

According to:
EU Directive on In Vitro Diagnostic Devices (98/79/EC) and amendments

1. TYPE OF EQUIPMENT:

Analyzing equipment for measuring Nitric Oxide in human breath (Fractional exhaled Nitric Oxide, FeNO) and Nasal Nitric Oxide (nNO) in the aspirated air from the nasal cavity.

2. BRAND NAME OR TRADE NAME:

NIOX VERO®
NIOX VERO® Plus

3. CLASSIFICATION MDD/IVDD, CLASS AND RULE:

In Vitro Diagnostic Device 98/79/EC, General IVD

4. TYPE DESIGNATION(S)/MODEL NO(S) AND NUMBER OF UNITS:

NIOX VERO®, article number 12-1000, with regional configurations:

NIOX VERO® (EU), article number 12-1100

NIOX VERO® (US), article number 12-1200

NIOX VERO® (CA), article number 12-1260

NIOX VERO® (JP), article number 12-1300

NIOX VERO® (CN), article number 12-1400

NIOX VERO® (UK), article number 12-1500

NIOX VERO® (AU), article number 12-1600

NIOX VERO® Breathing handle, article number 12-1010

NIOX VERO® Plus assembly kit, article number 14-0017

5. MANUFACTURER'S NAME, ADDRESS, TELEPHONE AND FAX NO:

Circassia AB
Hansellisgatan 13
SE-754 50 Uppsala
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6. SWEDISH MEDICAL PRODUCTS AGENCY ORGANIZATION NUMBER:

556549-1056

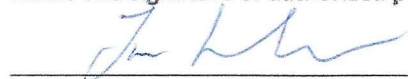
As manufacturer we declare under sole responsibility that the equipment follows the provisions of the Directives stated above.

CSOP-RA-01 ATT-RA-00010
Declaration of Conformity (EC)
Rev 01

Date and Place of issue

12 May 2020, Uppsala

Name and signature of authorized person

A handwritten signature in blue ink, appearing to read "Jan Lundquist", written over a horizontal line.

Jan Lundquist, Site Lead Uppsala, Sr. Director
Global Technical Operations