

1. Identifikacija pripomočka

Številka delovnega lista:	DN-26003
Številka naročila:	26003
Opis pripomočka:	Custom-made dental device
Namen uporabe:	Dental restoration
Datum izdelave:	04 January 2026
Pacient:	r

2. Podatki o proizvajalcu

	Dentro, zobozdravstvo in svetovanje d.o.o.
ID laboratorija:	55230
Licenca laboratorija:	55230
Matična številka:	6567452000
Naslov:	Podreber 14D, 1355 Polhov Gradec, Slovenia
/	info@dentro.si / 041706148

4. Podatki o predpisovalcu

Ime zobarja:	Dr. Testor Teser
	77
Ime klinike:	Test clinic
Naslov klinike:	Calle mar 3, 2000 Slovenj Gradec
/	info@mai.com / 041 706148

3. Klasifikacija pripomočka

EMDN koda:	Q010206 - Dental Prostheses
	Class IIa

5. Izdelki in sledljivost materialov

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

/								
---	--	--	--	--	--	--	--	--

6. Skladnost s Prilogo I

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


7. Izjava o skladnosti

8. Kontrola kakovosti in pooblastitev

Quality Control Inspection		Responsible Person (EU MDR Article 15)	
Kontrolor kakovosti:	Rommy Balzan Verbic	Odgovorna oseba:	Rommy Balzan Verbic
Datum pregleda:	04 January 2026	Odgovorna oseba (EU MDR člen 15)	zobni tehnik
	APPROVED		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.

Document Type: EU MDR Annex XIII
Manufacturer's Statement

od {generatedBy}: 04 January 2026 by
Admin User

Document ID: MDR-DN-26003
: 1.0