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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 Electrode Pack	NA	ELPACK	N/A	1569431111NOX_SASCABLESCE
Nox SAS Electrode Pack, 20 Units	NA	ELPACKKIT20	55 90 43	1569431111NOX_SASCABLESCE

Intended Purpose

The Nox SAS Electrode Pack includes Nox SAS Electrodes and Nox SAS Adhesive Strips. The Nox SAS Electrode Pack is used with the Nox SAS Cables to allow measuring of EMG/ECG/EEG signals during sleep studies. The Nox SAS Adhesive Strips are intended to secure the Nox SAS Cables that attach to the Nox SAS Electrodes to minimize the odds of the electrodes falling off the subject during sleep studies. The Nox SAS Electrode Pack 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 Electrode Pack 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.

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- 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