EC Certificate Full Quality Assurance System: Certificate GB20/965349



The management system of

Penion Estimated

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

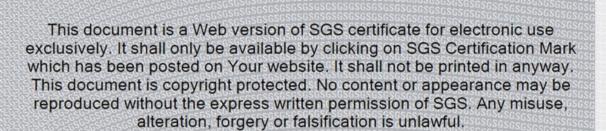
SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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

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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 Ila devices Oxygen Therapy Flowmeters & Bubble Humidifiers Medical Hose assemblies Class Ilb 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
 Sigma Delta Vaporizers and Accessories
 Sigma Delta Waporizers and Accessories
 Sigma Delta MRI Vaporizers and Accessories
 Sigma EVA Vaporizer
 AnaVue 4000 Patient Monitor and Accessories
 SESO 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.

Certificate GB20/965272

SGS

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

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Design, Manufacture, Service & commissioning of Anaesthesia and Anaesthetic Equipment, suction equipment, airway management and insufflation equipment and patient monitoring equipment.

This certificate is valid from 10 September 2021 until 13 October 2024 and remains valid subject to satisfactory surveillance audits.

Recertification audit due a minimum of 60 days before the expiration date Issue 2. Certified since 19 December 2016

Authorised by



Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

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Declaration of Conformity

Manufacturer Penlon Limited, Abingdon Science Park,

Barton Lane, Abingdon, OX14 3NB, UK

Product Name Prima 400 Series Anaesthesia Machine

Prima 440

Models Prima 445

Prima 450 Prima 460 Prima 465 Prima 451 MRI

Classification Class IIb, Rule 11

Conformity Assessment Route Annex II

GMDN Code 37710

Quality Management System

ISO 13485:2016

Notified Body

SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium

(ID Number: 1639)

CE Certificate Number

GB20/965349

Start of CE Marking

2013

European Authorised

Obelis s.a.

Representative

Bd. Général Wahis 53, 1030-Brussels, Belgium

We hereby declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Devices, as amended by Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.

Place and Date of Issue

Signed by:

Abingdon, 29th July 2021

Mary Ryan

PRINT NAME

Director of Innovation, Technology & Regulatory Affairs

EU PRRC

POSITION