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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

**Polymers**

according to the attached list

**Product list Family: Polymers, 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: Polymers, 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, 11.05.2023



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## Release

Task	Name	Function	Date	Signature
Author	Dylan Moretti	Junior Regulatory Affairs Manager	28.10.2021	
Review	Markus Blümli	Senior Product Manager	29.10.2021	

## Identification

Document No.: LDP-Polymers Revision: 03

Please save document under the following name: LDP-Polymers\_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

1.1.2 Product list

Family: Polymers

Catalog number	Product name	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01060003	Pekkton® ivory Press blanks	Pekkton® ivory	Polymers	Pekkton® (High performance polymer)	Ila	8, 1st indent	58288	764016651000036E4	07640166511793
01060152	Pekkton® ivory Milling blank 98.5/t12mm	Pekkton® ivory	Polymers	Pekkton® (High performance polymer)	Ila	8, 1st indent	58288	764016651000036E4	07640173099383
01060011	Pekkton® ivory Milling blank 98.5/t16mm	Pekkton® ivory	Polymers	Pekkton® (High performance polymer)	Ila	8, 1st indent	58288	764016651000036E4	07640166511458
01060020	Pekkton® ivory Milling blank 98.5/t20mm	Pekkton® ivory	Polymers	Pekkton® (High performance polymer)	Ila	8, 1st indent	58288	764016651000036E4	07640166511472
01060022	Pekkton® ivory Milling blank 98.5/t24mm	Pekkton® ivory	Polymers	Pekkton® (High performance polymer)	Ila	8, 1st indent	58288	764016651000036E4	07640166511489
01060089	Pekkton® ivory Milling blank 98.5/t28mm	Pekkton® ivory	Polymers	Pekkton® (High performance polymer)	Ila	8, 1st indent	58288	764016651000036E4	07640173099390
01060110	Pekkton® ivory Milling blank 95/t12mm	Pekkton® ivory	Polymers	Pekkton® (High performance polymer)	Ila	8, 1st indent	58288	764016651000036E4	07640173099406
01060028	Pekkton® ivory Milling blank 95/t16mm	Pekkton® ivory	Polymers	Pekkton® (High performance polymer)	Ila	8, 1st indent	58288	764016651000036E4	07640166511496
01060030	Pekkton® ivory Milling blank 95/t20mm	Pekkton® ivory	Polymers	Pekkton® (High performance polymer)	Ila	8, 1st indent	58288	764016651000036E4	07640166511502
01060131	Pekkton® ivory Milling blank 95/t25mm	Pekkton® ivory	Polymers	Pekkton® (High performance polymer)	Ila	8, 1st indent	58288	764016651000036E4	07640173099413
01060132	Pekkton® ivory Milling blank 95/t30mm	Pekkton® ivory	Polymers	Pekkton® (High performance polymer)	Ila	8, 1st indent	58288	764016651000036E4	07640173099420

### 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
Pekkton® (High performance polymer)	The polymer Pekkton® ivory, which is a dental material delivered as press blanks or milling blanks, is processed by dental technicians into custom-made devices and is intended for use with fixed dental prostheses (crowns and bridges) and removable dental prostheses for partially or fully edentulous patients. These restorations are tooth- or implant-supported and intended for short-term (temporary) or long-term (definitive restoration) use.

### 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	28.10.2021	All	DA5-3306 Neue Dokumentvorlage	DA5-3306 Neue Dokumentvorlage	dym