

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.

Volčia 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.:

OSV 00709/2025, 2025-05-29

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-0014/03

Certification date:

2024-07-31

Issue:

04/ 2025-06-10

Valid until:

2029-07-30

Managing Director of SIQ

Gregor Schoss

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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: Ila

Specific conditions for or

provisions or limitations to the

validity of certificate: /

Certification date: 2024-07-31

Issue: 04/ 2025-06-10

Valid until: 2029-07-30

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Maścia-Spasićeva ulica do

1000 Ljubljaha

Managing Director of SIQ

Gregor Schoss