

<b>EC DECLARATION OF CONFORMITY</b>	<b>Document Type:</b>	Template
	<b>Document ID:</b>	001258
	<b>Revision:</b>	06
	<b>Effective Date:</b>	13 Oct 2017

According to: LVFS 2001:7; Swedish legislation of 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

**3. Classification MDD/IVDD, class and rule:**

In Vitro Diagnostic Device 98/79/EC, other 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 12-1010

**5. Manufacturer's name, address, telephone and fax no:**

Circassia AB  
 Hanselligatan 13  
 SE-754 50 Uppsala  
 Sweden  
 Tel: +46 18 32 88 37 / Fax: +46 18 32 88 38

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

**Date and Place of issue**

13 October 2017, Oxford

**Name and signature of authorized person**

  
 \_\_\_\_\_  
 Steve Harris, CEO

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Steve Harris, CEO]

## Signature Manifest

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**Document Number:** 001258

**Revision:** 06

**Title:** Declaration of Conformity NIOX VERO

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All dates and times are in Greenwich Mean Time.

### Quick Approval

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### Approve Now

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Name/Signature	Title	Date	Meaning/Reason
Lyndsey Atkins (LTKINS)	Quality Assistant	19 Oct 2017, 12:41:14 PM	Approved