DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

Provox Coming Home

Basic UDI-DI: 7331791-KIT-0-000-0000-HL

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 Coming Home is an assortment of products and information for newly laryngectomized persons. It provides guidance on product use, lung rehabilitation, and stoma care at home.

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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REF	Device name	Class*	GMDN code
8224DERW	Provox Life Coming Home German	I	58705
8224DK	Provox Life Coming Home Denmark	I	58705
8224ENRW	Provox Life Coming Home English	I	58705
8224FI	Provox Life Coming Home Finland	I	58705
8224FRRW	Provox Life Coming Home French	I	58705
8224HU	Provox Life Coming Home Hungary	I	58705
8224IT	Provox Life Coming Home Italian	I	58705
8224JP23	Provox Life Coming Home Japan	I	58705
8224NL	Provox Life Coming Home Dutch	I	58705
8224NO	Provox Life Coming Home Norway	I	58705
8224SE	Provox Life Coming Home Sweden	I	58705
8224US21	Provox Life Coming Home USA	I	58705
8224CA	Provox Coming Home Canada	I	58705
8224DE	Provox Coming Home Germany	I	58705
8224EM	Provox Coming Home Generic	I	58705
8224ES	Provox Coming Home Spain	I	58705
8224FR	Provox Coming Home France	I	58705
8224JP	Provox Coming Home Japan	I	58705
8224PL	Provox Coming Home Poland	I	58705
8224PT	Provox Coming Home Portugal	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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Document Approvals
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