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:	Circassia AB
Manufacturer(s) Adress:	Hansellisgatan 13 SE-754 50 Uppsala Sweden
Name of the Device(s):	NIOX VERO® Nasal Kit, Adult NIOX VERO® Nasal Kit, Pediatric
Intended Use:	NIOX VERO® Nasal Kit is intended to be used as an accessory of NIOX VERO® device that measures 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):	12-1045 (Adult) 12-1065 (Pediatric)
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 Adress:	N/A (Class I Medical Device - CE marking self-declaration)
Notified Body Identification Number:	N/A (Class I Medical Device - CE marking self-declaration)

CIRCASSIA

Conformity Assessment Route:

Circassia 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 Circassia 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:

Jan Lundquist

Site Lead Uppsala, Vice President
Supply Chain & Technical Operations

Place and date of issue:

29-MAR-2021

Uppsala, Sweden