



Documentation Review

No. 201013.IMGSD91

Holder: **Ingenious Medical GmbH**
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Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Lap Forceps
Intended Purpose: It is intended to be used to grasp tissues

Model(s): (see the following annex)

Classification: Class I (Not Sterile according to the Manufacturer's declaration – therefore not requiring NB intervention.)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 15 October 2020

Approver
ECM Service Director
Luca Bodonni



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Technical Expert
Amanda Payne



Ente Certificazione Macchine

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Annex I

No. 201013.IMGSD91

Model(s):

CAT ORDER NO	EN DESCRIPTION
300-100-22	Bile duct scalpel 5*330mm
300-100-23	Bile duct scalpel 5*330mm
300-100-24	Bile duct scalpel 10*330mm
300-600-01	Purse Stitching Clamp for laparoscopic surgery
300-600-02	Purse Stitching Clamp for open surgery
300-600-00	Colon and Rectum Instruments, Ø10x330mm
300-500-06	L-Hook, Ø5x330mm
300-500-07	Ceramic Hook, Ø5x330mm
300-500-08	Spatula, Ø5x330mm
300-500-09	J-Hook, Ø5x330mm
300-500-10	Probe, Ø5x330mm
300-500-11	Needle, Ø5x330mm
300-500-12	Ball, Ø5x330mm
300-500-13	Knife, Ø5x330mm
300-500-249	L Hook Ø3x300mm
300-500-250	Probe Ø3x300mm
300-500-251	Spatula Ø3x300mm
300-500-252	Needle Ø3x300mm
300-500-25	Straight - Single Action (15mm) Ø5x330mm
300-500-26	Curved - Single Action (15mm) Ø5x330mm
300-500-27	Micro Curved (Dual Action) (10mm) Ø5x330mm
300-500-28	Micro (10mm) Ø5x330mm
300-500-29	Straight - Dual Action (15mm) Ø5x330mm
300-500-30	Curved - Dual Action (15mm) Ø5x330mm
300-500-31	Hook (10mm) Ø5x330mm
300-500-32	Straight - Single Action (15mm) Ø5x360mm
300-500-33	Curved - Single Action (15mm) Ø5x360mm
300-500-34	Micro Curved (Dual Action) (10mm) Ø5x360mm
300-500-35	Micro (10mm) Ø5x360mm
300-500-36	Straight - Dual Action (15mm) Ø5x360mm
300-500-37	Curved - Dual Action (15mm) Ø5x360mm
300-500-38	Hook (10mm) Ø5x360mm
300-500-39	Straight - Single Action (15mm) Ø5x450mm
300-500-40	Curved - Single Action (15mm) Ø5x450mm
300-500-41	Micro Curved (Dual Action) (10mm) Ø5x450mm
300-500-42	Micro (10mm) Ø5x450mm
300-500-43	Straight - Dual Action (15mm) Ø5x450mm
300-500-44	Curved - Dual Action (15mm) Ø5x450mm
300-500-45	Hook (10mm) Ø5x450mm
300-500-208	Straight Metzenbaum Scissor (26mm) Ø10x330mm
300-500-209	Curved Metzenbaum Scissor (25mm) Ø10x330mm
300-500-253	Straight Scissor (11mm) Ø3x300mm
00-500-254	Curved Scissor (10mm) Ø3x300mm
300-500-46	Straight (17mm) Ø5x220mm
300-500-47	Maryland (20mm) Ø5x220mm
300-500-48	Curved (45°)(14mm) Ø5x220mm
300-500-49	Maryland (17mm) Ø5x220mm
300-500-50	Maryland (25mm) Ø5x220mm
300-500-51	Mixer 90°(17mm) Ø5x220mm
300-500-52	Maryland (12mm) Ø5x220mm
300-500-53	Blunt (16mm) Ø5x220mm
300-500-54	Mixer(17mm) Ø5x220mm
300-500-55	Maryland (14mm) Ø5x220mm
300-500-56	Straight (17mm) Ø5x330mm
300-500-57	Maryland (20mm) Ø5x330mm
300-500-58	Curved (45°)(14mm) Ø5x330mm
300-500-59	Maryland (17mm) Ø5x330mm
300-500-60	Maryland (25mm) Ø5x330mm
300-500-61	Mixer 90°(17mm) Ø5x330mm
300-500-62	Maryland (12mm) Ø5x330mm
300-500-63	Blunt (16mm) Ø5x330mm
300-500-64	Mixer(17mm) Ø5x330mm
300-500-65	Maryland (14mm) Ø5x330mm



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300-500-66	Straight (17mm) Ø5x450mm
300-500-67	Maryland (20mm) Ø5x450mm
300-500-68	Curved (45°)(14mm) Ø5x450mm
300-500-69	Maryland (17mm) Ø5x450mm
300-500-70	Maryland (25mm) Ø5x450mm
300-500-71	Mixer 90°(17mm) Ø5x450mm
300-500-72	Maryland (12mm) Ø5x450mm
300-500-73	Blunt (16mm) Ø5x450mm
300-500-74	Mixer(17mm) Ø5x450mm
300-500-75	Maryland (14mm) Ø5x450mm
300-500-210	Maryland Dissector (31mm) Ø10x330mm
300-500-211	Mixer. Skew Facets Dissector (24mm) Ø10x330mm
300-500-76	Fenestrated Grasping Forceps (14mm) Ø5x220mm
300-500-77	Duck Nose Grasper (12mm) Ø5x220mm
300-500-78	Maxi Grasper (18mm) Ø5x220mm
300-500-79	Alligator Grasping Forceps (20mm) Ø5x220mm
300-500-80	Fenestrated Wave Grasping Forceps (17mm) Ø5x220mm
300-500-81	Alligator Grasping Forceps (14mm) Ø5x220mm
300-500-82	Fenestrated Grasping Forceps (25mm) Ø5x220mm
300-500-83	Claw Forceps (2 + 3 teeth), dual action(16mm) Ø5x220mm
300-500-84	Babcock Forceps (21mm) Ø5x220mm
300-500-85	Atraumatic Grasper (23mm) Ø5x220mm
300-500-86	Babcock Forceps (23mm) Ø5x220mm
300-500-87	Babcock Forceps (22mm) Ø5x220mm
300-500-88	Fenestrated Babcock Forceps (20mm) Ø5x220mm
300-500-89	Fenestrated Grasping Forceps (18mm) Ø5x220mm
300-500-90	Long Fenestrated Grasping Forceps (25mm) Ø5x220mm
300-500-91	Fenestrated Grasping Forceps (22mm) Ø5x220mm
300-500-92	Blunt Nose Forceps (16mm) Ø5x220mm
300-500-93	Dolphin Nose Grasper (16mm) Ø5x220mm
300-500-94	Fenestrated Grasping Forceps (25mm) Ø5x220mm
300-500-95	Biopsy Forceps (14mm) Ø5x220mm
300-500-96	Biopsy Forceps with thorn (14mm) Ø5x220mm
300-500-98	Fenestrated Grasping Forceps (14mm) Ø5x330mm
300-500-99	Duck Nose Grasper (12mm) Ø5x330mm
300-500-100	Maxi Grasper (18mm) Ø5x330mm
300-500-101	Alligator Grasping Forceps (20mm) Ø5x330mm
300-500-102	Fenestrated Wave Grasping Forceps (17mm) Ø5x330mm
300-500-103	Alligator Grasping Forceps (14mm) Ø5x330mm
300-500-104	Fenestrated Grasping Forceps (25mm) Ø5x330mm
300-500-105	Claw Forceps (2 + 3 teeth), dual action(16mm) Ø5x330mm
300-500-106	Babcock Forceps (21mm) Ø5x330mm
300-500-107	Atraumatic Grasper (23mm) Ø5x330mm
300-500-108	Babcock Forceps (23mm) Ø5x330mm
300-500-109	Babcock Forceps (22mm) Ø5x330mm
300-500-110	Fenestrated Babcock Forceps (20mm) Ø5x330mm
300-500-111	Fenestrated Grasping Forceps (18mm) Ø5x330mm
300-500-112	Long Fenestrated Grasping Forceps (25mm) Ø5x330mm
300-500-113	Fenestrated Grasping Forceps (22mm) Ø5x330mm
300-500-114	Blunt Nose Forceps (16mm) Ø5x330mm
300-500-115	Dolphin Nose Grasper (16mm) Ø5x330mm
300-500-116	Fenestrated Grasping Forceps (25mm) Ø5x330mm
300-500-117	Biopsy Forceps (14mm) Ø5x330mm
300-500-118	Biopsy Forceps with thorn (14mm) Ø5x220mm
300-500-120	Fenestrated Grasping Forceps (14mm) Ø5x450mm
300-500-121	Duck Nose Grasper (12mm) Ø5x450mm
300-500-122	Maxi Grasper (18mm) Ø5x450mm
300-500-123	Alligator Grasping Forceps (20mm) Ø5x450mm
300-500-124	Fenestrated Wave Grasping Forceps (17mm) Ø5x450mm
300-500-125	Alligator Grasping Forceps (14mm) Ø5x450mm
300-500-126	Fenestrated Grasping Forceps (25mm) Ø5x450mm
300-500-127	Claw Forceps (2 + 3 teeth), dual action(16mm) Ø5x450mm
300-500-128	Babcock Forceps (21mm) Ø5x450mm
300-500-129	Atraumatic Grasper (23mm) Ø5x450mm
300-500-130	Babcock Forceps (23mm) Ø5x450mm
300-500-131	Babcock Forceps (22mm) Ø5x450mm
300-500-132	Fenestrated Babcock Forceps (20mm) Ø5x450mm
300-500-133	Fenestrated Grasping Forceps (18mm) Ø5x450mm
300-500-134	Long Fenestrated Grasping Forceps (25mm) Ø5x450mm
300-500-135	Fenestrated Grasping Forceps (22mm) Ø5x450mm
300-500-136	Blunt Nose Forceps (16mm) Ø5x450mm
300-500-137	Dolphin Nose Grasper (16mm) Ø5x450mm
300-500-138	Fenestrated Grasping Forceps (25mm) Ø5x450mm
300-500-139	Biopsy Forceps (14mm) Ø5x450mm



300-500-140	Biopsy Forceps with thorn (14mm) Ø5x450mm
300-500-164	Oviduct Atraumatic Forceps (15mm) Ø5x330mm
300-500-165	Oviduct Atraumatic Forceps (11mm) Ø5x330mm
300-500-166	Fenestrated Grasping Forceps (18mm) Ø5x330mm
300-500-167	Grasping Forceps (18mm) Ø5x330mm
300-500-168	Allis Grasper (16mm) Ø5x330mm
300-500-169	Allis Grasper (18mm) Ø5x330mm
300-500-170	Allis Grasper (16mm) Ø5x330mm
300-500-171	Long Allis Grasper (18mm) Ø5x330mm
300-500-172	Atraumatic Forceps (14mm) Ø5x330mm
300-500-173	Fenestrated Atraumatic Grasper (18mm) Ø5x330mm
300-500-174	Fenestrated Atraumatic Grasper (16mm) Ø5x330mm
300-500-175	Claw Forceps (2+4 teeth), single action (12mm) Ø5x330mm
300-500-176	Cobra Grasping Forceps (2+4 teeth), dual action (12mm) Ø5x330mm
300-500-177	Atraumatic Forceps (16mm) Ø5x330mm
300-500-178	Claw Forceps (20mm) Ø5x330mm
300-500-179	Babcock Forceps (21mm) Ø5x330mm
300-500-180	Cobra Grasping Forceps (1 + 2 teeth), dual action (17mm) Ø5x330mm
300-500-181	Fenestrated Grasping Forceps (22mm) Ø5x330mm
300-500-182	Fenestrated Grasping Forceps (25mm) Ø5x330mm
300-500-183	Debaquey Forceps (35mm) Ø5x330mm
300-500-184	Fenestrated Bowel Grasper (35mm) Ø5x330mm
300-500-185	Endo-lung Palpation Forceps (38mm) Ø5x330mm
300-500-186	Oviduct Atraumatic Forceps (15mm) Ø5x450mm
300-500-187	Oviduct Atraumatic Forceps (11mm) Ø5x450mm
300-500-188	Fenestrated Grasping Forceps (18mm) Ø5x450mm
300-500-189	Grasping Forceps (18mm) Ø5x450mm
300-500-190	Allis Grasper (16mm) Ø5x450mm
300-500-191	Allis Grasper (18mm) Ø5x450mm
300-500-192	Allis Grasper (16mm) Ø5x450mm
300-500-193	Long Allis Grasper (18mm) Ø5x450mm
300-500-194	Atraumatic Forceps (14mm) Ø5x450mm
300-500-195	Fenestrated Atraumatic Grasper (18mm) Ø5x450mm
300-500-196	Fenestrated Atraumatic Grasper (16mm) Ø5x450mm
300-500-197	Claw Forceps (2+4 teeth), single action (12mm) Ø5x450mm
300-500-198	Cobra Grasping Forceps (2+4 teeth), dual action (12mm) Ø5x450mm
300-500-199	Atraumatic Forceps (16mm) Ø5x450mm
300-500-200	Claw Forceps (20mm) Ø5x450mm
300-500-201	Babcock Forceps (21mm) Ø5x450mm
300-500-202	Cobra Grasping Forceps (1 + 2 teeth), dual action (17mm) Ø5x450mm
300-500-203	Fenestrated Grasping Forceps (22mm) Ø5x450mm
300-500-204	Fenestrated Grasping Forceps (25mm) Ø5x450mm
300-500-205	Debaquey Forceps (35mm) Ø5x450mm
300-500-206	Fenestrated Bowel Grasper (35mm) Ø5x450mm
300-500-207	Endo-lung Palpation Forceps (38mm) Ø5x450mm
300-500-00	Straight (16mm), Ø5mmx330mm
300-500-01	Curved (16mm), Ø5mmx330mm
300-500-02	Straight, Ø5mmx330mm
300-500-03	Curved, Ø5mmx330mm
300-500-212	Large Spoon Grasper (24mm) Ø10x330mm
300-500-213	Claw Grasper (31mm) Ø10x330mm
300-500-214	Pennington Grasper (41mm) Ø10x330mm
300-500-215	Babcock Grasper (40mm) Ø10x330mm
300-500-216	Debaquey Grasper (47mm) Ø10x330mm
300-500-217	Dorsey Grasper (47mm) Ø10x330mm
300-500-218	TC Collin Grasper (40mm) Ø10x330mm
300-500-219	Alligator Grasper (39mm) Ø10x330mm
300-500-220	Babcock Debaquey Grasper (34mm) Ø10x330mm
300-500-221	Strong Atraumatic Clamp Grasper (40mm) Ø10x330mm
300-500-222	Teethless Grasper (44mm) Ø10x330mm
300-500-223	Reddick Grasper (30mm) Ø10x330mm
300-500-224	Long-jaw Grasper (70mm) Ø10x330mm
300-500-225	Straight Metzenbaum Scissor (26mm) Ø10x450mm
300-500-226	Curved Metzenbaum Scissor (25mm) Ø10x450mm
300-500-227	Maryland Dissector (31mm) Ø10x450mm
300-500-228	Mixer. Skew Facets Dissector (24mm) Ø10x450mm
300-500-229	Large Spoon Grasper (24mm) Ø10x450mm
300-500-230	Claw Grasper (31mm) Ø10x450mm
300-500-231	Pennington Grasper (41mm) Ø10x450mm
300-500-232	Babcock Grasper (40mm) Ø10x450mm
300-500-233	Debaquey Grasper (47mm) Ø10x450mm
300-500-234	Dorsey Grasper (47mm) Ø10x450mm
300-500-235	TC Collin Grasper (40mm) Ø10x450mm
300-500-236	Alligator Grasper (39mm) Ø10x450mm



300-500-237	Babcock Debaque Grasper (34mm) Ø10x450mm
300-500-238	Strong Atraumatic Clamp Grasper (40mm) Ø10x450mm
300-500-239	Teethless Grasper (44mm) Ø10x450mm
300-500-240	Reddick Grasper (30mm) Ø10x450mm
300-500-241	Long-jaw Grasper (70mm) Ø10x450mm
300-500-255	Maryland Dissector (9mm) Ø3x300mm
300-500-256	Mixer Dissector (9mm) Ø3x300mm
300-500-257	Fenestrated Grasping Forceps (9mm) Ø3x300mm
300-500-258	Alligator Grasping Forceps (10.5mm) Ø3x300mm
300-500-259	Fenestrated Grasping Forceps (11mm) Ø3x300mm
300-500-260	Allis Grasper (11mm) Ø3x300mm
300-500-261	Blunt Nose Forceps (9mm) Ø3x300mm

