

Declaration of Conformity

-Medical Device Directive 93/42/EEC-

**Nox Medical
Vatnagordum 18
IS-104, Reykjavik, Iceland**

confirm 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, 14 June 1993, and as amended by 2007/47/EC, concerning Medical Devices.

Product Type	Technical Names
NOX Nasal Pressure Cannula with Filter	NOX-CANAF
NOX Nasal Pressure Cannula with Luer Lock	NOX-CANA
NOX Filter Tube Connector	NOX-FTC

The products are categorized as ***Class I***, according to: ***Rule 1: Non-invasive devices***. The conformity assessment has been undertaken via ***Annex VII*** of the Council Directive 93/42/EEC.

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.

Furthermore Nox Medical holds an ISO 13485:2003/CMDCAS certified Quality Management System (Certificate No. FM540789) for the following scope:

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

Kolbrún Eydís Ottósdóttir
Regulatory Manager
Nox Medical

SUMMARY TESTING, VERIFICATION AND VALIDATION

The overall design and development process of the NOX cannulas/filter tube connector was according to internal quality management processes compliant with

- ✓ ISO 13485:2003
- ✓ Medical Device Directive (MDD)
- ✓ FDA Quality System Regulation (QSR)
- ✓ Canada Medical Device Regulation (CMDR)

The Nox cannulas/filter tube connector have been tested and verified in various phases to include internal testing, verification and validation as well as external testing to assure product safety, effectiveness and reliability. The design was verified and validated, including clinical evaluation, throughout the design process according to requirement specifications and intended use.

Simulated use testing of the Nox cannulas/filter tube connector has been conducted in a simulated clinical environment. The purpose with the validation was to make sure no unexpected difficulties arise and that the performance is as expected in the clinical environment. Cons and pros were reported and issues feed into formal process.

Clinical evaluation has been performed for the NOX cannulas/filter tube connector as part of the Nox T3™ system. The conclusion from the clinical evaluation for the T3 System is as follow:

“This clinical evaluation shows that all of the signals, analyses and parameters used in the current Nox T3™ and Noxturnal™ products have roots in widely approved standards for sleep diagnostics supported by relevant scientific literature.”

Usability testing according to “IEC 62366:2007: Medical devices – Application of usability engineering to medical devices” was performed to ensure reasonable usability of the Nox cannulas/filter tube connector, to minimize use errors and use-associated risks and to provide safety for the patient, user and others related to usability. The output of the usability process is fed back into the design process as needed to receive the usability goals for the product.

Usability testing has been undertaken for the Nox cannulas/filter tube connector as part of the NOX T3 System and is now completed with all usability goals passed.

The Nox cannulas are categorized as surface products in direct contact to mucosal membrane with a limited duration of contact, i.e. less than 24 hours. The same applies to the filter tube connector except it is in indirect contact to the mucosal membrane.

The NOX cannulas and filter tube connector are made of polymers. No parts contain latex. They are BPA/Phtalates free and parts that are in direct contact to mucosal membrane have gone through biocompatibility/toxicity testing. No parts are delivered sterile or need sterilization before use. Product delivered clean and ready for use. The NOX cannulas and filter tube connector are designed and manufactured with predefined stipulation for cleanliness.

The Nox cannulas/filter tube connector are thus deemed safe regarding biocompatibility and biology.

Risk analysis was performed for the Nox cannulas/filter tube connector according to "ISO14971:2009 Medical devices — Application of risk management to medical devices". As a result appropriate measures were implemented and their effectiveness verified and validated.

Appropriate methods are in place to obtain relevant production and post-production information

The overall residual risk posed by the medical devices has been evaluated, after all risk control measures have been implemented and verified. The remaining risk is found to be acceptable and out weighted by the benefits of using the Nox cannulas/filter tube connector and is in compliance with the company's criteria for risk acceptability. The Nox cannulas/filter tube connector is thus considered safe and effective for its intended use.

LIST OF STANDARDS

The Nox cannulas/filter tube connector comply with the following ***standards*** :

- ✓ ISO 14971:2009 Medical Devices - Application of risk management to medical devices
- ✓ EN 62366:2008 Medical devices - Application of usability engineering to medical devices
- ✓ ISO 15223-1:2007 and A1:2008- Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied

STATEMENT

The safety and effectiveness of the latest released Nox cannulas/filter tube connector have been demonstrated by thorough internal and external testing, verification, risk analysis, validation and clinical evaluation, according to its specification and intended use.

Furthermore the latest released Nox cannulas/filter tube connector are found to be in compliance with the following standards:

- ✓ ISO 14971:2009 Medical Devices - Application of risk management to medical devices
- ✓ EN 62366:2008 Medical devices - Application of usability engineering to medical devices
- ✓ ISO 15223-1:2007 and A1:2008- Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied

Based on all the verification testing, validation and clinical evaluation performed the latest released Nox cannulas/filter tube connector are deemed safe and effective for its intended use.

This statement applies to the newest release of the Nox cannulas/filter tube connector controlled within the internal projects: Watermark Release (2011-029).



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