# EC Certificate – Production Quality Assurance
## Directive 93/42/EEC on Medical Devices, Annex V
## Certificate No. MDD-143

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| Issued to: | FAPOMED – Dispositivos Médicos, S.A.<br>Av. Dr. Ribeiro de Magalhaes, 791<br>4610-108 Felgueiras, Portugal |
| Place of production: | FAPOMED– Dispositivos Médicos, S.A.<br>Av. Dr. Ribeiro de Magalhaes, 791<br>4610-108 Felgueiras, Portugal |
| Place of production:<br>Location: | FAPOMED– Dispositivos Médicos, S.A.<br>Zona Industrial de Baiao, Lugar de Rebolfe, Campelo<br>4640-134 Baiao, Portugal |
| Location: | Rua da Formiga, Lugar de Rebolfe,<br>Campelo, Zona Industrial de Baiao, lote 9 e 10<br>4640-173 Baiao, Portugal |
| Product category:<br>GMDN: | Sterile surgical Sets<br>/ |
| Product category:<br>GMDN: | Sterile surgical Procedure Trays<br>/ |

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 00985A/2019, 2019-12-02
OSV 00984/2019, 2019-09-10
OSV 01558/2019, 2020-02-11
OSV 00958/2020, 2020-09-28
OSV 01232/2020, 2020-10-21
OSV 01479/2020, 2021-01-29
OSV 00093/2021, 2021-03-04

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

SIQ Ljubljana
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