Medical Device Production Quality Assurance System Certificate
GB22/00000167

The management system of

Rocialle Healthcare Ltd

Cwm Cynon Business Park (North) Mountain Ash Rhondda Cynon Taff South Wales CF45 4ER 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
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 09 January 2024 until 14 February 2028 and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 20 May 2022
Certified activities performed by additional sites are listed on subsequent pages.

L. Henderson

Authorised by
Lynn Henderson

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Rocialle Healthcare Ltd

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

Sterile and non-sterile single use surgical instruments:
scissors, forceps, retractors, needle holders, curettes, blade handles, burrs, suction tubes, cannula, chisels and probes used during surgical procedures.

Sterile and non-sterile X-ray detectable swabs

Annex V Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

Sterile single use non surgical instruments for use during medical procedures.

Sterile single use quiver for storage of diathermy instruments during surgery.
Assembly packing and sterilisation and sterilisation of surgical and non surgical instruments and procedure packs in accordance with the requirements of Regulation 14

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

Previous certificate number: GB22/00000167
Change in between this certificate and previous one: Removal of elevators and dissectors from certificate scope.
Reference to Article 14 changed to Regulation 14.

Medical Device Production Quality Assurance System Certificate
GB22/00000167, continued

Rocialle Healthcare Ltd

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

Issue 4
Sites
Rocialle Healthcare Ltd Cwm Cynon Business Park (North) Mountain Ash Rhondda Cynon Taff South Wales CF45 4ER United Kingdom
Rocialle Healthcare Ltd Rocialle Warehouse Parc Agility Aberaman Park Industrial Estate Aberdare South Wales CF44 6DA United Kingdom