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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 T3® Recorder	56 10 10	(01)15694311110835(11)YYMMDD(21)902xxxxxx
Nox T3® Demo Recorder	56 10 19	(01)15694311110897(11)YYMMDD(21)982xxxxxx

Risk Classification and Conformity Assessment Procedure

The Nox T3 Recorder and Nox T3 Demo Recorder 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)

- ✓ EN 60601-1:2006 / A1:2013 / A11:2011 / A12:2014 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
- ✓ ETSI EN 301 489-1 V2.1.1 Electromagnetic compatibility and radio spectrum matters (ERM); Electromagnetic compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- ✓ ETSI 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
- ✓ ETSI 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 spread spectrum modulation techniques
- ✓ EN 62479:2010 (First Edition) 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® EPL (End Product Listing) based on Qualified Design ID: B012394

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

Reykjavik 15. Dec 2021 — Kolbrún E. Ottósd.

Place and Date of Issue

Kolbrún Eydís Ottósdóttir
Chief Compliance Officer Nox Medical

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