EU Quality Management System Certificate GB23/00000102

The management system of

CliniMed Ltd

Cavell House, Knaves Beech Way, Loudwater High Wycombe Buckinghamshire HP10 9QY United Kingdom
SRN Number: GB-MF-000023784
has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 10 July 2023 until 27 February 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 August 2027
Issue 2. Certified since 27 February 2023

Authorised by
Virginie Siloret
Global Medical Device Certification Manager
SGS Belgium NV NB 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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CliniMed Ltd

MDR EU Quality Management System certificate (Annex IX QMS)

Class I Sterile:
Codes: MDN1204, MDS1005

-Instillaquill, Sterile Single Use Extension Tube for use in gynecological investigations,
-CliniSorb, Sterile Single Use Activated Charcoal Secondary Wound Care Dressing for the management of wound odour
-LBF Sterile Single Use Wipes for the prevention of skin irritation
-LBF Sterile Single Use No Sting Barrier Film 1ml & 2ml Foam Applicators for the prevention of skin irritation
-LBF Sterile Single Use No Sting Barrier Film Spray (30ml and 50ml) for the prevention of skin irritation
-Appeel Adhesive Remover Sterile Sachet for use with stoma pouches and other adhesive appliances
-Appeel Adhesive Remover Sterile Wipe for use with stoma pouches and other adhesive appliances
-Appeel Adhesive Remover Sterile Foam Applicator for use with stoma pouches and other adhesive appliances
-Appeel Adhesive Remover Sterile Spray for use with stoma pouches and other adhesive appliances.

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to to NB1639@sgs.com.

Limitation:
N/A

Certification is based on following reports: - GB/PC/240482 - CTC 1.19

Authorized representative Name and address (if relevant): Advena Ltd, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta

Previous certificate number: N/A

Change in between this certificate and previous one: Change template to be in compliance with LPMDREG5007.