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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

EU Directive 2015/863 (RoHS 3)

Product Name	Trade Name/Mark	Technical Name	Catalog Number	Basic UDI-DI
Nox Mini USB Cable	NA	USBCPAC1	56 20 11	1569431111NOX_ITCABLESXM

Intended Purpose

The Nox Mini USB Cable is used to connect Nox sleep devices to a PC for device configuration and data download from the device.

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments.

Risk Classification

The Nox Mini USB Cable 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 60601-1:2006/A1:2013/A11:2011/A12:2014 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

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- EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 60601-1-6:2010+A1:2015 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 62366-1:2015 +A1:2020 Medical devices — Part 1: Application of usability engineering to medical devices

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