



Certificate GB12/85588.00

The management system of

# Rociale Healthcare Ltd

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

has been assessed and certified as meeting the requirements of

## ISO 13485:2016 EN ISO 13485:2016

For the following activities

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

This certificate is valid from 01 April 2021 until 14 February 2024  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 16 November 2023

Issue 15. Certified since 16 February 2004

Expiry date of last certificate: 14 February 2021

End date of last recertification audit: 20 January 2021

Multiple certificates have been issued for this scope

The main certificate is numbered GB12/85588.00

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

Authorised by

SGS United Kingdom Ltd

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Certificate GB12/85588.00, continued

## Rociale Healthcare Ltd

**ISO 13485:2016**  
**EN ISO 13485:2016**



Issue 15

Detailed scope

**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.**

**Provision of e-beam radiation sterilization services to third parties for medical devices in accordance with EN ISO 11137-1:2015**

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

Additional facilities

**Units 6, 7 and 8, C1 Trading Park, Aberaman Industrial Estate,  
Aberdare, CF44 6DA, UK**

**Grangstone, Girvan, Ayrshire , KA26 9PF, UK**

**Transit House Building 390, Alpha Freight Area,  
Glasgow Prestwick Airport, Ayrshire, KA9 2QA, UK**



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