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 A1® Recorder	56 14 10	(01)15694311110873(11)YYMMDD(21) 992xxxxxx
Nox A1® Demo Recorder	56 14 19	(01)15694311110880(11)YYMMDD(21) 972xxxxxx

Risk Classification and Conformity Assessment Procedure

The Nox A1 recorders 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 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:

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

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The design and manufacture of pediatric and adult sleep diagnostic devices.

Relevant Harmonized Standards/Common Technical Specifications (CTS)

- ✓ EN 60601-1:2006+A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ✓ EN 60601-1-2:2015 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 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ✓ EN 60601-1-11:2010 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 (except clause 8.3.1)
- ✓ EN ISO 14971:2019 Medical devices - Application of risk management to medical devices
- ✓ EN ISO 15223-1:2012 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 62366:2008+A1:2015 Medical devices - Application of usability engineering to medical devices
- ✓ EN 301 489-01 V2.1.1 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 V3.1.1 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 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): B012394

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

Reykjavik 31 August 2023 Kolbrún E. Ottósdóttir

Place and Date of Issue

Kolbrún Eydís Ottósdóttir
Chief Compliance Officer, Nox Medical

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