



DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox Luna HME

Basic UDI-DI: 7331791-HME-0-000-0009-Y4

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:

The Provox Luna HME is a single use heat- and moisture exchanger, attachable to the Provox Luna Adhesive, for night-time use after total laryngectomy.

Hörby, Sweden, date as stated on last page

A handwritten signature in blue ink, appearing to read "Henrik Heringslack".

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Henrik Heringslack, AtosMedical Site Manager
on behalf of Atos Medical AB.

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Competent Authority Medical Products Agency
Sweden

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REF	Device name	Class*	GMDN code
8013	Provox Luna HME (30 pcs)	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:

Coloplast Limited
Nene Hall
Peterborough Business Park
Peterborough
Cambridgeshire PE2 6FX

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 Approvals
Approved Date: 2026-06-16

Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 16-Jun-2026 13:18:53 GMT+0000
Approval Task Verdict: Approve	SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 16-Jun-2026 14:20:02 GMT+0000
Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Regulatory Affairs Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 16-Jun-2026 14:36:37 GMT+0000