EC Certificate Full Quality Assurance System: Certificate GB19/964728

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 II (excluding Section 4)

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 subsequent pages

Authorised by

SGS Belgium NV, Notified Body 1639
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P3 Medical Limited

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

Sterile insufflation tubing and irrigation tubing sets
Sterile and non-sterile vented tracheal introducers and tracheal tube guides (Bougies) for connection to active medical device
Sterile and non-sterile adaptors and connector sets for breathing circuits
Non-sterile anaesthesia tubing
Non-sterile rebreathing bags
Sterile single use ThoraQuik® Chest Decompression kit intended to treat patients presenting with spontaneous, secondary or tension pneumothorax, or with pleural effusions.

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.

Additional facilities

415 Oakshott Place, Preston, PR5 8AT, UK