

Medical Device Production Quality Assurance System Certificate  
GB22/00000167



The management system of

# Rociale 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

Sterile and non-sterile single use surgical instruments: scissors, forceps, retractors, elevators, dissectors, 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 of surgical and non surgical instruments and procedure packs in accordance with the requirements of Article 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

Certification is based on reports numbered GB/PC/228898

Previous certificate number: GB22/00000167

Change in between this certificate and previous one: N/A

This certificate is valid from 14 February 2023 until 14 February 2028 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 20 May 2022

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by

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# Rociale Healthcare Ltd

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

Issue 3
<b>Sites</b>
Rociale Healthcare Ltd Cwm Cynon Business Park (North) Mountain Ash Rhondda Cynon Taff South Wales CF45 4ER United Kingdom
Rociale Healthcare Ltd Rociale Warehouse Parc Agility Aberaman Park Industrial Estate Aberdare South Wales CF44 6DA United Kingdom

