Docusign Envelope ID: F996945D-E3B9-47CE-A592-FE0D77858387

Air Liquide HEALTHCARE

EU DECLARATION OF CONFORMITY

Manufacturer

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

SRN: FR-MF-000003649

Notified Body *for Regulation (EU) 2017/745*

GMED
1, rue Gaston Boissier
75724 Paris Cedex 15 – France

Notified body number: 0459

Medical Device	**xO / xO Smart**
Basic UDI-DI	37005043*XO7A*
References	Refer to attachment 1
Software version	From version 1.2.0
Classification	Class IIb *according to annex VIII of Regulation (EU) 2017/745*

We hereby declare under our sole responsibility that the above-mentioned medical device complies with the Regulation (EU) 2017/745 on medical devices.

The conformity assessment according to Annex IX of the Regulation (EU) 2017/745 has been performed by the above-mentioned Notified Body.

EC Certificate No: 39666 rev 1 – Expiry Date: 2029-04-02

Common specifications: *N/A*

Applicable to Smart models:

We hereby declare under our sole responsibility that the above-mentioned device complies with the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment and its transposition into national law of EU Member States.

Applicable to Smart models:

We hereby declare under our sole responsibility that the above-mentioned device complies with the Directive 2014/53/EU on radio equipment and its transposition into national law of EU Member States.

The conformity to the essential requirements set out in article 3 of this directive has been demonstrated by using the following standards:

Health and Safety (Art 3(1) (a)):	EN 62368-1 +A11	Version: N/A	Date: 2020
	EN 60601-1 + A1 + A2	Version: N/A	Date: 2020
Electromagnetic Compatibility (Art.3(1) (b)):	EN 301 489-1	Version: v2.1.1	Date: 2017
	EN 301 489-17	Version: v3.1.1	Date: 2017
Efficient use of radio spectrum (Art.3(2)):	EN 300 328	Version: v2.2.2	Date: 2020

A conformity assessment procedure according to Annex III of directive 2014/53/EU has been performed with the involvement of the following Notified Body:

Notified Body: LCIE
33 Avenue du Général Leclerc 92260 Fontenay-Aux-Roses - FRANCE
Notified Body number: 0081

EU-type examination certificate: RED_424 version 02

Antony, 19-févr.-2026

DocuSigned by:
Olivier VAROMME
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Olivier VAROMME
Director of Quality and Regulatory Affairs & PRRC
For Air Liquide medical Systems

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Attachment 1 – List of references covered by this declaration

Reference	Designation	UDI-DI	
		Unitary	Pack of 10 units
CK062538	XO O2 200B 25E OL NF 15L	03700504301081	13700504301088
CK062539	XO O2 200B 25E OL DIN 15L	03700504301104	13700504301101
CK062540	XO O2 200B 25E OL UNI 15L	03700504301128	13700504301125
CK062541	XO O2 200B 25E OL SS 15L	03700504301142	13700504301149
CK062542	XO O2 200B 25E OL CARBAMED 15L	03700504301326	13700504301323
CK062543	XO O2 200B 25E OL SIS 15L	03700504301241	13700504301248
CK062544	XO O2 200B 25E OL DISS 15L	03700504301340	13700504301347
CK062548	XO SMART O2 200B 25E OL NF 15L	03700504301166	13700504301163
CK062549	XO SMART O2 200B 25E OL DIN 15L	03700504301180	13700504301187
CK062550	XO SMART O2 200B 25E OL UNI 15L	03700504301203	13700504301200
CK062551	XO SMART O2 200B 25E OL SS 15L	03700504301227	13700504301224
CK062552	XO SMART O2 200B CARBAMED 15L	03700504301265	13700504301262
CK062553	XO SMART O2 200B OL SIS 15L	03700504301364	13700504301361
CK062554	XO SMART O2 200B OL BS 15L	03700504301302	13700504301309
CK062556	XO SMART O2 200B OL DISS 15L	03700504301876	13700504301873



XO O2 200B 25E OL XXX 15L



XO SMART O2 200B 25E OL XXX 15L