DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox HME Cap

Basic UDI-DI: 7331791-HME-A-000-0002-F2

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:
Provox HME Cap is a single patient use, dome-shaped titanium ring, that allows use of Provox FreeHands HME cassette (REF 8220, 8221) without Provox FreeHands FlexiVoice.

Provox HME Cap is only intended for use when using Provox FreeHands FlexiVoice is not recommended, i.e. when sleeping.

Provox HME Cap cannot be used with any other type of HME cassette. The front opening of the cap can be occluded manually to speak. Provox HME Cap can be cleaned and reused.

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
7730	Provox HME Cap	I	58705

*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

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Name: DoC Provox HME Cap 7331791-HME-A-000-0002-F2

Document Approvals
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