DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox® ShowerAid, Provox® Luna® ShowerAid

Basic UDI: 7331791-ADH-A-000-0000-U8

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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Intended Use:
The Provox ShowerAid is used to temporarily replace the Provox XtraMoist/Provox XtraFlow/Provox FreeHands/Provox FreeHands FlexiVoice/Provox Micron HME during showering. The device is for single patient use.

REF	Device name	Class*	GMDN code
7260	Provox ShowerAid	I	62047

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

Intended Use:
The Provox Luna ShowerAid is used with the Provox Luna Adhesive while taking a shower to avoid water from entering the stoma. Single patient use.

REF	Device name	Class*	GMDN code
8016	Provox Luna ShowerAid	I	62047

*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

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 14:05:07 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 18:39:23 GMT+0000