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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 Ir

according to the attached list

Product list Family: Class Ir, Revision 04

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 Ir, Revision 04

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, 11.05.2023



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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	13.09.2022	
Review	Markus Blümli	Senior Product Manager	13.09.2022	

Identification

Document No.: LDP-Class Ir Revision: 04

Please save document under the following name: LDP-Class Ir_V04

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
070243	CM root canal posts Reamer (White) Post size 1	CM Root Canal Posts	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640173092742
070244	CM root canal posts Reamer (Yellow) Post size 2	CM Root Canal Posts	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640173092759
070245	CM root canal posts Reamer (Red) Post size 3	CM Root Canal Posts	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640173092766
070246	CM root canal posts Reamer (Blue) Post size 4	CM Root Canal Posts	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640173092773
070247	CM root canal posts Reamer (Green) Post size 5	CM Root Canal Posts	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640173092780
070287	Root canal posts Mooser Reamer (White) Post size 1	Mooser Root Canal Posts	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640173092797
070288	Root canal posts Mooser Reamer (Red) Post size 3	Mooser Root Canal Posts	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640173092803
072318	Root canal posts Mooser Reamer (Yellow) Post size 2	Mooser Root Canal Posts	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640173091554
072319	Root canal posts Mooser Reamer (Blue) Post size 4	Mooser Root Canal Posts	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640173091561
070298	Rotex / Rotex-RD / Dalbo®-Rotex Root canal reamer (White) Anchor size 1	Rotex®	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640166514619
070299	Rotex / Rotex-RD / Dalbo®-Rotex Root canal reamer (Yellow) Anchor size 2	Rotex®	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640166514626
070300	Rotex / Rotex-RD Root canal reamer (Red) Anchor size 3	Rotex®	Class Ir	Reamers	Ir	6, 2nd indent	31878	764016651000019E4	07640173091882

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
Reamers	The reamers are used by the dentist in the manual preparation of root canals for the insertion of root-canal posts and anchors.

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
03	13.09.2022	1.1.2.1	MD5-3427 Reklassifizierung Dalbo Rotex RD Reamer DA5-3468 Korrekt. Familienname nach MDR	MD5-3427 Reklassifizierung Dalbo Rotex RD Reamer DA5-3468 Korrekt. Familienname nach MDR	dym