

Certificate GB12/85588.00



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

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Manufacture of sterile and non-sterile procedure packs, supplementary dressing packs, surgical procedure packs and trays, sterile and non-sterile single use surgical and non-surgical, instruments, swabs and medical textiles.

Manufacture of non-sterile medical face masks.

Distribution of sterile and non-sterile procedure pack components and medical device for acute and primary care. Provision of ebeam radiation sterilisation services to third parties for medical devices.

Design, manufacture and distribution of sterile and non-sterile gowns, drapes, clothing, covers and sterilisation wrap for use in healthcare facilities.

This certificate is valid from 14 February 2023 until 14 February 2026 and remains valid subject to satisfactory surveillance audits.

Issue 18. Certified since 16 February 2004

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

Authorised by
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ISO 13485:2016

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Issue 18
Sites
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



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