

## EC Declaration of Conformity

**Item designation:** Electrosurgery Units and Accessories

**Item number:** see list of products 04\_0404\_V01 attached

**Classification:** see list of products attached  
Class Is, IIa, IIb, Rule 1, 6, 9, 11  
acc. to Annex IX to the Council Directive 93/42/EEC

We

**Gebrüder Martin GmbH & Co. KG**  
KLS Martin Platz 1  
78532 Tuttlingen  
Germany

hereby declare on our sole responsibility that the medical devices specified above have been subjected to a conformity assessment procedure complying with Article 11 of the EC Council Directive 93/42/EEC.

The following assessment procedure has been used:

Annex II – excluding section 4 - to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices with amending Directive 2007/47/EC.

**Notified body:** DQS Medizinprodukte GmbH,  
August-Schanz-Straße 21, D-60433 Frankfurt (Germany)

**ID number:** 0297

**Applied standards:** DIN EN 60601-1 und EN 60601-2-2

Tuttlingen, 2021-05-05

  
Micl  
Präsident

  
Director Product Management  
Electrosurgery / Surgical Lasers

The present declaration of conformity is only valid together with the attached list of products as well as temporarily until 2024-05-26.

## Attachment 04\_0404\_V01 to EC Declaration of Conformity

Item number	Item Designation	Classification: Class	Classification: Rule
80-006-02-04	MARTIN MD 62 220/240 V	IIb	9
80-008-03-04	MINICUTTER 100-240 VOLT	IIb	9
80-010-02-04	MARTIN ME 102 230 V	IIb	9
80-040-11-04	ME MB 3 M VERSION, 220-240 V	IIb	9
80-040-11-10	ME MB 3 M VERSION, 100-127 V	IIb	9
80-040-12-04	ME MB 3 I VERSION, 220-240 V	IIb	9
80-040-12-10	ME MB 3 I VERSION, 100-127 V	IIb	9
80-042-00-04	MAXIUM WITH SOCKET MODULE MARTIN	IIb	9
80-042-02-04	MAXIUM WITH SOCKET MODULE INTERNATIONAL	IIb	9
80-042-04-04	MAXIUM WITH MODULE F.5MM INSTR.E-VERSION	IIb	9
80-042-06-04	maxium B, module M/I	IIb	9
80-043-00-04	maxium smart C,MMB,M-modul,100-240V	IIb	9
80-043-01-04	maxium smart C,MMB,I-modul,100-240V	IIb	9
80-043-02-04	maxium smart C,MMB,E-modul,100-240V	IIb	9
80-043-10-04	maxium smart Beam, Argon-unit	IIb	9
80-044-00-04	MAXIUM BEAMER	IIb	9
80-060-00-04	MARVAC SMOKE EVACUATION SYST. 220-240V	IIa	11
80-060-00-10	MARVAC SMOKE EVACUATION SYST. 100-127V	IIa	11
80-060-01-04	MAIN FILTER UNIT MARVAC	IIa	11
80-060-03-04	HANDLE W.CLIP-ON F. SMOKE EVACUATOR	IIb	9
80-060-05-04	EXTERNAL CURRENT DETECTION MARVAC	IIa	11
80-061-00-04	MARVAC SMOKE EVAC.SYST.LAP-MODE 220-240V	IIa	11
80-061-00-10	MARVAC SMOKE EVAC.SYST.LAP-MODE 100-127V	IIa	11
80-062-00-04	maxium smart Vac, Lap-Mode, 220-240 V	IIa	11
80-062-00-10	maxium smart Vac, Lap-Mode, 100-127 V	IIa	11
80-062-01-04	maxium smart Vac, 220-240 V	IIa	11
80-062-01-10	maxium smart Vac, 100-127 V	IIa	11
80-181-02-04	MABS-HANDLE, TWO PUSH BUTTONS	IIb	9
80-181-07-04	MABS-NEEDLE-ELECTRODE 40MM, ADJUSTABLE	IIb	9
80-181-08-04	MABS-NEEDLE-ELECTRODE ADJUSTABLE	IIb	9
80-181-10-04	MABS-BEAM ELECTRODE, DIAM. 5MM,WORK 25MM	IIb	9
80-181-11-04	MABS-BEAM ELECTR. DIAM 5MM, WORK 100MM	IIb	9
80-181-12-04	MABS-ELECTR. INCL.FIX.EQUIPM.D=5, WI=320	IIb	9
80-181-13-04	MABS-LANCET-ELECTR. DIAM 5MM. WORK 25MM	IIb	9
80-181-14-04	MABS-LANCET ELECTR. DIAM 5MM, WORK 115MM	IIb	9
80-181-15-04	MABS-NEEDLE-ELECTR. DIAM 5MM, WORK 25MM	IIb	9
80-181-16-04	MABS-NEEDLE ELECTR. DIAM 5MM, WORK 115MM	IIb	9
80-181-23-04	MABS-GIT-PROBE REUSABLE 2.3MM/2.3M	IIb	9
80-181-24-04	MABS-GIT-PROBE REUSABLE 3,2MM/2,3M	IIb	9
80-181-25-04	MABS-TBS-PROBE DISPOSABLE 1,8MM/1,6M	IIb	9
80-181-26-04	MABS-GIT-PROBE DISPOSABLE 1,8MM/3,2M	IIb	9
80-181-27-04	MABS-GIT-PROBE DISPOSABLE 2,3MM/2,3M	IIb	9
80-181-28-04	MABS-GIT-PROBE DISPOSABLE 3,2MM/2,3M	IIb	9
80-181-29-04	MABS-GIT-PROBE DISPOSABLE 2,3MM/3,4M	IIb	9
80-181-30-04	MABS CONNECTING CABLE 2,5M-PIN CONNECT.	IIb	9
80-181-32-04	GIT-PROBE,SIDEFIRE,SINGLE USE 2,3MM,2,3M	IIb	9
80-181-41-04	GIT-SNARE 15MM MULTIFIL .DISP.2,5MM/2,3M	IIb	9
80-181-42-04	GIT-SNARE 30MM MULTIF. DISP.2,5MM/2,3M	IIb	9
80-181-43-04	GIT-SNARE 15MM,MONOFIL.DISP.2,5MM/2,3M	IIb	9
80-181-44-04	GIT-SNARE 30MM,MONOFIL.DISP.2,5MM/2,3M	IIb	9
80-181-60-04	MABS-BEAM ELECTRODE, 320MM, BENDABLE	IIb	9
80-181-62-04	MABS-BEAM ELECTRODE, 115MM, BENDABLE	IIb	9
80-210-03-04	ELECTR. HDL., DBL.SW., 3PIN, Ø2.4MM, 3M	IIa	6
80-210-12-04	EL.HANDLE W.2PUSHBUT.4,0MM,3PIN,CABLE 5M	IIa	6

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80-210-13-04	smartPen, 2 buttons, ø4mm, 4m, I	Ila	6
80-210-16-04	EL.HANDLE W.2PUSHBUT.2,4MM,3PIN,4M	Ila	6
80-210-18-04	smartPen, 2 buttons, ø4mm, 4m, E	Ila	6
80-210-21-04	smartPen, 2 buttons, ø2,4mm, 4m, I	Ila	6
80-210-23-04	smartPen, rockerswitch, ø2,4mm, 4m, I	Ila	6
80-214-00-04	ELECTRODE HDL., W/O SWITCH, 1,6 MM, 3M	Ila	6
80-214-01-04	D-ELECTR. HDL, 1SW, SMALL COAX, 1,6MM 3M	Ila	6
80-214-12-04	smartPen, 0 buttons, ø1,6mm, 4m, M	Ila	6
80-214-13-04	smartPen, 1 button, ø1,6mm, 4m, M	Ila	6
80-217-05-04	smartPen, 1 button, ø4mm, 4m, M	Ila	6
80-217-13-04	smartPen, 2 buttons, ø4mm, 4m, M	Ila	6
80-219-42-04	HANDLE SURGY-PEN, 2 SW., 3 PIN, 4MM,4M	Ila	6
80-220-02-04	smartPen, 0 buttons, ø4mm, 4m, M	Ila	6
80-220-31-04	smartPen, 0 buttons, ø4mm, 4m, E	Ila	6
80-220-41-04	smartPen, 0 buttons, ø4mm, 4m, Bovie	Ila	6
80-221-02-04	DISPOS. HANDLE, W. SPATULA, 2 SW, 3-PIN	Ilb	9
80-227-00-04	smartPen, 2 buttons, ø4mm	Ila	6
80-332-03-04	NEUTRAL EL. RUBBER 8X16CM, PL. 6,3MM,4M	Ilb	9
80-342-05-04	NEUTRAL EL. RUBBER, 8X16cm, I-PLUG, 4M	Ilb	9
80-342-06-04	TWIN-PAD NEUTRAL ELECTRODE	Ilb	9
80-342-07-04	Twin-Pad II Neutral Electrode	Ilb	9
80-344-09-04	PCS disposable neutral electrode	Ilb	9
80-344-12-04	PCS disposable neutral electrode, baby	Ilb	9
80-344-13-04	Disposable neutral electrode, children	Ilb	9
80-344-14-04	Disposable neutral electrode, Adults	Ilb	9
80-461-01-04	NEEDLE ELECTRODE STRAIGHT F1, 1,6MM	Ilb	9
80-461-02-04	NEEDLE ELECTRODE ANG 45DEG F2 1,6MM	Ilb	9
80-461-03-04	NEEDLE ELECTRODE ANG 120 DEG F3	Ilb	9
80-461-04-04	NEEDLE ELECTRODE 1PAIR RI/LE 1,6MM	Ilb	9
80-461-06-04	LOOP ELECTRODE FIG. 6	Ilb	9
80-461-07-04	DISH ELECTRODE.D5MM, SHAFT ANGLED 45°	Ilb	9
80-461-11-04	WIRE LOOP ELECTRODE 3MM F11	Ilb	9
80-461-12-04	WIRE LOOP ELECTRODE 5MM F12	Ilb	9
80-461-13-04	WIRE LOOP ELECTRODE 8MM F13	Ilb	9
80-461-14-04	WIRE LOOP ELECTRODE F14 1,6MM	Ilb	9
80-461-15-04	WIRE LOOP ELECTRODE 7X1,5 F15	Ilb	9
80-461-16-04	HOOK ELECTRODE,7MM,45DG.ANGL.FIG.16	Ilb	9
80-461-17-04	WIRE LOOP ELECTR 6X1,3MM F17	Ilb	9
80-461-18-04	WIRE LOOP ELECTR 7X1,7MM F18	Ilb	9
80-461-19-04	WIRE LOOP ELECTRODE FIG.19	Ilb	9
80-461-20-04	WIRE LOOP ELECTRODE 7X1,4MM 45° FIG 20	Ilb	9
80-461-21-04	WIRE LOOP ELECTRODE STR 7X1,7MM F21	Ilb	9
80-461-22-04	LOOP ELECTRODE ELONGATED 45ANGLED FIG.22	Ilb	9
80-461-23-04	Implantology electrode	Ilb	9
80-461-24-04	WIRE LOOP ELECTRODE 45DEG, FIG 24, 8X5MM	Ilb	9
80-461-31-04	COAGUL NEEDLE ELECTRODE F31	Ilb	9
80-461-32-04	NEEDLE ELECTRODE COAGULATING FIG.32	Ilb	9
80-461-33-04	BALL ELECTRODE 1,7MM F33	Ilb	9
80-461-34-04	ELECTRODE BALL 3,0MM FIG 34	Ilb	9
80-461-35-04	COAGULATION AND FULG. ELECTRODE, FIG.35	Ilb	9
80-461-36-04	COAG. AND FULG. ELECTRODE, FIG.36	Ilb	9
80-461-37-04	NEEDLE ELECTRODE 45° ANGLED	Ilb	9
80-462-01-04	NEEDLE ELECTRODE STRAIGHT SHORT 0,2 MM	Ilb	9
80-462-02-04	NEEDLE-ELECTRODE 45 GRAD FIG. 2 SHORT	Ilb	9

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Item number	Item Designation	Classification: Class	Classification: Rule
80-462-11-04	WIRE LOOP ELECTR., SHORT 3MM DIAM.FIG.11	Iib	9
80-462-12-04	WIRE LOOP ELECTRODE SHORT 5MM DIAM.FIG12	Iib	9
80-462-13-04	WIRE LOOP ELECTRODE SHORT 8MM DIAM.FIG13	Iib	9
80-463-01-04	NEEDLE ELECTR. STRAIGHT SHORT 0,3MM FIG1	Iib	9
80-464-02-04	NEEDLE ELECTRODE FIG. 2 FLEXIBLE WIRE	Iib	9
80-464-38-04	NEEDLE ELECTRODE FIG. 38 FLEXIBLE WIRE	Iib	9
80-466-01-04	NEEDLE ELECTRODE STRAIGHT SHORT 0,6 MM	Iib	9
80-505-00-04	CLEANING PAD FOR HF-ELECTRODES	Is	1
80-510-04-04	LANCET ELECTRODE, STRAIGHT, 25MM, 4MM	Iib	9
80-510-06-04	LANCET ELECTRODE SYN., STRAIGHT,25MM,4MM	Iib	9
80-510-08-04	LANCET ELECTRODE SYN,STRAIGHT,25MM,2.4MM	Iib	9
80-510-12-04	LANCET ELECTRODE, STR., L=100MM, WL=20MM	Iib	9
80-511-04-04	LANCET ELECTRODE ANGULAR, 25MM, 4MM	Iib	9
80-511-06-04	LANCET ELECTRODE, SYN, ANGLED, 23 MM,4MM	Iib	9
80-515-04-04	KNIFE ELECTRODE, STRAIGHT, 28MM, 4MM	Iib	9
80-515-06-04	KNIFE ELECTRODE, SYN, STR., 39 MM, 4MM	Iib	9
80-515-08-04	KNIFE ELECTRODE, STRAIGHT, 20MM, 2.4MM	Iib	9
80-515-12-04	KNIFE ELECTRODE L=100MM, WL=29MM, 4MM	Iib	9
80-515-14-04	KNIFE ELECTRODE, L=100MM, WL=12MM, 4MM	Iib	9
80-515-16-04	KNIFE EL., ANGL., L=100MM, WL=12MM, 4MM	Iib	9
80-516-04-04	MAMMARIA SPATULA, 37MM, 4MM	Iib	9
80-516-06-04	MAMMARIA SPATULA SYN, 39MM, 4MM	Iib	9
80-519-04-04	NEEDLE ELECTRODE, STR., 22MM, 4MM	Iib	9
80-520-04-04	NEEDLE ELECTRODE, STR.. 30MM, 4MM	Iib	9
80-520-06-04	NEEDLE ELECTRODE, SYN, STR., 30MM, 4MM	Iib	9
80-520-08-04	NEEDLE ELECTRODE, STR., 17MM, 2.4MM	Iib	9
80-520-09-04	NEEDLE ELECTR., MICRO, 2,4MM	Iib	9
80-520-10-04	NEEDLE ELECTR., MICRO, 2,4MM, STERILE	Iib	9
80-521-02-04	NEEDLE ELECTRODE, WL=23MM, 4MM	Iib	9
80-521-04-04	NEEDLE ELECTRODE, SYN, 10MM, 4MM	Iib	9
80-522-04-04	NEEDLE ELECTRODE, SYN, 6MM, 4MM	Iib	9
80-540-04-04	WIRE LOOP ELECTRODE, D=5MM, 4MM	Iib	9
80-540-12-04	WIRE LOOP ELECTRODE, L=10CM,D=5MM	Iib	9
80-542-04-04	WIRE LOOP ELECTRODE, D=10MM, 4MM	Iib	9
80-542-06-04	WIRE LOOP ELECTRODE SYN, D=10MM, 4MM	Iib	9
80-542-08-04	WIRE LOOP ELECTR. Ø 10 MM, F. 2.4 MM HDL	Iib	9
80-542-12-04	WIRE LOOP ELECTRODE, L=10CM, D=10MM	Iib	9
80-545-04-04	WIRE LOOP ELECTRODE D=20MM, 4MM	Iib	9
80-550-04-04	RIBBON LOOP ELECTRODE, D=10MM, 4MM	Iib	9
80-550-06-04	RIBBON LOOP ELECTRODE, SYN, D=10MM, 4MM	Iib	9
80-552-04-04	RIBBON LOOP ELECTRODE, D=15MM, 4MM	Iib	9
80-560-04-04	BALL ELECTRODE, D=2MM, 4MM	Iib	9
80-560-06-04	BALL ELECTRODE, SYN, WL=8MM, D=2MM, 4MM	Iib	9
80-562-04-04	BALL ELECTRODE, D=4MM, 4MM	Iib	9
80-562-06-04	BALL ELECTRODE, SYN, WL=8MM, D=4MM, 4MM	Iib	9
80-562-08-04	BALL ELECTRODE, D=4MM, 2,4MM	Iib	9
80-563-04-04	BALL ELECTRODE, D=5MM, 4MM	Iib	9
80-563-05-04	ELECTRODE FOR WRINKLE SMOOTHING, 4MM	Iib	9
80-570-04-04	PLATE ELECTRODE 8X10MM, 4MM	Iib	9
80-570-18-04	MARCUT BIPOL-SCISSORS, CVD., 18 CM	Iib	9
80-570-21-04	MARCUT BIPOL-SCISSORS, CVD., 21 CM	Iib	9
80-570-23-04	MARCUT BIPOL-SCISSORS, CVD., 23 CM	Iib	9
80-570-28-04	MARCUT BIPOL-SCISSORS, CVD., 28 CM	Iib	9
80-571-18-04	MARCUT BIPOL-SCISSORS, SLIM, CVD. 18 CM	Iib	9

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Item number	Item Designation	Classification: Class	Classification: Rule
80-571-21-04	MARCUT BIPOL-SCISSORS, SLIM, CVD. 21 CM	Iib	9
80-571-23-04	MARCUT BIPOL-SCISSORS, SLIM, CVD. 23 CM	Iib	9
80-571-28-04	MARCUT BIPOL-SCISSORS, SLIM, CVD. 28 CM	Iib	9
80-572-04-04	PLATE ELECTRODE 10X10MM, 4MM	Iib	9
80-572-13-04	MARCUT BIPOL.SCISS.SUPER SLIM,CVD. 13 CM	Iib	9
80-572-14-04	MARCUT BIPOL.SCISS.SUPER SLIM,CVD. 14 CM	Iib	9
80-572-17-04	MARCUT BIPOL.SCISS.SUPER SLIM,CVD. 17 CM	Iib	9
80-574-04-04	ELECTRODE A PLAQUE 12X10MM 4mm	Iib	9
80-580-06-04	ELECTRODE SET SYN, 4MM	Iib	9
80-610-10-04	NEEDLE EL., ANGUL., L=100MM, AL=2MM, 4MM	Iib	9
80-612-10-04	BALL ELECTRODE ANGUL, L=100MM, D=2MM,4MM	Iib	9
80-630-12-04	Tubular shaft incl.bladeholder, 200MM	Iib	9
80-630-15-04	Blade for marseal	Ila	6
80-630-16-04	Blade for marSeal, sterile	Ila	6
80-630-34-04	Tubular shaft ms slim incl. blade rod, 3	Iib	9
80-630-35-04	Tubuar shaft ms slim incl. blade rod, 20	Iib	9
80-630-41-04	MARSEAL IQ CPL.W.INSTRUMENT-CODING,200MM	Iib	9
80-630-42-04	MARSEAL SLIM IQ CPL.INSTRUM.CODING 370MM	Iib	9
80-630-43-04	MARSEAL SLIM IQ CPL.INSTRUM.CODING 200MM	Iib	9
80-630-45-04	Handle for marseal IQ, cable 4M	Iib	9
80-630-50-04	MarSeal 5 IQ cpl.w. Instr. Cod. 370MM	Iib	9
80-630-51-04	Tubular shaft for marseal 5, 370MM	Iib	9
80-630-52-04	Handle for marseal 5 with connector IQ	Iib	9
80-630-53-04	Blade rod for marseal 5	Ila	6
80-630-56-04	Handle for marseal 5 w. connector Martin	Iib	9
80-630-83-04	Blade insert marSeal 5,370mm,sterile	Ila	6
80-630-90-04	marSeal 5 IQ short comp.instrum-cod200mm	Iib	9
80-630-91-04	Blade insert f.marSeal 5 IQ short, 200mm	Ila	6
80-630-92-04	Tubular shaft for marseal 5 IQ short, 20	Iib	9
80-632-00-04	Blade for marClamp CUT IQ, sterile,18cm	Ila	6
80-632-18-04	marClamp CUT IQ w.instrum.coding,18cm	Iib	9
80-633-00-04	marSeal5plus VS.,bi.,IQ.,Ø5mm,37CM	Iib	9
80-633-01-04	marSeal5plus Maryland.,bi.,IQ.,Ø5mm,45cm	Iib	9
80-633-02-04	marSeal5plus Maryland.,bi.,IQ.,Ø5mm,37cm	Iib	9
80-633-03-04	marSeal5plus Maryland.,bi.,IQ.,Ø5mm,23cm	Iib	9
80-633-04-04	marSeal5plus handle,bi.,IQ.,Ø5mm	Iib	9
80-633-05-04	marSeal5plus tubular shaft,bi.,Ø5mm,37cm	Iib	9
80-633-06-04	marSeal5plus tub.shaft, Maryl.,Ø5mm,45cm	Iib	9
80-633-07-04	marSeal5plus tub.shaft, Maryl.,Ø5mm,37cm	Iib	9
80-633-08-04	marSeal5plus tub.shaft, Maryl.,Ø5mm,23cm	Iib	9
80-633-09-04	marSeal5plus blade insert,37cm,sterile	Ila	6
80-633-10-04	marSeal5plus blade insert,23cm,sterile	Ila	6
80-633-11-04	marSeal5plus blade insert,37cm	Ila	6
80-633-14-04	marSeal5plus blade insert,23cm	Ila	6
80-633-15-04	marSeal5plus blade insert,45cm,sterile	Ila	6
80-633-16-04	marSeal5plus blade insert,45cm	Ila	6
80-651-00-04	BIPOLAR HOOK ELECTRODE, L=115MM	Iib	9
80-652-00-04	BIPOLAR ARTHR. ELECTR. "PHAZER"	Iib	9
80-674-12-04	BALL ELECTRODE, D=5MM, L=10CM, 4MM	Iib	9
80-674-13-04	BALL ELECTRODE, D=3MM, L=10CM, 4MM	Iib	9
80-675-13-04	NEEDLE ELECTR., L=10CM, AL=4MM, 4MM	Iib	9
80-676-13-04	BALL ELECTRODE, L=13CM D=3MM, 4MM	Iib	9
80-677-12-04	NEEDLE ELECTRODE, L=10CM, WL=15,5MM, 4MM	Iib	9
80-678-10-04	KNIFE ELECTR.F.2,4MM HANDLES,SHAFT 9CM	Iib	9

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Item number	Item Designation	Classification: Class	Classification: Rule
80-678-11-04	BALL ELECTRODE, L=9CM, D=3MM, 2,4MM	Iib	9
80-680-12-04	CONIZATION ELECTRODE, L=12CM, D=10MM,4MM	Iib	9
80-681-12-04	CONISATION ELECTRODE, LOOP DIAM. 15 MM	Iib	9
80-682-12-04	CONIZATION ELECTRODE, L=12CM, D=20MM,4MM	Iib	9
80-683-12-04	CONISATION ELECTRODE, LOOP DIAM 25 MM	Iib	9
80-684-12-04	SCARFI CONIZAT.ELEC.,L=11,5CM, D=2CM,4MM	Iib	9
80-685-12-04	SCARFI CONIZAT.ELEC.,L=11,5CM, D=3CM,4MM	Iib	9
80-686-12-04	SCARFI CONIZAT.ELEC.,L=11,5CM, D=4CM,4MM	Iib	9
80-690-12-04	NEEDLE ELECTRODE ARTHR., L=11,5CM, 1,5MM	Iib	9
80-691-12-04	NEEDLE ELECTRODE, ARHTR., L=11,5CM, 4MM	Iib	9
80-692-12-04	NEEDLE ELECTRODE, ARHTR., L=11,5CM, 2MM	Iib	9
80-693-12-04	KNIFE ELECTRODE ARTHR., L=11,5CM, 4MM	Iib	9
80-694-12-04	PALPATION ELECTR., ARTHR., L=11,5CM, 4MM	Iib	9
80-695-12-04	BALL ELECTR. ARTHROSCOPY,L=11,5CM, D=3MM	Iib	9
80-900-18-03	DRESS. FORCEPS, ISOL., W/O CONN., 18 CM	Iib	9
80-900-21-03	DRESS. FORCEPS, ISOL., W/O CONN., 21 CM	Iib	9
80-900-25-03	DRESS. FORCEPS, ISOL., W/O CONN., 25 CM	Iib	9
80-901-18-03	FORCEPS, CHIR., 1X2 T., ISOL., 18CM	Iib	9
80-901-21-03	FORCEPS, CHIR., 1X2 T., ISOL., 21CM	Iib	9
80-901-25-03	FORCEPS, CHIR., 1X2 T., ISOL., 25CM	Iib	9
80-902-18-03	DRESSING FORCEPS, ISOL., W. CONN., 18 CM	Iib	9
80-902-21-03	DRESSING FORCEPS, ISOL., W. CONN., 21 CM	Iib	9
80-902-25-03	DRESSING FORCEPS, ISOL., W. CONN., 25 CM	Iib	9
80-910-07-04	BIPOLAR FCPS., STR., SH., 0.3 MM, 8.5 CM	Iib	9
80-910-12-04	BIPOLAR FCPS., STR., SH., 0.3 MM, 12 CM	Iib	9
80-910-16-04	BIPOLAR FCPS., STR., SH., 0.3 MM, 16 CM	Iib	9
80-910-18-04	BIPOLAR FCPS., STR., SH., 0.3 MM, 18 CM	Iib	9
80-910-20-04	BIPOLAR FCPS., STR., SH., 0.3 MM, 20 CM	Iib	9
80-910-22-04	BIPOLAR FCPS., STR., SH., 0.3 MM, 22 CM	Iib	9
80-911-07-04	BIPOLAR FCPS., ANG., SH., 0.3 MM, 8,5 CM	Iib	9
80-911-12-04	BIPOLAR FCPS., ANG., SH., 0.3 MM, 12 CM	Iib	9
80-911-16-04	BIPOLAR FCPS., ANG., SH., 0.3 MM, 16 CM	Iib	9
80-911-18-04	BIPOLAR FCPS., ANG., SH., 0.3 MM, 18 CM	Iib	9
80-911-20-04	BIPOLAR FCPS., ANG., SH., 0.3 MM, 20 CM	Iib	9
80-924-12-04	BIPOLAR FCPS., STR., BL., 1.0 MM, 12 CM	Iib	9
80-924-16-04	BIPOLAR FCPS., STR., BL., 1.2 MM, 16 CM	Iib	9
80-924-18-04	BIPOLAR FCPS., STR., BL., 1.2 MM, 18 CM	Iib	9
80-924-20-04	BIPOLAR FCPS., STR., BL., 1.2 MM, 20 CM	Iib	9
80-924-22-04	BIPOLAR FCPS., STR., BL., 1.2 MM, 22 CM	Iib	9
80-924-24-04	BIPOLAR FCPS., STR., BL., 1.2 MM, 24 CM	Iib	9
80-924-26-04	BIPOLAR FCPS., STR., BL., 1.2 MM, 26 CM	Iib	9
80-924-30-04	BIPOLAR FCPS., STR., BL., 1.2 MM, 30 CM	Iib	9
80-925-12-04	BIPOLAR FCPS., ANG., BL., 1.0 MM, 12 CM	Iib	9
80-925-16-04	BIPOLAR FCPS., ANG., BL., 1.2 MM, 16 CM	Iib	9
80-925-18-04	BIPOLAR FCPS., ANG., BL., 1.2 MM, 18 CM	Iib	9
80-925-20-04	BIPOLAR FCPS., ANG., BL., 1.2 MM, 20 CM	Iib	9
80-925-22-04	BIPOLAR FCPS., ANG., BL., 1.2 MM, 22 CM	Iib	9
80-931-16-04	BIPOLAR FCPS., BAY., SH., 0.3 MM, 16 CM	Iib	9
80-931-18-04	BIPOLAR FCPS., BAY., SH., 0.3 MM, 18 CM	Iib	9
80-931-20-04	BIPOLAR FCPS., BAY., SH., 0.3 MM, 20 CM	Iib	9
80-931-24-04	BIPOLAR FCPS., BAY., SH., 0.3 MM, 24 CM	Iib	9
80-934-12-04	BIPOLAR FCPS., STR., BL., 2.0 MM, 12 CM	Iib	9
80-934-16-04	BIPOLAR FCPS., STR., BL., 2.0 MM, 16 CM	Iib	9
80-934-18-04	BIPOLAR FCPS., STR., BL., 2.0 MM, 18 CM	Iib	9

Attachment 04\_0404\_V01 to EC Declaration of Conformity

Item number	Item Designation	Classification: Class	Classification: Rule
80-934-20-04	BIPOLAR FCPS., STR., BL., 2.0 MM, 20 CM	Iib	9
80-934-22-04	BIPOLAR FCPS., STR., BL., 2.0 MM, 22 CM	Iib	9
80-934-24-04	BIPOLAR FCPS., STR., BL., 2.0 MM, 24 CM	Iib	9
80-934-26-04	BIPOLAR FCPS., STR., BL., 2.0 MM, 26 CM	Iib	9
80-934-30-04	BIPOLAR FCPS., STR., BL., 2.0 MM, 30 CM	Iib	9
80-935-16-04	BIPOLAR FCPS., ANG., BL., 2.0 MM, 16 CM	Iib	9
80-935-18-04	BIPOLAR FCPS., ANG., BL., 2.0 MM, 18 CM	Iib	9
80-935-20-04	BIPOLAR FCPS., ANG., BL., 2.0 MM, 20 CM	Iib	9
80-935-22-04	BIPOLAR FCPS., ANG., BL., 2.0 MM, 22 CM	Iib	9
80-935-24-04	BIPOLAR FCPS., ANG., BL., 2.0 MM, 24 CM	Iib	9
80-945-16-04	BIPOLAR FCPS., BAY., BL., 1.2 MM, 16 CM	Iib	9
80-945-18-04	BIPOLAR FCPS., BAY., BL., 1.2 MM, 18 CM	Iib	9
80-945-20-04	BIPOLAR FCPS., BAY., BL., 1.2 MM, 20 CM	Iib	9
80-945-24-04	BIPOLAR FCPS., BAY., BL., 1.2 MM, 24 CM	Iib	9
80-948-18-04	BIPOLAR FCPS., BAY., BL., 2.0 MM, 18 CM	Iib	9
80-948-20-04	BIPOLAR FCPS., BAY., BL., 2.0 MM, 20 CM	Iib	9
80-948-24-04	BIPOLAR FCPS., BAY., BL., 2.0 MM, 24 CM	Iib	9
80-948-30-04	BIPOLAR FCPS., BAY., BL., 2.0 MM, 30 CM	Iib	9
80-950-20-04	BIP. FCPS., NEURO , STR., 0.5 MM, 20 CM	Iib	9
80-951-20-04	BIP. FCPS., NEURO , ANG., 0.5 MM, 20 CM	Iib	9
80-975-16-04	MARCLAMP, IQ, 16CM, CABLE 4M	Iib	9
80-975-18-04	MARCLAMP, IQ, 18CM, CABLE 4M	Iib	9
80-975-23-04	MARCLAMP, IQ, 23CM, CABLE 4M	Iib	9
80-975-28-04	MARCLAMP, IQ, 28CM, CABLE 4M	Iib	9
80-976-23-04	MARCLAMP SHARK, IQ, 23 CM, CABLE 4M	Iib	9
80-977-23-04	MARCLAMP URO, ACC. TO KALEM, IQ,CABLE 4M	Iib	9
80-978-23-04	MARCLAMP IQ, GEMINI, 23 CM	Iib	9
80-981-01-04	NST-FLUSH-FCPS., BAJ.,STR.,0,5 MM, 20 CM	Iib	9
80-981-02-04	NST-FLUSH-FCPS., BAJ.,STR.,1,0 MM, 20 CM	Iib	9
80-981-03-04	NST-FLUSH-FCPS., BAJ.,STR.,0,5 MM, 23 CM	Iib	9
80-981-04-04	NST-FLUSH-FCPS., BAJ.,STR.,1,0 MM, 23 CM	Iib	9
80-981-05-04	NST-FLUSH-FCPS., STR.,1,5 MM, 20 CM	Iib	9
80-981-06-04	NST-FLUSH-FCPS., STR.,2,0 MM, 23 CM	Iib	9
80-981-08-04	NST-FLUSH-FCPS.,STR., 2,0 MM, 30 CM	Iib	9
80-982-12-04	NST-RED-FCPS., STR., SH. 0,3 MM, 12 CM	Iib	9
80-982-17-04	NST-RED-FCPS., STR., SH. 0,3 MM, 17 CM	Iib	9
80-982-20-04	NST-RED-FCPS., STR., SH. 0,3 MM, 20 CM	Iib	9
80-983-12-04	NST-RED-FCPS., ANG., SH. 0,3 MM, 12 CM	Iib	9
80-983-17-04	NST-RED-FCPS., ANG., SH. 0,3 MM, 17 CM	Iib	9
80-984-12-04	NST-RED-FCPS., STR., BL. 0,6 MM, 12 CM	Iib	9
80-984-17-04	NST-RED-FCPS., STR., BL. 0,6 MM, 17 CM	Iib	9
80-984-20-04	NST-RED-FCPS., STR., BL. 0,6 MM, 20 CM	Iib	9
80-985-12-04	NST-RED-FCPS., ANG., BL. 0,6 MM, 12 CM	Iib	9
80-985-17-04	NST-RED-FCPS., ANG., BL. 0,6 MM, 17 CM	Iib	9
80-985-20-04	NST-RED-FCPS., ANG., BL. 0,6 MM, 20 CM	Iib	9
80-986-12-04	NST-RED-FCPS., STR., BL. 1,0 MM, 12 CM	Iib	9
80-986-17-04	NST-RED-FCPS., STR., BL. 1,0 MM, 17 CM	Iib	9
80-986-20-04	NST-RED-FCPS., STR., BL. 1,0 MM, 20 CM	Iib	9
80-986-23-04	NST-RED-FCPS., STR., BL. 1,0 MM, 23 CM	Iib	9
80-987-12-04	NST-RED-FCPS., ANG., BL. 1,0 MM, 12 CM	Iib	9
80-987-17-04	NST-RED-FCPS., ANG., BL. 1,0 MM, 17 CM	Iib	9
80-987-20-04	NST-RED-FCPS., ANG., BL. 1,0 MM, 20 CM	Iib	9
80-987-23-04	NST-RED-FCPS., ANG., BL. 1,0 MM, 23 CM	Iib	9
80-988-17-04	NST-RED-FCPS., STR., BL. 2,0 MM, 17 CM	Iib	9

## Attachment 04\_0404\_V01 to EC Declaration of Conformity

Item number	Item Designation	Classification: Class	Classification: Rule
80-988-20-04	NST-RED-FCPS., STR., BL. 2,0 MM, 20 CM	Iib	9
80-988-23-04	NST-RED-FCPS., STR., BL. 2,0 MM, 23 CM	Iib	9
80-988-30-04	NST-RED-FCPS., STR., BL. 2,0 MM, 30 CM	Iib	9
80-989-17-04	NST-RED-FCPS., ANG., BL. 2,0 MM, 17 CM	Iib	9
80-989-20-04	NST-RED-FCPS., ANG., BL. 2,0 MM, 20 CM	Iib	9
80-989-23-04	NST-RED-FCPS., ANG., BL. 2,0 MM, 23 CM	Iib	9
80-989-25-04	NST-RED-FCPS., ANG., BL. 2,0 MM, 25 CM	Iib	9
80-989-28-04	NST-RED-FCPS., ANG., BL. 2,0 MM, 28 CM	Iib	9
80-989-30-04	NST-RED-FCPS., ANG., BL. 2,0 MM, 30 CM	Iib	9
80-990-17-04	NST-RED-FCPS., BAY., STR., 0,3 MM, 17 CM	Iib	9
80-990-20-04	NST-RED-FCPS., BAY., STR., 0,3 MM, 20 CM	Iib	9
80-990-23-04	NST-RED-FCPS., BAY., STR., 0,3 MM, 23 CM	Iib	9
80-990-25-04	NST-RED-FCPS., BAY., STR., 0,3 MM, 25 CM	Iib	9
80-991-17-04	NST-RED-FCPS., BAY., STR., 0,6 MM, 17 CM	Iib	9
80-991-20-04	NST-RED-FCPS., BAY., STR., 0,6 MM, 20 CM	Iib	9
80-991-23-04	NST-RED-FCPS., BAY., STR., 0,6 MM, 23 CM	Iib	9
80-991-25-04	NST-RED-FCPS., BAY., STR., 0,6 MM, 25 CM	Iib	9
80-992-17-04	NST-RED-FCPS., BAY., STR., 1,0 MM, 17 CM	Iib	9
80-992-20-04	NST-RED-FCPS., BAY., STR., 1,0 MM, 20 CM	Iib	9
80-992-23-04	NST-RED-FCPS., BAY., STR., 1,0 MM, 23 CM	Iib	9
80-992-25-04	NST-RED-FCPS., BAY., STR., 1,0 MM, 25 CM	Iib	9
80-993-17-04	NST-RED-FCPS., BAY., STR., 2,0 MM, 17 CM	Iib	9
80-993-20-04	NST-RED-FCPS., BAY., STR., 2,0 MM, 20 CM	Iib	9
80-993-23-04	NST-RED-FCPS., BAY., STR., 2,0 MM, 23 CM	Iib	9
80-993-25-04	NST-RED-FCPS., BAY., STR., 2,0 MM, 25 CM	Iib	9
80-994-20-04	NST-RED-FCPS. BAY. DOWNW.-B. 1,0 MM20cm	Iib	9
80-994-23-04	NST-RED-FCPS. BAY. DOWNW.-B. 1,0 MM 23cm	Iib	9
80-994-25-04	NST-RED-FCPS. BAY. DOWNW.-B.1,0MM25cm	Iib	9
80-995-20-04	NST-RED-FCPS., BAY., UPW.-B.,1,0MM, 20CM	Iib	9
80-995-23-04	NST-RED-FCPS., BAY., UPW.-B.,1,0MM, 23CM	Iib	9
80-996-23-04	NST-RED-FCPS., BAY., UPW.-B., 0,6 MM, 23	Iib	9
80-997-23-04	NST-RED-FCPS., BAY., DOWNW.-B., 0,6 MM,	Iib	9
80-997-25-04	NST-RED-FCPS., BAY., DOWNW.-B., 0,6 MM,	Iib	9
80-998-23-04	NST-RED-FCPS., CVD., STR., 0,5 MM, 23 CM	Iib	9
80-998-24-04	NST-RED-FCPS., ACC. MEUSER, 2MM, 18CM	Iib	9
80-999-23-04	NST-RED-FCPS., CVD., UPW.-B.,0,5 MM,23CM	Iib	9
80-999-24-04	NST-RED-FCPS., CVD.,DOWNW.-B.,0,5MM,23CM	Iib	9
83-520-39-04	Hook Electrode, mono, D=5mm,AL=470mm	Iib	9
83-525-30-04	smartLap electrode, mo.,ø5mm, L-hook	Iib	9
83-525-31-04	smartLap electrode, mo.,ø5mm, J-hook	Iib	9
83-525-32-04	smartLap electrode, mo.,ø5mm, needle	Iib	9
83-585-00-04	MARLAP HANDLE WITH SHAFT	Iib	9
83-585-01-04	MARLAP HANDLE	Iib	9
83-585-02-04	MARLAP SHAFT	Iib	9
83-585-03-04	MARLAP CUT, EXCHANGE. SCISSORS ELETRODE	Iib	9
83-585-05-04	MARLAP CLAMP,EXCH. FORC. ELEKTR.FENESTR.	Iib	9
83-585-06-04	MARLAP MARYLAND,EXCH.FORC.ELECTRODE,DVD	Iib	9
83-585-07-04	MARLAP CLAMP ELECTR.NON FENESTR.SMOOTH	Iib	9

## ATITIKTIES DEKLARACIJA CE

**Prekės pavadinimas:** Elektrochirurginiai aparatai ir priedai  
**Prekės numeris:** žiūrėti į pridėtą produktų sąrašą 04\_0404\_V01  
**Klasifikacija:** žiūrėti į pridėtą produktų sąrašą  
pagal 93/42 / EEC Tarybos Direktyvos IX priedo, Is, Iia, Iib klasės, 1, 6, 9, 11  
taisyklę

Mes

**Gebrüder Martin GmbH & Co. KG**  
**KLS Martin Platz 1**  
**78532 Tuttingenas**  
**Vokietija**

atsakingai pareiškiame, kad aukščiau nurodytiems medicinos prietaisams buvo atliktos atitikties įvertinimo procedūros, atitinkančios 93/42 / EEC CE Tarybos direktyvos 11 straipsnį.

Vertinimo procedūra buvo naudojama ši:

1993 m. birželio 14 d. Tarybos direktyvos 93/42/EEB dėl medicinos prietaisų, iš dalies keičiančios Direktyvą 2007/47/EB, II priedas, išskyrus 4 skirsnį

Notifikuotoji įstaiga: DQS Medizinprodukte GmbH,  
August-Schanz-Strasse 21, D-60433 Frankfurtas (Vokietija)  
ID numeris: 0297

Taikomi standartai: DIN EN 60601 – 1 ir EN 60601 – 2 - 2

Tuttingenas, 2021-05-05

i.v. /Parašas/

Michael Martin  
Prezidentas

i.v. /Parašas/

Uwe Ott  
Elektrochirurgijos ir Lazerio sistemų  
Kokybės valdymo vadovas

Ši atitikties deklaracija galioja tik su pridėtu produktų sąrašu iki 2024-05-26.

CE atitikties deklaracijos 14b priedas ,VA2.01.00Z 2017-11-24

puslapis 1/1