

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

Class I

according to the attached list

Product list Family: Class I, Revision 05

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: Class I, Revision 05

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

Notified Body:

Class I: Notified Body not required

Validity: 31.03.2024

This declaration of conformity is authenticated with the following signatures:

Biel/Bienne, 09.11.2023



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Release

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Author	Dylan Moretti	Regulatory Affairs Manager	26.10.2023	
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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
07000205	CM LOC® Multi-Tool for Pekkton® Retention insert	CM LOC®	Class I	Activators and Desactivators	I	1	64322	764016651000001DH	07640166511335
070197	Dalbo®-Classic /-B /-Z / Profix Activator	Dalbo®-Classic	Class I	Activators and Desactivators	I	1	64322	764016651000003DM	07640166514497
070199	Dalbo®-Classic /-B /-Z / Profix Deactivator	Dalbo®-Classic	Class I	Activators and Desactivators	I	1	64322	764016651000003DM	07640166514503
072609	Dalbo®-PLUS Screwdriver / Activator	Dalbo®-PLUS	Class I	Activators and Desactivators	I	1	64322	764016651000002DK	07640166514916
05001241	Dalbo®-PLUS Screwdriver / Activator	Dalbo®-PLUS	Class I	Activators and Desactivators	I	1	64322	764016651000002DK	07640166511410
07000389	Dalbo®-PLUS Screwdriver / Activator	Dalbo®-PLUS	Class I	Activators and Desactivators	I	1	64322	764016651000002DK	07640173095828
072597	Mini-Gerber PLUS Special socket key	Mini-Gerber Plus	Class I	Activators and Desactivators	I	1	64322	764016651000002DK	07640173091219
07050008	Pro-Snap Seating tool	Pro-Snap	Class I	Activators and Desactivators	I	1	64322	764016651000001DH	07640173091547
070198	Dolder® System / Round bar Activator set	Dolder® System	Class I	Activators and Desactivators	I	1	64322	764016651000002DK	07640166511830
070200	Dolder® System Desactivator micro	Dolder® System	Class I	Activators and Desactivators	I	1	64322	764016651000003DM	07640166514510
070201	Dolder® System Desactivator macro	Dolder® System	Class I	Activators and Desactivators	I	1	64322	764016651000003DM	07640166511847
072483	Mini-SG® F/R / Mini-SG® Insert remover	Mini-SG®	Class I	Activators and Desactivators	I	1	64322	764016651000001DH	07640173091776
072653	M-SG® Star 2 / Mini-SG® PLUS Screwdriver/Activator	Mini-SG® Plus	Class I	Activators and Desactivators	I	1	64322	764016651000002DK	07640173091295

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
07000056	Mini-SG® / Mini-SG® F/R / M-SG® Star 1 Insert remover	M-SG® Star 1	Class I	Activators and Desactivators	I	1	64322	764016651000001DH	07640166515197
070293	Slide Attachment SG Screwdriver insert	Slide Attachment SG®	Class I	Activators and Desactivators	I	1	64322	764016651000002DK	07640173093572
072505	Tecnoroach Activator	Tecnoroach	Class I	Activators and Desactivators	I	1	64322	764016651000003DM	07640173091196
07000223	CM LOC®FLEX Aligner	CM LOC® Flex	Class I	Aligners	I	1	64321	764016651000004DP	07640166512448
05001328	CM LOC® Processing insert	CM LOC®	Class I	Duplicating and Protection Aids	I	5, 1st indent	64321	764016651000007DV	07640166511274
CM031-03486-01	CM LOC® Processing insert	CM LOC®	Class I	Duplicating and Protection Aids	I	5, 1st indent	64321	764016651000007DV	07640166519072
072626	Dalbo®-PLUS Duplicating aid / spacer G	Dalbo®-PLUS	Class I	Duplicating and Protection Aids	I	5, 1st indent	64321	764016651000006DT	07640166514923
05001239	Dalbo®-PLUS Duplicating Aid	Dalbo®-PLUS	Class I	Duplicating and Protection Aids	I	5, 1st indent	64321	764016651000006DT	07640166511397
072466	Mini-Gerber / Mini-Gerber Plus Spacer / duplicating aid G	Mini-Gerber Plus	Class I	Duplicating and Protection Aids	I	5, 1st indent	64321	764016651000006DT	07640173093893
07050004	Pro-Snap Protection cap	Pro-Snap	Class I	Duplicating and Protection Aids	I	1	64321	764016651000007DV	07640173090991
072600	Mini-SG® F/R Duplicating aid G	Mini-SG® F/R	Class I	Duplicating and Protection Aids	I	1	64321	764016651000006DT	07640173091226
072649	Mini-SG® PLUS Duplicating aid G	Mini-SG® Plus	Class I	Duplicating and Protection Aids	I	1	64321	764016651000006DT	07640173091288
07000040	M-SG® Star 1 Duplicating aid G	M-SG® Star 1	Class I	Duplicating and Protection Aids	I	1	64321	764016651000006DT	07640166515173

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
07000041	M-SG® Star 2 Duplicating aid G	M-SG® Star 2	Class I	Duplicating and Protection Aids	I	1	64321	764016651000006DT	07640173093503
052164	Slide Attachment SG Mounting screw X	Slide Attachment SG®	Class I	Duplicating and Protection Aids	I	1	64321	764016651000008DX	07640166519324
072502	Slide Attachment SG Duplicating aid G	Slide Attachment SG®	Class I	Duplicating and Protection Aids	I	1	64321	764016651000006DT	07640173091783
07000217	CM LOC® Housing Extractor	CM LOC®	Class I	Extractors	I	1	64322	764016651000009DZ	07640166511359
072639	Dalbo®-PLUS Heating rod	Dalbo®-PLUS	Class I	Extractors	I	1	64322	764016651000010DJ	07640173091271
072605	Mini-Gerber PLUS Heating rod	Mini-Gerber Plus	Class I	Extractors	I	1	64322	764016651000010DJ	07640173091240
07000024	Dalbo®-PLUS Female part gauge	Dalbo®-PLUS	Class I	Gauges, non-Surgically Invasive	I	5, 1st indent	64322	764016651000011DL	07640173090977
07000026	Dalbo®-PLUS Gauge set	Dalbo®-PLUS	Class I	Gauges, non-Surgically Invasive	I	5, 1st indent	64322	764016651000012DN	07640166517733
07000027	Dalbo®-PLUS Male part gauge	Dalbo®-PLUS	Class I	Gauges, non-Surgically Invasive	I	1	64322	764016651000011DL	07640173090984
070205	Dalbo® / Baer Cylindrical Anchor Instrument For mounting of elastomeric ring	Dalbo®-Rotex	Class I	Handles	I	5, 1st indent	64322	764016651000016DW	07640166514534
070498	Dalbo®-Rotex by Dr. Dallla Bona Spanner key for spherical head	Dalbo®-Rotex	Class I	Handles	I	5, 1st indent	47829	764016651000013DQ	07640166514800
070500	Dalbo®-Rotex by Prof. Brunner Spanner key for spherical head	Dalbo®-Rotex	Class I	Handles	I	5, 1st indent	47829	764016651000013DQ	07640166514824

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
072414	CM Root canal posts and anchors Coupling piece	Dalbo®-Rotex	Class I	Handles	I	5, 1st indent	47829	764016651000014DS	07640166514855
070301	Rotex Spanner key (White) Anchor size 1	Rotex®	Class I	Handles	I	5, 1st indent	47829	764016651000013DQ	07640173092834
070302	Rotex Spanner key (Yellow) Anchor size 2	Rotex®	Class I	Handles	I	5, 1st indent	47829	764016651000013DQ	07640173092841
070303	Rotex Spanner key (Red) Anchor size 3	Rotex®	Class I	Handles	I	5, 1st indent	47829	764016651000013DQ	07640173092858
072459	Rotex-RD Spanner key Anchor size 1-3	Rotex®-RD	Class I	Handles	I	5, 1st indent	47829	764016651000013DQ	07640173091059
070221	Thomas spanner key	Slide Attachment SG®	Class I	Handles	I	5, 1st indent	47829	764016651000013DQ	07640166511861
07000213	CM LOC® Impression part	CM LOC®	Class I	Impression Parts	I	5, 1st indent	64323	764016651000017DY	07640166511298
07000219	CM LOC® Parallelometer insert	CM LOC®	Class I	Parallelometer Inserts	I	1	64322	764016651000018E2	07640166511366
070131	Dalbo®-Z / Dalbo®-B / Profix / Pro-Snap Parallelometer insert	Dalbo®-B	Class I	Parallelometer Inserts	I	1	64322	764016651000018E2	07640166514312
072637	Dalbo®-PLUS / Dalbo® Classic Special parallelometer insert	Dalbo®-PLUS	Class I	Parallelometer Inserts	I	1	64322	764016651000018E2	07640166514947
072460	Mini-Gerber PLUS Parallelometer insert	Mini-Gerber Plus	Class I	Parallelometer Inserts	I	1	64322	764016651000018E2	07640173091066
070143	Dolder® System Parallelometer insert micro (Bar attachment)	Dolder® System	Class I	Parallelometer Inserts	I	1	64322	764016651000018E2	07640166514343

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
070144	Dolder® System Parallelometer insert macro (Bar attachment)	Dolder® System	Class I	Parallelometer Inserts	I	1	64322	764016651000018E2	07640166514350
072515	Dolder® System Parallelometer insert micro (Resilient bar)	Dolder® System	Class I	Parallelometer Inserts	I	1	64322	764016651000018E2	07640166514893
072517	Dolder® System Parallelometer insert macro (Resilient bar)	Dolder® System	Class I	Parallelometer Inserts	I	1	64322	764016651000018E2	07640166514909
070146	Mini-Dalbo® / Dalbo®-S Parallelometer insert	Dalbo®-S	Class I	Parallelometer Inserts	I	1	64322	764016651000018E2	07640166514374
072627	M-SG® / Mini-SG® Special parallelometer insert	M-SG® Star 1	Class I	Parallelometer Inserts	I	1	64322	764016651000018E2	07640166514930
072507	Tecnoroach Parallelometer insert	Tecnoroach	Class I	Parallelometer Inserts	I	1	64322	764016651000018E2	07640173091202
07000200	CM LOC® Instrument Set	CM LOC®	Class I	Screwdrivers, invasive	I	5, 1st indent	64322	764016651000025DX	07640166511373
07000206	CM LOC® Screw Driver	CM LOC®	Class I	Screwdrivers, invasive	I	5, 1st indent	33968	764016651000022DR	07640166511342
07000222	CM LOC®FLEX Screw Driver	CM LOC® Flex	Class I	Screwdrivers, invasive	I	5, 1st indent	33968	764016651000022DR	07640166512431
07000266	Dalbo® Abutment Screw Driver	Dalbo®-PLUS	Class I	Screwdrivers, invasive	I	5, 1st indent	33968	764016651000022DR	07640166517689
07000008	CM-hex screw system Hex key (for cap and pin screw)	CM-hex screw system	Class I	Screwdrivers, invasive	I	5, 1st indent	33968	764016651000023DT	07640173093497
07050013	Mini-Presso-Matic Screwdriver	Mini-Presso- Matic	Class I	Screwdrivers, invasive	I	1	33968	764016651000024DV	07640173091424

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
07000201	CM LOC® Spacer	CM LOC®	Class I	Spacers	I	5, 1st indent	64321	764016651000026DZ	07640166511281
07000202	CM LOC® Block-out Spacer	CM LOC®	Class I	Spacers	I	5, 1st indent	64321	764016651000027E3	07640166511304
CM031-03487-01	CM LOC® Block-out Spacer	CM LOC®	Class I	Spacers	I	5, 1st indent	64321	764016651000027E3	07640166519065
070440	Dalbo®-B Spacer G	Dalbo®-B	Class I	Spacers	I	5, 1st indent	64321	764016651000026DZ	07640173090274
072625	Dalbo®-Classic Spacer G	Dalbo®-Classic	Class I	Spacers	I	5, 1st indent	64321	764016651000026DZ	07640173091264
050394	Dalbo®-PLUS /-Classic /-B /-Z Spacer disc tin	Dalbo®-PLUS	Class I	Spacers	I	5, 1st indent	64321	764016651000028E5	07640166513759
070439	Dalbo®-Z Spacer G	Dalbo®-Z	Class I	Spacers	I	5, 1st indent	64321	764016651000026DZ	07640173093619
050392	Eccentric Spacer disc gingival	Eccentric	Class I	Spacers	I	5, 1st indent	64321	764016651000028E5	07640173092063
050393	Eccentric Spacer disc occlusal	Eccentric	Class I	Spacers	I	5, 1st indent	64321	764016651000028E5	07640173092087
07050006	Pro-Snap Stabilizing ring G	Pro-Snap	Class I	Spacers	I	1	64321	764016651000031DS	07640173091011
052080	Dolder® System Spacer micro	Ackermann-Bar	Class I	Spacers	I	5, 1st indent	64321	764016651000030DQ	07640166514091
052081	Dolder® System Spacer macro	Dolder® System	Class I	Spacers	I	5, 1st indent	64321	764016651000030DQ	07640166514107
052082	Round bar with rider Spacer (Tin) 50 x 0.60mm	Round Bar with Rider	Class I	Spacers	I	5, 1st indent	64321	764016651000029E7	07640166511809

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
052085	Round bar with rider Spacer (Tin) 200 x 0.60mm	Round Bar with Rider	Class I	Spacers	I	5, 1st indent	64321	764016651000029E7	07640173093077
07000204	CM LOC® Analog	CM LOC®	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000034DY	07640166511328
07000312	Dalbo® Abutment Analog	Dalbo® Abutment	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000034DY	07640166517672
070157	Dalbo®-PLUS /-Classic /-B /-Z / Profix Transfer jig	Dalbo®-Z	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000032DU	07640166514404
070161	Eccentric Transfer jig	Eccentric	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000032DU	07640173090007
070167	Eccentric Transfer jig (male part with resilience)	Eccentric	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000032DU	07640173090014
072461	Mini-Gerber PLUS / Mini-Gerber Transfer jig	Mini-Gerber Plus	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000032DU	07640173091073
07050005	Pro-Snap Transfer jig	Pro-Snap	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000032DU	07640173091004
070171	Dolder® System Transfer jig micro L50	Dolder® System	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000033DW	07640166514435
070173	Dolder® System Transfer jig macro L50	Dolder® System	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000033DW	07640166514442
072293	Round bar with rider Transfer jig	Round Bar with Rider	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000033DW	07640166514831
070511	Dalbo®-Rotex by Dr. Dalla Bona Transfer jig	Dalbo®-Rotex	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000032DU	07640173091448
070512	Dalbo®-Rotex by Prof. Brunner Transfer jig	Dalbo®-Rotex	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000032DU	07640173091455

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
070176	Mini-Dalbo® Transfer jig	Mini-Dalbo®	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000032DU	07640166514466
072616	Mini-SG® F/R / Mini-SG® PLUS / Mini-SG® Transfer jig	Mini-SG®	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000032DU	07640173091257
07000042	M-SG® Star 1 / M-SG® Star 2 Transfer jig	M-SG® Star 1	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000032DU	07640166515180
070566	Slide Attachment SG Transfer jig	Slide Attachment SG®	Class I	Transfer Jigs and Analogs	I	1	64321	764016651000032DU	07640173091509
070222	Attachment tweezers	N/A	Class I	Tweezers	I	1	64322	764016651000035E2	07640166514565

1.1.2.2 Intended purposes

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

Functional Family	Intended purpose
Activators and Desactivators	The activators and desactivators are handheld tools used by dental technicians and dentists to adjust the retention force between the male and the female part of a dental precision attachment.
Aligners	The aligners are single-use tools used in combination with the CM LOC® FLEX dental abutments. The aligners act as a funnel when injecting adhesive to fix the abutment parts in the correct position.
Duplicating and Protection Aids	The duplicating and protection aids are used during the fabrication of the denture. The duplicating aids act as place-holders for the attachment female parts and hence create a precise housing for bonding the female part into the metal-framework. The protection parts are used to protect elements during processing.
Extractors	The extractors are tools used to remove the housing of an attachment from a denture when the attachment needs replacement.
Gauges, non-Surgically Invasive	The non-surgically invasive gauges include tools used for fine-tuning the adjustment of the attachments or the anchors.
Handles	The handles are hand-held instruments designed for holding root anchors, drills, reamers, and screwdrivers with an ISO 1797 compatible contra-angle connection.
Impression Parts	The impression parts are single-use devices used by the dentist to transfer the implant position and orientation from the intra-oral situation to the model in the laboratory.
Parallelometer Inserts	The parallelometer inserts are used for mounting attachments to crowns aligned parallel to each other.
Screwdrivers, invasive	The invasive screwdrivers are mechanical tools, consisting of a handle and a blade, which are intended to screw screws into or out of materials, to tighten or loosen them or to block them against rotation.
Spacers	The spacers are used by dental technician or dentist during final preparation of the denture. They replace the female part of the anchor during resin-polymerization to ensure that enough space is created to facilitate the final polymerization of the female part.
Transfer jigs, Analogs	The transfer jigs are used by the dental technician for simulating the final device position and connection on a stone master model. The analogs (abutment analogs) are intended to be used as a copy of a dental implant abutment, for a dental laboratory working model, to confirm the orientation/position of the final dental implant.
Tweezers	The tweezers are manipulations aids intended to pick-up or hold attachments or parts of them.

References

- List here all important documents which belong to this form

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
04	24.10.2023	1.1.2.1	Entfernung der Artikeln 072439, 072440, 07050012, 070210, 070211, 070395, 070470, 072432, 072433, 07050014, 070213, 070214 Entfernung dem Artikel 080376 Korrekturen in Produktnamen der Artikeln 07000389, 050394, 07000042 Klassifizierungsregel von Artikel 070440	DV5-3451 Diese Produkte sind desinvestiert DV5-3457 Dieses Produkt ist desinvestiert MA-3850 Produktnamen entsprechen nicht den Produktnamen auf den Etiketten MA-3850 Die falsche Klassifizierungsregel wurde definiert, weil das Produkt für eine "vorübergehende" Verwendung (weniger als 60 Minuten) bestimmt ist.	dym
04	24.10.2023	1.1.2.2	Entfernung des Verwendungszwecks der Funktionsfamilien "Auxiliary Screws" und "Drills, non surgical"	DV5-3451 Alle Produkte in diesen Funktionsfamilien sind desinvestiert.	dym