

1. Device Identification

Worksheet Number:	DN-26001
Order Number:	26001
Device Description:	Custom-made dental device
Intended Use:	Dental restoration
Manufacture Date:	03 January 2026
Patient:	Kristjn

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. Jože Krajnc
License Number:	SLO-D-67890
Clinic Name:	Smile Dental Maribor
Clinic Address:	Glavni trg 15, 2000 Maribor
Contact:	joze.krajnc@smiledentalmaribor.si / +386 2 345 6789

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

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		Responsible Person (EU MDR Article 15)	
QC Inspector:	Rommy Balzan Verbic	Responsible Person:	Rommy Balzan Verbic
Inspection Date:	03 January 2026	Title:	zobni tehnik
Result:	APPROVED	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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Sedež podjetja: Dentro, zobozdravstvo in svetovanje d.o.o., Podreber 14D, 1355 Polhov Gradec, Slovenia

Matična številka: 6567452000 | **ID za DDV:** 57425132

Osnovni kapital: 7.500 EUR | **Družba je vpisana pri Okrožnem sodišču Ljubljana.**