

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

Medical devices - Quality management systems - Requirements for regulatory purposes

For the following activities

Manufacture of sterile and non-sterile procedure packs, surgical procedure packs and trays, sterile and non-sterile single use

surgical and non-surgical instruments, sterile quivers and medical textiles.

Distribution of sterile and non-sterile procedure packs, components and medical devices for acute and primary care.

Sterilisation of medical devices and procedure packs by electron beam irradiation and ethylene oxide.

Provision of ethylene oxide sterilisation services to third parties for medical devices.

This certificate is valid from 16 February 2026 until 14 February 2029 and remains valid subject to satisfactory surveillance audits.

Issue 21. Certified since 16 February 2004

Multiple certificates have been issued for this scope, the main certificate is numbered GB12/85588.00

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

Last certificate expiry date 14 February 2026

Recertification audit date 15 October 2025

L. Moran

Authorised by

Liz Moran

Business Manager

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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ISO 13485:2016/EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

Issue 21

Sites

Rociale Healthcare Ltd
Cwm Cynon Business Park (North) Mountain Ash Rhondda Cynon Taff South Wales CF45 4ER United Kingdom
Manufacture of sterile and non-sterile procedure packs, surgical procedure packs and trays, sterile and non-sterile single use surgical and non-surgical instruments and medical textiles.

Rociale Healthcare Ltd
Parc Agility Aberaman Park Industrial Estate Aberdare South Wales CF44 6DA United Kingdom
Secondary packaging of procedure pack components.
Distribution of sterile and non-sterile procedure packs, components and medical devices for acute and primary care.
Sterilisation of medical devices and procedure packs by ethylene oxide.



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