# DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

## Provox XtraHME

## Basic UDI-DI: 7331791-HME-0-000-0000-X9

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 XtraHME Cassette is a single use, specialized device intended for patients breathing through a tracheostoma. It is a heat and moisture exchanger (HME) that heats and humidifies inhaled air by retaining heat and moist from exhaled air in the device. It partially restores lost breathing resistance. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.

Hörby, Sweden, date as stated on last page

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


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| **SRN number:** | **SE-MF-000000725** | | |
| **Competent Authority** | **Medical Products Agency**<br>Sweden | | |

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FOR THE PRODUCT(S)

## 7331791-HME-0-000-0000-X9

| REF | Device name | Class* | GMDN code |
|---|---|---|---|
| 7272 | Provox XtraFlow HME (20 pcs) | I | 58705 |
| 7272-18 | Provox XtraFlow HME (20 pcs) | I | 58705 |
| 7273 | Provox XtraMoist HME (20 pcs) | I | 58705 |
| 7273-18 | Provox XtraMoist HME (20 pcs) | I | 58705 |
| 7290 | Provox XtraMoist HME (30 pcs) | I | 58705 |
| 7290-18 | Provox XtraMoist HME (30 pcs) | I | 58705 |
| 7290ES | Provox XtraMoist HME | I | 58705 |
| 7291 | Provox XtraFlow HME (30 pcs) | I | 58705 |
| 7291-18 | Provox XtraFlow HME (30 pcs) | I | 58705 |
| 7291ES | Provox XtraFlow HME | I | 58705 |
| 8229 | Provox XtraFlow & XtraMoist HME (5+5pcs) | I | 58705 |
| 8229-18 | Provox XtraFlow & XtraMoist HME (5+5pcs) | 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
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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



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Name: DoC Provox XtraHME 7331791-HME-0-000-0000-X9

Document Approvals
Approved Date: 2026-06-16

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|---|---|
| Approval Task<br>Verdict: Approve | HENRIK.HERINGSLACK Henrik Heringslack, Site Director<br>(henrik.heringslack-atosmedical@coloplast.com)<br>Management<br>16-Jun-2026 13:21:58 GMT+0000 |

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| Approval Task<br>Verdict: Approve | SEHRBHNU Ulrika Svensson, Regulatory Affairs Specialist<br>(ulrika.svensson-atosmedical@coloplast.com)<br>Issuer<br>16-Jun-2026 14:36:18 GMT+0000 |