Medical Device Production Quality Assurance System Certificate
GB23/00000342

The management system of

Direct Leisure Supplies Ltd, trading as DLS Medical

Premier House Southgate Way Orton Southgate Peterborough Cambridgeshire PE2 6YG United Kingdom

has been assessed and certified as meeting the requirements of

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

For the following products

Class IIa:
- Sterile single use surgical instrument sets and single use surgical instruments for minor surgery
- Sterile single use surgical instrument sets and single use surgical instruments for gynaecology
- Sterile single use surgical instrument sets and single use surgical instruments for podiatry
- Sterile single use surgical instrument sets and single use surgical instruments for ophthalmology
- Sterile single use surgical instrument sets and single use surgical instruments for ENT
- Sterile single use surgical instrument sets and single use surgical instruments for Wound Care

Class Is:
Annex V Sterility aspects only
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions
Sterile single use surgical instruments for minor surgery, gynaecology, podiatry ophthalmology, ENT and wound care.

Class Im:
Annex V Metrological aspects only –
Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements
Medicine measures and measuring spoons.
Graduated containers.

Where the above scope includes class IIb or class III medical device(s), a valid Type Examination Certificate according to Annex III [as modified by Part 2 of Schedule 2A to The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certification is based on following reports: GB/PC/05933
Previous certificate number: N/A
Change in between this certificate and previous one: N/A

This certificate is valid from 31 October 2023 until 23 September 2028 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 15 September 2023

L. Henderson

Authorised by
Lynn Henderson

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Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]. The Medical Devices Regulations 2002, Regulation 14 on system and procedure packs, and devices to be sterilised before use

For the following products

Class Is:
Annex V Sterility aspects only
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile instrument packs for procedures and supplementary packs, sterile single use surgical instrument sets and single use surgical instruments for minor surgery, gynaecology, podiatry, ophthalmology, ENT and wound care - Manufactured in accordance with regulation 14.

Certification is based on following reports: GB/PC/05933
Previous certificate number: N/A
Change in between this certificate and previous one: N/A

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