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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 Snap-on Lead 50cm (20in), White	NA	ESNAP7PAC2	55 40 20	1569431111NOX_EXGCABLES9M
Nox Snap-on Lead 30cm (12in), Beige-White	NA	PESNAP7PAC2	55 40 21	1569431111NOX_EXGCABLES9M
Nox Snap-on Lead 100cm (40in), Green	NA	ESNAP8PAC1	55 40 22	1569431111NOX_EXGCABLES9M
Nox Snap-on Lead 50cm (20in), Beige-Green	NA	PESNAP8PAC1	55 40 23	1569431111NOX_EXGCABLES9M
Nox Snap-on Lead 150cm (60in), Grey	NA	ESNAP9PAC2	55 40 24	1569431111NOX_EXGCABLES9M
Nox Snap-on Lead 100 cm (40in), Beige-Grey	NA	PESNAP9PAC2	55 40 25	1569431111NOX_EXGCABLES9M
Nox Snap-on Lead 150cm (60in), Black	NA	ESNAP10PAC2	55 40 26	1569431111NOX_EXGCABLES9M
Nox Snap-on Lead 100cm (40in), Beige-Black	NA	PESNAP10PAC2	55 40 27	1569431111NOX_EXGCABLES9M

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Nox Snap-on Lead 100cm (40in), Orange	NA	ESNAP11PAC2	55 40 28	1569431111NOX_EXGCABLES9M
Nox Snap-on Double Lead 50/100cm (20/40in), Orange	NA	ESNAP1PAC1	55 43 10	1569431111NOX_EXGCABLES9M
Nox Snap-on Double Lead 30/50cm (12/20in), Beige-Orange	NA	PESNAP1PAC1	55 43 11	1569431111NOX_EXGCABLES9M
Nox Snap-on Double Lead 148/150cm (58/60in), Grey	NA	ESNAP2PAC1	55 43 12	1569431111NOX_EXGCABLES9M
Nox Snap-on Double Lead 98/100cm (39/40in), Beige-Grey	NA	PESNAP2PAC1	55 43 13	1569431111NOX_EXGCABLES9M
Nox Snap-on Double Lead 148/150cm (58/60in), Black	NA	ESNAP3PAC1	55 43 14	1569431111NOX_EXGCABLES9M
Nox Snap-on Double Lead 98/100cm (39/40in), Beige-Black	NA	PESNAP3PAC1	55 43 15	1569431111NOX_EXGCABLES9M
Nox Snap-on Double Lead 50/52cm (20/21in), White	NA	ESNAP4PAC1	55 43 16	1569431111NOX_EXGCABLES9M
Nox Snap-on Double Lead 30/32cm (12/13in), Beige-White	NA	PESNAP4PAC1	55 43 17	1569431111NOX_EXGCABLES9M
Nox A1 EEG Head Cable, Adult	NA	APSGH1PAC1	56 21 10	1569431111NOX_EXGCABLES9M
Nox A1 EEG Head Cable, Pediatric	NA	PPSGH1PAC1	56 21 11	1569431111NOX_EXGCABLES9M
Nox A1 EEG 5 Lead Gold Electrode Cable	NA	ECUP5AU1PAC1	55 44 11	1569431111NOX_LEADSW5

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Intended Purpose

The Nox Snap-on Leads are intended to enable recording of EMG/ECG signals during sleep studies. The leads are used with industry standard stud electrode pads.
The Nox Snap-on Leads are indicated for use in pediatric and adult patients.
The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.

The Nox A1 EEG Head Cables are intended to interconnect Nox A1 EEG 5 Lead Gold Electrode Cables and Nox sleep devices, to allow measuring of EEG signals. The Nox A1 EEG Head Cables are indicated for use on patients greater than 2 years of age. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.

The Nox A1 EEG 5 Lead Gold Electrode Cables are intended for measuring EEG signals. They function as accessories for Nox sleep devices. The Nox A1 EEG 5 Lead Gold Electrode Cables are indicated for use in patients greater than 2 years of age. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.

Risk Classification

The Nox Snap-on Leads 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 A1 EEG Head 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 A1 EEG 5 Lead Gold Electrode Cables are 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 + 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

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- 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
- ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

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 February 2023 — Kolbrún Eydís Ottósdóttir

Place and Date of Issue

Kolbrún Eydís Ottósdóttir
Chief Compliance Officer Nox Medical