

EU Declaration of Conformity

According to Regulation (EU) IVDR 2017/746 of the European Parliament and of the Council on Medical Devices
and amendments

Manufacturer(s) Name: NIOX AB

Manufacturer(s) Address: Hanselligatan 13
SE-754 50 Uppsala
Sweden

SRN Number: SE-MF-000010044

Name of the Device(s)	Product Code(s)/Catalogue Number(s):	Basic UDI	UDI-DI
NIOX PRO®	20-1000	735004703NIOXPROMZ	07350047030724
NIOX Breathing Handle	12-1010	735004703NIOXHANDLE6R	07350047030175
NIOX Sensor – 100	12-1610	735004703NIOXSENSORG2	07350047030267
NIOX Sensor - 300	12-1630	735004703NIOXSENSORG2	07350047030274
NIOX Sensor - 500	12-1650	735004703NIOXSENSORG2	07350047030281
NIOX PRO Power Adapter	20-1120	N/A	07350047030793
NIOX PRO Battery	20-1150	N/A	07350047030816
NIOX PRO Stand	12-1001	N/A	07350047030731
NIOX PRO USB Cable	12-1002	N/A	07350047030748
NIOX PRO Battery Lid	12-1008	N/A	07350047030755

Intended Use:

NIOX PRO® measures Nitric Oxide in human breath (Fractional exhaled Nitric Oxide, FeNO) and Nasal Nitric Oxide (nNO) in the aspirated air from the nasal cavity. NIOX PRO® is for use only as an In Vitro Diagnostic Device (IVD) and intended for near-patient testing.

FeNO

FeNO is increased in some airway inflammatory processes and decreases in response to anti-inflammatory treatment. FeNO measurement with NIOX PRO® is quantitative, non-invasive, simple, safe, and is used as part of assessment and monitoring of patients with conditions related to airway inflammation. NIOX PRO® is suitable for patients age 4 and above for FeNO measurements. As measurement requires patient cooperation, some children below the age of 7 may require additional coaching and encouragement. NIOX PRO® should be used as directed in the NIOX PRO® User Manual.

NIOX PRO® for FeNO measurement can be operated with two different exhalation times, 10 seconds and 6 seconds. The 10 second test is the preferred mode. For children who are not able to perform the 10 second test, the 6 second test is an alternative. The 6 second test should be used with caution in patients over the age of 10 years. It should not be used in adult patients.

nNO

Nasal Nitric Oxide has been shown to be decreased in patients with Primary Ciliary Dyskinesia (PCD). Measurement of nNO is a screening tool that can assist in the identification of cases of PCD according to ERS guidelines¹. Measurement of nNO with the NIOX PRO® Nasal Measurement Mode is non-invasive, simple, safe and repeatable in patients age 5 and above when measured according to the NIOX PRO® Nasal Measurement Mode User Manual. Suspected cases of PCD following screening with nNO should be confirmed according to published recommendations for PCD diagnosis and management.

1. Beydon N et al. Nasal nitric oxide measurement in children for the diagnosis of primary ciliary dyskinesia: European Respiratory Society technical standard. European Respiratory Journal. 2023;61(4).

Common Specifications (CS): N/A

Classification: Class B, near-patient

Notified Body Name: TÜV Rheinland LGA Products GmbH

Notified Body Address: Tillystraße 2
90431 Nürnberg

Germany

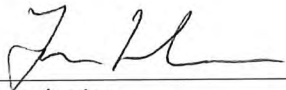
Notified Body Identification Number: 0197

Conformity Assessment Route: Annex IX (Full QMS)

Quality management certificate Number: HX 1379539-1

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) IVDR 2017/746 for in vitro diagnostic devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by TÜV Rheinland. All supporting documentation is retained at the premises of the manufacturer.

Signature:

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

Jan Lundquist

VP Supply Chain & Technical

Operations

Place and date of issue:

18 Jun 2026

Uppsala, Sweden