



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, 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 reports No.:
Not applicable

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-0014/04

Certification date: 2024-07-31

Issue: 05/ 2026-03-25

Valid until: 2029-07-30



Managing Director of SIQ

Gregor Schoss



EU Quality Management System Certificate
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: 05/ 2026-03-25
Valid until: 2029-07-30



Managing Director of SIQ
Gregor Schoss