NOXtec Development S.L.
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EU Declaration of Conformity

We, **NOXTEC DEVELOPMENT SL,** manufacturer SRN ES-MF-000009476, located in Guadarrama 22-24, Moralzarzal, 28411-Madrid, Spain, with a Quality Management System implemented in compliance with the requirements specified in EN ISO 13485:2016 standard,

Declare under our sole responsibility, that the products/devices described in the following tables:

Model	Description	Basic UDI - DI
NOXtec 1000	NO monitor and dosing with Automatic delivery system	8437023061100OLW
NOXtec 2000	NO monitor and dosing with Semiautomatic and Manual delivery system	8437023061200OM5
NOXtec 3000	NO monitor	8437023061300OMC

Are in conformity with **REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017** on medical devices.

Devices NOXtec 1000 and 2000 are classified as **IIb** in accordance with the **rule 12** of the Annex VIII.

Device NOXtec 3000 is classified as **Im** in accordance with the **rule 13** of the Annex VIII.

Are in conformity with the following standards:

- UNE-EN 60601-1-6:2010/A2:2021 (Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance-Collateral standard: Usability)
- UNE-EN 60601-1:2006/A2:2021 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Collateral standard- Electromagnetic disturbances - Requirements and tests).
- IEC 62304:2007/A1:2016 (Medical device software-Software life-cycle processes).
- UNE-EN 62366-1:2015/A1:2020 (Medical devices-Part 1: Application of usability engineering to medical devices).
- UNE-EN 61000-4-3:2020 (Electromagnetic compatibility (EMC)-Part 4-3: Testing and measurement techniques - Radiated. radiofrequency, electromagnetic field immunity test).
- UNE- EN 61000-3-3:2013/A2:2022 (Electromagnetic compatibility (EMC)-Part 3-3: Limits -Limitation of voltage changes. voltage fluctuations and flicker in public low voltage supply systems for equipment with rated current <=16A per phase and not subject to conditional connection).
- UNE-EN 61000-4-11:2021/AC2022-10 (Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques-Voltage dips, short interruptions and voltage variations immunity tests).
- UNE-EN 61000-4-4:2013 (Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test).
- UNE-EN 61000-4-6:2014 (Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields).
- UNE-EN 61000-4-5:2015.A1:2018 (Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test).
- UNE-EN 61000-4-8:2011 (Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test).
- UNE-EN 55011:2016/A2:2021 (Industrial, scientific and medical equipment - Radio- frequency disturbance characteristics -Limits and methods of measurements).

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- IEC 60601-1-8:2007/A2:2021 (Medical electrical equipment Part 1-8: General requirements for basic safety and essential performance-Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment; and medical electrical systems).
- UNE-EN 60601-1-2:2015/A1:2021 (Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests).
- WEEE directive 2012/19/UE (Waste electrical equipment).

This Declaration is covered by the certificate reg. number MDR 00026-A valid until **19/12/2028**, issued by notified body **KIWA Cermet Italia** with address Via Cadriano, 23, 40057 Granarolo, dell'Emilia BO, Italy and identification number **0476** in accordance with Annex IX of MDR 2017/745.

Firmado por ***5677** RIGOBERTO PEREZ DE ALEJO FORTUN (R: ****1316*) el día 09/01/2024 con un certificado emitido por AC Representación

Rigoberto Perez de Alejo

Technical Manager

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