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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

Product Name	Trade Name/Mark	Technical Name	Catalog Number	Basic UDI-DI
DeepRESP	N/A	DEEPRESP	N/A	1569431111NOXTURNAL2M

Intended Purpose

DeepRESP is intended as an aid in diagnosis of sleep disorders. Its main purpose is to retrieve and automatically analyse/score sleep study data recorded by Nox Medical devices. The results of the analysed data are transferred to another software for display, manual verification and scoring, and reporting.

Risk Classification and Conformity Assessment Procedure

The DeepRESP is categorized as ***Class IIa***, according to ***Rule 11: Software for diagnostic/therapeutic/monitoring purposes*** 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 Devices Regulation (EU) 2017/745.

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

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 62304:2006+A1:2015 Medical device software - Software life-cycle processes

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- EN ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer
- IEC 82304-1:2016 Health Software - Part 1: General requirements for product safety
- IEC 81001-5-1:2021 – Health software and health IT systems safety, effectiveness and security - Part 5-1: Security. Activities in the product life cycle
- ISO/IEC 29147:2018 Information technology - Security techniques - Vulnerability disclosure

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 2025-12-19 — Róbert Magnússon

Place and Date of Issue

Róbert Magnússon
VP of Quality & Regulatory Affairs Nox Medical