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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 SAS Body Cable – Right	NA	ESNAP4SASRMPAC1	56 22 13	1569431111NOX_SASCABLESCE
Nox SAS Body Cable – Left	NA	ESNAP4SASLMPAC1	56 22 14	1569431111NOX_SASCABLESCE
Nox SAS Head Cable	NA	ESNAP10SASLMPAC1	56 22 15	1569431111NOX_SASCABLESCE

Intended Purpose

The Nox SAS Body Cables are intended to enable the recording of EMG/ECG signals during sleep studies. The Nox SAS Body Cables are used with the Nox A1s recorder, the Nox SAS Head Cable, and the Nox SAS Electrode Pack. The Nox SAS Body Cables are indicated for use in adult patients. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient´s home.

The Nox SAS Head Cable is intended to enable the recording of EEG/EMG signals during sleep studies. The Nox SAS Head Cable is used with the Nox A1s recorder, the Nox SAS Body Cables, and the Nox SAS Electrode Pack. The Nox SAS Head Cable is indicated for use in adult patients. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient´s home.

Risk Classification

The Nox SAS Body Cables are categorized as ***Class I***, according to ***Rule 1: Non-invasive devices*** of Annex VIII of the Medical Device Regulation (EU) 2017/745.

The Nox SAS Head 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

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- 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 + Cor:2010 + A1:2013 + A12:2014 + AC:2014 + A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN 60601-1-11:2015 + A1:2021 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- EN 60601-1-2:2015+A1:2021 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+A2:2021 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
- 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

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 12 May 2023 — Kolbrún E. Ottósdóttir

Place and Date of Issue

Kolbrún Eydís Ottósdóttir
Chief Compliance Officer Nox Medical