

"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:

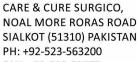
> See List of Instruments (EUAR Agreement)

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



FAX: +92-523-53777 WWW.CARECURESURGICO.COM





ISO 9001: 2008







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MDR 93/42/EEC as

Council Directive for Medical Devices

amended 2007/47/EC ISO 14971

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

ISO 15223-1

ISO 17664

Medical Devices – Symbols to be used with medical device labels, labeling

and information to be supplied part-1 - general requirements

cGMP

Medical Devices – Current Good Manufacturing Practices

ASTM-F899

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

Instruments

ISO 7153-1 ISO 21850-1 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

regulartion.

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

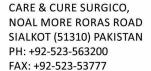
Signed for and on behalf of: Care & Cure Surgico



Name: ALI HASSAAN **Designation: DIRECTOR**

Place of Issue: Roras Road, Sialkot-Pakistan

Date of Issue: 22-05-2021



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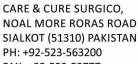




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Annex I – Agreement 240822/216

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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Annex I – Agreement 240822/216

Class I Surgical Instruments List

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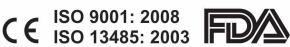


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1.	Scalpels & Knives
2.	Probes
3.	Scissors
4.	Forceps
5.	Needle Holders
6.	Chisels, Gouges
7.	Osteotomes
8.	Bone Curettes
9.	Bone Cutters
10.	Hand Drills
11.	Bone Levers/elevator
12.	Bone Holding Forceps
13.	Orthopaedic Rongeurs
14.	Bone Cutting Forceps
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











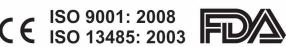
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28. Scalpels & Knives 29. Probes 30. Scissors 31. Forceps 32. Needle Holders 33. Chisels, Gouges 34. Osteotomes 35. Bone Curettes 36. Bone Cutters 37. Hand Drills 38. Bone Levers/elevator 39. Bone Holding Forceps	
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40. 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	

CARE & CURE SURGICO, **NOAL MORE RORAS ROAD** SIALKOT (51310) PAKISTAN PH: +92-523-563200









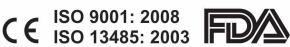


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59.	Rib Shears
60.	Rib Spreaders
61.	Bone Punches
62.	Rhinoplasty Knives
63.	Septum Elevators
64.	Nasal Chisels
65.	Nasal gouge
66.	Nasal files / Rasps
67.	Bone files / rasps
68.	Dissector
69.	Tonsil Dissector
70.	Tonsil Knives
71.	Tonsil Snares
72.	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

Place of Issue: Roras Road, Sialkot-Pakistan

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