding Forceps
40.	Orthopaedic Rongeurs
41.	Bone Cutting Forceps
42.	Intestinal grasping forceps
43.	Intestinal Clamps
44.	Abdominal Retractors
45.	Hooks
46.	Self-Retaining Retractor
47.	Kidney Stone Forceps
48.	Gall Stone forceps
49.	Uterine Curettes
50.	Uterine Scoops
51.	Uterine tenaculum Forceps
52.	Biopsy Forceps
53.	Umbilical cord scissors
54.	Crocodile forceps
55.	Dissecting forceps
56.	Surgical Bulldog Clamps
57.	Clamp manipulation forceps
58.	Spatulas

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ISO 9001: 2008
ISO 13485: 2003





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59.	Rib Shears
60.	Rib Spreaders
61.	Bone Punches
62.	Rhinoplasty Knives
63.	Septum Elevators
64.	Nasal Chisels
65.	Nasal gouge
66.	Nasal files / Rasps
67.	Bone files / rasps
68.	Dissector
69.	Tonsil Dissector
70.	Tonsil Knives
71.	Tonsil Snares
72.	Retractors
73.	Wire Saws
74.	Tweezers
75.	Disimpaction Forceps
76.	Chin Retractor
77.	Periosteal elevators
78.	Curettes
79.	Spoons
80.	Trocars
81.	Bone Saws
82.	Bone Spoons
83.	Fixation Forceps
84.	Suture Forceps
85.	Tracheal Hooks



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Note:

- Medical Devices fall under class Is, Im, IIa, IIb and III require notified body certificate as per EU MDR 93/42/EEC.
- Medical Devices fall under class Ir, Is, Im, IIa, IIb and III require notified body certificate as per EU MDR 2017/745.
- It is hereby certified that above mentioned list of instruments and classification is correct as per EU MDR 93/42/EEC

Before placing the medical devices in the market, we hereby confirm that these medical devices meet the requirement

Signature:

Name: ALI HASSAAN

Designation: DIRECTOR

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