EC Certificate Production Quality Assurance System: Certificate GB19/964727

The management system of

P3 Medical Limited

1 Newbridge Close, Bristol, BS4 4AX, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 16 December 2019 until 24 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 10 May 1996
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered GB/PC/06145

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

Pieter Weterings
Certification Manager

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P3 Medical Limited

Directive 93/42/EEC

on medical devices, Annex V

Issue 1

Detailed scope

Soda Lime Type Carbon Dioxide absorbent material for use in anaesthetic circuits and other closed respiratory systems,
Sterile laryngeal mask airways,
Sterile single use plastic endobronchial tubes.
Sterile, single use endotracheal tubes

Annex V Restricted to the aspects of manufacture concerns to securing and maintaining sterility conditions.

Sterile cautery tip cleaners for cleaning of electro cautery devices during surgery,
Sterile drapes and equipment covers for the use of maintaining a sterile field,
Sterile surgical skin markers and rulers (non-measuring),
Sterile procedure packs (containing drapes, equipment covers, hollowware, swabs, ultrasound gel, vaginal specula and forceps) - under Article 12
Sterile, non-vented tracheal introducers (Bougies).

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.

Additional facilities

415 Oakshott Place, Preston, PR5 8AT, UK