001258 NIOX VERO® DECLARATION OF CONFORMITY
Rev. 08

CIRCASSIA

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
Sweden

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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.

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Date and Place of issue	Name and signature of authorized person
12 May 2020, Uppsala	Jan Lundquist, Site Lead Uppsala, Sr. Director Global Technical Operations