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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 RIP Belts Disposable - Size Pediatric - 20 sets	NA	RIPDP20	55 10 10	1569431111NOX_RIPBELTS6W
Nox RIP Belts Disposable - Size Small - 20 sets	NA	RIPDS20	55 10 20	1569431111NOX_RIPBELTS6W
Nox RIP Belts Disposable - Size Medium - 20 sets	NA	RIPDM20	55 10 30	1569431111NOX_RIPBELTS6W
Nox RIP Belts Disposable - Size Large - 20 sets	NA	RIPDL20	55 10 40	1569431111NOX_RIPBELTS6W
Nox RIP Belts Disposable - Size Extra Large - 14 sets	NA	RIPDXL14	55 10 50	1569431111NOX_RIPBELTS6W
Nox RIP Belts Disposable - Size Pediatric - 1 set	NA	RIPDP2	95 10 12	1569431111NOX_RIPBELTS6W
Nox RIP Belts Disposable - Size Small - 1 set	NA	RIPDS2	95 10 22	1569431111NOX_RIPBELTS6W
Nox RIP Belts Disposable - Size Medium - 1 set	NA	RIPDM2	95 10 32	1569431111NOX_RIPBELTS6W

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Nox RIP Belts Disposable - Size Large - 1 set	NA	RIPDL2	95 10 42	1569431111NOX_RIPBELTS6W
Nox RIP Belts Disposable - Size Extra Large - 1 set	NA	RIPDXL2	95 10 52	1569431111NOX_RIPBELTS6W
Nox Abdomen Cable	NA	ATC1PAC1	56 20 10	1569431111NOX_RIPCABLESEU
Nox Abdomen Cable, s	NA	ATC1SPAC1	56 12 12	1569431111NOX_RIPCABLESEU

Intended Purpose

The Nox RIP Belts Disposable are intended for measuring of respiratory effort signals. They function as accessories for sleep/polysomnography (PSG) systems. The Nox RIP Belts Disposable 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 Abdomen Cables are intended to interconnect Nox RIP Belts Disposable (respiratory effort sensors) and Nox sleep devices, to allow measuring of respiratory effort signals. The Nox Abdomen 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.

Risk Classification

The Nox RIP Belts Disposable 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 Abdomen 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
- EN60601-1:2006+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

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- 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

* ATC1PAC1: EN 60601-1:2006/A1:2013/A11:2011/A12:2014 , EN 60601-1-11:2015, EN 60601-1-6:2010+A1:2015 and EN 60601-1-2:2015

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.

Rvk 2 March 2023 — Kolbrún E Ottósdóttir

Place and Date of Issue

Kolbrún Eydís Ottósdóttir
Chief Compliance Officer Nox Medical