

EU Declaration of Conformity

According to Regulation (EU) MDR 2017/745 of the European Parliament and of the Council
of 5 April 2017 on Medical Devices and amendments

Manufacturer(s) Name:	NIOX AB
Manufacturer(s) Address:	Hansellisgatan 13 SE-754 50 Uppsala Sweden
Manufacturer(s) SRN:	SE-MF-000010044
Name of the Device(s):	NIOX Filter
Intended Use:	NIOX Filter is intended to be used as an accessory of NIOX devices that measure Nitric Oxide in human breath (Fractional exhaled Nitric Oxide, FeNO) and Nasal Nitric Oxide (nNO) in the aspirated air from the nasal cavity.
Product Code(s)/Catalogue Number(s) Basic UDI /UDI:	12-1018 – N/A 12-1015 (Qty: 20) - 735004703NIOXFILTERAW / 07350047030489 12-1020 (Qty: 100) – 735004703NIOXFILTERAW / 07350047030199 20-1018 – N/A 20-1015 - 735004703NIOXFILTERAW / 07350047030779 20-1020 - 735004703NIOXFILTERAW / 07350047030786
Common Specifications (CS)	N/A
Classification:	Class I (according to Regulation (EU) MDR 2017/745, Annex VIII, Rule 5)



Notified Body Name: N/A
(Class I Medical Device - CE marking self-declaration)

Notified Body Address: N/A
(Class I Medical Device - CE marking self-declaration)

Notified Body Identification Number: N/A
(Class I Medical Device - CE marking self-declaration)

Conformity Assessment Route: NIOX AB uses the following procedures for the CE-labeling of their products according the Regulation (EU) MDR 2017/745:

Class I: EU conformity declaration according to Annex IV

This EU Declaration of Conformity is issued under the sole responsibility of NIOX AB. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 by TÜV Rheinland. All supporting documentation is retained at the premises of the manufacturer.

Signature:

A handwritten signature in black ink, appearing to be "Jan Lundquist".

Jan Lundquist

Site Lead Uppsala,
VP Supply Chain & Technical
Operations

Place and date of issue:

2026-JUN-18

Uppsala, Sweden

