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EU Declaration of Conformity

Nox Medical

Katrinartuni 2, IS-105, Reykjavik, Iceland

SRN: IS-MF-000000950

hereby declares under its sole responsibility that the medical device(s) listed below comply with the following Union legislation(s):

Medical Device Regulation (EU) 2017/745

Product Name	Trade Name/Mark	Technical Name	Catalog Number	Basic UDI-DI
Nox Filter Tube Connector	NA	FTC50	55 21 10	1569431111NOX_FTCS8

Intended Purpose

The intended use of the Nox Filter Tube Connectors is to allow for the connection of luer-lock nasal pressure cannulas/mask pressure tubes to Nox sleep devices.

The Nox Filter Tube Connectors are intended to be used in hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.

Risk Classification

The Nox Filter Tube Connector is categorized as ***Class I***, according to ***Rule 1: Non-invasive devices*** of Annex VIII of the Medical Device Regulation (EU) 2017/745.

Standards/Common Technical Specifications (CTS) Used

- ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 14971:2019+A11:2021 Medical devices – Application of risk management to medical devices
- ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied.
- EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer
- EN 62366-1:2015 +A1:2020 Medical devices — Part 1: Application of usability engineering to medical devices

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Additional Information:

Nox Medical holds an ISO 13485:2016/MDSAP certified Quality Management System (certificate no. MDSAP 688545) for the following scope:

The design and manufacture of pediatric and adult sleep diagnostic devices.

Reykjavik 3 Febr. 2023 — Kolbrún Eydís Ottósdóttir

Place and Date of Issue

Kolbrún Eydís Ottósdóttir
Chief Compliance Officer Nox Medical