

EU MDR ANNEX XIII

Manufacturer's Statement for Custom-Made Devices

Document No: DN-25005 | Generated: 31 December 2023

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://dento.si>

Registration No: 6567452000

Tax ID: 57425132

1. Device Identification

Worksheet Number:	DN-25005
Device Description:	Crown restoration for premolar - QC rejection test
Intended Use:	Permanent crown for tooth #15 - testing QC rejection workflow
Manufacture Date:	31 December 2025
Patient:	E2E Test Patient 005
Order Number:	25005

2. Prescriber Information

Dentist Name:	Emiliya Naseva, dr. dent. med
Clinic Name:	EMIDENT dentalni center d.o.o.
Clinic Address:	Vrtojbenska cesta 73, 5290 Šempeter pri Gorici
Contact:	email@emident.si / +386041

3. Products Manufactured

Product Code	Product Name	Quantity	Teeth
PRD-013	zirkonij monolit	1	15

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.
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5. Declaration of Conformity

We, **Dentro, zdravstvo 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: 31 December 2025

Result: **APPROVED**

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: 31 December 2025

Quality Control

Admin User

QC Inspector

Date: 31 December 2025

⚠ RETENTION REQUIREMENT: This document must be retained until 31 December 2035 (10 years from generation date) in accordance with EU MDR Article 10(8) requirements.