DENTRO
zobozdravstvene storitve in svetovanje d.o.o.

EU MDR ANNEX XIII - Manufacturer's Statement for Custom-Made Devices

MDR-DN-26002

Document Number | Generated: 03 January 2026

1. Device Identification

Worksheet Number:	**DN-26002**
Order Number:	26002
Device Description:	AA
Intended Use:	Dental restoration
Manufacture Date:	03 January 2026
Patient:	Matjaz

2. Manufacturer Information

Manufacturer Name:	**Dentro, zobozdravstvo in svetovanje d.o.o.**
Laboratory ID:	55230
Laboratory License:	55230
Registration Number:	6567452000
Address:	Podreber 14D, 1355 Polhov Gradec, Slovenia
Contact:	info@dentro.si / 041706148

3. Device Classification

EMDN Code:	**Q010206 - Dental Prostheses**
Risk Class:	Class IIa

4. Prescriber Information

Dentist Name:	**Dr. Testor Teser**
License Number:	77
Clinic Name:	Test clicnic
Clinic Address:	Calle mar 3, 2000 Slovenj Gradec
Contact:	info@mai.com / 041 706148

5. Products & Material Traceability

Complete list of all products manufactured and materials used, including LOT numbers for full traceability as required by EU MDR.

Code/LOT	Name	Manufacturer	Qty	Expiry	Tooth	CE	Bio
📦 **PRODUCT: CR-CER-001 - Ceramic Crown (Qty: 1) | Teeth: 11, 21**							
CERA-21 **LOT: LOT-778**	ColorCem 21	Cerma	1 gram	30 June 2027	21	—	✓

6. Annex I Compliance

✓ **FULL COMPLIANCE**
This device fully complies with all Annex I general safety and performance requirements of EU MDR 2017/745. No deviations recorded.

7. 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.

8. Quality Control & Authorization

Quality Control Inspection

QC Inspector:	Rommy Balzan Verbic
Inspection Date:	03 January 2026
Result:	APPROVED

Responsible Person (EU MDR Article 15)

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

Authorized Signature - Responsible Person

Rommy Balzan Verbic
zobni tehnik
License: 42555
Date: 03 January 2026

⚠ **RETENTION REQUIREMENT: This document must be retained until 03 January 2036 (10 years from generation date) in accordance with EU MDR Article 10(8) requirements.**

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