

EC DECLARATION OF CONFORMITY

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According to:

LVFS 2003:11; Swedish legislation of EU Directive on Medical devices (93/42/EEC) and amendments

1. Type of equipment:

Single-use bacterial/viral patient filter to be used together with NIOX VERO® devices for FeNO measurements

2. Brand name or trade name:

NIOX VERO Filter NIOX NOVA Filter

3. Classification MDD/IVDD, class and rule:

Medical Device, Class I. Classification rule 5, according to annex IX of 93/42/EEC

4. Type designation(s)/Model no(s) and number of units:

NIOX VERO Filter, article number: 12-1018 (1pcs), 12-1020 (100pcs) NIOX NOVA Filter, article number: 13-1018 (1pcs), 13-1020 (100pcs)

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

Circassia AB Råsundavägen 18 SE-169 67 Solna Sweden tel +46 8 629 0780 fax +46 8 629 0781

6. Harmonized safety standards applied (as applicable):

N/A

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

Date and Place of issue

Name and signature of authorized person

21-NOV-2016, Oxford

Steve Harris, CEC

Document	000935	Revision:	02	Release	Page 1 of 1
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