Certificate GB20/966950

The quality management system of

Flexicare Medical Limited

Cynon Valley Business Park Mountain Ash CF45 4ER United Kingdom
Facility number: F003808

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002; Schedule 3, Part 1 - Full Quality Assurance System
Brazil: RDC ANVISA 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021 - Field Actions; RDC ANVISA n. 67/2009 - Vigilance
Canada: Medical Devices Regulations (SOR/98-282) Part 1 - General
Japan: MHLW Ministerial Ordinance No.169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021); Japan PMD Act (as applicable)
USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing; 21 CFR Part 820 - Quality System Regulation

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

This certificate is valid from Effective date 2026-05-11 until Expiry date 2029-05-10 and remains valid subject to satisfactory surveillance audits.
Issue 5. Certified since 2020-10-21
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Virginie Siloret
Head of Certification and Compliance
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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.

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Flexicare Medical Limited

MDSAP (ISO 13485:2016)

Issue 5

Design, manufacture and distribution of sterile and non-sterile respiratory devices for use in anaesthesia, emergency and intensive care: Bougies, Stylets, Laryngoscopes, Laryngoscope handles and laryngoscope blades, Oropharyngeal Airways, Suction tubing, Nasopharyngeal airways, Suction catheter, Endotracheal tubes, Laryngeal mask airways, Humidification chambers, Suction Yankauers, Drainage kit for nasal surgery Breathing circuits, Humidification circuits, Breathing filters, Heat and moisture exchangers (HMEs), Heat and moisture exchange (HME) filters, Oxygen and aerosol therapy devices, Pocket resuscitation first aid masks, Anaesthesia facemasks, Oxygen tubes, Resus Bag resuscitators, Carbon dioxide absorbent, Respiratory humidifiers,Endoscopy bite block with O2 delivery and CO2 monitoring, Infant Nasal CPAP Therapy device, Manual Resuscitators, Airway devices/monitoring equipment and accessories.

Design, manufacture and distribution of sterile and non-sterile urology devices: Catheter valves, Intermittent catheters, Urine drainage bags, Urimeters, Sterile Stoma Plugs.

Design, manufacture and distribution of enema devices (enema tip, cuff, inflator, tubing and drainage bag for administration, retention and recovery of barium enema) and ostomy bags.

Design, Manufacture of lung function meters, nebuliser systems for use in oxygen therapy and inhalation anaesthesia, Emergency and intensive care.

Design, servicing and manufacture of nebulisers, nebuliser compressors and design and manufacturing of respiratory diagnostic equipment (Peak Flow Meters) for use in Anaesthesia, Emergency and Intensive Care.

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Certificate GB20/966950, continued

Flexicare Medical Limited

MDSAP (ISO 13485:2016)

Issue 5

Sites

Flexicare Medical Limited
Unit 3C Business Park Pontllanfraith Blackwood NP12 2XH United Kingdom

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