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

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Henrik Heringslack, Atos Medical Site Manager
on behalf of 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	I	62175
7253-18	Provox Adhesive Flexiderm Round	I	62175
7254	Provox Adhesive Flexiderm Oval	I	62175
7254-18	Provox Adhesive Flexiderm Oval	I	62175
7255	Provox Adhesive Optiderm Round	I	62175
7255-18	Provox Adhesive Optiderm Round	I	62175
7256	Provox Adhesive Optiderm Oval	I	62175
7256-18	Provox Adhesive Optiderm Oval	I	62175
7253ES	Provox Adhesive Flexiderm Round	I	62175
7254ES	Provox Adhesive Flexiderm Oval	I	62175
7254JP	Provox Adhesive Flexiderm Oval	I	62175
7256JP	Provox Adhesive Optiderm Oval	I	62175
7331	Provox Adhesive FlexiDerm Plus	I	62175
7331-18	Provox Adhesive FlexiDerm Plus	I	62175
7332	Provox Adhesive OptiDerm Plus	I	62175
7332-18	Provox Adhesive OptiDerm Plus	I	62175
7265	Provox XtraBase Adhesive	I	62175
7265-18	Provox XtraBase Adhesive	I	62175
7289	Provox StabiliBase (15 pcs)	I	62175
7289-18	Provox StabiliBase (15 pcs)	I	62175
7318	Provox StabiliBase OptiDerm (15pc)	I	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.

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 Number: VV-0544274 Status: Approved Version: 12.0
Name: DoC Provox Adhesives 7331791-ADH-0-000-0000-CQ

Document Approvals

Approved Date: 2026-06-09

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Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 09-Jun-2026 13:25:49 GMT+0000

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