EU MDR ANNEX XIII

Manufacturer's Statement for Custom-Made Devices

Document No: DN-25006 | Generated: 03 January 2026

Manufacturer Information

Smilelab d.o.o.
Laboratory ID: SI-LAB-2024-001
License: ZT-SI-12345
Cesta v Mestni log 1, 1000 Ljubljana, Slovenia
Tel: +386 1 234 5678 | Email: info@smilelab.si
Web: https://www.smilelab.si
Registration No: 1234567000
Tax ID: SI12345678

1. Device Identification

Worksheet Number:	**DN-25006**
Device Description:	Custom-made dental device
Intended Use:	Dental restoration
Manufacture Date:	03 January 2026
Patient:	E2E Test Patient 006
Order Number:	25006

2. Prescriber Information

Dentist Name:	**Emiliya Naseva, dr. dent. med**
License Number:	9999999
Clinic Name:	EMIDENT dentalni center d.o.o.
Clinic Address:	Vrtojbenska cesta 73, 5290 Šempeter pri Gorici
Contact:	kristjan@krisbal.com / +386041

3. Products Manufactured

Product Code	Product Name	Quantity	Teeth
CR-CER-001	Ceramic Crown	1	N/A
PRD-008	keramični inlay (PRESS, E-MAX, GC)	1	N/A

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.
TIT-001	Grade 5 Titanium	*Ceramic Crown*	Nobel Biocare	**LOT-TIT-001-2024-001**	02 October 2028	1 piece		—	✓
Zr-xyz	Zirkonium XYZ	*keramični inlay (PRESS, E-MAX, GC)*	DentalHai	**LOT-003-E2E**		1 gram		—	✓

5. Declaration of Conformity

We, **Smilelab 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:	Ana Kovač
Inspection Date:	03 January 2026
Result:	**APPROVED**

7. Responsible Person & Authorization

Responsible Person:	**Dr. Ivan Novak**
Title:	Kvalitetni vodja / Quality Manager
License:	QM-SI-67890
Contact:	ivan.novak@smilelab.si / +386 40 123 456

Responsible Person

Dr. Ivan Novak

Kvalitetni vodja / Quality Manager

Date: 03 January 2026

Quality Control

Ana Kovač

QC Inspector

Date: 03 January 2026

⚠ **RETENTION REQUIREMENT: This document must be retained until 03 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
Generated: 03 January 2026 by Ana Kovač

Document ID: MDR-DN-25006