

EN

EU Declaration of Conformity

We, the company Cendres+Métaux SA, Rue de Boujean 122, CH-2501 Biel/Bienne, hereby declare under sole responsibility that the following products

Slide Attachments

according to the attached list

Product list Family: Slide Attachments, Revision 01

are in conformity with the following normative documents:

Regulation (EU) 2017/745 (MDR) and, where applicable, other relevant Union legislation providing for the issuing of an EU declaration of conformity.

Common specifications applied:

N.A.

Classification according to Annex VIII, MDR (EU) 2017/745,

Basic UDI-DI according to Annex VI Part C MDR (EU) 2017/745,

And **Intended Purpose** according to the attached list:

Product list Family: Slide Attachments, Revision 01

Conformity assessment procedure: MDR (EU) 2017/745 Annex IX

Notified Body:

mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart / Germany (CE 0483)

Validity: 22.02.2027

This declaration of conformity is authenticated with the following signatures:

Biel/Bienne, 29.05.2024



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** Person responsible for compliance with the regulatory requirements MDR (EU) 2017/745 in accordance with Article 15.*

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Release

Task	Name	Function	Date	Signature
Author	Dylan Moretti	Regulatory Affairs Manager	27.03.2023	
Review	Markus Blümli	Senior Product Manager	29.03.2023	

Identification

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Purpose

This template defines the content of Section 1.1 of the Technical Documentation for Medical Devices based on MDR (EU) 2017/745 and RL 00001387 "Maintenance of technical documentation for dental medical devices".

1.1.2.1 List of products

Listing of the medical devices that are covered by the technical documentation. The following information are in the list:

- Catalog number
- Product name
- Device group
- Family
- Functional family
- Class MDR
- Rule MDR
- GMDN code
- Basic UDI-DI
- UDI

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
050697	Mini-Dalbo® Female part E	Mini-Dalbo®	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640166513827
051659	Mini-Dalbo® DK	Mini-Dalbo®	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173090755
051662	Mini-Dalbo® Female part D	Mini-Dalbo®	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173092995
055364	Mini-SG® DK	Mini-SG®	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173090830
055371	Mini-SG® Female part D	Mini-SG®	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173090847
055487	Mini-SG® XK	Mini-SG®	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173090861
055489	Mini-SG® Female part X	Mini-SG®	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640166517702
05003614	Mini-SG® MK	Mini-SG®	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640239932111
05003615	Mini-SG® Female part M	Mini-SG®	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640239932128
055925	Mini-SG® / Mini-SG® F/R Tuning Female part E	Mini-SG®	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173093480
055531	Mini-SG® F/R Female part T	Mini-SG® F/R	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173090342
055532	Mini-SG® F/R TK	Mini-SG® F/R	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173090878
055677	Mini-SG® F/R Female part C	Mini-SG® F/R	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173090373
055699	Mini-SG® F/R CK	Mini-SG® F/R	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173093282

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
055718	Mini-SG® F/R Retention insert G Orange (normal retention)	Mini-SG® F/R	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173093299
055766	Mini-SG® F/R Retention insert G Violet (strong retention)	Mini-SG® F/R	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173093336
055804	Mini-SG® PLUS TK	Mini-SG® Plus	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173090922
055807	Mini-SG® PLUS Female part T	Mini-SG® Plus	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173090397
055356	Mini-SG® / Mini-SG® F/R / M-SG® Star 1 Friction insert G Red (normal friction)	M-SG® Star 1	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173093121
055357	Mini-SG® / Mini-SG® F/R / M-SG® Star 1 Friction insert G Green (strong friction)	M-SG® Star 1	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640166516125
055358	Mini-SG® / Mini-SG® F/R / M-SG® Star 1 Friction insert G Blue (extra-strong friction)	M-SG® Star 1	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173093145
055691	Mini-SG® / Mini-SG® F/R / M-SG® Star 1 Friction insert G Yellow (smooth friction)	M-SG® Star 1	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173093268
05000432	M-SG® Star 1 TK for casting	M-SG® Star 1	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173091127
05000433	M-SG® Star 1 Female part T	M-SG® Star 1	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640166515098
05000673	M-SG® Star 1 MK for casting	M-SG® Star 1	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173090441
05000674	M-SG® Star 1 Female part M	M-SG® Star 1	Slide Attachments	Female parts	Ila	5, 3rd indent	38580	764016651000067EF	07640173090458

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
055774	Mini-SG® PLUS / M-SG® Star 2 Friction insert G Orange (normal friction)	M-SG® Star 2	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640173093350
055775	Mini-SG® PLUS / M-SG® Star 2 Activating screw T	M-SG® Star 2	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640166514206
055811	Mini-SG® PLUS / M-SG® Star 2 Friction insert G Violet (strong friction)	M-SG® Star 2	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640173093411
05000413	M-SG® Star 2 TK for casting	M-SG® Star 2	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640173093862
05000414	M-SG® Star 2 Female part T	M-SG® Star 2	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640166515050
052158	Slide Attachment SG DK	Slide Attachment SG®	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640173090816
052159	Slide Attachment SG Female part D	Slide Attachment SG®	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640173090823
052161	Slide Attachment SG Activating screw O	Slide Attachment SG®	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640173092049
052163	Slide Attachment SG Friction insert G white (normal friction)	Slide Attachment SG®	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640173092018
05000057	Slide Attachment SG Friction insert G violet (strong friction)	Slide Attachment SG®	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640173091158
055410	Tecnoroach Female part E	Tecnoroach	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640173092131
055411	Tecnoroach EK	Tecnoroach	Slide Attachments	Female parts	IIa	5, 3rd indent	38580	764016651000067EF	07640173090854
050701	Mini-Dalbo® EC	Mini-Dalbo®	Slide Attachments	Male parts	IIa	8, 1st indent	38580	764016651000051DY	07640166513841

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
050960	Mini-Dalbo® Male part C	Mini-Dalbo®	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640166513865
055919	Mini-SG® XC	Mini-SG®	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640173093718
055534	Mini-SG® F/R TV	Mini-SG® F/R	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640173090359
055543	Mini-SG® F/R TC	Mini-SG® F/R	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640173093237
055544	Mini-SG® / Mini-SG® F/R / Mini-SG® PLUS Male part C	Mini-SG® F/R	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640173093244
055675	Mini-SG® F/R CC	Mini-SG® F/R	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640173090366
055517	Mini-SG® F/R / Mini-SG® PLUS Male part V	Mini-SG® F/R / PLUS	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640173093206
055802	Mini-SG® PLUS TV	Mini-SG® Plus	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640173090380
05000407	M-SG® Star 1 / M-SG® Star 2 Male part C for casting-on	M-SG® Star 1	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640166515005
05000429	M-SG® Star 1 TC for casting-on	M-SG® Star 1	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640166515067
05000411	M-SG® Star 2 TC for casting-on	M-SG® Star 2	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640166515036
052157	Slide Attachment SG DC	Slide Attachment SG®	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640173090809
052160	Slide Attachment SG Male part C	Slide Attachment SG®	Slide Attachments	Male parts	Ila	8, 1st indent	38580	764016651000051DY	07640173092032

1.1.2.2 Intended purposes

Listing of the intended purposes for the functional families that are covered by the technical documentation.

Generally, the products are intended for prosthetic restorations and to support procedures in dental clinic or laboratory. The intended purpose corresponding to each functional family is defined as follows:

Functional Family	Intended purpose
Female parts	The Female parts, which are part of prosthetic retaining elements, are inserted (bonding, polymerizing, or casting) into the removable denture, and are intended for use in prosthetic restorations when implant prosthetics are not suitable, and to support procedures in the dental clinic or laboratory.
Male parts	The Male parts, which are part of prosthetic retaining elements, are connected (casting or soldering) to an abutment tooth and are intended for use in prosthetic restorations when implant prosthetics are not suitable, and to support procedures in the dental clinic or laboratory.

References

- CS-Female parts; Chapter A.1.1.3 of DMR Slide Attachments
- CS-Male parts; Chapter A.1.1.3 of DMR Slide Attachments

Change Control

This change control lists the changes for the technical content. Changes to form FO 7.456 are documented in Appendix FO 7.456-A.

Old Version	Change date	Pos. / Section	Description of change	Reason of change	Applicant
N/A	27.03.2023	All	New creation	Establishing the technical file according to MDR	dym