EC Certificate Production Quality Assurance System: Certificate GB19/964719.00

The management system of

Rocialle 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

Directive 93/42/EEC

on medical devices, Annex V.

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 01 April 2021 until 14 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 06 June 1996

Certification is based on reports numbered GB/PC/ 228898

Multiple certificates have been issued for this scope
The main certificate is GB19/964719.00

Authorised by

Global Medical Devices Head of Notified Body

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Rocialle Healthcare Ltd

Directive 93/42/EEC

on medical devices, Annex V

Issue 3

Detailed scope

Sterile and non-sterile single use surgical instruments: scissors, forceps, retractors,

elevators, dissectors, needle holders and curettes used during surgical procedures, sterile X-ray detectable swabs

Annex V Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

Sterile single use non surgical instruments for use during medical procedures.

Sterile, single-use swabs and bandages.

Sterile, single use gowns, drapes, towels - used to maintain the sterile field during surgical and medical procedures.

Sterile Dressing Packs.

Sterile single use quiver for storage of diathermy instruments during surgery.

Assembly packing and sterilisation of surgical and non surgical instruments and procedure packs in accordance with the requirements of Article 12.

Surgical drapes, drape packs, surgical gowns and theatre clothing.

Non-instrument surgical procedure packs.

Medical equipment covers and bags. Sterilisation wrap.

Where the above scope includes Class IIb or Class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in Addition to this certificate to place the device on the market.