

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

NOX RIP Semi-disposable Belts
– Version 0120

Technical Names and Description

Set of two belts: NOX-PRIP1, NOX-MRIP1 and NOX-ARIP1
Packages of 10 sets of belts: NOX-RIPS10, NOX-RIPM10 and NOX-RIPL10

NOX RIP Disposable Belts
– Version 0110

Single belts: NOX-RIPDP, NOX-RIPDS, NOX-RIPDM and NOX-RIPDL
Packages of 20 sets of belts: NOX-RIPDP20, NOX-RIPDS20, NOX-RIPDM20 and NOX-RIPDL20

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.

The products listed above are categorized as **Class I**, according to: **Rule 12: All other active devices are in Class I**. The conformity assessment has been undertaken via **Annex VII** of the Council Directive 93/42/EEC.

Kolbrún Eydís Ottósdóttir
Regulatory Manager
Nox Medical

SUMMARY TESTING, VERIFICATION AND VALIDATION

The overall design and development process of the NOX RIP belts 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 RIP belts 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 RIP belts 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.

Signal comparison studies results demonstrate the reliability and usability of the respiratory effort signals recorded with the NOX RIP belts in combination with the Nox T3™ system.

Clinical evaluation has been performed for the NOX RIP belts as part of the Nox T3™ system. This evaluation included comparison for Apnea/Hypopnea scoring of Noxturnal™ as reflected by the Apnea/Hypopnea Index (AHI) compared to manual scoring of full Embla N70000 PSG data, published literature and post marketing feedback. 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 RIP belts, 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 was fed back into the design process as needed to receive the usability goals for the product. Usability testing has been completed for the RIP belts with all usability goals passed.

The NOX RIP belts are intended to be worn over clothing and are thus in no direct contact to the patient's skin. Only standard materials are used for products components. No part contains latex. No parts sterilized or need sterilization before use. The NOX RIP belts are designed and manufactured with predefined stipulation for cleanliness. The Nox RIP belts are categorized as surface products in indirect contact to skin with a limited duration of contact, i.e. less than 24 hours. Result of biocompatibility evaluation (type of product and materials used) requires no additional biocompatibility tests to be performed on the products. The NOX RIP belts are thus deemed safe regarding biocompatibility and biology.

Risk analysis was performed for the NOX RIP belts 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 device 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 RIP belts and is in compliance with the company's criteria for risk acceptability. The NOX RIP belts are thus considered safe and effective for its intended use.

LIST OF STANDARDS

The NOX RIP belts comply with the following **standards**:

- ✓ EN 60601-1:2006 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- ✓ IEC 60601-1-2:2007:Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ✓ 21CFR898:2007 – FDA Performance standard for electrode lead wires and patient cables
- ✓ ISO 14971:2009 Medical Devices - Application of risk management 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
- ✓ EN 62366:2008 Medical devices - Application of usability engineering to medical devices

STATEMENT

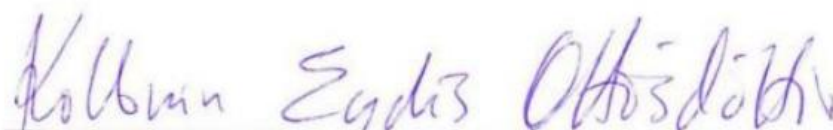
All design changes to the original NOX RIP belts have been controlled within an ISO 13485:2003 Quality Management System that strives to comply with all applicable requirements of MDD, FDA QSR and CMDR.

The safety and effectiveness of the latest released NOX RIP Belts has 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 RIP belts are found to be in compliance with all applicable standards.

Based on all the verification testing, validation and clinical evaluation performed the latest released NOX RIP belts is deemed safe and effective for its intended use.

This statement applies to the newest release of the NOX RIP belts controlled within the internal project: Watermark (2011-029).



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