

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

For the following activities

Sterile and non-sterile single use surgical instruments: scissors, forceps, retractors, elevators, dissectors, needle holders and curettes 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 swabs and bandages.

Sterile, single use gowns, drapes, towels - used to maintain the sterile field during surgical and medical procedures.

Sterile Dressing Packs.

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 12.

Surgical drapes, drape packs, surgical gowns and theatre clothing.

Non-instrument surgical procedure packs.

Medical equipment covers and bags.

This certificate is valid from 20 May 2022 until 14 February 2023 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 20 May 2022.

Certified activities performed by additional sites listed on subsequent pages.

Authorised by



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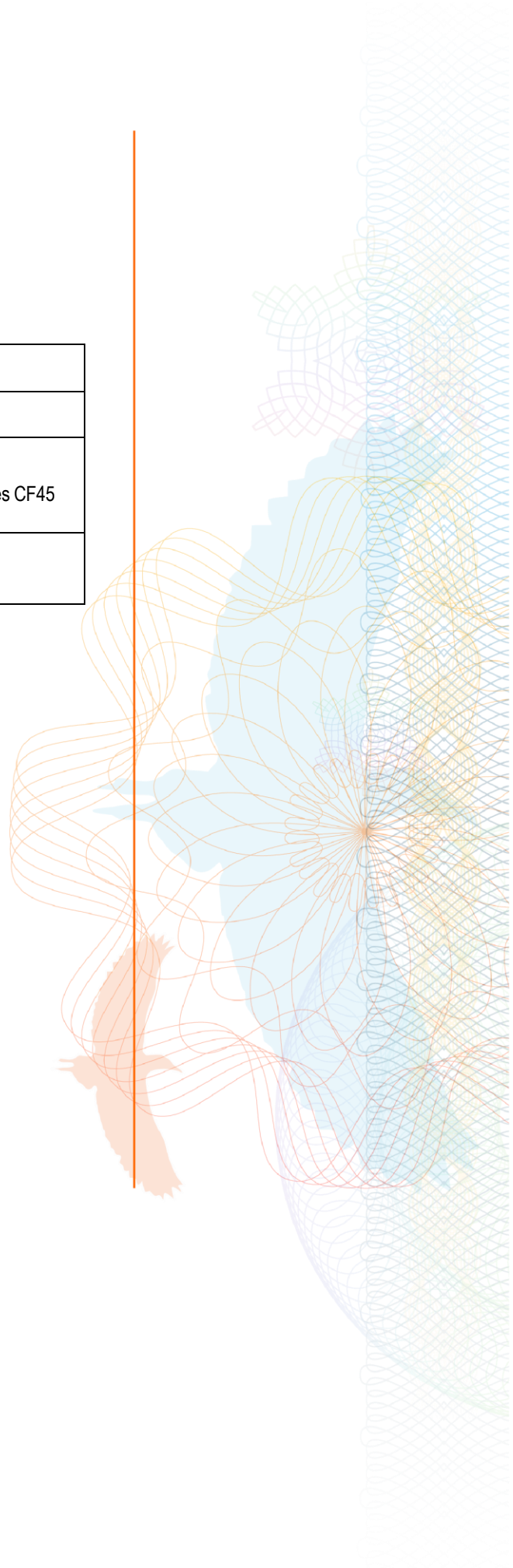
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# Rociale Healthcare Ltd

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

Issue 2
<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 Parc Agility, Aberaman Park Industrial Estate Aberdare CF44 6DA United Kingdom



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