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.

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

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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

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

Reykjavik, 15 Nóvemb. 2022 Kolbrún E. Ottósd.

Place and Date of Issue

Kolbrún Eydís Ottósdóttir
Chief Compliance Officer Nox Medical

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