

EG-Konformitätserklärung für Medizinprodukte
nach Verordnung (EU) 2017/745

Hersteller <i>Manufacturer</i>	a1 medical GmbH Liptinger Str. 88 78532 Tuttlingen
Produkte <i>Devices</i>	Wiederverwendbare Chirurgische Instrumente – Produktfamilie schneidende Instrumente <i>Reusable Surgical instruments – device family cutting instruments</i>
Klassifizierung <i>Risk Classification</i>	Risikoklasse I Regel 1 und Regel 5 nach Anh. VIII, VO (EU) 2017/745 <i>Risk Class I rule 1 and rule 5 acc. Ann. VIII, VO (EU) 2017/745</i>
Single Registration Number <i>Single Registration Number</i>	DE-MF-000006489 <i>DE-MF-000006489</i>
MD Code nach NBOG WD 2017-2 <i>MD Code acc. NBOG WD 2017-2</i>	MDN 1206
GMDN Code <i>GMDN Code</i>	Siehe Anhangliste <i>See attached list</i>
CND Code <i>CND Code</i>	Siehe Anhangliste <i>See attached list</i>
Konformitätsbewertungsverfahren <i>Conformity Assessment Route</i>	VO 2017/745, Anhang IV Kapitel II und III <i>VO 2017/745, Annex IV, Section II and III</i>

Wir erklären hiermit unter eigener Verantwortung, dass oben angegebenen und im Anhang gelisteten Produkte den einschlägigen Anforderungen der Verordnung (EU) 2017/745 für Medizinprodukte entsprechen.
We hereby declare under our sole responsibility that the medical devices specified above and listed in the attached device list meet the provisions of the Council Regulation 2017/745 for Medical Devices.

Ferner bestätigen wir, dass wir ein Qualitätsmanagementsystem eingeführt haben, welches den folgenden, harmonisierten Standards entspricht:
We further declare that we have implemented a quality management system which complies with the following harmonized standards:

EN ISO 13485: 2021

Die gelisteten Produkte können daher mit der Kennung  legal in Verkehr gebracht werden.
The devices may therefore be placed into market labelled with 

Diese Erklärung ist gültig bis einschließlich 14.01.2027
This Declaration is valid for all manufactured devices specified in the attached list until 2027-01-14

25.11.2024
Datum / Date


Nazim Özbek – Vice President

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Konformitätserklärung Wiederverwendbare Chirurgische Instrumente

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Konformitätserklärung – Produktliste Declaration of Conformity Attachment – Device List

Artnr a1	UDI-DI	Gebrauchs- einheit	Basis UDI-DI	Artikelbezeichnung	CND Code	CND Bezeichnung	UMDNS	UMDNS Bezeichnung	GMDN	GMDN Bezeichnung	DIMDI - Formularnr.	DIMDI - Registrierung
C-0550	4251047902741	PGS00004	42510479PGS00004BV	Universal Trephine Handle	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-0630	4251047902819	PGS00004	42510479PGS00004BV	Eliot Trephine blade handle "standard model"	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-0670	4251047902857	PGS00004	42510479PGS00004BV	Bard-Parker Scalpel Handle #3	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-0680	4251047902871	PGS00004	42510479PGS00004BV	Bard-Parker Scalpel Handle #9	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-0690	4251047902895	PGS00004	42510479PGS00004BV	Chuck Scalpel Handle round, serrated, 10.0cm	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-1000	4251047932458	PGS00011	42510479PGS00011BS	CTS - Cornea Transplant System, complete consisting of	L1704	REUSABLE BLADES, OPHTHALMIC	14-148	Trephine Korneal	32822	Trephine instrument, corneal, manually-operated	00144419	DE/CA39/1331/32
C-1100	4251047932465	PGS00004	42510479PGS00004BV	CTS Anterior Chamber System, complete consisting of	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-1101	4251047932472	PGS00004	42510479PGS00004BV	CTS Anterior Chamber, only	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-1102	4251047932489	PGS00004	42510479PGS00004BV	CTS Central Plug with o-ring for Anterior Chamber	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-1104	4251047932502	PGS00004	42510479PGS00004BV	CTS T-screwdriver for Central Plug and DMEK-Teflon Plug	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-1105	4251047932519	PGS00004	42510479PGS00004BV	CTS Fixation Ring Plate, inner-Ø 11.0mm, for Anterior Chamber	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-1106	4251047932526	PGS00004	42510479PGS00004BV	CTS Fixation Ring Plate, inner-Ø 12.0mm for Anterior Chamber	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-1107	4251047932533	PGS00004	42510479PGS00004BV	CTS Tensioning Screw for Anterior Chamber	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-1117	4251047939181	PGS00004	42510479PGS00004BV	CTS Tensioning Screw for Anterior Chamber, modified	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-1200	4251047932564	PGS00011	42510479PGS00011BS	CTS Trepanation-System, complete, consisting of	L1704	REUSABLE BLADES, OPHTHALMIC	14-148	Trephine Korneal	32822	Trephine instrument, corneal, manually-operated	00144419	DE/CA39/1331/32
C-1201	4251047932571	PGS00004	42510479PGS00004BV	CTS Trepanation-Guide for the Trephine Core, only	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
C-1202	4251047932588	PGS00004	42510479PGS00004BV	CTS Trephine Core, only	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
HS-0001TS	4251047928437	PGS00004	42510479PGS00004BV	Titanium Handle only, for Single Hook System	L1799	OPHTHALMIC INSTRUMENTS - OTHERS	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
HS-0002TS	4251047928444	PGS00004	42510479PGS00004BV	Titanium Handle only, for Double Hook System	L1799	OPHTHALMIC INSTRUMENTS - OTHERS	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
N-0660	4251047919596	PGS00004	42510479PGS00004BV	Castroviejo Blade Breaker and Holder, with sliding lock, length 13.5cm	L1799	OPHTHALMIC INSTRUMENTS - OTHERS	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20

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Konformitätserklärung Wiederverwendbare Chirurgische Instrumente

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N-0660C	4251047917943	PGS00004	42510479PGS00004BV	Castroviejo Blade Breaker and Holder, with sliding lock, length 13.5cm, ceramic coated	L1799	OPHTHALMIC INSTRUMENTS - OTHERS	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
N-0670	4251047919619	PGS00004	42510479PGS00004BV	Swiss Model Blade Breaker & Holder, straight, flat inside surface, length 12.0cm	L1799	OPHTHALMIC INSTRUMENTS - OTHERS	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
N-0670C	4251047917950	PGS00004	42510479PGS00004BV	Swiss Model Blade Breaker & Holder, straight, flat inside surface, length 12.0cm, ceramic coated	L1799	OPHTHALMIC INSTRUMENTS - OTHERS	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
N-0680	4251047919633	PGS00004	42510479PGS00004BV	Swiss Model Blade Breaker & Holder, straight, concave inside surface, length 12.0cm	L1799	OPHTHALMIC INSTRUMENTS - OTHERS	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
N-0680C	4251047917974	PGS00004	42510479PGS00004BV	Swiss Model Blade Breaker & Holder, straight, concave inside surface, length 12.0cm, ceramic coated	L1799	OPHTHALMIC INSTRUMENTS - OTHERS	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
N-0690	4251047919657	PGS00004	42510479PGS00004BV	Troutman-Chris Blade Breaker & Holder, with concave/ convex inside surface, length 9.5cm	L1799	OPHTHALMIC INSTRUMENTS - OTHERS	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20
N-0690C	4251047917981	PGS00004	42510479PGS00004BV	Troutman-Chris Blade Breaker & Holder, with concave/ convex inside surface, length 9.5cm, ceramic coated	L1799	OPHTHALMIC INSTRUMENTS - OTHERS	12-236	Messerhalter	44959	Razor blade breaker/holder	00144435	DE/CA39/1331/20

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