nox medical

Declaration of Conformity

-Medical Device Directive 93/42/EEC-

Nox Medical
Katrinartuni 2, IS-105, Reykjavik, Iceland

confirms that the products listed below that bear the CE marking conform to the Essential Requirements defined within Annex I of the European Council Directive 93/42/EEC of 14 June 1993, amended by Directive 2007/47/EC, concerning medical devices.

Product Name	Catalog Number	UDI
Noxturnal	N/A	(01)15694311110255(8012)VVvvrr
Noxturnal CD	53 90 10	(01)15694311110255(8012)VVvvrr(11)YYMMDD(10)YYMMDD

Risk Classification and Conformity Assessment Procedure

Noxturnal and Noxturnal CD are categorized as ***Class IIa***, according to ***Rule 10: Active device intended for diagnosis***. The conformity assessment has been undertaken via ***Annex II*** of the Council Directive 93/42/EEC.

Name and Address of Notified Body

BSI
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

Applicable CE Certificates

Nox Medical is certified to ***Full Quality Assurance*** by BSI (certificate no. CE 532571), i.e. to fully comply with the requirements of Council Directive 93/42/EEC, Annex II, section 3.2 in respect of:

Design and manufacture of sleep diagnostic devices.

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.

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Relevant Harmonized Standards/Common Technical Specifications (CTS)

- ✓ ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
- ✓ 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 60601-1-6:2010 + A1:2015 + A2:2021 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ✓ EN ISO 14971:2019 + A11:2021 Medical devices - Application of risk management to medical devices
- ✓ EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
- ✓ EN 62304:2006 + A1:2015 Medical device software - Software life cycle processes
- ✓ EN 62366-1:2015+A1:2020 Medical Devices – Part 1: Application of usability engineering to medical devices
- ✓ ANSI/AAMI SW96:2023 Standard for medical device security—Security risk management for device manufacturers
- ✓ IEC 81001-5-1:2021 – Health software and health IT systems safety, effectiveness and security —Security.
- ✓ ISO/IEC 29147:2018 Information technology - Security techniques - Vulnerability disclosure
- ✓ AAMI TIR57:2016 Principles for Medical Device Security – Risk Management
- ✓ IEC 82304-1:2016 Health Software — General requirements for product safety

This Declaration of Conformity is under the sole responsibility of Nox Medical.

Reykjavik 18 December 2024 — Kolbrún E. Ottósdóttir

Place and Date of Issue

Kolbrún Eydís Ottósdóttir
Chief Compliance Officer Nox Medical

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