



EC Certificate Production Quality Assurance System: Certificate GB19/964735

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 01 March 2021 until 19 January 2023
and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 18 January 1999

Certification is based on reports numbered GB/PC/ 08642

Authorised by

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639

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LPMD5008 - Certificate CE1639 Annex V - EN rev. 02

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Andersen Caledonia Limited

Directive 93/42/EEC

on medical devices, Annex V

Issue 6

Detailed scope

Sterile Single Use Surgical Instruments and Supplementary Devices:

Sterile Surgical Scissors, Sterile Surgical Retractors, Sterile Surgical Grasping Forceps, Sterile Surgical Dissecting Forceps, Sterile Surgical Suction Tubes, Sterile Surgical Trocar & Cannula for Hormone Implant, Sterile Surgical Curettes, Sterile Surgical Hooks, Sterile Surgical Vasectomy Forceps, Sterile Surgical SPY712 Intravitreal Delivery Guide, Sterile Surgical Clamps, Sterile Surgical Dissectors.

Sterile Orthodontic Devices:

Dental/Oral Wires, Eyelet Wires, Tie Wires and Snare Wires.

Class 1 sterile -Sterility Aspects Only -Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Single Use Non Invasive or Body Orifice Invasive, Medical Instruments and Supplementary Devices:

Sterile Dressing Scissors, Sterile Needle Holders, Sterile Scalpel Handles, Sterile Dilators, Sterile Dental Syringe without Needle for use with re-filled Cartridges, Sterile Grasping Forceps, Sterile Probes, Sterile Clamps, Sterile Hooks, Sterile Speculum, Sterile Podiatry Instruments. Sterile Drapes, Sterile Gauze swabs, Sterile Spatulas and Sterile Depressors Sterile Quivers. Sterile Surgical Gowns Sterile Nasal Swabs

Sterile procedure packs 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 the device on the market.