



Certifikat / Certificate

*for
Management System*

FAPOMED - Dispositivos Médicos, S.A.

Av. Dr. Ribeiro de Magalhaes, 791, 4610-108 Felgueiras, Portugal

Design, manufacture, subcontract manufacture and sterilization of surgical gowns, drapes, sets, procedure trays and covers for operating theatre equipment.

Management of subcontract sterilization services for surgical gowns, drapes, sets, procedure trays and covers for operating theatre equipment.

Location: Felgueiras, Av. Dr. Ribeiro de Magalhães, 791, 4610-108 Felgueiras, Portugal

Location: Baião, Zona Industrial de Baião, 4640-134 Baião, Portugal

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

Sterilization of surgical gowns, drapes, sets, procedure trays and covers for operating theatre equipment according to ISO 11135.

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

Sterilization services according to ISO 11135.

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

Manufacture and subcontract manufacture of surgical gowns, drapes, and covers for operating theatre equipment. Management of subcontract sterilization services for surgical gowns, drapes, and covers for operating theatre equipment.

Location: Fapomed Ukraine, Ostrovskogo str. 46, Goscha, Rivne Region 35400, Ukraine

*adequately operates and maintains a management system
which meets the requirements of the standard*

ISO 13485:2016

Certificate No. / Certification date

M-158 / 2019-09-12

Issue 03 / 2022-09-05 Valid until: 2025-09-12

Director of SIQ Ljubljana

Gregor Schoss



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SIST EN ISO/IEC 17021-1
CS-001



SIQ Ljubljana, Mašera-Spasičeva ulica 10, 1000 Ljubljana, Slovenija

Certificate

SIQ Ljubljana has issued an IQNET recognized certificate that the organization:

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

has implemented and maintains a
Medical devices - Quality System

for the following scope:

Design, manufacture, subcontract manufacture and sterilization of surgical gowns, drapes, sets, procedure trays and covers for operating theatre equipment. Management of subcontract sterilization services for surgical gowns, drapes, sets, procedure trays and covers for operating theatre equipment.
Location: Felgueiras, Av. Dr. Ribeiro de Magalhães, 791, 4610-108 Felgueiras, Portugal Location: Baião, Zona Industrial de Baião, 4640-134 Baião, Portugal
Location: Rua da Formiga, Lugar de Rebolfe-Campelo- Zona Industrial de Baião, lote 9 e 10;4640-173 Baião, Portugal

Sterilization of surgical gowns, drapes, sets, procedure trays and covers for operating theatre equipment according to ISO 11135.
Location: Rua da Formiga, Lugar de Rebolfe-Campelo- Zona Industrial de Baião, lote 9 e 10;4640-173 Baião, Portugal
Sterilization services according to ISO 11135.
Location: Rua da Formiga, Lugar de Rebolfe-Campelo- Zona Industrial de Baião, lote 9 e 10;4640-173 Baião, Portugal

Manufacture and subcontract manufacture of surgical gowns, drapes, and covers for operating theatre equipment. Management of subcontract sterilization services for surgical gowns, drapes, and covers for operating theatre equipment.
Location: Fapomed Ukraine, Ostrovskogo str. 46, Goscha, Rivne Region 35400, Ukraine

which fulfils the requirements of the following **standard**:

ISO 13485:2016

Issued on: **2022-09-05**
First issued on: **2019-09-12**
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Registration Number: **SI - M-158**


Alex Stoichitoiu
President of IQNET


Gregor Schoss
Managing director of SIQ Ljubljana



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