Penlon

Manufacturer's Declaration

In relation to Regulation 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	**Penlon Limited**
Manufacturer address and contact details	Abingdon Science Park, Barton Lane, Abingdon, Oxfordshire, OX14 3NB, UK T: +44(0) 1235 547000 www.penlon.com
Single Registration Number (SRN)	GB-MF-000025115

Authorised Representative name	**Obelis S.A**
Authorised Representative address and contact details	Bd. Général Wahis 53, 1030-Brussels, Belgium T: +32 (0) 27325954 www.obelis.net
Single Registration Number (SRN)	BE-AR-000000106

Notified Body name and number where the MDR application was contract signed	**TÜV SÜD Product Service GmbH, 0123** ☒ See attached schedule
Notified Body name and number that issued the Directive Certificate	SGS Belgium NV, 1639 ☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made	GB20/965349 ☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	13 October 2023 ☒ See attached schedule
End date of extended validity/transition period	31 December 2028 ☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate,** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed device(s) in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120,3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

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➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☒ Expired/expires *after* 20 March 2023:

☒ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024
☒ A QMS in accordance with Article 10(9) MDR is in place.
☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- The devices have not been significantly changed in their design and intended purpose since 26 May 2021.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Mary Ryan

Mary Ryan
Director Innovation, Technology & Regulatory Affairs, EU PRRC

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PENLON LTD
QUALITY & REGULATORY DEPT
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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
AVS Anaesthesia Ventilator and Accessories	GB20/965349	13/10/2023	SGS Belgium NV, 1639	TÜV SÜD Product Service GmbH, 0123	31/12/2028	
AVS MRI Anaesthesia Ventilator and Accessories						
Prima 320 Anaesthetic Machine and Accessories	GB20/965349	13/10/2023	SGS Belgium NV, 1639	TÜV SÜD Product Service GmbH, 0123	31/12/2028	
Prima 320 Advance Anaesthetic Machine and Accessories						
Prima 440 Anaesthetic Machine and Accessories	GB20/965349	13/10/2023	SGS Belgium NV, 1639	TÜV SÜD Product Service GmbH, 0123	31/12/2028	
Prima 445 Anaesthetic Machine and Accessories						
Prima 450 Anaesthetic Machine and Accessories						
Prima 451 MRI Anaesthetic Machine and Accessories						
Prima 460 Anaesthetic Machine and Accessories						
Prima 465 Anaesthesia Machine and Accessories	GB20/965349	13/10/2023	SGS Belgium NV, 1639	TÜV SÜD Product Service GmbH, 0123	31/12/2028	

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Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sigma EVA Vaporizer	GB20/965349	13/10/2023	SGS Belgium NV, 1639	TÜV SÜD Product Service GmbH, 0123	31/12/2028	
Sigma Delta Vaporizers and Accessories Sigma Delta MRI Vaporizers and Accessories	GB20/965349	13/10/2023	SGS Belgium NV, 1639	TÜV SÜD Product Service GmbH, 0123	31/12/2028	
Oxygen Flowmeters Bubble Humidifiers	GB20/965349	13/10/2023	SGS Belgium NV, 1639	TÜV SÜD Product Service GmbH, 0123	31/12/2028	
*A200SP Absorber, is an accessory / component of the Prima 400 Series (Prima 440, 445, 450, 451 MRI, 460, 465), hence it will not be sold separately.	GB20/965349	13/10/2023	SGS Belgium NV, 1639	TÜV SÜD Product Service GmbH, 0123	31/12/2028	

[1] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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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

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

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**

Penlon Limited

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.

Penlon

Declaration of Conformity

Manufacturer	Penlon Limited, Abingdon Science Park, Barton Lane, Abingdon, OX14 3NB, UK
Product Name	Penlon Oxygen Therapy Flowmeters & Bubble Humidifiers *(Refer Appendix A for Product Identification)*
Classification	Class IIa, Rule 2
Conformity Assessment Route	Annex II
GMDN Code	Flowmeters (61365), Bubble Humidifiers (35113)
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	1999
European Authorised Representative	Obelis s.a. 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 Abingdon, 24th May 2023

Signed by:

Mary P Ryan

SIGNATURE

Mary Ryan

PRINT NAME

Director of Innovation, Technology & Regulatory Affairs EU PRRC

POSITION

Penlon

Appendix A: Product Identification

Model / Product Name	Catalogue / Reference	Version (Product Descriptions)	Basic UDI-DI	GMDN
Flowmeter	9910-029	Single O_2 Flowmeter, tubing nipple and Mk4 O_2 probe	5051977OTS-FMYH	61365
	9910-034	Twin O_2 Flowmeters, tubing nipples and Mk4 O_2 probe		
	9910-050	Twin O_2 Flowmeters, tubing nipples and 3/8" BSP connector		
	9910-030	Single Air Flowmeter, tubing nipple and Mk4 4-bar Air probe		
	9910-020	Single O_2 Flowmeter, tubing nipple and 3/8" BSP connector		
	9910-021	Single Air Flowmeter, tubing nipple and 3/8" BSP connector		
	9910-032	Twin Air Flowmeters, tubing nipples and Mk4 4-bar Air probe		
	9910-216	Single O_2 Flowmeter, tubing nipple and 1/8" NPT Universal thread		
	5009161	Single O_2 Flowmeter, tubing nipple and right-angled probe		
	9910-176	Single O_2 Flowmeter with threaded outlet (9/16" UNF), Mk4 O_2 probe		
	9910-193	Single Air Flowmeter with threaded outlet (9/16" UNF), and Mk4, 4-bar Air probe		
	9910-177	Single O_2 Flowmeter, with threaded outlet (9/16" UNF) and 3/8" BSP connector		
	9910-233	Single O_2 Flowmeter, with threaded outlet (9/16" UNF) and 1/8" NPT connector		
	5007275	MRI Flowmeter, Oxygen, single tube, direct probe, nipple outlet	5051977OTS-FMMRINV	61365
Bubble Humidifier	9410-007	Standard Bubble Humidifier	5051977OTS-BHXT	35113
	9410-006	Bubble Humidifier with Occlusion Protection		

Penlon

UK DECLARATION OF CONFORMITY

UK CA 0120

Manufacturer

Penlon Limited,
Abingdon Science Park,
Barton Lane,
Abingdon, OX14 3NB, UK

This declaration is issued under the sole responsibility of the manufacturer.

Product Type	:	**Medical Gas Flowmeter, Thorpe Tube** **Non-heated respiratory humidifier**
Product Identification	:	See Appendix A for list of Catalog numbers
Basic-UDI-DI	:	Refer Appendix A
Device Classification, Rule	:	Class IIa, Rule 2
Conformity Assessment Route	:	Part II of The Medical Devices Regulations 2002, Annex II excluding section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]
Approved Body Name	:	SGS United Kingdom
Approved Body Number	:	0120
Certificate Number and Date	:	GB23/00000206, Issue: 25 Jan 2024, Valid until: 13 Jan 2029

Penlon Limited declares that the above-mentioned product(s) meet the provisions of the **Medical Devices Regulations 2002 (SI 618, as amended)**. The product has been subjected to conformity assessment procedures set out in the Medical Devices Regulations 2002. All supporting documentation is retained on the premises of the manufacturer.

Place and Date of Issue: Abingdon, 15 October 2024

Signed by:

SIGNATURE

Daniel Harrison

PRINT NAME

QARA Manager

POSITION

This declaration will be renewed on any significant change of product, product range, standards and laws.

Penlon

UK DECLARATION OF CONFORMITY

UK CA 0120

Appendix A: Product Identification

Catalogue / Reference	Model (Product Name) / Version (Product Descriptions)	Basic UDI-DI	GMDN
9910-029	Single O_2 Flowmeter, tubing nipple and Mk4 O_2 probe	5051977OTS-FMYH	61365
9910-034	Twin O_2 Flowmeters, tubing nipples and Mk4 O_2 probe		
9910-050	Twin O_2 Flowmeters, tubing nipples and 3/8" BSP connector		
9910-030	Single Air Flowmeter, tubing nipple and Mk4 4-bar Air probe		
9910-020	Single O_2 Flowmeter, tubing nipple and 3/8" BSP connector		
9910-021	Single Air Flowmeter, tubing nipple and 3/8" BSP connector		
9910-032	Twin Air Flowmeters, tubing nipples and Mk4 4-bar Air probe		
9910-216	Single O_2 Flowmeter, tubing nipple and 1/8" NPT Universal thread		
5009161	Single O_2 Flowmeter, tubing nipple and right-angled probe		
9910-176	Single O_2 Flowmeter with threaded outlet (9/16" UNF), Mk4 O_2 probe		
9910-193	Single Air Flowmeter with threaded outlet (9/16" UNF), and Mk4, 4-bar Air probe		
9910-177	Single O_2 Flowmeter, with threaded outlet (9/16" UNF) and 3/8" BSP connector		
9910-233	Single O_2 Flowmeter, with threaded outlet (9/16" UNF) and 1/8" NPT connector		
5007275	MRI Flowmeter, Oxygen, single tube, direct probe, nipple outlet	5051977OTS-FMMRINV	61365
9410-007	Standard Bubble Humidifier	5051977OTS-BHXT	35113
9410-006	Bubble Humidifier with Occlusion Protection		