Medical Device Full Quality Assurance System Certificate
GB23/00000275

The management system of

RB Medical Engineering Ltd

Unit 2 Alton Road Industrial Estate Ross-on-Wye Herefordshire HR9 5NS United Kingdom

has been assessed and certified as meeting the requirements of

Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

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

This certificate is valid from 26 September 2024 until 20 August 2029 and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 11 July 2023

L. Henderson

Authorised by
Lynn Henderson

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Medical Device Full Quality Assurance System Certificate
GB23/00000275, continued

RB Medical Engineering Ltd

Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

Issue 4

Diathermy unit instruments: Sterile TUR Electrodes, Sterile Diathermy Electrodes, Sterile Single-use Bipolar Forceps.
Light Duty Cautery Sets, Battery Powered Cautery Sets, Cautery Handles, Sterile & Non-Sterile Cautery Burners.
Sterile and Non-Sterile Suction Irrigation Sets, Sterile Single-use Forceps, Sterile Surgical Scissors & Cutting Instruments, Sterile Single-use Retractors, Sterile Single-use Suction Tubes.

Class I Sterile: “Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions”
Single use cutting devices, syringe
Single use retractors, speculum

Where the above scope includes class III medical device(s), a valid Design Examination Certificate according to Annex II (Section 4) [as modified by Part 2 of Schedule 2A of 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 reports numbered GB/PC/240492
Previous certificate number: N/A
Change in between this certificate and previous one: Reclassification of two devices as class 1s