

## 1. Identifikacija pričomočka

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

## 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

## 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.

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

## 6. Skladnost s Prilogom 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

Kontrolor kakovosti: Dr. Ivan Novak

Datum pregleda: 08 January 2026

APPROVED

### Responsible Person (EU MDR Article 15)

Odgovorna oseba: Dr. Ivan Novak

Odgovorna oseba (EU MDR člen 15) Kvalitetni vodja / Quality Manager

QM-SI-67890

/ ivan.novak@smilelab.si / +386 40 123 456



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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.**

**Document Type:** EU MDR Annex XIII  
Manufacturer's Statement

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