

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox Adhesives

Basic UDI-DI: 7331791-ADH-0-000-0000-CQ

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 Adhesives are single use devices intended for laryngectomized patients breathing through a tracheostoma. The devices are attached to the skin around the tracheostoma in order to provide attachment of components of the Provox HME System.

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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FOR THE PRODUCT(S)

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| REF | Device name | Class* | GMDN code |
|---------|------------------------------------|--------|-----------|
| 7253 | Provox Adhesive Flexiderm Round | 1 | 62175 |
| 7253-18 | Provox Adhesive Flexiderm Round | 1 | 62175 |
| 7254 | Provox Adhesive Flexiderm Oval | 1 | 62175 |
| 7254-18 | Provox Adhesive Flexiderm Oval | 1 | 62175 |
| 7255 | Provox Adhesive Optiderm Round | 1 | 62175 |
| 7255-18 | Provox Adhesive Optiderm Round | 1 | 62175 |
| 7256 | Provox Adhesive Optiderm Oval | 1 | 62175 |
| 7256-18 | Provox Adhesive Optiderm Oval | 1 | 62175 |
| 7253ES | Provox Adhesive Flexiderm Round | 1 | 62175 |
| 7254ES | Provox Adhesive Flexiderm Oval | 1 | 62175 |
| 7254JP | Provox Adhesive Flexiderm Oval | 1 | 62175 |
| 7256JP | Provox Adhesive Optiderm Oval | 1 | 62175 |
| 7331 | Provox Adhesive FlexiDerm Plus | 1 | 62175 |
| 7331-18 | Provox Adhesive FlexiDerm Plus | 1 | 62175 |
| 7332 | Provox Adhesive OptiDerm Plus | 1 | 62175 |
| 7332-18 | Provox Adhesive OptiDerm Plus | 1 | 62175 |
| 7265 | Provox XtraBase Adhesive | I | 62175 |
| 7265-18 | Provox XtraBase Adhesive | 1 | 62175 |
| 8235 | Provox FlexiDerm Oval (3pcs) | 1 | 62175 |
| 8237 | Provox Optiderm Oval (3pcs) | 1 | 62175 |
| 7289 | Provox StabiliBase (15 pcs) | 1 | 62175 |
| 7289-18 | Provox StabiliBase (15 pcs) | 1 | 62175 |
| 7299 | Provox StabiliBase (3 pcs) | 1 | 62175 |
| 7318 | Provox StabiliBase OptiDerm (15pc) | 1 | 62175 |

^{*}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.

Name: DoC Provox Adhesives 7331791-ADH-0-000-0000-CQ

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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| Approval Task Verdict: Approve | SEHRBHNU Ulrika Svensson, Regulatory Affairs Professional (ulrika.svensson-atosmedical@coloplast.com) Issuer 09-May-2025 07:25:35 GMT+0000 | |
|-----------------------------------|---|--|
| Approval Task Verdict: Approve | MARRIC Martin Richardson, VP, International Manufacturing, Sweden, Germany & China (martin.richardson-atosmedical@coloplast.com) Management 09-May-2025 07:55:02 GMT+0000 | |
| Approval Task Verdict: Approve | SEHRBPNH Håkan Persson, Quality Manager (hakan.persson-atosmedical@coloplast.com) Quality 11-May-2025 06:05:45 GMT+0000 | |

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