EU-Declaration of Conformity

EU-Konformitätserklärung

We,
Wir,

edelweiss dentistry products gmbh
Dammstraße 68
6922 Wolfurt
Austria

Single Registration Number (SRN):
AT-MF-000005413

herewith declare under our sole responsibility that
erklären hiermit in alleiniger Verantwortung, dass

all products listed on the article list*
alle Produkte der Artikelliste*

** The complete device list is enclosed in Annex A*
** Die vollständige Produktliste ist in Anhang A aufgeführt*

Basic UDI-DI ***Basis UDI-DI***	**Intended Use** **Zweckbestimmung**	**MDR-Codes** ***MDR-Code***
912004632BlockFA	edelweiss CAD/CAM BLOCK is used for the fabrication of indirect single-tooth restorations using CAD/CAM technology. *edelweiss CAD/CAM BLOCK dient zur Herstellung indirekter Einzelzahn-Restaurationen mittels CAD/CAM Technologie.*	MDN 1103 MDS 1007 MDT 2002 MDT 2011
912004632iBlockSK	edelweiss CAD/CAM BLOCK is used for the fabrication of indirect single-tooth restorations using CAD/CAM technology. *edelweiss CAD/CAM BLOCK dient zur Herstellung indirekter Einzelzahn-Restaurationen mittels CAD/CAM Technologie.*	MDN 1209 MDS 1007 MDT 2002 MDT 2011
912004632VeneerWP	edelweiss VENEERs provide the anatomical basis for individual or complete reconstructions in the anterior region. *edelweiss VENEERs bilden die anatomische Grundlage für individuelle oder komplette Rekonstruktionen im Frontzahnbereich*.	MDN 1103 MDS 1011 MDT 2002 MDT 2011
912004632Occlusion7Q	edelweiss OCCLUSIONs provide the anatomical basis for single or complete reconstructions and for raising the vertical dimensions in the posterior region. *edelweiss OCCLUSIONs stellen die anatomische Grundlage für Einzel- oder Komplett- Rekonstruktionen sowie zur Hebung der vertikalen Dimensionen im Seitenzahnbereich dar.*	MDN 1103 MDS 1011 MDT 2002 MDT 2011
912004632PaedCrownNY	edelweiss PEDIATRIC CROWNs provide the anatomical basis for individual or complete reconstructions of the deciduous teeth in the anterior and posterior region as single crowns. *edelweiss PEDIATRIC CROWNs bilden als Einzelkronen die anatomische Grundlage für individuelle oder komplette Rekonstruktionen der Milchzähne im Front- und Seitenzahnbereich*.	MDN 1103 MDS 1011 MDT 2002 MDT 2011
912004632PaedVeneerX7	PEDIATRIC VENEERs as single veneers form the anatomical basis for individual or complete reconstructions of deciduous teeth in the anterior region. *PEDIATRIC VENEERs bilden als Einzelveneers die anatomische Grundlage für einzelne oder komplette Rekonstruktionen von Milchzähnen im Frontzahnbereich.*	MDN 1103 MDS 1011 MDT 2002 MDT 2011

- are manufactured under consideration of European Regulation (EU) 2017/745
- *werden gemäß Verordnung (EU) 2017/745 hergestellt*
- have been assessed acc. to Regulation (EU) 2017/745, Annex IX – Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation (Chapter I & III)
- *bewertet wurden gemäß Verordnung (EU) 2017/745, Anhang IX* – Konformitätsbewertung auf der Grundlage eines Qualitätsmanagementsystems und einer Bewertung der technischen Dokumentation (*Kapitel I & III)*
- have been classified acc. to Regulation (EU) 2017/745, Annex VIII - Classification Rules
- *klassifiziert wurden gemäß Verordnung (EU) 2017/745, Anhang VIII – Klassifizierungsregeln*
- are conform to all applicable general safety and performance requirements of the Regulation (EU) 2017/745
- *konform sind mit allen anwendbaren Grundlegenden Sicherheits- und Leistungsanforderungen der Verordnung (EU) 2017/745*

and may therefore be placed into market, labelled with:
und somit auf den Markt gebracht werden dürfen, gekennzeichnet mit: CE 0482

The conformity assessment of aforementioned devices has been performed in cooperation with our accredited Notified Body:
Die Konformitätsbewertung der oben genannten Produkte wurden in Zusammenarbeit mit unserer akkreditierten Benannten Stelle durchgeführt:
DNV MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg, Germany

This Declaration of Conformity is valid from 30.03.2026 to 27.06.2030
Diese Konformitätserklärung ist gültig von 30.03.2026 bis 27.06.2030

Relevant harmonized standards and common specifications:
Relevante harmonisierte Normen und gemeinsame Spezifikationen:

DIN EN ISO 13485 :2021
DIN EN ISO 14971 :2022
DIN EN ISO 15223-1 :2022

Registration No.:
Registrier Nr.: 7053GB448260306

Medical devices classification(s) and nomenclature(s) summary:
Klassifizierung der Medizinprodukte und Nomenklatur(en):

EMDN-Code ***EMDN-Code***	**Description** ***Beschreibung***	**Rule** ***Regel***	***Class*** ***Klasse***
Q010699	MATERIALS FOR THE PREPARATION OF CUSTOM-MADE DENTAL DEVICES - OTHER	5	IIa
Q010699	MATERIALS FOR THE PREPARATION OF CUSTOM-MADE DENTAL DEVICES - OTHER	8	IIa
Q01020502	PRE-FORMED DENTAL CROWNS	8	IIa

PA03_CAD/CAM Block PA04_Veneer&Occlusion				
Issue Date: **Ausgabedatum:**	30.03.2026	**Revision:** **Revision:**	01	

Digital unterschrieben von Jakob Unterweger
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Datum: 2026.03.30 '08:01:21 +02'00

shaping the future of dentistry

Wolfurt	30.03.2026	
Place / Ort	*Issue Date / Datum*	*Jakob Unterweger, QMB*

Annex A / Anhang A

Article number ***Artikelnummer***	**Article description** **Artikelbeschreibung**	**Class** ***Klasse***	**Rule** ***Regel***	**EMDN Code** ***EMDN Code***
19100	5pcs Set edelweiss CAD/CAM T-BLOCK Universal Enamel	IIa	8	Q010699
19101	5pcs Set edelweiss CAD/CAM C-BLOCK A0	IIa	8	Q010699
19102	5pcs Set edelweiss CAD/CAM C-BLOCK A1	IIa	8	Q010699
19103	5pcs Set edelweiss CAD/CAM C-BLOCK A2	IIa	8	Q010699
19104	5pcs Set edelweiss CAD/CAM C-BLOCK A3	IIa	8	Q010699
19100.A	5pcs Set edelweiss CAD/CAM i-BLOCK (ØS) Universal Enamel	IIa	5	Q010699
19101.A	5pcs Set edelweiss CAD/CAM i-BLOCK (ØS) A0	IIa	5	Q010699
19102.A	5pcs Set edelweiss CAD/CAM i-BLOCK (ØS) A1	IIa	5	Q010699
19103.A	5pcs Set edelweiss CAD/CAM i-BLOCK (ØS) A2	IIa	5	Q010699
19104.A	5pcs Set edelweiss CAD/CAM i-BLOCK (ØS) A3	IIa	5	Q010699
19100.A.L	5pcs Set edelweiss CAD/CAM i-BLOCK (ØL) Universal Enamel	IIa	5	Q010699
19101.A.L	5pcs Set edelweiss CAD/CAM i-BLOCK (ØL) A0	IIa	5	Q010699
19102.A.L	5pcs Set edelweiss CAD/CAM i-BLOCK (ØL) A1	IIa	5	Q010699
19103.A.L	5pcs Set edelweiss CAD/CAM i-BLOCK (ØL) A2	IIa	5	Q010699
19104.A.L	5pcs Set edelweiss CAD/CAM i-BLOCK (ØL) A3	IIa	5	Q010699
21100	5pcs Set edelweiss CAD/CAM T-BLOCK Universal Enamel (10/12/16mm)	IIa	8	Q010699
21101	5pcs Set edelweiss CAD/CAM C-BLOCK A0 (10/12/16mm)	IIa	8	Q010699
21102	5pcs Set edelweiss CAD/CAM C-BLOCK A1 (10/12/16mm)	IIa	8	Q010699
21103	5pcs Set edelweiss CAD/CAM C-BLOCK A2 (10/12/16mm)	IIa	8	Q010699
21104	5pcs Set edelweiss CAD/CAM C-BLOCK A3 (10/12/16mm)	IIa	8	Q010699
13000	VENEER SET 14-24 S up	IIa	8	Q01020502
13010	VENEER SET 14-24 M up	IIa	8	Q01020502
13020	VENEER SET 14-24 L up	IIa	8	Q01020502
13030	VENEER SET 44-34 S low	IIa	8	Q01020502
13040	VENEER SET 44-34 M low	IIa	8	Q01020502
14121	VENEER SET 13-23 XS up	IIa	8	Q01020502
10100	VENEER SET 13-23 S up	IIa	8	Q01020502
10110	VENEER SET 13-23 M up	IIa	8	Q01020502
10120	VENEER SET 13-23 L up	IIa	8	Q01020502
10130	VENEER SET 43-33 S low	IIa	8	Q01020502
10140	VENEER SET 43-33 M low	IIa	8	Q01020502
14122	VENEER 11/21 XS	IIa	8	Q01020502
10180	VENEER 11/21 S	IIa	8	Q01020502
10181	VENEER 11/21 M	IIa	8	Q01020502
10182	VENEER 11/21 L	IIa	8	Q01020502
14123	VENEER 12/22 XS	IIa	8	Q01020502
10183	VENEER 12/22 S	IIa	8	Q01020502
10184	VENEER 12/22 M	IIa	8	Q01020502
10185	VENEER 12/22 L	IIa	8	Q01020502
14124	VENEER 11 XS	IIa	8	Q01020502

10150	VENEER 11 S	IIa	8	Q01020502
10151	VENEER 11 M	IIa	8	Q01020502
10152	VENEER 11 L	IIa	8	Q01020502
14125	VENEER 12 XS	IIa	8	Q01020502
10153	VENEER 12 S	IIa	8	Q01020502
10154	VENEER 12 M	IIa	8	Q01020502
10155	VENEER 12 L	IIa	8	Q01020502
14126	VENEER 13 XS	IIa	8	Q01020502
10156	VENEER 13 S	IIa	8	Q01020502
10157	VENEER 13 M	IIa	8	Q01020502
10158	VENEER 13 L	IIa	8	Q01020502
13100	VENEER 14 S	IIa	8	Q01020502
13101	VENEER 14 M	IIa	8	Q01020502
13102	VENEER 14 L	IIa	8	Q01020502
13103	VENEER 15 S	IIa	8	Q01020502
13104	VENEER 15 M	IIa	8	Q01020502
13105	VENEER 15 L	IIa	8	Q01020502
14127	VENEER 21 XS	IIa	8	Q01020502
10159	VENEER 21 S	IIa	8	Q01020502
10160	VENEER 21 M	IIa	8	Q01020502
10161	VENEER 21 L	IIa	8	Q01020502
14128	VENEER 22 XS	IIa	8	Q01020502
10162	VENEER 22 S	IIa	8	Q01020502
10163	VENEER 22 M	IIa	8	Q01020502
10164	VENEER 22 L	IIa	8	Q01020502
14129	VENEER 23 XS	IIa	8	Q01020502
10165	VENEER 23 S	IIa	8	Q01020502
10166	VENEER 23 M	IIa	8	Q01020502
10167	VENEER 23 L	IIa	8	Q01020502
13106	VENEER 24 S	IIa	8	Q01020502
13107	VENEER 24 M	IIa	8	Q01020502
13108	VENEER 24 L	IIa	8	Q01020502
13109	VENEER 25 S	IIa	8	Q01020502
13110	VENEER 25 M	IIa	8	Q01020502
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10170	VENEER 32 S	IIa	8	Q01020502
10171	VENEER 32 M	IIa	8	Q01020502
10172	VENEER 33 S	IIa	8	Q01020502
10173	VENEER 33 M	IIa	8	Q01020502
13112	VENEER 34 S	IIa	8	Q01020502
13113	VENEER 34 M	IIa	8	Q01020502
13114	VENEER 35 S	IIa	8	Q01020502
13115	VENEER 35 M	IIa	8	Q01020502
10174	VENEER 41 S	IIa	8	Q01020502

10175	VENEER 41 M	IIa	8	Q01020502
10176	VENEER 42 S	IIa	8	Q01020502
10177	VENEER 42 M	IIa	8	Q01020502
10178	VENEER 43 S	IIa	8	Q01020502
10179	VENEER 43 M	IIa	8	Q01020502
13116	VENEER 44 S	IIa	8	Q01020502
13117	VENEER 44 M	IIa	8	Q01020502
13118	VENEER 45 S	IIa	8	Q01020502
13119	VENEER 45 M	IIa	8	Q01020502
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13190	OCCLUSION VD SET 47-37 M low	IIa	8	Q01020502
13195	OCCLUSION VD SET 47-37 L low	IIa	8	Q01020502
13150	OCCLUSION VD SET 17-14 S up	IIa	8	Q01020502
13151	OCCLUSION VD SET 17-14 M up	IIa	8	Q01020502
13152	OCCLUSION VD SET 17-14 L up	IIa	8	Q01020502
13153	OCCLUSION VD SET 24-27 S up	IIa	8	Q01020502
13154	OCCLUSION VD SET 24-27 M up	IIa	8	Q01020502
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13156	OCCLUSION VD SET 34-37 S low	IIa	8	Q01020502
13157	OCCLUSION VD SET 34-37 M low	IIa	8	Q01020502
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13160	OCCLUSION VD SET 47-44 M low	IIa	8	Q01020502
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17208	Pediatric Crown 63/H Size S	IIa	8	Q01020502
17209	Pediatric Crown 64/I Size S	IIa	8	Q01020502
17210	Pediatric Crown 65/J Size S	IIa	8	Q01020502
17211	Pediatric Crown 71/O Size S	IIa	8	Q01020502
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17213	Pediatric Crown 73/M Size S	IIa	8	Q01020502
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17215	Pediatric Crown 75/K Size S	IIa	8	Q01020502
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17217	Pediatric Crown 82/Q Size S	IIa	8	Q01020502

17218	Pediatric Crown 83/R Size S	IIa	8	Q01020502
17219	Pediatric Crown 84/S Size S	IIa	8	Q01020502
17220	Pediatric Crown 85/T Size S	IIa	8	Q01020502
17221	Pediatric Crown 51/E Size M	IIa	8	Q01020502
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17235	Pediatric Crown 75/K Size M	IIa	8	Q01020502
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17244.XL	Pediatric Crown 54/B Size XL	IIa	8	Q01020502
17245.XL	Pediatric Crown 55/A Size XL	IIa	8	Q01020502
17246.XL	Pediatric Crown 61/F Size XL	IIa	8	Q01020502
17247.XL	Pediatric Crown 62/G Size XL	IIa	8	Q01020502
17248.XL	Pediatric Crown 63/H Size XL	IIa	8	Q01020502
17249.XL	Pediatric Crown 64/I Size XL	IIa	8	Q01020502
17250.XL	Pediatric Crown 65/J Size XL	IIa	8	Q01020502
17251.XL	Pediatric Crown 71/O Size XL	IIa	8	Q01020502
17252.XL	Pediatric Crown 72/N Size XL	IIa	8	Q01020502
17253.XL	Pediatric Crown 73/M Size XL	IIa	8	Q01020502
17254.XL	Pediatric Crown 74/L Size XL	IIa	8	Q01020502
17255.XL	Pediatric Crown 75/K Size XL	IIa	8	Q01020502
17256.XL	Pediatric Crown 81/P Size XL	IIa	8	Q01020502
17257.XL	Pediatric Crown 82/Q Size XL	IIa	8	Q01020502
17258.XL	Pediatric Crown 83/R Size XL	IIa	8	Q01020502
17259.XL	Pediatric Crown 84/S Size XL	IIa	8	Q01020502
17260.XL	Pediatric Crown 85/T Size XL	IIa	8	Q01020502
10150.K	Pediatric Veneer 51/E Size S	IIa	8	Q01020502
10151.K	Pediatric Veneer 51/E Size M	IIa	8	Q01020502
10152.K	Pediatric Veneer 51/E Size L	IIa	8	Q01020502
10152.K.XL	Pediatric Veneer 51/E Size XL	IIa	8	Q01020502
10153.K	Pediatric Veneer 52/D Size S	IIa	8	Q01020502
10154.K	Pediatric Veneer 52/D Size M	IIa	8	Q01020502
10155.K	Pediatric Veneer 52/D Size L	IIa	8	Q01020502
10155.K.XL	Pediatric Veneer 52/D Size XL	IIa	8	Q01020502
10156.K	Pediatric Veneer 53/C Size S	IIa	8	Q01020502
10157.K	Pediatric Veneer 53/C Size M	IIa	8	Q01020502
10158.K	Pediatric Veneer 53/C Size L	IIa	8	Q01020502
10158.K.XL	Pediatric Veneer 53/C Size XL	IIa	8	Q01020502
10159.K	Pediatric Veneer 61/F Size S	IIa	8	Q01020502
10160.K	Pediatric Veneer 61/F Size M	IIa	8	Q01020502
10161.K	Pediatric Veneer 61/F Size L	IIa	8	Q01020502
10161.K.XL	Pediatric Veneer 61/F Size XL	IIa	8	Q01020502
10162.K	Pediatric Veneer 62/G Size S	IIa	8	Q01020502
10163.K	Pediatric Veneer 62/G Size M	IIa	8	Q01020502
10164.K	Pediatric Veneer 62/G Size L	IIa	8	Q01020502
10164.K.XL	Pediatric Veneer 62/G Size XL	IIa	8	Q01020502
10165.K	Pediatric Veneer 63/H Size S	IIa	8	Q01020502
10166.K	Pediatric Veneer 63/H Size M	IIa	8	Q01020502
10167.K	Pediatric Veneer 63/H Size L	IIa	8	Q01020502
10167.K.XL	Pediatric Veneer 63/H Size XL	IIa	8	Q01020502
17035	edelweiss VENEER 11 S LONG	IIa	8	Q01020502
17036	edelweiss VENEER 11 M LONG	IIa	8	Q01020502
17037	edelweiss VENEER 11 L LONG	IIa	8	Q01020502
17038	edelweiss VENEER 12 S LONG	IIa	8	Q01020502
17039	edelweiss VENEER 12 M LONG	IIa	8	Q01020502

17040	edelweiss VENEER 12 L LONG	IIa	8	Q01020502
17041	edelweiss VENEER 13 S LONG	IIa	8	Q01020502
17042	edelweiss VENEER 13 M LONG	IIa	8	Q01020502
17043	edelweiss VENEER 13 L LONG	IIa	8	Q01020502
17044	edelweiss VENEER 14 S LONG	IIa	8	Q01020502
17045	edelweiss VENEER 14 M LONG	IIa	8	Q01020502
17046	edelweiss VENEER 14 L LONG	IIa	8	Q01020502
17047	edelweiss VENEER 15 S LONG	IIa	8	Q01020502
17048	edelweiss VENEER 15 M LONG	IIa	8	Q01020502
17049	edelweiss VENEER 15 L LONG	IIa	8	Q01020502
17050	edelweiss VENEER 21 S LONG	IIa	8	Q01020502
17051	edelweiss VENEER 21 M LONG	IIa	8	Q01020502
17052	edelweiss VENEER 21 L LONG	IIa	8	Q01020502
17053	edelweiss VENEER 22 S LONG	IIa	8	Q01020502
17054	edelweiss VENEER 22 M LONG	IIa	8	Q01020502
17055	edelweiss VENEER 22 L LONG	IIa	8	Q01020502
17056	edelweiss VENEER 23 S LONG	IIa	8	Q01020502
17057	edelweiss VENEER 23 M LONG	IIa	8	Q01020502
17058	edelweiss VENEER 23 L LONG	IIa	8	Q01020502
17059	edelweiss VENEER 24 S LONG	IIa	8	Q01020502
17060	edelweiss VENEER 24 M LONG	IIa	8	Q01020502
17061	edelweiss VENEER 24 L LONG	IIa	8	Q01020502
17062	edelweiss VENEER 25 S LONG	IIa	8	Q01020502
17063	edelweiss VENEER 25 M LONG	IIa	8	Q01020502
17064	edelweiss VENEER 25 L LONG	IIa	8	Q01020502
17065	edelweiss VENEER 11/21 S LONG	IIa	8	Q01020502
17066	edelweiss VENEER 11/21 M LONG	IIa	8	Q01020502
17067	edelweiss VENEER 11/21 L LONG	IIa	8	Q01020502
17068	edelweiss VENEER 12/22 S LONG	IIa	8	Q01020502
17069	edelweiss VENEER 12/22 M LONG	IIa	8	Q01020502
17070	edelweiss VENEER 12/22 L LONG	IIa	8	Q01020502
17074	edelweiss VENEER SET 13-23 S up LONG	IIa	8	Q01020502
17075	edelweiss VENEER SET 13-23 M up LONG	IIa	8	Q01020502
17076	edelweiss VENEER SET 13-23 L up LONG	IIa	8	Q01020502
17071	edelweiss VENEER SET 14-24 S up LONG	IIa	8	Q01020502
17072	edelweiss VENEER SET 14-24 M up LONG	IIa	8	Q01020502
17073	edelweiss VENEER SET 14-24 L up LONG	IIa	8	Q01020502