

# Declaration of Conformity

-Medical Device Directive 93/42/EEC-

## Nox Medical Katrínartúni 2, IS-105, Reykjavík, 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 T3s Recorder	56 10 11	(01)15694311111436(11)YYMMDD(21) 300xxxxxx

### Risk Classification and Conformity Assessment Procedure

The Nox T3s 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  
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.***

## 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 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: 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.

Reykjavík 23 August 2024

Place and Date of Issue

Kolbrún E. Ottósdóttir

Kolbrún Eydís Ottósdóttir  
Chief Compliance Officer, Nox Medical