EC Certificate Production Quality Assurance System: Certificate GB12/85587

The management system of

Rocialle, a trading division of Berendsen UK Ltd, part of the Berendsen plc Group.

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 17 July 2015 until 19 February 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 February 2018
Issue 10. Certified since 06 June 1996

Certification is based on reports numbered GB/PC 228898

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

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 14 0315 M2

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Directive 93/42/EEC

on medical devices, Annex V

Issue 10

Detailed scope

Sterile single use surgical instruments: scissors, forceps, retractors, elevators, dissectors, needle holders and curettes used during surgical procedures.

Sterile - X ray detectable swabs.

Metrological aspects only - Restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

Syringes without needles for use during medical procedures.

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

Sterilisation of sterile single use-non surgical scissors for use during medical procedures
Sterile, single use gowns, swabs, drapes and towels – used to maintain the sterile field during surgical and medical procedures.
Sterile, single-use bulb syringes for the use of irrigation during surgical procedures

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

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 that device on the market.

Additional facilities

Warehouse: Units 6, 7 and 8, C1 Trading Park, Aberaman Industrial Estate, Aberaman, Aberdare, South Wales, CF44 6DA, UK