

Certificate GB02/56692

SGS

The management system of

Eakin Surgical Ltd

Greypoint Cardiff Business Park Llanishen CF14 5WF Cardiff United Kingdom

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Design and manufacture of:

Sterile pulse lavage system;

Sterile and non-sterile single use Non-Cannulated Instruments for use in ENT, general gynaecology, ophthalmology, oral and maxillofacial, orthopaedic, paediatric and spinal surgeries;

Sterile and non-sterile single use Suction Tubes and Aspiration Needles for use in ENT, oral and maxillofacial, plastics, paediatrics and general surgeries;

Sterile single use Cannula Devices for use in ENT, general gynaecology, oral and maxillofacial, paediatrics and general surgeries;

Sterile single use Diathermy Suctions.

Provision of contract Ethylene Oxide sterilisation services in accordance with ISO 11135:2014.

Distribution of active and non-active medical devices for surgical use

This certificate is valid from 28 July 2023 until 02 August 2026 and remains valid subject to satisfactory surveillance audits.

Issue 32. Certified since 02 August 2002

Jonathan M. Hall

Authorised by
Jonathan Hall

Global Head - Certification Services

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