

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

Bars

according to the attached list

Product list Family: Bars, 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: Bars, 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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CHRN-MF-20000343
SRN: CH-MF-000030696

Release

Task	Name	Function	Date	Signature
Author	Dylan Moretti	Regulatory Affairs Manager	06.05.2022	
Review	Markus Blümli	Senior Product Manager	06.05.2022	

Identification

Document No.: LDP-Bars Revision: 01

Please save document under the following name: LDP-Bars_V01

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
05050010	Ackermann-Bar A Female part E	Ackermann-Bar	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640166515142
05050011	Ackermann-Bar B Female part E	Ackermann-Bar	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640166515159
052043	Dolder® System Female part E micro L50	Dolder® System	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640166514077
052046	Dolder® System Female part E macro L50	Dolder® System	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640166514084
054746	Dolder® System Female part E micro L25	Dolder® System	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640166514114
054747	Dolder® System Female part E macro L25	Dolder® System	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640166514121
05000680	Dolder® System Female part T micro L47.5	Dolder® System	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640173091387
05000681	Dolder® System Female part T macro L47.5	Dolder® System	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640173091394
05001125	Dolder® System Female part D macro L50	Dolder® System	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640173091622
05001201	Dolder® System Female part D micro L50	Dolder® System	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640173091639
050527	Round bar with rider Female part E	Round Bar with Rider	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640166513797
055801	Round bar with rider Female part E	Round Bar with Rider	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640166514213
05000679	Round bar with rider Female part E L50	Round Bar with Rider	Bars	Female parts	Ila	5, 3rd indent	38577	764016651000055E8	07640166515111
05050014	Ackermann-Bar Male part P3 L60	Ackermann-Bar	Bars	Male parts	Ilb	8, general	38577	764016651000052E2	07640173092162
052053	Dolder® System Male part E macro L50 (Bar attachment)	Dolder® System	Bars	Male parts	Ilb	8, general	38577	764016651000052E2	07640173091974

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
052057	Dolder® System Male part E micro L50 (Resilient bar)	Dolder® System	Bars	Male parts	IIb	8, general	38577	764016651000052E2	07640173091981
052061	Dolder® System Male part E macro L50 (Resilient bar)	Dolder® System	Bars	Male parts	IIb	8, general	38577	764016651000052E2	07640173091998
05000289	Dolder® System Male part E micro L50 (Bar attachment)	Dolder® System	Bars	Male parts	IIb	8, general	38577	764016651000052E2	07640173091110
052028	Round bar with rider Male part P3 L200	Round Bar with Rider	Bars	Male parts	IIb	8, general	38577	764016651000052E2	07640173093039
052030	Round bar with rider Male part P3 L50	Round Bar with Rider	Bars	Male parts	IIb	8, general	38577	764016651000052E2	07640173093046

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, which are part of prosthetic retaining elements, are polymerized into the removable dentures, and are intended for use in prosthetic restorations and to support procedures in the dental clinic or laboratory.
Male parts	The male parts, which are part of prosthetic retaining elements, are fixed to at least two anchoring elements, and are intended for use in prosthetic restoration and to support procedures in the dental clinic or laboratory.

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
N/A	06.05.2022	All	New creation	Establishing the technical file according to MDR.	dym