EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III

Certificate No. MDR-0014

Issued to:	POLIDENT d.o.o. Volčja Draga 42, 5293 Volčja Draga, Slovenija
SRN of the manufacturer:	SI-MF-000000740
EU authorised representative:	Not applicable
SRN of EU authorised representative:	Not applicable

SIQ has audited the quality management system in accordance with MDR Annex IX and found that the above-mentioned Manufacturer's quality management system meets the requirements of the Regulation (EU) 2017/745 concerning medical devices, Annex IX. Devices covered by the Manufacturer's quality management system are listed on the page(s) below.

This certificate is based on:

Audit report No.:
OSV 01708/2024, 2024-12-23

See also decision of NB`s commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality management system is subject to periodical surveillance as referred to in Regulation (EU) 2017/745 concerning medical devices Annex IX and continues to meet the above requirements.

Reference to any previous certificate: MDR-0014/02

Certification date:	2024-07-31
Issue:	03/2024-12-23
Valid until:	2029-07-30

Managing Director of SIQ

Gregor Schoss

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Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III

Certificate No. MDR-0014

Device:	Materials for the preparation of custom-made dental devices – other
EMDN:	Q010699
Intended purpose:	/
Classification:	IIa

Specific conditions for or provisions or limitations to the validity of certificate: /

Certification date: 2024-07-31

Issue: 03/2024-12-23

Valid until: 2029-07-30

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