



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, 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 03 November 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 16. Certified since 16 February 2004

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.  
The validity of this certificate depends on the validity of the main certificate.

Authorised by



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# Rociale Healthcare Ltd

## ISO 13485:2016 EN ISO 13485:2016



Issue 16

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

**Parc Agility, Aberaman Park Industrial Estate, Aberdare, CF44 6DA, UK**

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

**5 Whitfield Drive, Heathfield Industrial Estate, Ayrshire, KA8 9RX, UK**



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