EU Quality Management System Certificate

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

Certificate No. MDR-0013

Issued to:	FAPOMED - Dispositivos Médicos, S.A. Av. Dr. Ribeiro de Magalhaes, 791, 4610-108 Felgueiras, Portugal
SRN of the manufacturer:	PT-PR-000004889
EU authorised representative:	N/A
SRN of EU authorised representative:	N/A

SIQ has audited the quality management system in accordance with Article 22, Systems and procedure packs and MDR Annex IX – restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions – 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 00726/2024, 2024-05-30
OSV 00725A/2024, 2024-07-19

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:	2024-07-24
Issue:	01/2024-07-24
Valid until:	2029-07-23

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

Managing Director of SIQ
Gregor Schoss

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Certificate No. MDR-0013

Device:	CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES – OTHER
EMDN:	V0599
Intended purpose:	Systems and Procedure Packs are combinations of products packaged together and placed on the market with the intention of being used for a specific medical purpose. They are sterile and single use.
Classification:	Is or IIa, defined by individual component
Specific conditions for or provisions or limitations to the validity of certificate:	/

Certification date:	2024-07-24
Issue:	01/2024-07-24
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