

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

Root Canal Posts and Anchors

according to the attached list

Product list Family: Root Canal Posts and Anchors, Revision 03

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: Root Canal Posts and Anchors, Revision 03

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



Dylan Moretti
Regulatory Affairs Manager *
Cendres+Métaux SA



Matthias Walther
Director of Quality & Regulatory
Cendres+Métaux SA

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

Authorised representative in the EU:

QualRep Services B.V.
Utrechtseweg 310 – Bldg B42
NL-6812 AR Arnhem
The Netherlands
E-Mail: globalreg@Qservegroup.com
NL-AR-000000537

EC Certificate Reg. No. D1470400016
CHRN-MF-20000343
SRN: CH-MF-000030696

Release

Task	Name	Function	Date	Signature
Author	Dylan Moretti	Regulatory Affairs Manager	01.11.2022	
Review	Markus Blümli	Senior Product Manager	02.11.2022	

Identification

Document No.: LDP-Root Canal Posts and Anchors Revision: 03

Please save document under the following name: LDP-Root Canal Posts and Anchors_V03

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
051868	Dalbo®-Rotex Female part G	Dalbo®-Rotex	Root Canal Posts and Anchors	Female parts	Ila	5, 3rd indent	46307	764016651000063E7	07640173092667
070481	CM root canal posts Post gauge Post size 1-5	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal gauges	Ila	6, general	31846	764016651000061E3	07640166519331
070483	Root canal posts Mooser Post gauge Post size 1-4	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal gauges	Ila	6, general	31846	764016651000061E3	07640166519348
072321	CM root canal posts Root canal drill (Yellow) Post size 2	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640173091578
072326	CM root canal posts Root canal drill (White) Post size 1	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640173091585
072327	CM root canal posts Root canal drill (Red) Post size 3	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640173091592
072328	CM root canal posts Root canal drill (Blue) Post size 4	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640173091608
072329	CM root canal posts Root canal drill (Green) Post size 5	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640173091615
070499	Dalbo®-Rotex by Dr. Dallia Bona Face cutting drill (White) Anchor size 1	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166514817

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
072473	Dalbo®-Rotex by Prof. Brunner Face cutting drill (Yellow) Anchor size 2	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640173091769
072474	Dalbo®-Rotex by Dr. Dalla Bona Face cutting drill (Yellow) Anchor size 2	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166514879
072310	Root canal posts Mooser Root canal drill (White) Post size 1	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166512561
072311	Root canal posts Mooser Root canal drill (Yellow) Post size 2	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166512578
072312	Root canal posts Mooser Root canal drill (Red) Post size 3	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166512585
072313	Root canal posts Mooser Root canal drill (Blue) Post size 4	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166512592
072314	Root canal posts Mooser Pilot reamer (White) Post size 1	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166512608
072315	Root canal posts Mooser Pilot reamer (Yellow) Post size 2	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166512615

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
072316	Root canal posts Mooser Pilot reamer (Red) Post size 3	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166512622
072317	Root canal posts Mooser Pilot reamer (Blue) Post size 4	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166512639
MD.200004436	MP-Post MP root canal drill	MP Post	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166515302
MD.200004441	MP-Post root canal drill yellow Size 1	MP Post	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166515319
MD.200004442	MP-Post MP auxiliary drill	MP Post	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166515326
MD.200004447	MP-Post root canal drill red Size 2	MP Post	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166515333
MD.200004451	MP-Post root canal drill blue Size 3	MP Post	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166515340
MD.200004455	MP-Post root canal drill green Size 4	MP Post	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166515357
070295	Rotex / Dalbo®-Rotex Face cutting drill (White) Anchor size 1	Rotex®	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166514602
070296	Rotex Face cutting drill (Yellow) Anchor size 2	Rotex®	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640173092810

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
070297	Rotex Face cutting drill (Red) Anchor size 3	Rotex®	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640173092827
070380	Rotex / Rotex-RD / Dalbo®-Rotex Root canal drill (White) Anchor size 1	Rotex®	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166514718
070381	Rotex / Rotex-RD / Dalbo®-Rotex Root canal drill (Yellow) Anchor size 2	Rotex®	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166514725
070382	Rotex / Rotex-RD Root canal drill (Red) Anchor size 3	Rotex®	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640166514732
072470	Rotex-RD Face cutting drill (White) Anchor size 1	Rotex®-RD	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640173091097
072471	Rotex-RD Face cutting drill (Yellow) Anchor size 2	Rotex®-RD	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640173091745
072472	Rotex-RD Face cutting drill (Red) Anchor size 3	Rotex®-RD	Root Canal Posts and Anchors	Root Canal mechanic instruments	Ila	6, general	40529	764016651000060DZ	07640173091752
05003194	CM root canal post Adhesive head C (Size 1)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099185
05003195	CM root canal post Adhesive head C (Size 2)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099192

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
05003202	CM root canal post Adhesive head C (Size 3)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099208
05003210	CM root canal post Adhesive head C (Size 4)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099215
05003211	CM root canal post Adhesive head C (Size 5)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099222
05003219	CM root canal post Adhesive head C (Size 1) (with cement flow-off groove)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099239
05003226	CM root canal post Adhesive head C (Size 2) (with cement flow-off groove)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099246
05003234	CM root canal post Adhesive head C (Size 3) (with cement flow-off groove)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099253
05003242	CM root canal post Adhesive head C (Size 4) (with cement flow-off groove)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099260
05003250	CM root canal post Adhesive head C (Size 5) (with cement flow-off groove)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099277

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
05003584	CM root canal post Flat head T (Size 1) (with cement flow-off groove)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099338
05003585	CM root canal post Flat head T (Size 2) (with cement flow-off groove)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099345
05003586	CM root canal post Flat head T (Size 3) (with cement flow-off groove)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099352
05003587	CM root canal post Flat head T (Size 4) (with cement flow-off groove)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099369
05003588	CM root canal post Flat head T (Size 5) (with cement flow-off groove)	CM Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099376
051864	Dalbo®-Rotex GT (Size 1) by Dr. Dalla Bona	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173090199
051865	Dalbo®-Rotex GT (Size 2) by Dr. Dalla Bona	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173090212
051866	Dalbo®-Rotex GT (Size 1) by Prof. Brunner	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173090236

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
051867	Dalbo®-Rotex GT (Size 2) by Prof. Brunner	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173090762
051869	Dalbo®-Rotex by Dr. Dalla Bona Male part T (Size 1)	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173092681
051870	Dalbo®-Rotex by Dr. Dalla Bona Male part T (Size 2)	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173090151
051871	Dalbo®-Rotex by Prof. Brunner Male part T (Size 1)	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640166510161
051872	Dalbo®-Rotex by Prof. Brunner Male part T (Size 2)	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173092711
051904	Dalbo®-Rotex Introduction set (Brunner/Dalla Bona)	Dalbo®-Rotex	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000059EG	07640173099772
05003505	Root canal post Mooser Adhesive head C (Size 1)	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099062
05003506	Root canal post Mooser Adhesive head C (Size 2)	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099079
05003507	Root canal post Mooser Adhesive head C (Size 3)	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099086
05003509	Root canal post Mooser Adhesive head C (Size 4)	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099093

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
05003589	Root canal post Mooser Flat head T (Size 1)	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099109
05003590	Root canal post Mooser Flat head T (Size 2)	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099130
05003591	Root canal post Mooser Flat head T (Size 3)	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099147
05003592	Root canal post Mooser Flat head T (Size 4)	Mooser Root Canal Posts	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640173099161
MD.200004301	MP-Post X yellow Size 1	MP Post	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640166515265
MD.200004310	MP-Post X red Size 2	MP Post	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640166515272
MD.200004319	MP-Post X blue Size 3	MP Post	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640166515289
MD.200004328	MP-Post X green Size 4	MP Post	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000048EB	07640166515296
051289	Rotex T Size 1	Rotex®	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173092599
051290	Rotex T Size 2	Rotex®	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173092612
051291	Rotex T Size 3	Rotex®	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173092636
051497	Rotex Introduction set	Rotex®	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000059EG	07640173092650
055195	Rotex-RD T Size 1	Rotex®-RD	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173091820

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
055196	Rotex-RD T Size 2	Rotex®-RD	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173091844
055197	Rotex-RD T Size 3	Rotex®-RD	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000049ED	07640173091868
055236	Rotex-RD Introduction set	Rotex®-RD	Root Canal Posts and Anchors	Root Canal Posts and Anchors	Ila	8, 1st indent	38609	764016651000059EG	07640173092735

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
Female parts	The Female parts G (G = Galak, mouth-resistant plastic), which are used for prosthetic restoration in the context of endodontic treatment, are directly polymerized into the removable dentures and are intended for use in prosthetic restorations on root canal caps and to support procedures in the dental clinic or laboratory.
Root Canal gauges	The Root Canal gauges, which are used for prosthetic restoration in the context of endodontic treatment, are intended to check the sinking depth and the parietal fit of the root post after the root canal cavity has been prepared with the manual or mechanical driven reamer.
Root Canal mechanic instruments	The Root Canal mechanic instruments, which are used for prosthetic restoration in the context of endodontic treatment, are intended to cut and drill into the root canal to enlarge it to the adequate size.
Root Canal Posts and Anchors	The Root Canal Posts and Anchors, which are used for prosthetic restoration in the context of endodontic treatment, are inserted into the tooth if a dental crown is largely destroyed and are intended for stabilizing tooth roots and for providing retention for root caps, abutments, or posts crowns. Moreover, the Root Canal Anchors are also used for direct abutments and larger fillings with amalgam or composite, or for temporary fixation of hybrid and partial dentures.

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
02	01.11.2022	1.1.2.1 & 1.1.2.2	FF change from "Temporary Root Canal Posts" to "Root Canal Posts and Anchors" for Products (05003584; 05003585; 05003586; 05003587; 05003588; 05003589; 05003590; 05003591; 05003592; MD.200004301; MD. 200004310; MD.200004319; MD.200004328). These products have therefore the Basic UDI-DI 764016651000048EB. Deletion of the FF "Temporary Root Canal Posts". Name change for the FF "Temporary female parts" to "Female parts".	These products were classified in the wrong FF. They are not temporary. No more products in this FF. Incorrect name The products are not temporary.	dym