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
Nox A1s Recorder	56 14 11	(01)15694311111559(11)YYMMDD(21) 1xxxxxxxx

Risk Classification and Conformity Assessment Procedure

The Nox A1s recorder is 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 Group The Netherlands B.V
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.

Nox Medical, Katrinartuni 2, IS-105, Reykjavik, Iceland, +354-570-7170, www.noxmedical.com

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 60601-1-2:2015 + 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 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 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 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices
- ✓ 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
- ✓ EN 301 489-1 V2.2.3:2019-11 Electromagnetic compatibility and radio spectrum matters (ERM); Electromagnetic compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- ✓ EN 301 489-17 V3.2.4:2020-09 Electromagnetic compatibility and radio spectrum matters (ERM) Electromagnetic compatibility (EMC) standard for radio equipment Part 17: Specific conditions for broadband data and Transmission systems
- ✓ EN 300 328 V2.2.2:2019 Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques
- ✓ EN 62479:2010 Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz–300 GHz)
- ✓ Bluetooth® compliance Qualified Design Listing (QD ID): D046760
- ✓ 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

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

Nox Medical, Katrinartuni 2, IS-105, Reykjavik, Iceland, +354-570-7170, www.noxmedical.com

Reykjavik 23 August 2024 Kolbrún E. Ottósdóttir

Place and Date of Issue

Kolbrún Eydís Ottósdóttir
Chief Compliance Officer, Nox Medical

Nox Medical, Katrinartuni 2, IS-105, Reykjavik, Iceland, +354-570-7170, www.noxmedical.com