DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Adhesives

Basic UDI: 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:
There are more than one Intended Use in this declaration of conformity. The Intended Use for each group is stated before the group table.

Hörby, Sweden, date as stated on last page

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

Manufacturer:	**Atos Medical AB** Kraftgatan 8, SE-242 35 Hörby Sweden	Telephone: Email: Web:	+46 (0)415 198 00 Info@atosmedical.com www.atosmedical.com
SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

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FOR THE PRODUCT(S)

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Intended Use:
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.

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
8233	Provox XtraBase (3pcs)	I	62175
8234	Provox FlexiDerm Round (3pcs)	I	62175
8235	Provox FlexiDerm Oval (3pcs)	I	62175
8236	Provox Optiderm Round (3pcs)	I	62175
8237	Provox Optiderm Oval (3pcs)	I	62175
8238	Provox FlexiDerm Plus (3pcs)	I	62175
8239	Provox Optiderm Plus (3pcs)	I	62175

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

Intended Use:
The Provox StabiliBase adhesive is a single use device intended for laryngectomized patients breathing through a tracheostoma. The device is attached to the skin around the tracheostoma in order to provide attachment of components of the Provox HME System.

REF	Device name	Class*	GMDN code
7289	Provox StabiliBase (15 pcs)	I	62175
7289-18	Provox StabiliBase (15 pcs)	I	62175
7299	Provox StabiliBase (3 pcs)	I	62175

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

Intended Use:
Provox StabiliBase OptiDerm adhesive is a single use device intended for laryngectomized patients breathing through a tracheostoma. The device is attached to the skin around the tracheostoma in order to provide attachment of components of the Provox HME System.

REF	Device name	Class*	GMDN code
7318	Provox StabiliBase OptiDerm (15pc)	I	62175
7328	Provox StabiliBase OptiDerm (3pcs)	I	62175

*Product Classification according to Annex VIII EU Medical Device Regulation 2017/745

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Intended Use:
The Provox Luna Adhesive is a skin-friendly, single use adhesive that provides attachment for the Provox Luna HME for night-time use after total laryngectomy.

REF	Device name	Class*	GMDN code
8014	Provox Luna Adhesive	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:
Atos Medical UK Ltd Tottle Road
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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: 2.0
Name: DoC Provox Adhesives 7331791-ADH-0-000-0000-CQ

Document Approvals

Approved Date: 2023-08-22

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 22-Aug-2023 15:51:03 GMT+0000

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