



EC Certificate Full Quality Assurance System: Certificate GB19/964515

The management system of

Eakin Surgical Ltd

Cardiff Business Park, Llanishen, Cardiff, CF14 5WF, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Sterile and non-sterile single use non-cannulated instruments for ENT, general gynaecology, ophthalmology, oral and maxillofacial, orthopaedic, paediatric and spinal surgeries, sterile suction irrigator, Sterile and non-sterile single use Suction Tubes and Aspiration Needles for use in ENT, Oral & Maxillofacial, Plastics, Paediatrics and General Surgery, sterile diathermy suctions, Sterile Tibbs Cannulae for flushing of peripheral blood vessels.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 21 May 2021 until 02 August 2023 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 03 May 2002

Certification is based on reports numbered GBPC 02665

Authorised by

Global Medical Devices Head of Notified Body

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