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Declaration of Conformity

-Medical Device Directive 93/42/EEC-

Scope: Nox Cannulas

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 Nasal Pressure Cannula with Filter – 40 units	55 20 10	(01) 15694311110224 (11)YYMMDD(10)YYMMDD

Risk Classification and Conformity Assessment Procedure

The Nox Nasal Pressure Cannulas are categorized as ***Class IIa***, according to ***Rule 5: Invasive devices***. 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

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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)

- ✓ EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ✓ 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 62366:2008+A1:2015 Medical devices – Application of usability engineering to medical devices *(only applicable to the Nox Nasal Pressure Cannula with Luer-Lock)*
- ✓ EN 62366-1:2015+A1:2020 Medical devices – Part 1: Application of usability engineering to medical devices *(only applicable to the Nox Nasal Pressure Cannula with Filter)*

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

Reykjavik 24. Sept 24 — Kolbrún E. Ottósdóttir

Place and Date of Issue

Kolbrún Eydís Ottósdóttir
Chief Compliance Officer Nox Medical

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