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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Nox Medical
Manufacturer address and contact details	Katrínartúni 2, Reykjavík, IS-105 Iceland
Single Registration Number (SRN) (if available)	IS-MF-000000950

Authorised Representative name (if applicable)	NA
Authorised Representative address and contact details	NA
Single Registration Number (SRN) (if available)	NA

Notified body name (if applicable)	BSI Group
Notified body number (if applicable)	2797
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE 532571
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2023-08-27
End date of extended validity/transition period	2028-12-31

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate** as listed above

- Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.
- Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII.

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR will be put in place no later than 26 May 2024.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Nox Medical

Reykjavik 27 August 2023

Harpa Arnard.

Harpa Arnardottir

Chief Quality Officer

harpa@noxmedical.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
Nox A1s Recorder	CE 532571	2023-08-27	BSI Group NB no. 2797	BSI Group NB no. 2797	2028-12-31	NA
Nox T3s Recorder	CE 532571	2023-08-27	BSI Group NB no. 2797	BSI Group NB no. 2797	2028-12-31	NA
Noxturnal	CE 532571	2023-08-27	BSI Group NB no. 2797	BSI Group NB no. 2797	2028-12-31	NA
Noxturnal App	CE 532571	2023-08-27	BSI Group NB no. 2797	BSI Group NB no. 2797	2028-12-31	NA
Nox Cannula with Filter	CE 532571	2023-08-27	BSI Group NB no. 2797	BSI Group NB no. 2797	2028-12-31	NA
Nox C1 Access Point	CE 532571	2023-08-27	BSI Group NB no. 2797	BSI Group NB no. 2797	2028-12-31	NA