

### **DECLARATION OF CONFORMITY**

FOR THE PRODUCT(S)

# Provox Life Experience Packs

Basic UDI-DI: 7331791-KIT-0-000-0005-J3

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.

Provox Life Adhesives are single use adhesives that provide attachment for Provox Life HMEs and accessories after total laryngectomy.

Hörby, Sweden, date as stated on last page

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

Manufacturer: Atos Medical AB

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SRN number: SE-MF-000000725

Competent Authority Medical Products Agency

Sweden

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#### 7331791-KIT-0-000-0005-J3

| REF  | Device name                              | Class* | GMDN code |
|------|--|--------|-----------|
| 8060 | Provox Life Day & Night Experience Round | 1      | 58705     |
| 8061 | Provox Life Day & Night Experience Oval  | 1      | 58705     |
| 8062 | Provox Life Day & Night Experience Plus  | 1      | 58705     |
| 8063 | Provox Life Day & Night EXP Sensitive    | 1      | 58705     |
| 8064 | Provox Life Day & Night EXP Stability    | I      | 58705     |

<sup>\*</sup>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

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## Document Approvals Approved Date: 2024-12-06

| Approval Task<br>Verdict: Approve | SEHRBHNU Ulrika Svensson, Regulatory Affairs<br>Professional<br>(ulrika.svensson-atosmedical@coloplast.com)<br>Issuer<br>22-Nov-2024 09:12:48 GMT+0000                    |
|-----------------------------------|---|
| Approval Task<br>Verdict: Approve | SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 22-Nov-2024 09:47:07 GMT+0000   |
| Approval Task<br>Verdict: Approve | MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 06-Dec-2024 07:27:39 GMT+0000 |

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