DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox Life HMEs

Basic UDI: 7331791-HME-0-000-0001-XC

This Declaration of Conformity is issued under the sole responsibility of Atos Medical AB. Atos Medical AB declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled and, clause 6.6 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

Intended use/purpose:
Provox Life HMEs are single use heat- and moisture exchangers for patients breathing through a tracheostoma.

Hörby, Sweden, date as stated on last page

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Martin Richardson, Senior Vice President Operations & Quality
on behalf of the CEO of Atos Medical AB.

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

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REF	Device name	Class*	GMDN code
7475	Provox Life Sample Pack Protect HME	I	58705
7476	Provox Life Sample Pack Energy HME	I	58705
8072	Provox Life Night HME Experience	I	58705
8073	Provox Life Energy HME Experience	I	58705
8074	Provox Life Protect HME Experience	I	58705
8262	Provox Life Night HME	I	58705
8264	Provox Life Home HME Experience	I	58705
8265	Provox Life Go HME Experience	I	58705
8310	Provox Life Go HME	I	58705
8311	Provox Life Home HME	I	58705
8312	Provox Life Energy HME	I	58705
8313	Provox Life Protect HME	I	58705

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

In compliance with Therapeutic Goods (Medical Devices) Regulations 2002
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

In compliance with UK Medical Devices Regulations 2002 as amended
Each kind of medical device to which the system has been applied fulfils the applicable obligations imposed by Annex VII and the device meets the provisions of the applicable section of the Medical Devices Regulations.

Authorized representative/UK Responsible Person:
Atos Medical UK Ltd Tottle Road
Cartwright House
Nottingham
Nottinghamshire NG2 1RT
England, United Kingdom

Common Specification(s) as per Article 9, and other Union Legislation(s)
- No relevant Common Specifications as defined in Article 9 to list.
- No relevant Union Legislations to list
- No European Representative

Document Number: VV-0544318 Status: Approved Version: 6.0
Name: DoC Provox Life HMEs 7331791-HME-0-000-0001-XC

Document Approvals

Approved Date: 2024-09-29

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