

EC REP CERTIFICATE



CMC MEDICAL DEVICES & DRUGS SL NO. CMC/CE/2021/11052021.1

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized
Representative of
CARNEGIE SURGICAL LLC.
151 One Mile Road, East Windsor, NJ 08512, USA

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/991/2021**

CE

Issued on: 11/05/2021

Valid until: 10/05/2022


Authorized Signatory
CMC Medical Devices & Drugs SL

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ANNEX I Medical Device Products



NON-STERILE, NON-MEASURING, NON-POWERED STAINLESS STEEL SURGICAL & DENTAL INSTRUMENTS

Sr.#	UMDNS Code	Description	Classification	Registration No.
1	11950	Hammers, Percussion	I	ES/US/CNS/0001
2	11893	Goniometers	I	ES/US/CNS/0002
3	10546	Calipers	I	ES/US/CNS/0003
4	12849	Otosopes	I	ES/US/CNS/0004
5	12815	Ophthalmoscopes	I	ES/US/CNS/0005
6	11963	Headlights	I	ES/US/CNS/0006
7	11726	Fittings/Adapters	I	ES/US/CNS/0007
8	11774	Forceps	I	ES/US/CNS/0008
9	15076	Laryngoscopes, Rigid	I	ES/US/CNS/0009
10	17972	Tubing, Stainless Steel	I	ES/US/CNS/0010
11	16883	Suction Tips, General-Purpose	I	ES/US/CNS/0011
12	14154	Trocars	I	ES/US/CNS/0012
13	11927	Guides	I	ES/US/CNS/0013
14	12235	Knife Handles	I	ES/US/CNS/0014
15	12252	Knives, Scalpel	I	ES/US/CNS/0015
16	11179	Dermatomes	I	ES/US/CNS/0016
17	13480	Scissors	I	ES/US/CNS/0017
18	14257	Tweezers	I	ES/US/CNS/0018
19	10861	Clamps	I	ES/US/CNS/0019
20	13373	Retractors	I	ES/US/CNS/0020
21	13645	Spatulas	I	ES/US/CNS/0021
22	12028	Hooks	I	ES/US/CNS/0022
23	13117	Probes	I	ES/US/CNS/0023
24	10172	Applicators	I	ES/US/CNS/0024
25	13823	Strippers	I	ES/US/CNS/0025
26	15580	Extractors	I	ES/US/CNS/0026
27	12726	Needle Holders	I	ES/US/CNS/0027
28	13707	Spreaders	I	ES/US/CNS/0028
29	12239	Knives	I	ES/US/CNS/0029
30	13416	Rongeurs	I	ES/US/CNS/0030
31	17507	Taps, Bone	I	ES/US/CNS/0031
32	12421	Mallets	I	ES/US/CNS/0032
33	16210	Splints, Hand/Finger	I	ES/US/CNS/0033
34	11394	Elastomers, Silicone Rubber	I	ES/US/CNS/0034
35	15609	Trays	I	ES/US/CNS/0035
36	15573	Cutters	I	ES/US/CNS/0036
37	11084	Curettes	I	ES/US/CNS/0037

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Sr.#	UMDNS Code	Description	Classification	Registration No.
38	10824	Chisels	I	ES/US/CNS/0038
39	11895	Gouges	I	ES/US/CNS/0039
40	12844	Osteotomes	I	ES/US/CNS/0040
41	11504	Elevators	I	ES/US/CNS/0041
42	13287	Raspatories	I	ES/US/CNS/0042
43	15275	Awls	I	ES/US/CNS/0043
44	13297	Reamers, Orthopedic	I	ES/US/CNS/0044
45	11345	Driver/Extractors	I	ES/US/CNS/0045
46	16443	Appliers, Aneurysm Clip	I	ES/US/CNS/0046
47	13416	Rongeurs	I	ES/US/CNS/0047
48	11254	Dilators	I	ES/US/CNS/0048
49	15586	Jars	I	ES/US/CNS/0049
50	17673	Approximators	I	ES/US/CNS/0050
51	13730	Sterilization Containers	I	ES/US/CNS/0051
52	15602	Specula	I	ES/US/CNS/0052
53	13117	Probes	I	ES/US/CNS/0053
54	10561	Cannulae	I	ES/US/CNS/0054
55	14175	Tubes	I	ES/US/CNS/0055
56	13929	Syringes	I	ES/US/CNS/0056
57	10685	Catheters	I	ES/US/CNS/0057
58	11775	Forceps, Biopsy	I	ES/US/CNS/0058
59	13630	Snares	I	ES/US/CNS/0059
60	12729	Needles	I	ES/US/CNS/0060
61	11290	Dissectors	I	ES/US/CNS/0061
62	14255	Tuning Forks	I	ES/US/CNS/0062
63	13448	Saws	I	ES/US/CNS/0063
64	11059	Crushers	I	ES/US/CNS/0064
65	13288	Tubing, Stainless Steel	I	ES/US/CNS/0065
66	13228	Punches	I	ES/US/CNS/0066
67	11822	Gags	I	ES/US/CNS/0067
68	14066	Tongue Depressors	I	ES/US/CNS/0068
69	11788	Forceps, Obstetrical	I	ES/US/CNS/0069
70	17595	Protectors, Teeth	I	ES/US/CNS/0070
71	13454	Scalers	I	ES/US/CNS/0071
72	12547	Mirrors	I	ES/US/CNS/0072
73	12393	Loops	I	ES/US/CNS/0073
74	15308	Cables, Fiberoptic	I	ES/US/CNS/0074
75	15560	Bougies	I	ES/US/CNS/0075
76	13642	Sounds	I	ES/US/CNS/0076
77	15573	Cutters	I	ES/US/CNS/0077
78	16825	Syringe Tip Caps	I	ES/US/CNS/0078
79	15635	Retractors, Fiberoptic-Illuminated	I	ES/US/CNS/0079
80	13390	Retractors, Self-Retaining Operating	I	ES/US/CNS/0080
81	16222	Protectors, Surgical Instrument	I	ES/US/CNS/0081
82	12440	Markers	I	ES/US/CNS/0082
83	15954	Grids, Radiographic	I	ES/US/CNS/0083
84	16043	Reconstruction Blocks, Plastic Surgery	I	ES/US/CNS/0084

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Sr.#	UMDNS Code	Description	Classification	Registration No.
85	11701	Files	I	ES/US/CNS/0085
86	13938	Dental Syringes	I	ES/US/CNS/0086
87	15561	Bowls	I	ES/US/CNS/0087
88	15554	Basins	I	ES/US/CNS/0088
89	15572	Cups	I	ES/US/CNS/0089
90	14427	Kick Buckets	I	ES/US/CNS/0090
91	15981	Oxygen Canister/IV Pole Holders, Wheelchair	I	ES/US/CNS/0091
92	10787	Chairs	I	ES/US/CNS/0092
93	16017	Stools	I	ES/US/CNS/0093
94	16337	Batteries, Medical Device	I	ES/US/CNS/0094
95	17954	Bone Drills	I	ES/US/CNS/0095

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