EU Quality Management System Certificate

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

Certificate No. MDR-0044

Issued to:	MediAkris d.o.o. Kočevarjeva ulica 4, 8000 Novo mesto, Slovenia
SRN of the manufacturer:	SI-MF-000048191
EU authorised representative:	Not applicable
SRN of EU authorised representative:	Not applicable

SIQ has audited the quality management system – restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions – 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 01645/2025, 2025-12-23
OSV 00129/2026, 2026-03-11
OSV 00533/2026, 2026-04-30
OSV 00582A/2026, 2026-06-02

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: /

Certification date:	2026-06-30
Issue:	01/ 2026-06-30
Valid until:	2031-06-29

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

Managing Director of SIQ
Gregor Schoss

SIQ Ljubljana, Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia, Notified Body No. 1304
tel.: +386 1 4778 100 • fax: +386 1 4778 444 • e-mail: info@siq.si • http://www.siq.si