

EC DECLARATION OF CONFORMITY

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz Strasse 4-10
72810 Gomaringen / Germany

We hereby declare in sole responsibility that the medical devices listed on the following pages are conform with the essential requirements of the following standard:

Medical Device Directive (Council Directive 93/42/EEC of 14 June 1993)

with applied standards:

EN ISO 14971 / EN 60601-1 / EN 60601-2-2 / EN ISO 10993-1 / EN ISO 13485 / DIN EN 1041

CE Marking

Class IIa according to annex II CE 0123
Class IIb according to annex II CE 0123

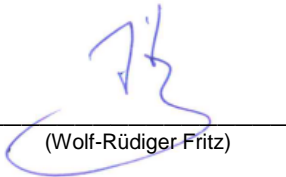
Notified Body

TÜV Product Service
Ridlerstr. 65, D-80339 München
Nr. 0123

The declaration of conformity is valid until: 08.03.2022

Gomaringen, 08.03.2017

Quality Management /
Regulatory Affairs


(Wolf-Rüdiger Fritz)

REF	Product description	Class	Rule	UMDNS	GMDN
741-100	ERGO 320R, handle, COMFORT, cable, 4.5 m	IIb	9	11-502	61873
741-101	ERGO 320R, handle	IIb	9	11-502	61873
741-234	ERGO 320R, shaft tube, ø 5 mm, 340 mm	IIb	9	11-502	61873
741-812	ERGO 320R Set, atraumatic grasping forceps, 340 mm, COMFORT	IIb	9	11-502	61873
741-814	ERGO 320R Set, atraumatic grasping forceps, 340 mm	IIb	9	11-502	61873
741-822	ERGO 320R Set, grasping forceps, fenestrated, curved, 340 mm, COMFORT	IIb	9	11-502	61873
741-823	ERGO 320R Set, grasping forceps, fenestrated, curved, 340 mm	IIb	9	11-502	61873
741-827	ERGO 320R Set, grasping forceps with 2x3 teeth, 340 mm, COMFORT	IIb	9	11-502	61873
741-828	ERGO 320R Set, grasping forceps with 2x3 teeth, 340 mm	IIb	9	11-502	61873
741-832	ERGO 320R Set, Metzenbaum scissors, 340 mm, COMFORT	IIb	9	11-502	61873
741-833	ERGO 320R Set, Metzenbaum scissors, 340 mm	IIb	9	11-502	61873
741-842	ERGO 320R Set, Maryland dissector, 340 mm, COMFORT	IIb	9	11-502	61873
741-843	ERGO 320R Set, Maryland dissector, 340 mm	IIb	9	11-502	61873
742-106	ERGO 325R, handle, rotatable, with lock	IIb	9	11-502	61873
742-234	ERGO 325R, shaft tube, ø 5 mm, 340 mm	IIb	9	11-502	61873
742-310	ERGO 320R/325R, jaw atraumatic grasping forceps, fenestrated, 340 mm	IIb	9	11-502	61873
742-320	ERGO 320R/325R, jaw grasping forceps, fenestrated, curved, 340 mm	IIb	9	11-502	61873
742-330	ERGO 320R/325R, jaw Metzenbaum scissors, 340 mm	IIb	9	11-502	61873
742-340	ERGO 320R/325R, jaw Maryland dissector, 340 mm	IIb	9	11-502	61873
742-350	ERGO 320R/325R, jaw grasping forceps with 2x3 teeth, 340 mm	IIb	9	11-502	61873
742-816	ERGO 325R Set, atraumatic grasping forceps, 340 mm, rotatable, with lock	IIb	9	11-502	61873
742-826	ERGO 325R Set, grasp. forceps, fenes., curved, 340 mm, rotatable, with lock	IIb	9	11-502	61873
742-829	ERGO 325R Set, grasp. forceps with 2x3 teeth, 340 mm, rotatable, with lock	IIb	9	11-502	61873
742-836	ERGO 325R Set, Metzenbaum scissors, 340 mm, rotatable, with lock	IIb	9	11-502	61873
742-846	ERGO 325R Set, Maryland dissector, 340 mm, rotatable, with lock	IIb	9	11-502	61873
743-100	ERGO 330R, handle, COMFORT, cable, 4.5 m	IIb	9	11-502	61873
743-101	ERGO 330R, handle	IIb	9	11-502	61873
743-225	ERGO 330R, shaft tube, ø 5 mm, 250 mm	IIb	9	11-502	61873
743-234	ERGO 330R, shaft tube, ø 5 mm, 340 mm	IIb	9	11-502	61873
743-325	ERGO 330R, jaw, 250 mm	IIb	9	11-502	61873
743-334	ERGO 330R, jaw, 340 mm	IIb	9	11-502	61873
743-425	ERGO 330R, drive rod, 250 mm	IIb	9	11-502	61873
743-434	ERGO 330R, drive rod, 340 mm	IIb	9	11-502	61873
743-525	ERGO 330R, blade holding tube, 250 mm	IIb	9	11-502	61873

REF	Product description	Class	Rule	UMDNS	GMDN
743-534	ERGO 330R, blade holding tube, 340 mm	IIb	9	11-502	61873
743-851	ERGO 330R Set, coagulation forceps with cutting blade, 340 mm, COMFORT	IIb	9	11-502	61873
743-852	ERGO 330R Set, coagulation forceps with cutting blade, 340 mm	IIb	9	11-502	61873
743-853	ERGO 330R Set, coagulation forceps with cutting blade, 340 mm	IIb	9	11-502	61873
743-854	ERGO 330R Set, coagulation forceps with cutting blade, 250 mm	IIb	9	11-502	61873
743-999	ERGO 330R, blade, sterile (20 pcs.)	IIb	9	11-502	61873
744-100	ERGO 335R, handle, COMFORT, cable, 4.5 m	IIb	9	11-502	61873
744-101	ERGO 335R, handle	IIb	9	11-502	61873
744-220	ERGO 335R, shaft tube, ø 3 mm, 290 mm	IIb	9	11-502	61873
744-229	ERGO 335R, shaft tube, ø 3 mm, 290 mm	IIb	9	11-502	61873
744-312	ERGO 335R, jaw atraumatic grasping forceps, fenestrated, 200 mm	IIb	9	11-502	61873
744-313	ERGO 335R, jaw atraumatic grasping forceps, fenestrated, 290 mm	IIb	9	11-502	61873
744-342	ERGO 335R, jaw Maryland dissector, 200 mm	IIb	9	11-502	61873
744-343	ERGO 335R, jaw Maryland dissector, 290 mm	IIb	9	11-502	61873
744-812	ERGO 335R Set, atraumatic grasping forceps, ø 3 mm, 290 mm, COMFORT	IIb	9	11-502	61873
744-813	ERGO 335R Set, atraumatic grasping forceps, ø 3 mm, 200 mm, COMFORT	IIb	9	11-502	61873
744-815	ERGO 335R Set, atraumatic grasping forceps, ø 3 mm, 290 mm	IIb	9	11-502	61873
744-816	ERGO 335R Set, atraumatic grasping forceps, ø 3 mm, 200 mm	IIb	9	11-502	61873
744-844	ERGO 335R Set, Maryland dissector, ø 3 mm, 290 mm, COMFORT	IIb	9	11-502	61873
744-845	ERGO 335R Set, Maryland dissector, ø 3 mm, 200 mm, COMFORT	IIb	9	11-502	61873
744-847	ERGO 335R Set, Maryland dissector, ø 3 mm, 290 mm	IIb	9	11-502	61873
744-848	ERGO 335R Set, Maryland dissector, ø 3 mm, 200 mm	IIb	9	11-502	61873
745-100	Trocar sleeve, metal tube, smooth, insufflation stopcock, ø 3,4 mm, 100mm	IIa	7	14-154	37148
745-120	Silicon valve for trocar sleeve (5 pcs.)	IIa	7	14-154	37148
745-130	Sealing for trocar sleeve (5 pcs.)	IIa	7	14-154	37148
745-200	Trocar, pyramid-shaped, 145 mm	IIa	7	14-154	37148