EU MDR ANNEX XIII

Manufacturer's Statement for Custom-Made Devices

Document No: DN-25003 | Generated: 02 January 2026

Manufacturer Information

Dentro, zobozdravstvo in svetovanje d.o.o.
Laboratory ID: 55230
License: 55230
Podreber 14D, 1355 Polhov Gradec, Slovenia
Tel: 041706148 | Email: info@dentro.si
Web: https://dentro.si
Registration No: 6567452000
Tax ID: 57425132

1. Device Identification

Worksheet Number:	**DN-25003**
Device Description:	dental prothesys
Intended Use:	nosi i pucas
Manufacture Date:	02 January 2026
Patient:	mma
Order Number:	25003

2. Prescriber Information

Dentist Name:	**Emiliya Naseva, dr. dent. med**
License Number:	9999999
Clinic Name:	EMIDENT dentalni center d.o.o.
Clinic Address:	Vrtojbenska cesta 73, 5290 Šempeter pri Gorici
Contact:	kristjan@krisbal.com / +386041

3. Products Manufactured

Product Code	Product Name	Quantity	Teeth
PRD-003	Bredent polzilo + montaža za 1 element	1	23, 24, 34
PRD-007	keramična faseta	1	23, 24, 34

4. Material Traceability

Complete list of all materials used in the manufacture of this custom-made device, including LOT numbers for full traceability as required by EU MDR.

Code	Material Name	Product	Manufacturer	LOT Number	Expiry	Qty Used	Tooth	CE	Biocomp.
CERA-21	ColorCem 21	*Bredent polzilo + montaža za 1 element*	Cerma	**LOT-778**	30 June 2027	1 gram	23	—	✓
Zr-xyz	Zirkonium XYZ	*Bredent polzilo + montaža za 1 element*	DentalHai	**LOT-003-E2E**		1 gram	34	—	✓
CERA-21	ColorCem 21	*Bredent polzilo + montaža za 1 element*	Cerma	**LOT-778**	30 June 2027	1 gram		—	✓
Zr-xyz	Zirkonium XYZ	*Bredent polzilo + montaža za 1 element*	DentalHai	**LOT-2451**	30 September 2026	1 gram		—	✓
Zr-xyz	Zirkonium XYZ	*keramična faseta*	DentalHai	**LOT-003-E2E**		5 gram	24	—	✓

5. Declaration of Conformity

We, **Dentro, zobozdravstvo in svetovanje d.o.o.**, hereby declare that the custom-made dental device described in this document has been manufactured in accordance with:

- Regulation (EU) 2017/745 (Medical Device Regulation)
- Annex XIII requirements for custom-made devices
- ISO 10993 Biocompatibility standards
- Applicable harmonized standards and technical specifications

ISO 10993 Biocompatibility: All materials used in this device comply with ISO 10993 standards for biological evaluation of medical devices.

CE Marking: All materials used are CE marked where applicable, ensuring compliance with EU safety and performance requirements.

This device has been manufactured specifically for the patient identified in this statement and is intended solely for use by that patient. The device meets the essential safety and performance requirements applicable to it.

6. Quality Control

QC Inspector:	Admin User
Inspection Date:	02 January 2026
Result:	**APPROVED**
Notes:	supe rprileganje, barva pravilna, vse OK

7. Responsible Person & Authorization

Responsible Person:	**Rommy Balzan Verbic**
Title:	zobni tehnik
License:	42555
Contact:	info@dentro.si / 041 706 148

Responsible Person

Rommy Balzan Verbic

zobni tehnik

Date: 02 January 2026

Quality Control

Admin User

QC Inspector

Date: 02 January 2026

⚠ **RETENTION REQUIREMENT: This document must be retained until 02 January 2036 (10 years from generation date) in accordance with EU MDR Article 10(8) requirements.**