

Declaration of Conformity

according to Directive 93/42/EEC

Product/Product group: Medical Device Class IIa

Article no.: see product list, Rev. 26, pages 2-8

MDD Class: IIa, Rule (see product list)
according to Directive 93/42/EEC Annex IX

Manufacturer: Bausch & Lomb GmbH
Im Schuhmachergewann 4
D-69123 Heidelberg
GERMANY

We hereby declare in sole responsibility the conformity of the above mentioned product with Directive 93/42/EEC Annex II, excluding section 4. Design, manufacture and final inspection of above product are carried out in compliance with the EC Directive 93/42/EEC and the applicable European harmonized standards.

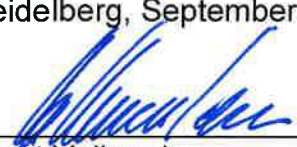
Notified Body: TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany

Identification number 0197

Registration No.: HD 60141442 0001 Expiry Date: 2024-05-26

Declaration of
Conformity Expiry Date: 2024-05-26

Heidelberg, September 5th, 2019



Horst Vollmerhausen
Director Operations Heidelberg

Product List Rev. 26

Item Number	Item Description	Rule
D8200	BIPOLAR FORCEPS	6
D8201	REUSABLE ERASER	6
D8203	REUSABLE INTRAOCULAR DIATHERMY	6
E3050 6.0G	TANNE DISPOSABLE TREPHINE, 6.0	6
E3050 6.25G	TANNE DISPOSABLE TREPHINE, 6.2	6
E3050 6.5G	TANNE DISPOSABLE TREPHINE, 6.5	6
E3050 6.75G	TANNE DISPOSABLE TREPHINE, 6.7	6
E3050 7.0G	TANNE DISPOSABLE TREPHINE, 7.0	6
E3050 7.25G	TANNE DISPOSABLE TREPHINE, 7.2	6
E3050 7.5G	TANNE DISPOSABLE TREPHINE, 7.5	6
E3050 7.75G	TANNE DISPOSABLE TREPHINE, 7.7	6
E3050 8.0G	TANNE DISPOSABLE TREPHINE, 8.0	6
E3050 8.25G	TANNE DISPOSABLE TREPHINE, 8.2	6
E3050 8.5G	TANNE DISPOSABLE TREPHINE, 8.5	6
E3050 8.75G	TANNE DISPOSABLE TREPHINE, 8.7	6
E3050 9.0G	TANNE DISPOSABLE TREPHINE, 9.0	6
E3050 9.25G	TANNE DISPOSABLE TREPHINE, 9.2	6
E3096 6.0G	DISP. TREPH.BLADE STER. 6.00MM	6
E3096 6.0LG	TREPHINE BLADE LONG STERILE 6.	6
E3096 6.2G	DISP. TREPH.BLADE STER. 6.25MM	6
E3096 6.5G	DISP. TREPH.BLADE STER. 6.50MM	6
E3096 6.5LG	TREPHINE BLADE LONG STERILE 6.	6
E3096 6.7G	DISP. TREPH.BLADE STER. 6.75MM	6
E3096 6.7LG	TREPHINE BLADE LONG STERILE 6.	6
E3096 7.0G	DISP. TREPH.BLADE STER. 7.00MM	6
E3096 7.0LG	TREPHINE BLADE LONG STERILE 7.	6
E3096 7.2G	DISP. TREPH.BLADE STER. 7.25MM	6
E3096 7.2LG	TREPHINE BLADE LONG STERILE 7.	6
E3096 7.5G	DISP. TREPH.BLADE STER. 7.50MM	6
E3096 7.5LG	TREPHINE BLADE LONG STERILE 7.	6
E3096 7.7G	DISP. TREPH.BLADE STER. 7.75MM	6
E3096 7.7LG	TREPHINE BLADE LONG STERILE 7.	6
E3096 8.0G	DISP. TREPH.BLADE STER. 8.00MM	6
E3096 8.0LG	TREPHINE BLADE LONG STERILE 8.	6
E3096 8.2G	DISP. TREPH.BLADE STER. 8.25MM	6
E3096 8.2LG	TREPHINE BLADE LONG STERILE 8.	6
E3096 8.5G	DISP. TREPH.BLADE STER. 8.50MM	6
E3096 8.5LG	TREPHINE BLADE LONG STER.8.5MM	6
E3096 8.7G	DISP. TREPH.BLADE STER. 8.75MM	6
E3096 8.7LG	TREPHINE BLADE LONG STER.8.7MM	6
E3096 9.0G	DISP. TREPH.BLADE STER. 9.00MM	6
E3096 9.0LG	TREPHINE BLADE LONG STER.9.0MM	6
E3096 9.2G	DISP. TREPH.BLADE STER. 9.25MM	6
E3096 9.2LG	TREPHINE BLADE LONG STER.9.2MM	6
E3096 9.5G	DISP. TREPH.BLADE STER. 9.50MM	6
E3096 9.5LG	TREPHINE BLADE LONG STER.9.5MM	6
E4971 G	SIMCOE IRRIGATION/ASPIRATION U	6

Item Number	Item Description	Rule
E4971 RG	SIMCOE REVERSE IRRIGATION/ASPI	6
E5002	VISCOUS FLUID INJECTION TUBING	6
E7920	BIPOLAR PENCIL 25GA TAPERED	6
E7924	25G BIPOLAR PENCIL TPD 12/B	6
E7925	25G BIPOLAR PENCIL BLNT 12B	6
E7926	BIPOLAR PENCIL 25GA TAPERD 12/B	6
E7927	BIPOLAR PENCIL 25GA BLUNT 12/B	6
E7928	BIPOL.PEN SCLERAL LEMO 12/BX	6
E7929	BIPOL.PEN 20GA LEMO 12/BX	6
E7930	23G BIPOLAR PNCL TPD LEMO 12/B	6
E7931	23G BIPOLAR PNCL TPD 2PIN 12/B	6
E7932	27GA BIPOLAR ERASER TAPERED 12B	6
E7933	27GA BIPOLAR ERASER 2-PIN 12B	6
PPT036	PPT B+L SAMPLE FRA STER.6B	6
PPT049	PPT MICS 6/B	6
PPT072	PPT CH PARAY LE MONIAL 6B	6
PPT079	CLINIQUE LA CIOTAT 6/B	6
PPT082-6	PPT OMC DR.DIJKSTRA 6B	6
PPT083-6	PPT OMC DR. ZAAL 6B	6
PPT084	DR VERHAEGHE DR VANWIJNSBERGHE	6
PPT087-6	PPT AUGENZENTRUM BRUCHSAL 6B	6
PPT090	PPT CL COURLANCY 51	6
PPT091-6	PPT AUGENZENTRUM HEPPENHEIM 6B	6
PPT092-6	PPT DR. DE MAEYER 6B	6
PPT096	PPT AUGENZENTRUM KRAICHGAU	6
PPT099	PPT FREEVIS PROF. DR. KNORZ 6B	6
PPT100	PPT DR. KRETZ 6B	6
PPT101	PPT AUGENPRAXISKL.VOGELSANG 6B	6
PPT102	PPT DR. KRETZ 6B	6
PPT103	PPT HELIGON 6B	6
PPT104	PPT DR. ROSENTHAL ANTERIOR 6B	6
PPT106	PPT DR BUEHLER 6B	6
PPT109	PPT STANDARD BIAXIAL 6B	6
PPT110	PPT DR. HAEGELE 6B	6
PPT111	PPT ST.WORLDEYE AMSTERDAM 6B	6
PPT112	PPT CH BIGORRE 6B	6
PPT500	B+L ELC 1 6/B	6
SUB7515	KNIFE, STAB, 15°, DOUBLE BEVEL 12B	6
SUB7520	KNIFE, MVR 20GA STRAIGHT 12B	6
SUB7522	KNIFE, STAB, 22.5°, DOUBLE BEVEL 12B	6
SUB7528	KNIFE, CLEAR CORNEA, 2.85MM, ANGLED 12B	6
SUB7530	KNIFE, STAB, 30°, DOUBLE BEVEL 12B	6
SUB7545	KNIFE, STAB, 45°, DOUBLE BEVEL 12B	6
SUB7548ADB	KNIFE, SLIT, 2.2MM, ANGLED, DOUBLE BEVEL 12B	6
SUB7549ADB	KNIFE, SLIT, 2.4MM, ANGLED, DOUBLE BEVEL 12B	6
SUB7550A	KNIFE, SLIT, 2.5MM, ANGLED BEVEL UP 12B	6
SUB7552ADB	KNIFE, SLIT, 2.80MM, ANGLED, DOUBLE BEV. 12B	6
SUB7553A	KNIFE, SLIT, 2.85MM, ANGLED, BEVEL UP 12B	6
SUB7556A	KNIFE, SLIT, 3.0MM, ANGLED, BEVEL UP 12B	6
SUB7557A	KNIFE, SLIT, 3.2MM, ANGLED, BEVEL UP 12B	6

Item Number	Item Description	Rule
SUB7559A	KNIFE, SLIT, 2.75MM, ANGLED BEVEL UP 12B	6
SUB7582	KNIFE, TRAPEZOID, 2.85X3.2MM, ANGLED 12B	6
SUB7596	KNIFE, TRAPEZOID, 1.5X2.0MM, ANGLED 12B	6
SUB7599	KNIFE, TRAPEZOID, 1.5X1.7 MM, ANGLED 12B	6
SUB7600	KNIFE, TRAPEZOID, 1.6X1.8MM, ANGLED 12B	6
SUB7601	KNIFE, TRAPEZOID, 2.0X2.2 MM, ANGLED 12B	6
SUE01-12	CAPSULORHEXIS FORCEPS 12/BOX	6
SUE02-12	BONN FORCEPS 12/BOX	6
SUE03-12	TYING FORCEPS STRAIGHT 12/BOX	6
SUE04-12	MCPHERSON TYING FORCEPS 12/BOX	6
SUE05-12	PIERSE TYING FORCEPS 12/BOX	6
SUE06-12	MICS CAPSULORHEXIS FORCEPS 12/BOX	6
SUE07-12	CAPSULORH.FCPS W/MARKINGS 12/BOX	6
SUE08-12	MICS CAPSULORH FCPS CURVED 12/BOX	6
SUF01	KOCH STOP CHOP MANIPUL 12B	6
SUF02	SINSKEY IOL HOOK 12/BOX	6
SUF03	PHACO SPATULA 12/BOX	6
SUF04	DRYSDALE NUCLEUS MANIPULATOR 12B	6
SUF05	NUCLEUS Y-HOOK HORIZONTAL 12B	6
SUF06	NUCLEUS Y-HOOK VERTICAL 12B	6
SUH01	BARRAQUER LID SPECULUM 24B	5
SUH04	SPECULUM ADJUSTABLE 6B	5
SUI03-12	23G ASYM PEELING FORCEPS 12/B	6
SUI05-12	25G ASYM PEELING FORCEPS 12B	6
SUI07-12	23G ILM FORCEPS 12/BOX	6
SUI07EA	23G ILM FORCEPS 1/BOX	6
SUI08-12	25G ILM FORCEPS 12/BOX	6
SUI08EA	25G ILM FORCEPS 1/B	6
SUI09-12	20G ILM FORCEPS 12BOX	6
SUI09EA	20G ILM FORCEPS 1/BOX	6
SUI10-12	20G SERRATED FORCEPS 12B	6
SUI11-12	23G SERRATED FORCEPS 12B	6
SUI12-12	25G SERRATED FORCEPS 12/B	6
SUI13-12	27G ENDGRIPPING FORCEPS 12B	6
SUI14-12	27GA SERRATED FORCEPS	6
SUI20-12	MICS KAPS.PINZ 1.0MM 12BOX	6
SUJ01	23G PASSIVE ASP HP W/SOFT TIP 12B	6
SUJ02	25G PASSIVE ASP HP W/SOFT TIP 12B	6
SUJ03	23G PASSIVE ASP HP W/SOFT TIP CAN.12B	6
SUJ06	23G PASSIVE ASP HP W/BLUNT NEEDLE 12B	6
SUJ07	25G PASSIVE ASP HP W/BLUNT NEEDLE 12B	6
SUJ08	20G BACKFLUSH HPC BLUNT 6/B	6
SUJ09	20G BACKFLUSH HPC BRUSH 6/B	6
SUJ10	20G BACKFLUSH HPC TUBE 6/B	6
SUJ11	23G BACKFLUSH HPC BLUNT 6/B	6
SUJ12	23G BACKFLUSH HPC BRUSH 6/B	6
SUJ13	23G BACKFLUSH HPC TUBE 6/B	6
SUJ14	25G BACKFLUSH HPC BLUNT 6/B	6
SUJ17	27GA BACKFLUSH HDP BLUNT 6B	6
SUK01	23G MEMBRANE PICK 130DEG 8/B	6

Item Number	Item Description	Rule
SUK02	25G MEMBRANE PICK 130DEG 8/B	6
SUP01	MICS ZERO PHACO HDP 30° MILL	6
SUP04	ZERO PHACO HDP 2.2MM 30D 12B	6
SUP05	21G ZERO PHACO ASP. HDP. 30°	6
SUP06	ZERO PHACO HDP II 30° 2.2MM 12B	6
SUP06ST	ZERO PHACO HDP II 30° 2.2MM STEL 12B	6
16131	ECO CUT NEEDLE BLADE 1.1MM 50B	6
16134	ECOCUT SCLEROTOMY BL.1.4MM 50B	6
16145 2.5	PHACOBLADE SHORT 2.5MM ST.50/B	6
16145 2.8	PHACOBLADE SHORT 2.8MM ST.50/B	6
16145 3.0	PHACOBLADE SHORT 3.0MM ST.50/B	6
16145 3.2	PHACOBLADE SHORT 3.2MM ST.50/B	6
16150	CRESCENT BLADE STERILE 50/BOX	6
16155	BLADE 15DEG STERILE 50/BOX	6
16500G	SPECIAL BLADE"G"STERILE 50/BX	6
16501S	SPECIAL BLADE"S"STERILE 50/BX	6
16510K	SPECIAL BLADE"K"STERILE 50/BX	6
52135	SPECULUM LASIK W/ ASPIRATION	6
52136	SPECULUM LASIK W/ASP.VALVE RND	6
52137	SPECULUM LASIK W/ASP.VALVE OPN	6
52138	SPECULUM W.ASPIRAT.VALVES 12MM	6
65023S-12	23G ENDGRIPPING FORCEPS 12/BX	6
65025S-12	25G ENDGRIPPING FORCEPS 12/BX	6
81055	BANGERTER PROBE CANNULA 60 X 0	6
81056	BANGERTER PROBE CANNULA 40 X 0	6
81061-6	ANEL LACHRYMAL CANN.STRAIG 6/B	6
81071	LACHRYMAL CANNULA, STAINL. STE	6
81072	LACHRYMAL CANNULA, STAINL. STE	6
81073	LACHRYMAL CANNULA, STAINL. STE	6
81074	LACHRYMAL CANNULA, STNL.STEEL,	6
81075Y1	LACHRYMAL CANNULA, MOD. MARBUR	6
81075Y3	LACHRYMAL CANNULA MOD.MARBURG	6
81075Y4	LACHRYMAL CANNULA, MOD. MARBUR	6
81075Y5	LACHRYMAL CANNULA, MOD. MARBUR	6
81080-6	LACHRYMAL CANN.PROBE POINT 6/B	6
82020S	CORNEAL IRRIGATOR STERILE 60/B	6
83010	LASIK IRRIGATING CANNULA 27GA	6
83011	CANNULA LASIK SIDE&CENTRL.PORT	6
84010	CYCLODIALYSIS CANNULA	6
84021	BINKHORST CANNULA, RIGHT	6
84022	BINKHORST CANNULA, LEFT	6
85021	IRRIGATING CANNULA, MOD. BONN	6
85041	ENZYME CANNULA	6
85050-6	SAUTTER AIR INJECT.CANNULA 6/B	6
85050Y1-6	SAUTTER AIR INJECT.CANNULA 6/B	6
85100-6	AIR INJECT.CANNUL.MOD.TUEB.6/B	6
85110-6	CANNULA PROBE POINT M.HAMB.6/B	6
85121	ULLERICH ASPIRATING CANNULA, S	6
85240	SHEETS IRRIGATING VECTUS	6
85250	KRATZ CAPSULE POLISHER, SANDBL	6

Item Number	Item Description	Rule
85251Y2	KAMMAN CAPSULE POLISHER, SANDB	6
85260	KRATZ CANNULA WITH COLLAR BUTT	6
85266	ENGELS CAPSULE POLISHER	6
85268	ASPIRATION CANNULA F. BIMANUEL	6
85269	IRRIGATION CANNULA F. BIMANUEL	6
85272	ONG IRRIGATION CANNULA F.BIMAN	6
85640	HEALON INJECTION CANNULA	6
85730	CHARLEUX IRRIGATING CANNULA	6
85761	I/A-HNDPCE.STRGHT.SILICON 20GA	6
85762	I/A-HANDPIECE STRGHT. SIL.16GA	6
85763	I/A-HANDPIECE CURVED SILICONE	6
85764	I/A- HANDPIECE CRVD.SIL.17GA	6
85765	I/A- HANDPCE SIL. 60DEG.16GA	6
85766	I/A-HANDPIECE SIL. 60DEG.17GA	6
85768	I/A-HANDPIECE SIL.90DEG.0.3MM	6
85770	I/A-HNDPCE SILCN+SLVE.20°0.3MM	6
85771	I/A-HANDPCE SIL.+SLEEVE 90DEG	6
85772R	ASPIRATION HANDPIECE MALE	6
85774R	ASP HDPIECE.ROUGD.TAPRD.TIP0.3	6
85775	IRR HANDPIECE ROUGHENED TAPERE	6
85776R	ASPIRATION HANDPIECE ROUGHENED	6
85777	IRRIGATION HANDPIECE ROUGHENED	6
85778R	HANDPIECE ASPIRN.CRVD.0.3MM	6
85779	HANDPIECE IRRIGATN.CRVD.0.5MM	6
85780S	ASP HANDPIECE STERILE 12/BOX	6
85781S	IRR HANDPIECE STERILE 12/BOX	6
85782S	I/A HANDP.STRAIGHT,17G 12/BOX	6
85783S	I/A HANDP.CURVED,17G 12/BOX	6
85783ST	I/A HANDPIECE CURVED 17G 12/B	6
85784S	I/A HANDP.TIP 45DEG.17G.12BOX	6
85784ST	I/A HANDPIECE45° ANG.17G 12/BX	6
85785S	I/A HANDP.STRAIG.W.SLEEVE 12BX	6
85786S	I/A HANDP.TIP 90DEG.16G.12BOX	6
85786ST	I/A HANDPIECE90° ANG.16G 12/BX	6
85787S	IRR HANDPIECE SMOOTH 12/BOX	6
85787ST	IRR. HANDPIECE SMOOTH 12/BX	6
85788S	IRR.HANDPIECE CENTR.PORT 12/BX	6
85789S	IRR HANDPIECE 22G END-OUT 12/B	6
85790S	ASP HANDPIECE 22G ROUGH 12/BOX	6
85791	SCHAMMAS CAPSULE POLISHER	6
85791S	23G IRR HANDPIECE END-OUT 12/B	6
85792S	23G ASP HANDPIECE ROUGH 12/BOX	6
85794ST	I/A HNDP CVD W/SLEEVE 1.8 12/BX	6
85795ST	I/A HNDP 45D W/SLEEVE 1.8 12/BX	6
85795STR	IA HDP ROUGH 45D SLEEVE 1.8 12B	6
85800	IRRIGATING CHOPPER 19G	6
85802	ASPIRATION HANDPIECE 19G	6
85803	IRRIGATION HANDPIECE 19G	6
85804	ASP HANDPIECE 0,9 MM	6
85805	IRR HANDPIECE 0,9 MM	6

BAUSCH + LOMB

CONTROLLED DOCUMENT MDD Class IIa Declared Status: Approved Approved Date: 06/Sep/2019

Item Number	Item Description	Rule
85806S	22G IRR HANDPIECE SMOOTH 12B	6
85806ST	22G IRR HP SMOOTH STELL 12B	6
85807S	23G IRR HANDPIECE SMOOTH 12B	6
85807ST	23G IRR HP SMOOTH STELL 12B	6
85809	DIVIDER IRRIGATION 19GA	6
85850	CHARLEUX IRRIGATION/ASPIR.CANN	6
85900S	ASP HPC STERILE LAT.PORT 12/BX	6
85901S19	ASP HANDPIECE 19G 12/BOX	6
85901S20	ASP HANDPIECE 20G 12/BOX	6
85902ST19	IRR. HANDPIECE SMOOTH 19G 12/B	6
85902S19	IRR HANDPIECE SMOOTH,19G,12/BX	6
85902S20	IRR HANDPIECE SMOOTH,20G,12/BX	6
85903ST19	CHOPPER IRR END-OUT 19G 12/B	6
85903S19	IRR CHOPPER END-OUT 19G 12/BOX	6
85903S20	IRR CHOPPER END-OUT 20G 12/BOX	6
85904S20	20G IRR HANDPIECE ROUGH 12/B	6
85910S	I/A HANDPC45° SIL.TIP MIL 12/B	6
85910S EA	SIL. COATED I/A 45° MILL.1/B	6
85910ST	I/A HANPC45° SILI TIP ST 12B	6
85910ST EA	SIL. COATED I/A 45° STELL.1/B	6
85912S	I/A HDP.SIL.TIP STRGHT.MILL 12/B	6
85912S EA	I/A HDP.SIL.TIP STRGHT.MILL 1/B	6
85912ST	I/A HDP.SIL.TIP STRGHT.STEL.12/B	6
85912ST EA	I/A HDP.SIL.TIP STRGHT.STEL.1/B	6
85913S	SILICONE I/A HANDP CURVED 12B	6
85913S EA	SILICONE I/A HANDP CURVED 1B	6
85913ST	SIL I/A HANDP CURVED STELL 12B	6
85913ST EA	SIL I/A HANDP CURVED STELL 1B	6
85914S	MICS I/A HDP.SIL.TIP STRGHT.MILL 12/B	6
85914S EA	MICS I/A HDP.SIL.TIP STRGHT.MILL 1B	6
85914ST	MICS I/A HDP.SIL.TIP STRGHT.STEL 12/B	6
85914ST EA	MICS I/A HDP.SIL.TIP STRGHT.STEL 1B	6
85915S	MICS SILICONE I/A HDPC 45° 12B	6
85915S EA	MICS SILICONE I/A HDPC 45° 1B	6
85915ST	MICS SIL I/A HDP 45° STELL 12B	6
85915ST EA	MICS SIL I/A HDP 45° STELL 1B	6
85950	ASPIRATION HANDPIECE, MALE	6
85951	I/A HANDPIECE 20° with sleeve	6
85955	IRRIGATION HANDPIECE, FEMALE	6
85957	22G IRRIGATION HANDPIECE	6
85958	23G IRRIGATION HANDPIECE	6
85967	22G ASPIRATION HANDPIECE	6
85968	23G ASPIRATION HANDPIECE	6
86011	INFUSION HOLDER, CHAMFERED, 4	6
86014	LUCKE INFUS.CANNULA SELF FIXA.	6
86015Y2	SILICONE OIL INFUSION HLDR.5MM	6
86015Y3	SILICONE OIL INFUSION HLDR.6MM	6
86016	LUCKE VISCOUS FLUID INJ.CANNU.	6
87121-6	RETROB.CANNULA STRGHT 50MM 6/B	6
87122-6	RETRO.CANNUL.STRGHT 40MM 6/BOX	6

BAUSCH + LOMB

Item Number	Item Description	Rule
93011	TUBING FOR SPECULUM W/ASPIRATN	6
93012	ASP.SPECULA TUBING EXTENSION	6
93100S	DONOR CORNEA HOLDER STER.10/B	2

CONTROLLED DOCUMENT SIGNATURE PAGE

Document Name :TRN-000207808

Document Title :Declaration of conformity MDD Class IIa

Document ID :MDD_Class_IIa_Declaration_of_Conformity

Signed By	Date (GMT)	Justification
Klingenburg Antje	09/06/2019 11:17:15	Document Management