

1. Identifikacija pripomočka

Številka delovnega lista:	DN-2026-002
Številka naročila:	2026-002
Opis pripomočka:	Custom-made dental device
Namen uporabe:	Dental restoration
Datum izdelave:	08 January 2026
Pacient:	test

2. Podatki o proizvajalcu

Smilelab d.o.o.	
ID laboratorija:	SI-LAB-2024-001
Licenca laboratorija:	ZT-SI-12345
Matična številka:	1234567000
Naslov:	Cesta v Mestni log 1, 1000 Ljubljana, Slovenia
/	info@smilelab.si / +386 1 234 5678

4. Podatki o predpisovalcu

Ime zobarja:	Dr. Test Dentist
	LIC-E2E-001
Ime klinike:	Test Dental Clinic
Naslov klinike:	Test Street 123, 1000 Ljubljana
/	test.dentist@e2e-test.com / +386 1 234 5678

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.

/							
: PRD-001 - akrilna funkcijska žlica (1) : 22, 25							
MAT-E2E-1767831447383 LOT:: LOT-E2E-1767831447388	E2E Test Zirconia	Test Manufacturer GmbH	1 gram	08 January 2027	22	—	✓

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:	Dr. Ivan Novak	Odgovorna oseba:	Dr. Ivan Novak
Datum pregleda:	08 January 2026	Odgovorna oseba (EU MDR člen 15)	Kvalitetni vodja / Quality Manager
APPROVED			QM-SI-67890
		/	ivan.novak@smilelab.si / +386 40 123 456



Dr. Ivan Novak

Kvalitetni vodja / Quality Manager

: QM-SI-67890

: 08 January 2026

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

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Manufacturer's Statement

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