

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

**In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618**

This is to certify that the Quality Management System of:

**Fapomed – Dispositivos Médicos, S.A.
Av. Dr. Ribeiro de Magalhaes
4610-108 Felgueiras
Portugal**

has been assessed against the requirements of Annex V of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 0940308/B

Original Approval: 2 July 1998

Current Certificate: 31 May 2019

Certificate Expiry: 31 January 2022

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited

EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE CERTIFICATE LRQ 0940308/B SCHEDULE

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Fapomed – Dispositivos Médicos, S.A.
Av. Dr. Ribeiro de Magalhaes
4610-108 Felgueiras
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Scope: Manufacture and supply of sterile surgical sets and procedure trays. Only those aspect of manufacture concerned with securing and maintaining sterile conditions of single use surgical gowns, drapes, surgical sets and covers for operating theatre equipment

Class I Sterile Medical Devices

Sterile Surgical Sets
Sterile Surgical Drapes
Sterile Surgical Gowns
Sterile Operating Theatre Equipment Covers

Class IIa Medical Devices

Sterile Surgical Procedure Trays
Sterile Surgical Sets

Schedule Issue: 03

Date of Schedule Issue: 31 May 2019

LRQA Notified Body Number 0088



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