



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

<b>Hersteller</b> <i>Manufacturer</i>	<b>a1 medical GmbH</b> <b>Lessingstraße 50</b> <b>78532 Tuttlingen</b>
<b>Produkte</b> <i>Devices</i>	Wiederverwendbare Chirurgische Instrumente – Produktfamilie schneidende Instrumente <i>Reusable Surgical instruments – device family cutting instruments</i>
<b>Klassifizierung</b> <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>
<b>Single Registration Number</b> <i>Single Registration Number</i>	DE-MF-000006489 <i>DE-MF-000006489</i>
<b>Zertifikatsnummer</b> <i>Number of Certificate</i>	D1479100004 <i>D1479100004</i>
<b>MD Code nach NBOG WD 2017-2</b> <i>MD Code acc. NBOG WD 2017-2</i>	MDN 1206
<b>GMDN Code</b> <i>GMDN Code</i>	Siehe Anhangliste <i>See attached list</i>
<b>CND Code</b> <i>CND Code</i>	Siehe Anhangliste <i>See attached list</i>
<b>Konformitätsbewertungsverfahren</b> <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 22.03.2029  
*This Declaration is valid for all manufactured devices specified in the attached list until 2029-03-22*

23.03.2026  
Datum / Date

  
Nazim Özbek – Vice President

<b>QM-Vermerk:</b>	<b>Revision: 7</b>
<b>Dokument:</b> 04x01_Konformitätserklärung_schneidend_I_v07	<b>Datum:</b> 23.03.2026 <b>Seite:</b> 1 von 3

# Konformitätserklärung Wiederverwendbare Chirurgische Instrumente

a1 medical

## Konformitätserklärung – Produktliste Declaration of Conformity Attachment – Device List

Artnr a1	UDI-DI	Gebrauchseinheit	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	00367506	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	00367506	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	00367506	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	00367506	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	00367506	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	00367534	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	00367506	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	00367506	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	00367506	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	00367506	DE/CA39/1331/20
C-1105	4251047932519	PGS00004	42510479PGS00004BV	CTS Fixation Ring Plate, inner- $\emptyset$ 11.0mm, for Anterior Chamber	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00367506	DE/CA39/1331/20
C-1106	4251047932526	PGS00004	42510479PGS00004BV	CTS Fixation Ring Plate, inner- $\emptyset$ 12.0mm for Anterior Chamber	L1704	REUSABLE BLADES, OPHTHALMIC	12-236	Messerhalter	44959	Razor blade breaker/holder	00367506	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	00367506	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	00367506	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	00367534	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	00367506	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	00367506	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	00367506	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	00367506	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	00367506	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	00367506	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	00367506	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	00367506	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	00367506	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	00367506	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	00367506	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	00367506	DE/CA39/1331/20

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