EC Certificate Production Quality Assurance System: Certificate GB99/15368

The management system of

Andersen Caledonia Limited

Caledonian House, Phoenix Crescent, Strathclyde Business Park
Lanarkshire, ML4 3NJ, 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 19 January 2018 until 19 January 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 09 December 2020
Issue 24. Certified since 18 January 1999

Certification is based on reports numbered GB/PC 08642

Authorised by

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Andersen Caledonia Limited

Directive 93/42/EEC

on medical devices, Annex V

Issue 24

Detailed scope

Sterile Single Use surgical instruments i.Mosquito Halstead forceps curved ii.Mayo Scissors straight iii.Long Mayo Scissors curved iv.Polypus forceps bonney v.Iris non toothed forceps

Class 1 sterile -Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Single Use instruments Rampley Sponge holder (non invasive) Sterile tubing and pressure valve kit. Single use – intended to be used with inflation/deflation devices used with balloon and bellows type catheters Sterile Single Use instruments spackman cannula – (invasive in body orifice)

Sterile procedure pack in accordance with article 12 of the medical device directive

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.