



Certificate GB13/87980

The management system of

Rociale Healthcare Ltd

Cwm Cynon Business Park (North), Mountain Ash,
Rhondda Cynon Taff, South Wales, CF45 4ER, UK

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 14 February 2021 until 14 February 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 13. Certified since 15 February 2013

This is a multi-site certification.
Additional site details are listed on the subsequent page.



Authorised by

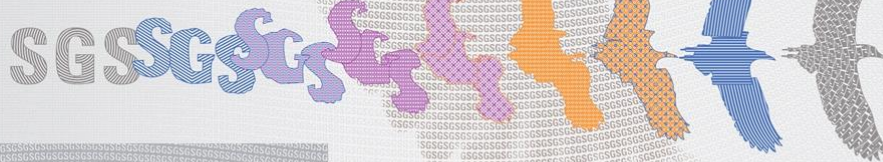


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Certificate GB13/87980, continued



Rociale Healthcare Ltd

ISO 9001:2015

Issue 13

Detailed scope



Scope: Mountain Ash

Manufacture, assembly and sterilisation of procedure packs, supplementary dressing packs, surgical procedure packs and trays, sterile, single-use surgical instruments, sterile and non-sterile consumables.

Secondary packaging of medicinal products. Manufacture of face coverings and medical face masks.

Provision of e-beam radiation sterilisation services for medical devices to third parties.

Distribution of sterile and non-sterile procedure pack components, medical devices and personal, protective equipment

Scope: Aberaman

Storage and despatch of medical devices, medical procedure packs, medicinal products, personal protective equipment and related consumables.

Distribution of sterile and non-sterile procedure pack components, medical devices and personal, protective equipment.

Secondary packaging of medical devices and medicinal products.

Scope: Prestwick

Storage and despatch of medical devices, medical procedure packs, personal protective equipment and related consumables.

Distribution of sterile and non-sterile procedure pack components, medical devices and personal, protective equipment.

Scope: Girvan

Design, manufacture and inspection of sterile theatre products.

Distribution of sterile and non-sterile procedure pack components, medical devices and personal, protective equipment.

Additional facilities

Rociale Healthcare Ltd, Units 1, 2, 5, 6, 7 & 8, C1 Trade Park, Aberaman Industrial Estate, Aberaman, Aberdare, CF44 6DA, UK

Rociale Healthcare Ltd Trading as Guardian Surgical, Grangestone, Girvan, Ayrshire, KA26 9PF, UK

Rociale Healthcare Ltd Trading as Guardian Surgical, Transit House Building 390, Alpha Freight Area, Glasgow Prestwick Airport, Ayrshire, KA9 2QA, UK



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