Medical Device Full Quality Assurance System Certificate GB23/00000071

The management system of

Eakin Surgical Ltd

Greypoint Cardiff Business Park Llanishen Cardiff CF14 5WF United Kingdom

has been assessed and certified as meeting the requirements of

Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

For the following products

Sterile Kerrison punches (single-use) used for the resection of bone

Sterile Myringotomy Knife (single-use) to make incisions into the tympanic membrane during myringotomy procedures

Sterile Myringotomy Kit (single-use)- Includes following components: Zoellner Tips, Suction 6fg, Ear Speculum, Forceps, M. Knife, Horne Probe, Inserter for performing myringotomy procedures

Sterile Vein Hook (single-use) for phlebectomy

Sterile and non-sterile Suction Tubes (single-use) for use during clinical procedures to remove fluids and debris

Sterile and non-sterile Zoellner Tips (single-use) for use during clinical procedures to remove fluids and debris

Sterile Aspiration Needle (single-use) for use in laparoscopic surgery through a 3mm or 5mm port to aspirate fluids

Sterile Blunt Aspiration Tube (single-use) for use in laparoscopic surgery through a 3mm or 5mm port to aspirate fluids

Sterile Diathermy Suctions (single-use) for use in surgery to deliver monopolar energy for coagulation and to remove fluids, plume and debris

Sterile Curved, Angled, Straight Cannula devices (single-use) to flush or apply suction during surgery

Where the above scope includes class III medical device(s), a valid Design Examination Certificate according to Annex II (Section 4) [as modified by Part 2 of Schedule 2A of 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/02665

Previous certificate number: N/A

Change in between this certificate and previous one: Scope has been technically reworded to clarify specific device names and intended uses. The devices covered by this scope are exactly the same, except for removal of Sterile Tibbs Cannulae from the scope.

This certificate is valid from 28 July 2023 until 28 July 2028 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 06 February 2023

L. Henderson

Authorised by
Lynn Henderson

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