DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox FreeHands FlexiVoice

Basic UDI-DI: 7331791-HME-0-000-0007-XW

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 FreeHands FlexiVoice combines pulmonary rehabilitation using a Heat and Moisture Exchanger with voice rehabilitation using an Automatic Speaking Valve or Manual Occlusion, in laryngectomized patients using a voice prosthesis.

Hörby, Sweden, date as stated on last page

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Henrik Heringslack, Atos Medical Site Manager
on behalf 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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REF	Device name	Class*	GMDN code
7757	Provox FreeHands FlexiVoice Set Plus	I	36071
7760	Provox FreeHands FlexiVoice Set	I	36071
8161	Provox FreeHands FlexiVoice Light	I	36071
8162	Provox FreeHands FlexiVoice Medium	I	36071
8163	Provox FreeHands FlexiVoice Strong	I	36071
8165	Provox FreeHands FlexiVoice Arch (5 pcs)	I	36071
8166	Provox FreeHands FlexiVoice XtraStrong	I	36071
8210	Provox Life FreeHands FlexiVoice Set Plus	I	36071

*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-0544264 Status: Approved Version: 8.0
Name: DoC Provox FreeHands FlexiVoice 7331791-HME-0-000-0007-XW

Document Approvals

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