

EU Declaration of Conformity

Nox Medical

Katrinartuni 2, IS-105, Reykjavik, Iceland

SRN: IS-MF-00000950

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
Noxturnal Web	N/A	NOXTURNAL_WEB	N/A	1569431111NOXTURNAL2M

Intended Purpose

Noxturnal Web is intended as an aid in diagnosis of sleep disorders. Its main purpose is to allow for the display, and manual analysis/scoring, of the sleep study data recorded by Nox Medical devices. Additionally, it allows for the navigation, organization, reporting and interpretation of sleep study data/recordings.

Risk Classification and Conformity Assessment Procedure

The Noxturnal Web 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 Device 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 62366-1:2015+A1:2020 Medical devices — Part 1: Application of usability engineering to medical devices
- 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