



EC Certificate Production Full Quality Assurance System: Certificate GB19/964516

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 V

For the following products

Sterile pulse lavage system.

Annex V (sterility aspects only) Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Spackmann Cannula

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 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 17 October 1997

Certification is based on reports numbered GB/PC/ 02665

Authorised by

Global Medical Devices Head of Notified Body

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