

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 devices for acute and primary care. Provision of ebeam radiation sterilization 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 22 April 2022 until 14 February 2024 and remains valid subject to satisfactory surveillance audits.

Issue 17. Certified since 16 February 2004.

Certified activities performed by additional sites listed on subsequent pages.

Authorised by



SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com



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Rociale Healthcare Ltd

ISO 13485:2016

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Issue 17
Sites
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 South Wales CF44 6DA United Kingdom
Rociale Healthcare Ltd Units 6, 7 and 8, C1 Trading Park Aberaman Industrial Estate Aberdare South Wales CF44 6DA United Kingdom



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