
DECLARATION OF CONFORMITY

FOR THE PRODUCT(S)

TrachPhone

Basic UDI-DI: 7331791-HME-0-000-0006-XT

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 1.8 of Schedule 3 to the Australian Therapeutic Goods (Medical Devices) Regulations 2002 including amendments in effect at the issuance date.

Intended use/purpose:

TrachPhone is a single use Heat and Moisture Exchanger (HME) which is intended for pulmonary rehabilitation in patients self-ventilating through a tracheostoma.

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**

Notified Body: **DNV Product Assurance AS**
Identification no. 2460

Notified Body certificate C520850
number:

Conformity Assessment Procedure: Quality management system and on assessment of technical documentation as per Annex IX

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REF	Device name	Class*	GMDN code
7704	TrachPhone (50 pcs)	Ila	58705
7707	TrachPhone (30 pcs)	Ila	58705
7723	TrachPhone (5 pcs)	Ila	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.

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: 2026-10-04

Approval Task Verdict: Approve	SOFTHO Sofia Thomasson, Regulatory Affairs Specialist (sofia.thomasson-atosmedical@coloplast.com) Issuer 02-Oct-2026 10:08:06 GMT+0000
Approval Task Verdict: Approve	HENRIK.HERINGSLACK Henrik Heringslack, Site Director (henrik.heringslack-atosmedical@coloplast.com) Management 02-Oct-2026 13:42:48 GMT+0000
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