



EC Certificate Full Quality Assurance System: Certificate GB20/965349

The management system of

# Penlon Limited

Abingdon Science Park, Barton Lane, Abingdon, Oxfordshire, OX14 3NB, 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 01 December 2020 until 13 October 2023 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 03 January 2017 and first certified by SGS Belgium NV since 28 February 2020

Certification is based on reports numbered GB/PC 240635

Authorised by

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LPMD5007 - Certificate CE1639 Annex II-4 - EN rev. 02

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# Penlon Limited

## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

**Non-sterile anaesthesia and anaesthetic equipment, insufflation equipment, patient monitoring, oxygen therapy systems and medical hose assemblies.**

Oxygen therapy flowmeters & bubble humidifiers;

AVS Ventilator, AVS MRI Ventilator & Nuffield 200 Ventilator;

Anaesthesia workstations with integrated ventilator - Prima 300 range:

Prima 320 / Prima 330e / Prima 320 Advance / Prima 325/Prima 465

Anaesthesia workstation Prima 400 series:

Prima 440, Prima 445, Prima 450, Prima 451 MRI, Prima 460, Prima 465;

A200 SP Absorber & A200SP MRI Absorber for use

as part of a closed breathing system for anaesthesia;

Sigma EVA Vaporizer, Sigma Delta Vaporizer & Sigma Delta MRI Vaporizer

for the provision of accurate concentrations

of the anaesthetic drugs into the fresh gas supply;

Penlon Oxygen Therapy Range to provide controlled flow

of humidified Oxygen to be administered to a patient:

AnaVue 4000 Patient Monitor

ESO 2 Emergency Ventilator restricted for the treatment of COVID-19 (SARS-CoV-2)

Vivid Vue Patient Monitors range models: Vivid Vue 8, Vivid Vue 10 and Vivid Vue 12

Appendix Page to note following devices:

Class IIa devices

- Oxygen Therapy Flowmeters & Bubble Humidifiers

- Medical Hose assemblies

Class IIb devices

- AVS Anaesthesia Ventilator and Accessories

- AVS MRI Anaesthesia Ventilator and Accessories

- Nuffield 200 Ventilator and accessories

- Prima 320 Anaesthetic Machine and Accessories

- Prima 320 Advance Anaesthetic Machine and Accessories

- Prima 325 Anaesthetic Machine and Accessories

- Prima 330e Anaesthetic Machine and Accessories

- Prima 450 Anaesthetic Machine and Accessories

- Prima 460 Anaesthetic Machine and Accessories

- Prima 465 Anaesthesia Machine and Accessories

- Prima 440 Anaesthetic Machine and Accessories

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## Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

- Prima 445 Anaesthetic Machine and Accessories
- Prima 451 MRI Anaesthetic Machine and Accessories
- A200SP Absorber and Accessories
- A200SP MRI Absorber and Accessories
- Sigma Delta Vaporizers and Accessories
- Sigma Delta MRI Vaporizers and Accessories
- Sigma EVA Vaporizer
- AnaVue 4000 Patient Monitor and Accessories
- ESO 2 Emergency Ventilator restricted for the treatment of COVID-19 (SARS-CoV-2)
- Vivid Vue Patient Monitors range models: Vivid Vue 8, Vivid Vue 10 and Vivid Vue 12 and Accessories

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.