DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® Skin Barrier, Provox® Wipes

Basic UDI: 7331791-ADH-A-000-0004-UL

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.

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SRN number:	**SE-MF-000000725**		
Competent Authority	**Medical Products Agency** Sweden		

Document Number: VV-0544752 Status: Approved Version: 3.0
Name: DoC Provox Skin Barrier, Provox Wipes 7331791-ADH-A-000-0004-UL

DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

7331791-ADH-A-000-0004-UL

Intended Use:
Provox Skin Barrier is a single use wipe for laryngectomized patients that forms a barrier between Provox Adhesive and the skin.

REF	Device name	Class*	GMDN code
8011	Provox Skin Barrier	I	58978

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

Intended Use:
Provox Wipes is a combination of Provox Skin Barrier, Provox Adhesive Remover and Provox Cleaning Towel.

Provox Skin Barrier: Provox Skin Barrier is a single use wipe for laryngectomized patients that forms a barrier between Provox Adhesive and the skin.

Provox Adhesive Remover: Provox Adhesive Remover is a single use wipe to help laryngectomized patients remove Provox Adhesives and Provox Silicone Glue.

Provox Cleaning Towel: Provox Cleaning Towel is intended for cleaning around the stoma, it will remove oil from the skin. They are intended to be used before application of Provox Adhesives.

REF	Device name	Class*	GMDN code
8243	Provox Wipes	I	58978

*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:
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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 Approvals

Approved Date: 2023-09-07

Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Quality Assurance Specialist (ulrika.svensson-atosmedical@coloplast.com) Issuer 07-Sep-2023 12:35:38 GMT+0000

Approval Task Verdict: Approve	MARRIC Martin Richardson, SVP, Atos Medical, Global Operations - Corporate VP, Coloplast (martin.richardson-atosmedical@coloplast.com) Management 07-Sep-2023 12:42:52 GMT+0000