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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 listed below complies with the following Union legislations:

Medical Device Regulation (EU) 2017/745

Directive 2015/863/EU (RoHS 3)

Product Name	Trade Name/ Mark	Technical Name	Catalog Number	Basic UDI-DI
Nox Nasal Pressure Cannula with Filter	N/A	NOX-MDR_CANAF	N/A	1569431111NOX_CANNULASWP
Nox Nasal Pressure Cannula with Filter, package of 40 units	N/A	NOX-MDR_CANAF40	552011	1569431111NOX_CANNULASWP

Intended Purpose

The intended use of the Nox Nasal Pressure Cannula with Filter is to allow for the measuring of respiratory airflow when connected to a pressure port of a sleep recorder during a sleep study. The cannula is intended for single patient use only.

The Nox Nasal Pressure Cannula with Filter is intended for adult patients.

The Nox Nasal Pressure Cannula with Filter is intended to be used in hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.

Risk Classification and Conformity Assessment Procedure

The Nox Nasal Pressure Cannula with Filter is categorized as ***Class IIa***, according to ***Rule 5: Invasive Devices*** of Annex VIII of the Medical Device Regulation (EU) 2017/745.

The conformity assessment has been undertaken via **ANNEX IX, Chapters I and III,** of the Medical Device Regulation (EU) 2017/745.

Nox Medical is certified by BSI to place Class IIa medical devices on the market (certificate no. MDR 786178 R000), which includes: Polysomnographic device, Polysomnographic device – Software, and Polysomnographic device – Accessories.

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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
- EN ISO 15223-1:2021 Medical devices — Symbols to be used with medical device labels, labelling 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
- EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2023 Biological evaluation of medical devices — Part 10: Tests for skin sensitization
- EN ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation

Notified Body:

BSI
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
NB Number: 2797

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 and therapeutic devices.

Reykjavik 2026-02-02 Róbert Magnússon

Place and Date of Issue

Róbert Magnússon
VP of Quality and Regulatory Affairs
Nox Medical