



EC Certificate – Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V
Certificate No. MDD-142

Issued to: FAPOMED – Dispositivos Médicos, S.A.
Av. Dr. Ribeiro de Magalhaes, 791
4610-108 Felgueiras, Portugal

Place of production: FAPOMED– Dispositivos Médicos, S.A.
Av. Dr. Ribeiro de Magalhaes, 791
4610-108 Felgueiras, Portugal

Place of production: FAPOMED– Dispositivos Médicos, S.A.
Location: Zona Industrial de Baiao, Lugar de Rebolfe, Campelo 4640-134 Baiao, Portugal

Location: Rua da Formiga, Lugar de Rebolfe,
Campelo, Zona Industrial de Baiao, lote 9 e 10
4640-173 Baiao, Portugal

Place of production: FAPOMED Ukraine, LLC
Ostrovskogo str. 46, Goscha, Rivne Region 35400, Ukraine

Product category: Sterile surgical drapes
GMDN: /

Product category: Sterile surgical gowns
GMDN: /

Product category: Sterile operating theatre equipment covers
GMDN: /

Product category: Sterile surgical sets
GMDN: /

SIQ has audited the quality system in accordance with MDD Annex V, restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex V, including all subsequent amendments. This certificate is based on

Audit report No.:

OSV 00941/2019, 2019-09-03
OSV 00985B/2019, 2019-12-02
OSV 00984A/2019, 2019-12-02
OSV 01558/2019, 2020-02-11
OSV 01265/2020, 2021-01-28
OSV 01479/2020, 2021-01-29

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

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex V (4), restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions, and continues to meet the above requirements.

Certification date: 2019-09-10

Issue: 3/2021-04-22

Valid until: 2024-05-26



Managing Director of SIQ

Igor Likar