DENTRO
zobozdravstvene storitve in svetovanje d.o.o.

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

MDR-DN-26004

Document Number | Generated: 04 January 2026

1. Device Identification

Worksheet Number:	**DN-26004**
Order Number:	26004
Device Description:	Custom-made dental device
Intended Use:	Dental restoration
Manufacture Date:	04 January 2026
Patient:	Test Patient Internal

2. Manufacturer Information

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

4. Prescriber Information

Dentist Name:	**Dr. Internal Tester**
Clinic Name:	E2E Test Clinic Internal
Clinic Address:	Test Street 123, 1000 Ljubljana
/	internal.test@example.com / +386 1 999 8888

3. Device Classification

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

5. Products & Material Traceability

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

/							
📦 **: PRD-003 - Bredent polzilo + montaža za 1 element (1) | : 22, 23**							
CER-001 **LOT:: LOT-CER-001-2025-001**	IPS e.max CAD	Ivoclar Vivadent	1 piece	02 January 2028	22	—	✓

6. Annex I 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

8. Quality Control & Authorization

Quality Control Inspection

QC Inspector:	Rommy Balzan Verbic
Inspection Date:	04 January 2026
	APPROVED

Responsible Person (EU MDR Article 15)

Responsible Person:	**Rommy Balzan Verbic**
Responsible Person (EU MDR Article 15)	zobni tehnik
	42555
/	info@dentro.si / 041 706 148

Rommy Balzan Verbic
zobni tehnik
: 42555
: 04 January 2026

⚠ **: 04 January 2036 (10 years from generation date) in accordance with EU MDR Article 10(8) requirements.**

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