Air Liquide Medical Systems S.A.
Parc de Haute Technologie
6, rue Georges Besse
92182 Antony Cedex - France

To whom it may concern

Internal reference: DQ23_368

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic 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	Air Liquide Medical Systems S.A.
Manufacturer address and contact details	Parc de Haute Technologie 6, rue Georges Besse 92182 Antony Cedex – France Tel : +33 1 40 96 66 00
Single Registration Number (SRN)	FR-MF-000003649
Notified body name	GMED
Notified body number	0459
Directive Certificate numbers to which this confirmation is made	- 7405 rev. 21 (Ventilation medical devices) - 33855 rev. 5(Medical devices for supplying medical gases)
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	May 26th, 2024
End date of extended validity/transition period	December 31st, 2028

Digitally signed by Botnaru Andrei
Date: 2024.07.01 10:40:53 EEST
Reason: MoldSign Signature
Location: Moldova

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificates** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met, and
- the listed **devices** 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:

➢ **Directive Certificates** as listed above

- Directive Certificates as listed above covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards;
- Expires after 20 March 2023.
- Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made by us to a notified body for the devices listed in the attached schedule or their substitutes and signed written agreements is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has performed an audit report ending by the recommendation of the issuance of a certificate for the MDR-compliant QMS, once the Technical documentation assessment is satisfactory completed.

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

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- 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:

Full Company Name:	Air Liquide Medical Systems S.A.
Location & Date:	Antony, on 20-déc.-2023
Signature, Print Name, Title:	DocuSigned by: VAROMME Olivier 9C3123924CD9483... Olivier Varomme Quality and Regulatory Affairs Director, PRRC
Contact Details:	olivier.varomme@airliquide.com

Schedule of Devices

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

Identification of the device	Directive Certificate number to which this confirmation is made	Original expiry date as indicated on the Directive Certificate 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 lodged/contract signed	End date of extended validity / transition period	Substitute Devices
Monnal T60 Advanced 37005043MT60ED	7405 rev. 21	May 26th, 2024	GMED - 0459	GMED - 0459	December 31st, 2028	Monnal T60
Monnal TEO 37005043MONNALTEO9H	7405 rev. 21	May 26th, 2024	GMED - 0459	GMED - 0459	December 31st, 2028	Monnal T75
xO / xO Smart 37005043XO7A	33855 rev. 5	May 26th, 2024	GMED - 0459	GMED - 0459	December 31st, 2028	Compact G2

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