EU MDR ANNEX XIII

Manufacturer's Statement for Custom-Made Devices

Document No: DN-25003 | Generated: 29 December 2025

Manufacturer Information

Dentro D.o.o.
Calle Marrajo, 10, 35660 Corralejo, United States
Tel: 699636573 | Email: kristjan@krisbal.com
Web: https://freelance-anchor.com

1. Device Identification

Worksheet Number:	**DN-25003**
Device Description:	Implant 1x
Intended Use:	Dental restoration
Manufacture Date:	29 December 2025
Patient:	Rommy
Order Number:	25003

2. Prescriber Information

Dentist Name:	
License Number:	SLO-D-12345
Clinic Name:	Dental Clinic Ljubljana Center
Clinic Address:	Slovenska cesta 25, 1000 Ljubljana
Contact:	petra.zupan@dentalclinic.si / +386 1 234 5678

3. Products Manufactured

Product Code	Product Name	Quantity	Teeth
SP-013	Wizil kovinska baza, enostavna	1	21
IM-010	implantološko podprta totalna proteza	1	21

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	Manufacturer	LOT Number	Expiry Date	Qty Used	Tooth	CE	Biocomp.
CER-002	VITA ENAMIC	VITA Zahnfabrik	**LOT-CER-002-2024-002**	26 November 2028	2 piece		—	✓
TIT-001	Grade 5 Titanium	Nobel Biocare	**LOT-TIT-001-2025-001**	26 December 2027	1 piece		—	✓
test123	testing ceramic	Dentro	**4444**	31 March 2026	1 gram		—	✓

5. Declaration of Conformity

We, **Dentro 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:	Admin User
Inspection Date:	29 December 2025
Result:	APPROVED
Notes:	Everything fits perfect!

7. Responsible Person & Authorization

Responsible Person:	**Kristjan Balzan**
Title:	Freelancer
Contact:	kristjan@krisbal.com / 699636573

Responsible Person

Kristjan Balzan
Freelancer
Date: 29 December 2025

Quality Control

Admin User
QC Inspector
Date: 29 December 2025

⚠ **RETENTION REQUIREMENT: This document must be retained until 29 December 2035 (10 years from generation date) in accordance with EU MDR Article 10(8) requirements.**