

Certificate of Registration



Registration No.: EAR/US/7349

This is to certify that KB International has agreed to fulfill all duties and responsibilities as the European Authorized Representative for the manufacturer mentioned below.

Manufacturer Name: CARNEGIE SURGICAL LLC SRN # US-MF-000018009

Address: 151 One Mile Road, East Windsor, Cranbury, NJ 08512, USA

And

European Authorised Representative: KB INTERNATIONAL SRN # HU-AR-000034102

Address: Auróra utca, 13. al. 1, Budapest - 1084, Hungary

Product Category: Surgical & Dental Instruments (See Annex A for Product List)

Classification: Class I

The product(s) category described mentioned above is in conformity with:
applicable conformity assessment procedure as per Annex VII & V, EU MDD 93/42/EEC
as amended by the Directive 2007/47/EC.

Manufacturer issued the Declaration of Conformity and conforms that above-mentioned products meets the requirements of Medical Device Directive and the relevant applicable standards. This document will become to be invalid once th the notification status is changed or the EAR agreement is terminated.

AR Start: 25-07-2025

AR End: 24-07-2026



Authorised Signatory



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KB INTERNATIONAL (EAR SRN # HU-AR-000034102)

Auróra utca, 13. al. 1, 1084 - Budapest, Hungary

Web: www.kb-intl.com Email: info@kb-intl.com Tel: +36 70 6790786

The certificate remains valid until the expiration agreement of EAR agreement, 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 regulations and standards, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all products of the brand included in the mandate written.

Certificate of Registration



Annex A

Registration No.: EAR/US/7349

Sr. #	Product Name	Risk Class	UMDNS
1	Hammers, Percussion	Class I	11950
2	Goniometers	Class I	11893
3	Calipers	Class I	10546
4	Otoscopies	Class I	12849
5	Ophthalmoscopes	Class I	12815
6	Headlights	Class I	11963
7	Fittings/Adapters	Class I	11726
8	Forceps	Class I	11774
9	Laryngoscopes, Rigid	Class I	15076
10	Tubing, Stainless Steel	Class I	17972
11	Suction Tips, General-Purpose	Class I	16883
12	Trocars	Class I	14154
13	Guides	Class I	11927
14	Knife Handles	Class I	12235
15	Knives, Scalpel	Class I	12252
16	Dermatomes	Class I	11179
17	Scissors	Class I	13480
18	Tweezers	Class I	14257
19	Clamps	Class I	10861
20	Retractors	Class I	13373
21	Spatulas	Class I	13645
22	Hooks	Class I	12028
23	Probes	Class I	13117
24	Applicators	Class I	10172
25	Strippers	Class I	13823
26	Extractors	Class I	15580
27	Needle Holders	Class I	12726
28	Spreaders	Class I	13707
29	Knives	Class I	12239
30	Rongeurs	Class I	13416
31	Taps, Bone	Class I	17507
32	Mallets	Class I	12421
33	Splints, Hand/Finger	Class I	16210



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Annex A

Registration No.: EAR/US/7349

Sr. #	Product Name	Risk Class	UMDNS
34	Elastomers, Silicone Rubber	Class I	11394
35	Trays	Class I	15609
36	Cutters	Class I	15573
37	Curettes	Class I	11084
38	Chisels	Class I	10824
39	Gouges	Class I	11895
40	Osteotomes	Class I	12844
41	Elevators	Class I	11504
42	Raspatories	Class I	13287
43	Awls	Class I	15275
44	Reamers, Orthopedic	Class I	13297
45	Driver/Extractors	Class I	11345
46	Appliers, Aneurysm Clip	Class I	16443
47	Rongeurs	Class I	13416
48	Dilators	Class I	11254
49	Jars	Class I	15586
50	Approximators	Class I	17673
51	Sterilization Containers	Class I	13730
52	Specula	Class I	15602
53	Probes	Class I	13117
54	Cannulae	Class I	10561
55	Tubes	Class I	14175
56	Syringes	Class I	13929
57	Catheters	Class I	10685
58	Forceps, Biopsy	Class I	11775
59	Snares	Class I	13630
60	Needles	Class I	12729
61	Dissectors	Class I	11290
62	Tuning Forks	Class I	14255
63	Saws	Class I	13448
64	Crushers	Class I	11059
65	Rasps	Class I	13288
66	Punches	Class I	13228



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Annex A

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Sr. #	Product Name	Risk Class	UMDNS
67	Gags	Class I	11822
68	Tongue Depressors	Class I	14066
69	Forceps, Obstetrical	Class I	11788
70	Protectors, Teeth	Class I	17595
71	Scalers	Class I	13454
72	Mirrors	Class I	12547
73	Loops	Class I	12393
74	Cables, Fiberoptic	Class I	15308
75	Bougies	Class I	15560
76	Sounds	Class I	13642
77	Cutters	Class I	15573
78	Syringe Tip Caps	Class I	16825
79	Retractors, Fiberoptic-Illuminated	Class I	15635
80	Retractors, Self-Retaining Operating	Class I	13390
81	Protectors, Surgical Instrument	Class I	16222
82	Markers	Class I	12440
83	Grids, Radiographic	Class I	15954
84	Reconstruction Blocks, Plastic Surgery	Class I	16043
85	Files	Class I	11701
86	Dental Syringes	Class I	13938
87	Bowls	Class I	15561
88	Basins	Class I	15554
89	Cups	Class I	15572
90	Kick Buckets	Class I	14427
91	Oxygen Canister/IV Pole Holders, Wheelchair	Class I	15981
92	Chairs	Class I	10787
93	Stools	Class I	16017
94	Batteries, Medical Device	Class I	16337
95	Bone Drills	Class I	17954



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