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covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023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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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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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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