

Declaration of Conformity

according to Directive 93/42/EEC

Product/ Product group: Medical Device Class I, Reusable Instruments

Article no.: see product list, Rev. 10, pages 2-11

MDD Class: I, 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 VII. 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.

Certificate: EN ISO 13485:2016

Certificate Registration no.: SX 60136091 0001 valid until: 2022-02-11

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Heidelberg, February 11th, 2019



Horst Vollmerhausen
Director Operations Heidelberg
Safety Officer pursuant to §30 Medical Device Act, MPG

Product List Rev. 10

Item Number	Item Description	Rule
E0100 E	ECONO DIAMOND KNIFE 45 DEGREE	6
E0100 M	UNIV DIAMOND KNF W/MINI BLADE	6
E0102 AML	KNIFE DIAMOND TUNNEL	6
E0102 M	DIAMOND CRESCENT KNIFE ANGLED	6
E0103	UNIV DIA KNIFE W/1MM TRIFACBLD	6
E0103 E	ECONO DIAMOND KNIFE TRIFACET	6
E0104 ACC1.8	DIAMOND KNIFE CLEAR CORNEA 1.8	6
E0104 ACC2.2	DIAMOND KNIFE CLEAR CORNEA 2.2	6
E0104 ACC2.5	DIAMOND 2.5 ANG CC SHRP SIDE	6
E0104 ACC2.5/29	DIAMOND 2.5-2.9 KERATOME ANG	6
E0104 ACC2.8	KNIFE DIAMOND KERATOME	6
E0104 ACC2.8/31	DIAMOND 2.8-3.1 KERATOME ANG	6
E0104 ACC3.0	DIAMOND 3.0 ANG CC SHRP SIDE	6
E0105 M	TRIPLE EDGE ARCUATE	6
E0108 LS	OSHER TRIFACET TUNNELKNIFE W.	6
E0112	STEP DIA KNIFE TRIFALET	6
E0117	KNIFE DIAMOND STEP ANDERSON	6
E0118	KNIFE DIAMOND TRIFACET 1.4MM	6
E0119	DIAMOND KNIFE 19GA WEINSTOCK	6
E0123	LRI STEP KNIFE NICHAMIN	6
E0421	TRAB HARMS W/HDL PAIR 1RT-1LT	6
E0577	HOOK LENS OSHER	6
E0577 C	CURVED OSHER HOOK	6
E0713 G	KOCH STOP AND CHOP MANIPULATOR	6
E0780	CURETTE MEYERHOEFER NO 0 1.5MM	6
E0781	CURT MEYERHOEFER NO 1 1.75MM	6
E0782	CURETTE MEYERHOEFER NO 2 2MM	6
E0783	CURETTE MEYERHOEFER NO 3 2.5MM	6
E0784	CURETTE MEYERHOEFER NO 4 3.5MM	6
E0790	CURETTE SKEELE 2MM	6
E1069	PLATE LID BERKE-JAEGER	6
E1400	FCP DRESSING STR DEL SERR	6
E1404	FCP DRESSING STR HEAVY SERR	6
E1406	FCP DRESSING LGT CVD DEL SERR	6
E1408	FCP DRESSING STRG CVD DEL.SERR	6
E1410	FCP DRESSING LGT CVD HVY SERR	6
E1416	FORCEPS IRIS BRACKEN	6
E1420	FCP TISSUE STR DELICATE 1X2	6
E1475	FCP GIL CVD DELICATE SERRATED	6
E1500	FORCEPS BISHOP HARMON 1X2	6
E1500 C	FORCEPS BISHOP HARMON CVD 1X2	6
E1502	FCP BISHOP HARMON DELICATE 1X2	6
E1506	FORCEPS BISHOP HARMON SERRATED	6
E1560	FCP FIXATION GRAEFE NARROW JAW	6
E1572	FCP FIX GRAEFE WIDE JAW W/LOCK	6
E1600	FCP FIX GREEN 12MM W/O LOCK	6

Item Number	Item Description	Rule
E1654	FORCEPS FIXATION LESTER 1X2	6
E1656	FORCEPS FIXATION LESTER 2X3	6
E1684	FCP FIX ELSHNIG HVY 1X2 W/O LK	6
E1724	FORCEPS FIXATION IOWA STATE	6
E1730	FORCEP FIXATION THORPE	6
E1732	FCP FIX THORPE 2X3DEL .12MM45D	6
E1793	FORCEP FIXATION CASTROVIEJO	6
E1795	FORCEP FIXATION CASTROVIEJO	6
E1796 S	FCP SUT SANDERS-CAST W/HV SHFT	6
E1797	FORCEPS SUTURE CASTROVIEJO	6
E1798	FORCEPS SUTURE CASTROVIEJO	6
E1805	SUTURING FORCEP FINE	6
E1805 XD	FCP SUT FINE-CAST X-DEL .12MM	6
E1805 XDWH	FCP SUT FN-CS XDEL .12MM WD HDL	6
E1809	FCP SUT EUROPE BONN .12MM TETH	6
E1811	SUTURING FORCEP STORZ - BONN	6
E1811 G	BONN SUTURING FORCEPS	6
E1813 A	FCP SUT COR'L MCPHERSN ANG 1X2	6
E1813 AK	FCP KELMAN-MCPHER 8MM ANG 1X2	6
E1813 S	FCP SUT COR'L MCPHERSN STR 1X2	6
E1815 ABG	BECHERT-MCPHERSON ANGLED TYING	6
E1815 AK	FCP KELMAN-MCPHER 8MM ANG JAW	6
E1815 AKG	KELMAN-MCPHERSON ANGLED TYING	6
E1815 S	FORCEPS TYING STRAIGHT	6
E1830	FORCEPS SUTURING SAUER	6
E1890	FCP UTLY NUGENT SMOOTH JAWS	6
E1892	FCP UTLY NUGENT SERRATED JAWS	6
E2002 F	UTRATA CAPSULRHXS.FORCEPS DEL.	6
E2002 GE	UTRATA CAPSULORHEXIS FORCEPS	6
E2156	FORCEPS CILIA STORZ WIDE JAWS	1
E2160	FCP CILIA STORZ NARROW JAWS	1
E2304	TUCKER TENDON BISHOP	6
E2404	CALIPER CASTROVIEJO	6
E2405	CALIPER MARKING CASTROVIEJO	6
E2410	CALIPER JAMESON	6
E2604	FCP CHALAZION DESMARES 12X20MM	6
E2610	FORCEPS CHALAZION FRANCIS	6
E2614	FORCEPS CHALAZION HEATH	6
E2618	FORCEPS CHALAZION HUNT	6
E2630	FORCEPS CHALAZION LAMBERT SM	6
E2632	FORCEPS CHALAZION LAMBERT LG	6
E2640	FORCEPS CHALAZION BAIRD	6
E2798	PUNCH DECEMET MEMBRANE KELLY	6
E3190	FCP COR'L KATZIN-BARAQUER .4MM	6
E3197	FCP COR'L UTLY TROUTMAN-BARAQR	6
E3199	FCP COR'L TROUTMN-BARAQR .12MM	6
E3199 GW	GILS/WELSH SMTH COLIBR CAP FCP	6

Item Number	Item Description	Rule
E3217 L	FOGLA LEFT SIDE SCISSORS	6
E3217 R	FOGLA CORNEAL SCISSORS	6
E3218 L	SCS CAST CVD LEFT MINI MODEL	6
E3218 MM	SCS CAST CORNEAL MINIMINI MODL	6
E3218 R	SCS CAST CVD RIGHT MINI MODEL	6
E3220	SCISSORS CORNEAL CASTROVIEJO	6
E3221	SCS KERATOPLASTY CAST PRB TIP	6
E3222 R	SCS KERATOPLASTY CAST RND RT	6
E3223	SCS COR'L CAST ANGLED (FINE)	6
E3231 L	CNL SCS STORZ MINIATURE LEFT	6
E3231 R	CNL SCS STORZ MINIATURE RIGHT	6
E3232	SCS COR'L KATZIN CVD LEFT MINI	6
E3233	SCS COR KATZIN CVD RIGHT MINI	6
E3243	CLAYMAN WESTCOTT SCS-CVD,BLNT	6
E3300	SCS COR'L SEC CASTROVIEJO RT	6
E3301	SCS COR'L SEC CASTROVIEJO LT	6
E3304	SCS COR'L CAST RT MINIATURE	6
E3304 M	SCS COR SEC CAST RT MID-MINI	6
E3305	SCS COR'L CAST LEFT MINIATURE	6
E3305 M	SCS COR'L SEC CAST LT MID-MINI	6
E3305 MC	SCS COR SEC MCPHERSON-CAST LT	6
E3305 X	SCS COR'L SEC CAST LT SUB MINI	6
E3306	SCS COR'L TROUTMAN RIGHT MINI	6
E3307	SCS COR'L TROUTMAN LEFT MINI	6
E3311	SCS COR'L TROUTMAN CAST LEFT	6
E3315	SCISSORS CONJUNCTIVA TROUTMAN	6
E3316	SCS CONJ STORZ WESTCOT WD MINI	6
E3320 L	SCS TENOTOMY WESTCOTT LEFT	6
E3320 R	SCS TENOTOMY WESTCOTT RIGHT	6
E3320 RS	SCS SHEPARD-WESTCOT UP BLD SER	6
E3320 RX	SCS WESTCOTT RT SUB MINIATURE	6
E3321	SCISSORS STITCH WESTCOTT TYPE	6
E3321 MWH	SCS KERATO UTLY STICH CAST MIN	6
E3322	SCISSORS UTILITY WESTCOTT TYPE	6
E3340	SCS STITCH FINE MINI OF E-3343	6
E3340 WH	SCS STITCH FINE WD HDL MINI	6
E3343	SCISSORS IRIS STRAIGHT	6
E3344	SCISSORS IRIS CURVED	6
E3347	SCS IRIS MCPHRSN VANAS CVD MIN	6
E3349	SCS IRIS COHAN-VANNAS CVD MINI	6
E3360	SCS DEWECKER BLUNT & SHARP	6
E3366	SCS BARRAQUER BLUNT & BLUNT	6
E3383 C	CLAYMAN VANNAS SCISSORS CURVED	6
E3383 S	CLAYMAN VANNAS SCS STRAIGHT	6
E3386	SCISSORS VANNAS STRAIGHT	6
E3387	SCISSORS VANNAS CURVED	6
E3388	SCISSORS VANNAS ANGLED ON FLAT	6
E3388 GW	GILLS WELSH VANNAS SCISSORS	6

Item Number	Item Description	Rule
E3388 GWL	GILLS WELSH VANNAS SCS LNG MDL	6
E3389	SCISSORS VANNAS ANGLED ON EDGE	6
E3390 A	CAPSULE SCISSORS 10MM ANG BLDS	6
E3391	SCS I-O STORZ SQUEEZE HANDLE	6
E3397 I	SCISSORS IRIS CURVED STORZ	6
E3404	SCS IRIS STR DELICATE	6
E3405	SCISSORS IRIS CURVED DELICATE	6
E3406	SCISSORS IRIS STRAIGHT LIGHT	6
E3408	SCISSORS IRIS CURVED LIGHT	6
E3410 I	SCISSOR STRAIGHT POINTED STORZ	6
E3412 I	SCISSOR CURVED POINTED STORZ	6
E3418 I	SCISSOR CURVED BLUNT STORZ	6
E3424	SCISSORS EYE STRAIGHT HEAVY	6
E3426	SCISSORS EYE CURVED HEAVY	6
E3436	SCS EYE ANGULAR PROBE POINT	6
E3450	SCS CONJUNCT WILMER-CONVERSE	6
E3490	SCS CORNEAL AEBLI STRAIGHT	6
E3552 I	SCISSOR CURVED HEAVY STEVENS	6
E3554 I	SCISSOR STRAIGHT LIGHT STEVENS	6
E3556 I	SCISSOR CURVED LIGHT STEVENS	6
E3560	SCS TEN STEVENS STRAIGHT	6
E3562	SCS TEN STEVENS CURVED	6
E3570 I	SCISSOR STRAIGHT STRABISMUS	6
E3571 I	SCISSOR CURVED STRABISMUS	6
E3572 I	SCISSOR STRONG CURVED STORZ	6
E3576	SCS STRABISMUS KNAPP STRAIGHT	6
E3577	SCS STRABISMUS KNAPP LGT CVD	6
E3578	SCS STRABISMUS KNAPP STRNG CVD	6
E3580	SCISSORS SUTURE LITTLER	6
E3585 I	SCISSOR UTILITY CURVED STORZ	6
E3590 I	SCISSOR STITCH STORZ	6
E3592 I	SCISSOR STITCH ORIGINAL STORZ	6
E3651	SCS ENUCLEATION HEAVY MED CVD	6
E3652	SCS ENUCLEATION HEAVY STRG CVD	6
E3720	SPOON ENUCLEATION WELLS	6
E3740	SPOON EVISCERATION BUNGE LARGE	6
E3742	SPOON EVISCERATION BUNGE SMALL	6
E3807 WO	NEEDLE HOLDER OSHER W/O LOCK	1
E3828 CW	NH BARRAQUER MOST DEL CVD W/LK	1
E3828 CWO	NH BARRAQUER DEL CVD W/O LOCK	1
E3828 SW	NH BARRAQUER MOST DEL STR W/LK	1
E3828 SWO	NH BARRAQUER DEL STR W/O LOCK	1
E3835	NH MCPHERSON CURVED W/LOCK	1
E3836 C	NH COHAN MINI MICRO CVD W/O LK	1
E3836 CW	NH COHAN MINI MICRO CVD W/LOCK	1
E3839 X	NEEDLE HOLDER TROUTMAN W/LOCK	1
E3839 XWH	NH TROUTMAN W/LK WD HDL CVD	1
E3842	NH BARRAQUER STD DIA W/O LOCK	1

Item Number	Item Description	Rule
E3843	NH BARRAQUER LARGE DIAMETER	1
E3844	NH BARRAQUER SMALL DIAMETER	1
E3845	NH BARRAQUER CVD RD HANDLE	1
E3848	NEEDLE HOLDER CASTROVIEJO	1
E3849	NEEDLE HOLDER CASTROVIEJO	1
E3850	NEEDLE HOLDER CASTROVIEJO	1
E3852	NH CASTROVIEJO DIAMOND HARD	1
E3861	NEEDLE HOLDER CASTROVIEJO	1
E3861 WHMC	NH CAST MICRO CVD WH W/LOCK	1
E3862	NEEDLE HOLDER CASTROVIEJO	1
E3864	NEEDLE HOLDER CASTROVIEJO HVY	1
E3876	NEEDLE HOLDER DERF	1
E3897	SERREFINE MC F/10-0 SUTURES	1
E3900	SERREFINE SMALL	1
E3904	SERREFINE DIEFENBACH LG 2 1/4"	1
E3915	FCP MOSQUITO HARTMAN STRAIGHT	6
E3916	FCP MOSQUITO HARTMAN CURVED	6
E3920	FCP MOSQUITO HALSTED STR N5500	6
E3922	FCP MOSQUITO HALSTED CVD N5502	6
E4040	SPECULUM CASTROVIEJO SMALL	6
E4041	SPECULUM CASTROVIEJO MEDIUM	6
E4072	SPEC EYE MELLINGER FENESTR BLD	6
E4073	SPEC EYE MELLINGER SOLID BLDS	6
E4198	PRB LACH 0000-000 BOWMAN S.S.	6
E4500	RETR LACH SAC STV'SN W/FEN BLD	6
E4590	RONG LACH SAC BELZ USD CALAHAN	6
E4921CE	IRR A-C BISHP-HRMN COMP W/BULB	6
E4942CE	ADAPTER FOR IRRIGATORS (S3634)	1
E5005	SCLERAL PILOT TUBES PKGD SNGL	6
E5006	SCLERAL PILOT TUBE TROCAR	6
E5378	FCP SLEEVE SPREADING WATZKE	6
E5652	INTRODUCER&HLDR SPHERE CARTER	5
E6760	FORCEPS DRESSING NON-MAGNETIC	6
E6764	FORCEPS TISSUE NON-MAGNETIC	6
E6768	FCP FIX LESTER 1X2 TH NON-MAG	6
E6772	FCP MOSQTO HALSTED STR NON-MAG	1
E6773	FCP MOSQTO HALSTED CVD NON-MAG	1
E6774	CLP TOWL X-ACT SHAEDEL NON-MAG	1
E9046 A	DIAMOND KNIFE SINGLE EDGE	6
E9056 A	DIAMOND KNIFE DOUBLE EDGE	6
12050A	CHALAZION KNIFE, DELICATE	6
13091A	FOREIGN BODY SPUD, STRAIGHT	6
13100A	PLANGE FOREIGN BODY SPUD	6
13121	SLIDING FOREIGN BODY SPUD	6
13131A	KUHNT CORNEAL SCARIFIER FIG. 1	6
13132A	KUHNT CORNEAL SCARIFIER FIG. 2	6
13135	SCRAPER CORNEAL LASIK	6
13410A	ULLERICH KERATOME, STRAIGHT	6

Item Number	Item Description	Rule
13420A	KERATOME MOD. HAMBURG	6
13580Y5	UNIVERSAL DIAMOND-KNIFE "ML"	6
13580Y7	DIAMOND KNIFE "M-DL"	6
16021A	SCLERAL KNIFE MOD. BONN 7 MM	6
22020	EYE SCISSORS ANGLED	6
23010	CASTROVIEJO CORNEAL SCISSORS	6
23060	EYE SCISSORS MOD.BONN CVD.89MM	6
23121	TROUTMAN MICROSCISSORS, RIGHT	6
23122	TROUTMAN MICROSCISSORS, LEFT	6
23130	MICRO SCISSORS, STRAIGHT	6
23140	MICRO SCISSORS, CURVED	6
23150	MICRO KERATOMY SCISSORS, STRON	6
23160	MICRO SCISSORS, CURVED UP	6
23201	KATZIN CORNEAL SCISSORS, RIGTH	6
23202	KATZIN CORNEAL SCISSORS, LEFT	6
24020	EYE SCISSORS, CURVED, DELICATE	6
24050	EYE SCISSORS, CURVED 90MM	6
24071	NOYES IRIS SCISSORS, BLUNT/BLU	6
24072	NOYES IRIS SCISSORS, SHARP/BLU	6
24081	VANNAS CAPSULOTOMY SCISSORS, S	6
24082	VANNAS CAPSULOTOMY SCISSORS, C	6
24083	VANNAS CAPSUL.SCISSORS,TUEBING	6
24084	VANNAS CAPSULOT. SCISSORS, TUE	6
25030	ONG CAPSULE SCISSORS	6
25030Y1	ONG CAPSULE SCS. CVD AS 24084	6
25030Y2	ONG CAPSULE SCS., SLIGHTLY CUR	6
25040	UTHOFF CAPSULE SCISSORS	6
27012	STEVENS TENOTOMY SCISSORS, SHO	6
27041	STRABISMUS SCISSORS, SH0RT BLA	6
27042	STRABISMUS SCISSORS, SHORT BLA	6
27051	STRABISMUS SCISSORS, LONG BLAD	6
27052	STRABISMUS SCISSORS, LONG BLAD	6
27060	WESTCOTT TENOTOMY SCISSORS, BL	6
27062	WESTCOTT TENOTOMY SCISSORS, SH	6
27070	STRABISMUS SCISSORS, MOD. BONN	6
27082	STEVENS TENOTOMY SCISSORS, LON	6
27100	WESTCOTT MICRO TENOTOMY SCISSO	6
51011	WILDER LACHRYMAL DILATOR FINE	6
51012	WILDER LACHRYMAL DILATR.MEDIUM	6
51013	WILDER LACHRYMAL DILATR.STRONG	6
51100	LACHRYMAL DILATOR, MOD. GIESSE	6
51130	LACHRYMAL DILATOR, FINE	6
51171	PIGTAIL PROBE W. 0.5 MM SUTURE	6
51171Y1	PIGTAIL PROBE, 0.5MM SUTURE EY	6
52021	WEISS EYE SPECULUM,CHLD,RGHT,S	6
52022	WEISS EYE SPECULUM,CHLD,LFT,SO	6
52051	DESMARRES LID RETRACTOR,SIZE 1	6

Item Number	Item Description	Rule
52053	DESMARRES LID RETRACTOR,SIZE 3	6
52070	SAUER EYE SPECULUM, CHILD SIZE	6
52092	JAEGER LID PLATE, PLASTIC	6
52111	PRETORI EYE SPECULUM, LEFT	6
52112	PRETORI EYE SPECULUM, RIGHT	6
52121	BARRAQUER EYE SPECULUM LARGE B	6
52121H	SPEC EYE BARRAQUER ADLT HVY WR	6
52121K	SPECULUM EYE KRATZ-BARRAQUER	6
52123Y1	BARRAQUER-OSTERHUIS EYE SPECUL	6
52125Y1	BARRAQUER EYE SPECULUM F.CHILD	6
52131	MELLINGER EYE SPECULUM	6
52132	MELLINGER EYE SPECULUM, CHILD	6
52141	MELLINGER/BEARD EYE SPECULUM	6
52142	MELLINGER/BEARD EYE SPECULUM,	6
52191	DESMARRES LID RETRACTOR INFANT	6
52201	COOK EYE SPECULUM, SMALL	6
52201Y3	COOK EYE SPECULUM SMALL, 5MM B	6
52202	COOK EYE SPECULUM, MEDIUM	6
52203	COOK EYE SPECULUM, LARGE	6
52250	BANGERTER EYE SPECULUM	6
53000T	CORNEAL MARKER LASIK KOHNEN	6
53001T	CORNEAL MARKER LASIK 8.5MM	6
53003T	FLAP LIFTER LASIK KOHNEN TITAN	6
53004T	SPATULA LASIK KOHNEN TIT.	6
53005T	CONE ALCOHOL LASEK 8.5MM	6
53006T	CONE ALCOHOL LASEK 9.5MM	6
53008T	TREPHINE LASEK 8.0MM	6
53009T	TREPHINE LASEK 9.0MM	6
53010T	SPATULA EPITHELIUM LASEK	6
53011T	HOE EPITHELIUM LASEK	6
53012T	KOHNEN-KOCH I LASIK COMB.INSTR	6
53013T	KOHNEN-KOCH II LASIK COMB.INST	6
53014T	TREPHINE/CONE ALCOHOL8.0/8.5MM	6
53031	HARMS TRABECULOTOME, RIGHT	6
53032	HARMS TRABECULOTOME, LEFT	6
53100	CORNEAL MARKER LASIK 7.5MM	6
53300	INTACS SPATULA, RIGHT	6
53301	INTACS SPATULA, LEFT	6
54055	IRISRETRACTOR W/FLEXIBLE FIXNG	6
54113A	WECKER IRIS SPATULA CONICAL	6
54121A	BANGERTER IRIS SPATULA, 1.5 MM	6
54161	CASTROVIEJO SPATULA, 10 MM LON	6
54190A	IRIS HOOK BONN VERY DELICATE	6
54250	WECKER SPATULA, MOD. FRANKFURT	6
54270A	SPATULA, FLAT-ANGLED	6
54270Y2A	SPATULA, FLAT-ANGLED, 10 MM	6
54270Y4	SPATULA ANGLED 0.5X0.3MM ROUND	6
54290	DARDENNE IRIS HOOK, ROUNDED	6

Item Number	Item Description	Rule
54410	LUND IRIS HOOK	6
54420	HERMEKING SPATULA	6
55290	REPOSITION HOOK, MOD. MAINZ	6
55300	REPOSITION HOOK, MOD. FRANKFUR	6
55305	HAEFLIGER PHACO CLAEVER, RIGHT	6
55306	HAEFLIGER PHACO CLEAVER, LEFT	6
55310	JACOBI REPOSITION HOOK	6
55350	CAPSULE SPATULA, DELICATE	6
55415	NUCLEUS ROTATOR NEUHANN	6
55461	GREITE SOFT LENS MANIPULATOR	6
55470	RENTSCH REPOSITION HOOK DOUBLE	6
55480	LENS MANIPULATOR AND CHOPPER	6
55481	IRIS HOOK AND NUCLEUS CHOPPER	6
55482	NUCLEUS SPATULA AND CHOPPER	6
55483	NUCLEUS DIVIDINGHOOK SEMISHARP	6
55484	MANIP. DRYSDALE-KOCH STOP CHOP	6
55485	MENAPACE NUCLEUS DIVIDER	6
56040A	MEYER-SCHWICKERATH LOCALISATOR	6
56060	BULB RINGS, SET OF 6, DIAM.: 1	6
56081	RULER, MOD. GIESSEN, 30 MM	6
56120	FINK MARKER	6
56201A	LAQUA LOCALIZER, DOUBLE-ENDED	6
56210A	KREISSIG LOCALIZER, DOUBLE-END	6
56320A	LOCALIZER LUCKE	6
57012A	GRAEFE STRABISMUS HOOK, MEDIUM	6
57013A	GRAEFE STRABISMUS HOOK, LARGE	6
57051	CASTROVIEJO CALIPER 0-15MM	6
57052	CASTROVIEJO CALIPER,	6
57061	AXENFELD LACHRYMAL SAC RETRACT	6
57071	ROLLET LACHRYMAL SAC RETRACTOR	6
57091	ARRUGA RETRACTOR, METAL	6
57150	SPATULA MODELL GIESSEN	6
57190A	STRABISMUS HOOK MOD. BONN	6
57200A	STRABISMUS HOOK, EXTRA DELICAT	6
57260A	STRABISMUS HOOK, MOD. HAMBURG	6
57440A	STRABISMUS HOOK MOD.ESSEN SMAL	6
61010	BEER CILIA FORCEPS ROUND POINT	1
61040	HENRY CILIA FORCEPS	1
61050	GRADLE CILIA FORCEPS	1
61080	BARRAQUER CILIA FORCEPS	1
62021	DESMARRES CHALAZION FORCEPS 20MM	6
62022	DESMARRES CHALAZION FORCEPS 26MM	6
62041	CASTROVIEJO SUTURING FORCEPS,	6
62042	CASTROVIEJO SUTURING FORCEPS,	6
62045Y1	MOORFIELD SUTURING FORCEPS	6
62071	PAUFIQUE UNIV. SUT. FORCEPS	6
62072	PAUFIQUE UNIV. SUT. FORCEPS, D	6
62110	CASTROVIEJO STRNG.FORCPS.0.5MM	6

Item Number	Item Description	Rule
62130	DRAEGER CONJUNCTIVA FORCEPS	6
63020	CORNEAL FLAP FORCEPS LASIK	6
63031	COLIBRI TYPE FORCEPS	6
63032	COLIBRI FORCEPS EXTRA DELICATE	6
63038	TROUTMAN-BARRAQUER COLIBRI TYP	6
63051	HARMS TYING FORCEPS MOD. TUEBI	6
63052	TYING FORCEPS, MOD. TUEBINGEN,	6
63053	HARMS TYING FORCEPS MOD. TUEBI	6
63070	PAUFIQUE TYING FORCEPS	6
63071	PAUFIQUE TYING FORCEPS, EXTRA	6
63080	BARRAQUER TYING FORCEPS	6
63120	SUTURING FORCEPS, MOD. ZUERICH	6
63120Y1	SUTURING FORCEPS, MOD. ZUERICH	6
63130	COLIBRI SUTURE REMOVAL FORCEPS	6
63140	MICRO TYING FORCEPS	6
63150	KELMAN-MCPHERSON TYING FORCEPS	6
63160	MCPHERSON TYING FORCEPS, STRAI	6
63250	TUBINGEN TYING FORCEPS EXT.DEL.	6
64011	DRESSING FORCEPS STRGHT.1.0MM	6
64020	TISSUE FORCEPS, STRAIGHT, 0.7	6
64021	TISSUE FORCEPS, STRAIGHT, 1.0	6
64022	TISSUE FORCEPS, CURVED, 1.0	6
64023	TISSUE FORCEPS, STRAIGHT, 1.2	6
64090	IRIS FORCEPS, BONN, DELICATE	6
64091	IRIS FORCEPS BONN DEL.ANGLED	6
64220	IRIS FORCEPS, BONN-CONRAD, SE	6
64230	IRIS FORCEPS, MOD. BONN-ULM	6
65050	CAPSULORHEXIS FORCEPS, CURVED	6
65150G	BARSEWISCH ANTERIOR CHAMBER FORCEPS	6
65245	IOL GRASPING FORCEPS	6
65256	IMPLANTATION-FORCEPS F. FOLDA	6
65360Y1	FORCEPS FOR VITRECTOMY NAILS	6
65365	GRASPING FCPS TROKAR PORT	6
65370	WITSCHER CAPSULE FORCEPS	6
65400	DODEN LENS IMPLANTAT.FORCEPS W	6
65470	WITSCHER IMPLANT FORCEPS	6
65520	FORCEPS FOLDING AKREOS	6
65530	IOL-EXPLANTATION FORCEPS	6
66030	ELSCHNIG SCLERAL FORCEPS	6
67120	DE DECKER MUSCLE FORCEPS	6
67601	FORCEPS FOR WIDENING STRIPS	6
72020	KALT NEEDLE HOLDER, STRAIGHT	1
72040	ARRUGA NEEDLE HOLDER	1
72051	CASTROVIEJO NDLE HOLDER, W/O L	1
72052	CASTROVIEJO NDLE HOLDER W.LOCK	1
72053	CASTROVIEJO NDLE HOLDER, W/O L	1
72054	CASTROVIEJO NDLE HOLDER, W. L	1
72060	BARRAQUER BREAKER AND HOLDER	1

Item Number	Item Description	Rule
72141	TROUTMAN-CHRIS BREAKER AND HOL	1
72221	BLADE-HOLDER ANGLED	1
72225	BLADE-HOLDER STRAIGHT	1
73021	BARRAQUER NEEDLE HOLDER, W/O L	1
73022	BARRAQUER NEEDLE HOLDER, W. L	1
73023	BARRAQUER NEEDLE HOLDER, W/O L	1
73030	BARRAQUER NEEDLE HOLDER, ORIGI	1
73050	BARRAQUER NEEDLE HOLDER SHORT	1
73111	BARRAQUER NEEDLE HOLDER, W/O L	1
77011	DIEFFENBACH SERREFINE, STRAIGH	1
77012	DIEFFENBACH SERREFINE, CURVED	1
77021	HALSTEAD ARTERY FORCEPS 1 X 2	1
85190	ASPIRATING HANDPIECE	6
85201	ASPIRATING CANNULA, 0.9 MM	6
85201Y1	HEIMANN ASPIRATING CANNULA,W.R	6
86028	PEG FOR PILOT-TUBE 0,9	1
90010	OCULO-PRESSOR SIMPLEX, HOMBURG	1
90012	MANOMETER W. BULB FOR OCULO-PR	1
90013	SILICONE BALL W/O BAND F. OCUL	1
90014	BAND F. OCULO-PRESSOR W. VELCR	1
96060	SCLERAL PLUG 6/BOX	1
99195	T-CONNECTR.METAL F.ASPIR.SPEC.	1
99272	KLEIN EYE SHIELD, CHILD SIZE	1
99273	KLEIN EYE SHIELD, INFANT	1
99275	KLEIN EYE SHIELD 50/B	1
99281Y4	KLEIN EYE SHIELD,CENTR.PORT,20	1
99441Y1	CORNEA SILICONE LIGHT SHIELD B	6
99441Y2	CORNEA SILICONE LIGHT SHIELD L	6
99500	KILP LENS	1
99501	KILP REPLACEMENT RING F/LENS	1
99501Y1	CLEMENS LENS HOLDER	1
99516	GAUGE 16MM F.ORBITA IMPLANT	1
99518	GAUGE 18MM F.ORBITA IMPLANT	1
99520	GAUGE 20MM F.ORBITA IMPLANT	1
99522	GAUGE 22MM F.ORBITA IMPLANT	1

**Annex to
Declaration of conformity of 11.02.2019
according to directive 93/42/EEC**

Product/ Product group: Medical Device Class 1, Reusable Instruments

Article no.: see product list, Rev. 10, pages 2-11

MDD Class: I, according to Directive 93/42/EEC Annex IX

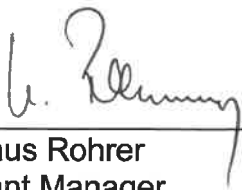
Manufacturer: Bausch & Lomb GmbH
Im Schuhmachergewann 4
D-69123 Heidelberg
GERMANY

We hereby declare that the products listed in the Annex to this declaration of conformity are not marketed anymore as per MDD 93/42/ECC. The declaration of conformity from 11.02.2019 is only applicable with this annex and is no more valid for the products listed in this annex.

The declaration of conformity from 11.02.2019 is

Valid until: 2024-05-25

Heidelberg, November 22nd, 2021



Klaus Rohrer
Plant Manager

Product List Annex to declaration of conformity from 11.02.2019

Item Number	Item Description
E4040	SPECULUM CASTROVIEJO SMALL
E4041	SPECULUM CASTROVIEJO MEDIUM
52021	WEISS EYE SPECULUM,CHLD,RGHT,S
52022	WEISS EYE SPECULUM,CHLD,LFT,SO
52051	DESMARRES LID RETRACTOR,SIZE 1
52053	DESMARRES LID RETRACTOR,SIZE 3
52070	SAUER EYE SPECULUM, CHILD SIZE
52092	JAEGER LID PLATE, PLASTIC
52111	PRETORI EYE SPECULUM, LEFT
52112	PRETORI EYE SPECULUM, RIGHT
52121	BARRAQUER EYE SPECULUM LARGE B
52121H	SPEC EYE BARRAQUER ADLT HVY WR
52121K	SPECULUM EYE KRATZ-BARRAQUER
52123Y1	BARRAQUER-OSTERHUIS EYESPECUL
52125Y1	BARRAQUER EYESPECULUM F.CHILD
52131	MELLINGER EYE SPECULUM
52132	MELLINGER EYE SPECULUM, CHILD
52141	MELLINGER/BEARD EYE SPECULUM
52142	MELLINGER/BEARD EYE SPECULUM,
52191	DESMARRES LID RETRACTOR INFANT
52201	COOK EYE SPECULUM, SMALL
52201Y3	COOK EYE SPECULUM SMALL, 5MM B
52202	COOK EYE SPECULUM, MEDIUM
52203	COOK EYE SPECULUM, LARGE
52250	BANGERTEREYESPECULUM
E2404	CALIPER CASTROVIEJO
E2405	CALIPER MARKING CASTROVIEJO
E2410	CALIPERJAMESON
56081	RULER, MOD. GIESSEN, 30 MM
57051	CASTROVIEJO CALIPER 0-15MM
57052	CASTROVIEJO CALIPER,
90010	OCULO-PRESSOR SIMPLEX, HOMBURG
90012	MANOMETER W. BULB FOR OCULO-PR
90013	SILICONE BALL W/O BAND F. OCUL
90014	BAND F. OCULO-PRESSOR W. VELCR
99195	T-CONNECTR.METAL F.ASPIR.SPEC.
99272	KLEIN EYE SHIELD, CHILD SIZE
99273	KLEIN EYE SHIELD, INFANT
99275	KLEIN EYE SHIELD 50/B
99281Y4	KLEIN EYESHIELD,CENTR.PORT,20
99441Y1	CORNEA SILICONE LIGHT SHIELD B
99441Y2	CORNEA SILICONE LIGHT SHIELD L
99500	KILP LENS
99501	KILP REPLACEMENT RING F/LENS

99501Y1	CLEMENS LENS HOLDER
99516	GAUGE 16MM F.ORBITA IMPLANT
99518	GAUGE 18MM F.ORBITA IMPLANT
99520	GAUGE 20MM F.ORBITA IMPLANT
99522	GAUGE 22MM F.ORBITA IMPLANT

**Annex II to
Declaration of conformity of 11.02.2019
according to directive 93/42/EEC**

Product/ Product group: Medical Device Class 1, Reusable Instruments

Article no.: see product list, Rev. 10, pages 2-11

MDD Class: I, according to Directive 93/42/EEC Annex IX

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

In Annex to Declaration of conformity of 11.02.2019 according to directive 93/42/EEC, Bausch and Lomb declared that the products listed in the Annex to this declaration of conformity are not marketed anymore as per MDD 93/42/ECC. The declaration of conformity from 11.02.2019 is only applicable with this annex and is no more valid for the products listed in this annex.

Updated assessment, considering MDCG 2020-2, Class I Transitional provisions under Article 120 (3 and 4) – (MDR), March 2020, some of the products listed in Annex to Declaration of conformity of 11.02.2019 according to directive 93/42/EEC do meet the following criteria:

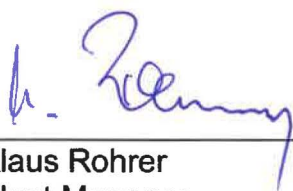
1. The device continues to comply with Directive 93/42/EEC
2. A notified body will need to be involved under the MDR (e.g. re-usable surgical instruments or up-classified devices)
3. A valid Declaration of Conformity, according to Annex VII of the MDD, must be drawn up before 26 May 2021
4. No significant changes to the design or intended purpose of the device after 26 May 2021
5. The requirements of the MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in Directive 93/42/EEC.6 This shall be in place on the 26 May 2021.

Therefore corrected MDR Article 120 (3) allows these devices are placed on the marked until 26.05.2024.

The declaration of conformity from 11.02.2019 is

Valid until: 2024-05-26

Heidelberg, December 15th, 2022



Klaus Rohrer
Plant Manager

Revision history of Annex II
Rev 0, August 03 rd , 2022
Rev 1, December 5 th , 2022: Needle holders added as up-classified to IIa. date update under point 3.,4.and 5. from 2020 to 2021 as of MDCG 2020-2 Rev.1

Product List Annex to declaration of conformity from 11.02.2019

Item Number	Item Description	Transition period as per MDR § 120/3 applicable	Justification
E4040	SPECULUM CASTROVIEJO SMALL	yes	Up-classified to IIa
E4041	SPECULUM CASTROVIEJO MEDIUM	yes	Up-classified to IIa
E4072	SPEC EYE MELLINGER FENESTR BLD	yes	Up-classified to IIa
52021	WEISS EYE SPECULUM SPECULUM,CHLD,RGHT,S	yes	Up-classified to IIa
52022	WEISS EYE SPECULUM SPECULUM,CHLD,LFT,SO	yes	Up-classified to IIa
52051	DESMARRES LID RETRACTOR, SIZE 1	no	N/A
52053	DESMARRES LID RETRACTOR RETRACTOR,SIZE 3	no	N/A
52070	SAUER EYE SPECULUM, CHILD SIZE	yes	Up-classified to IIa
52092	JAEGER LID PLATE, PLASTIC	yes	Up-classified to IIa
52111	PRETORI EYE SPECULUM, LEFT	yes	Up-classified to IIa
52112	PRETORI EYE SPECULUM, RIGHT	yes	Up-classified to IIa
52121	BARRAQUER EYE SPECULUM LARGE B	yes	Up-classified to IIa
52121H	SPEC EYE BARRAQUER ADLT HVY WR	yes	Up-classified to IIa
52121K	SPECULUM EYE KRATZ-BARRAQUER	yes	Up-classified to IIa
52123Y1	BARRAQUER-OSTERHUIS EYESPECULUM	yes	Up-classified to IIa
52125Y1	BARRAQUER EYESPECULUM F.CHILD	yes	Up-classified to IIa
52131	MELLINGER EYE SPECULUM	yes	Up-classified to IIa
52132	MELLINGER EYE SPECULUM, CHILD	yes	Up-classified to IIa
52141	MELLINGER/BEARD EYE SPECULUM	yes	Up-classified to IIa
52142	MELLINGER/BEARD EYE SPECULUM,	yes	Up-classified to IIa
52191	DESMARRES LID RETRACTOR INFANT	no	N/A
52201	COOK EYE SPECULUM, SMALL	yes	Up-classified to IIa
52201Y3	COOK EYE SPECULUM SMALL, 5MM B	yes	Up-classified to IIa
52202	COOK EYE SPECULUM, MEDIUM	yes	Up-classified to IIa
52203	COOK EYE SPECULUM, LARGE	yes	Up-classified to IIa
52250	BANGERTEREYESPECULUM	yes	Up-classified to IIa
E2404	CALIPER CASTROVIEJO	yes	Class Im
E2405	CALIPER MARKING CASTROVIEJO	yes	Class Im
E2410	CALIPERJAMESON	yes	Class Im
57051	CASTROVIEJO CALIPER 0-15MM	yes	Class Im
57052	CASTROVIEJO CALIPER,	yes	Class Im
90010	OCULO-PRESSOR SIMPLEX, HOMBURG	no	N/A
90012	MANOMETER W. BULB FOR OCULO-PR	no	N/A
90013	SILICONE BALL W/O BAND F. OCUL	no	N/A
90014	BAND F. OCULO-PRESSOR W. VELCR	no	N/A
99195	T-CONNECTR.METAL F.ASPIR.SPEC.	no	N/A
99272	KLEIN EYE SHIELD, CHILD SIZE	no	N/A
99273	KLEIN EYE SHIELD, INFANT	no	N/A

99275	KLEIN EYE SHIELD 50/B	no	N/A
99281Y4	KLEIN EYESHIELD,CENTR.PORT,20	no	N/A
99441Y1	CORNEA SILICONE LIGHT SHIELD B	yes	Up-classified to IIa
99441Y2	CORNEA SILICONE LIGHT SHIELD L	yes	Up-classified to IIa
99500	KILP LENS	no	N/A
99501	KILP REPLACEMENT RING F/LENS	no	N/A
99501Y1	CLEMENS LENS HOLDER	no	N/A
99516	GAUGE 16MM F.ORBITA IMPLANT	no	N/A
99518	GAUGE 18MM F.ORBITA IMPLANT	no	N/A
99520	GAUGE 20MM F.ORBITA IMPLANT	no	N/A
99522	GAUGE 22MM F.ORBITA IMPLANT	no	N/A
72051	CASTROVIEJO NDLE HOLDER, W/O L	yes	Up-classified to IIa
72053	CASTROVIEJO NDLE HOLDER, W/O L	yes	Up-classified to IIa
72054	CASTROVIEJO NDLE HOLDER, W. L	yes	Up-classified to IIa
73021	BARRAQUER NEEDLE HOLDER, W/O L	yes	Up-classified to IIa
73022	BARRAQUER NEEDLE HOLDER, W. L	yes	Up-classified to IIa
73030	BARRAQUER NEEDLE HOLDER, ORIGI	yes	Up-classified to IIa
73050	BARRAQUER NEEDLE HOLDER SHORT	yes	Up-classified to IIa
73111	BARRAQUER NEEDLE HOLDER, W/O L	yes	Up-classified to IIa
E3807 WO	NEEDLE HOLDER OSHER W/O LOCK	yes	Up-classified to IIa
E3828 CWO	NH BARRAQUER DEL CVD W/O LOCK	yes	Up-classified to IIa
E3836 C	NH COHAN MINI MICRO CVD W/O LK	yes	Up-classified to IIa
E3842	NH BARRAQUER STD DIA W/O LOCK	yes	Up-classified to IIa
E3843	NH BARRAQUER LARGE DIAMETER	yes	Up-classified to IIa
E3844	NH BARRAQUER SMALL DIAMETER	yes	Up-classified to IIa
E3848	NEEDLE HOLDER CASTROVIEJO	yes	Up-classified to IIa
E3849	NEEDLE HOLDER CASTROVIEJO	yes	Up-classified to IIa
E3850	NEEDLE HOLDER CASTROVIEJO	yes	Up-classified to IIa
E3852	NH CASTROVIEJO DIAMOND HARD	yes	Up-classified to IIa
E3861 WHMC	NH CAST MICRO CVD WH W/LOCK	yes	Up-classified to IIa
E3864	NEEDLE HOLDER CASTROVIEJO HVY	yes	Up-classified to IIa
E3876	NEEDLE HOLDER DERF	yes	Up-classified to IIa

**Annex II to
Declaration of conformity of 11.02.2019
according to directive 93/42/EEC**

Product/ Product group: Medical Device Class 1, Reusable Instruments

Article no.: see product list, Rev. 10, pages 2-11

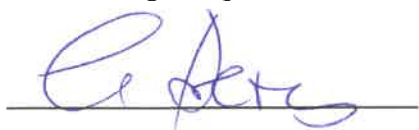
MDD Class: I, according to Directive 93/42/EEC Annex IX

The adress of the Manufacturer: Bausch & Lomb GmbH
Im Schuhmachergewann 4
D-69123 Heidelberg
GERMANY

Has changed to the new address: Bausch & Lomb GmbH
Lilienthalstrasse 16, 18
69124 Eppelheim
GERMANY

The DoC from 11.02.2019 remains valid.

Heidelberg, August 24th, 2023



ppa. Carolin Drewes
Head of Product Strategy & Development

TÜV Rheinland LGA Products GmbH • 51105 Köln

Bausch und Lomb GmbH
Lilienthalstr. 16, 18
69214 Eppelheim
Germany

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date October 27, 2023

Application for : **QMS**
Certificate No. : HD 1333770-1
Requirement : MDD Annex II excl. 4
Confirmation letter ID : DOC_2023-08-03_HD 1333770-1
Report no. : 1143237-10

**Update of information to Certificate no. HD 1333770-1,
issued on 2021-05-10**

Dear Mr. Edgar Mattern,

The change notification received on 2023-05-24 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.

We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer address

Old Manufacturer address: Im Schuhmachergewann 4
69123 Heidelberg, Germany

New Manufacturer address: Lilienthalstr. 16,18
69214 Eppelheim, Germany

Best regards,

X Daniele Wiedemuth

Signiert von: Daniele Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com

www.tuv.com/safety

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Thomas Weigand, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr. Michael Fübi

TÜV Rheinland LGA Products GmbH • 51105 Köln

Bausch und Lomb GmbH
Herr Edgar Mattern
Lilienthalstr. 16, 18

69214 Eppelheim

Kontakt

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com
Datum 24. August 2023

Antrag auf : **QMS**
Zertifikats-Nr. : HD 1333770-1
Prüfgrundlage : MDD Annex II excl. 4
Bestätigungsschreiben ID: DOC_2023-08-03_HD 1333770-1
Berichts-Nr. : 1143237-10

Sehr geehrter Herr Mattern,

Aktualisierung der Angaben von Zertifikat HD 1333770-1, Ausgabedatum 10.05.2021

Die am 2023-05-24 eingegangene Änderungsmitteilung zu den Angaben auf dem oben angegebenen Zertifikat wurde bewertet und die Angaben bestätigt.

Wir bestätigen, dass die Änderungsmitteilung nicht als wesentliche Änderung der Auslegung oder der Zweckbestimmung gemäß Verordnung (EU) 2017/745 über Medizinprodukte (MDR), Artikel 120 Absatz 3, angesehen wird.

Mit diesem Dokument möchten wir die folgenden aktualisierten Angaben zu dem oben angegebenen Zertifikat bestätigen

Geänderte Adresse des Herstellers

Bisherige Adresse des Herstellers:

Im Schuhmachergewann 4, 69123
Heidelberg, Germany

Neue Adresse des Herstellers:

Lilienthalstr. 16,18, 69214 Eppelheim,
Germany

Mit freundlichen Grüßen

X *Daniele Wiedemuth*

Signiert von: Daniele Wiedemuth

Dipl.-Ing. (FH) D. Wiedemuth
Zertifizierungsstelle

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Deutschland

Sitz der Gesellschaft

Tillystraße 2
90431 Nürnberg

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Geschäftsführung

Dipl.-Ing.
Jörg Mähler, Sprecher

Dipl.-Kfm.
Dr. Jörg Schlösser

Nürnberg HRB 26013
UST-ID Nr.: DE 811835490

Vorsitzender des
Aufsichtsrates

Dr. Michael Fübi