Medical Device Production Quality Assurance System
Certificate GB24/00000238

The management system of

Andersen Caledonia Limited

Caledonian House Phoenix Crescent Strathclyde Business Park Bellshill Lanarkshire ML4 3NJ
United Kingdom

has been assessed and certified as meeting the requirements of

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 14 November 2024 until 14 November 2029 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 14 November 2024

L. Henderson

Authorised by
Lynn Henderson

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Andersen Caledonia Limited

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

Issue 1

Sterile SP.eye™ Sharp safe Intravitreal injection system,

Sterile Single Use:
General Purpose Surgical Scissors,
Umbilical Cord Scissor,
Gynaecological scissors,
Self-Retaining Surgical retractors,
Hand Held surgical retractors,
Eyelid Clamp,
Dental Cheek Retractor,
Tracheal Surgery Dilators,
Surgical Soft-tissue Manipulation Grasping Forceps,
Dissecting Forceps,
Open Surgery Biopsy Forceps,
Suction Tubes,
Trocar and Cannula for Hormone Implant,
Bone Curettes,
Ophthalmic curette,
Surgical Soft-tissue Manipulation Forceps Curette,
General Purpose Curette,
Endaural Surgical Curette Hooks,
Soft Tissue Surgical Hooks,
Adenoid Curette Hooks,
Surgical Soft-tissue Manipulation Vasectomy Forceps,
Maxillofacial Bone Wire/Bars,
Orthodontic Product Range (ENT Snare wires),
Ophthalmic Needle,
Surgical Soft-Tissue Manipulation Forcep Clamps,
Bone Lever/Elevator Dissector,
Single-Use Dissector,
Open surgery Dissectors,
Abdominal/ENT/Orthopaedic Surgical Probe Dissector.

Annex V Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:
Sterile Dressing Scissors, Sterile Needle holders, Sterile Scalpel Handles, Sterile Dilators, Sterile Dental

Medical Device Production Quality Assurance System
Certificate GB24/00000238, continued

Andersen Caledonia Limited

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

Issue 1

syringe without needle for use with pre-filled cartridges, Sterile Grasping Forceps, Sterile Probes, Sterile Clamps, Sterile Speculum, Sterile Podiatry Instruments (Non-Surgical), Sterile Drapes, Sterile Gauze, Sterile Swabs, Sterile Spatulas, Sterile Depressors, Sterile Quivers

Where the above scope includes class IIb or class III medical device(s), a valid Type Examination Certificate according to Annex III [as modified by Part 2 of Schedule 2A to The MDR 2002] is a mandatory requirement for each device in addition to this certificate to place that device on the market

Certification is based on reports numbered GB/PC/08642
Previous certificate number: N/A
Change in between this certificate and previous one: N/A