Manufacturers declaration NIOX VERO test-kits	Document Type:	Default Template
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DECLARATION OF CONFORMITY
PROCEDURE PACKS - NIOX VERO Test kit 60, 100, 300, 500, 1000

Manufacturer of procedure pack:

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

Contents of procedure pack:

NIOX VERO Sensor, Electrochemical sensor, CE-marked by Aerocrine AB
Classification: In Vitro Diagnostic Device 98/79/EC, other IVD

NIOX VERO Patient Filter, Bacterial/Viral filter, CE-marked by Aerocrine AB
Classification: Medical Device Directive 93/42/EEC, Class I

Procedure pack brand name:	Article no:	Contents of package:
NIOX VERO Test kit 60	12-1806	1 NIOX VERO sensor 60 + 60 NIOX VERO filters
NIOX VERO Test kit 100	12-1810	1 NIOX VERO sensor 100 + 100 NIOX VERO filters
NIOX VERO Test kit 300	12-1830	1 NIOX VERO sensor 300 + 300 NIOX VERO filters
NIOX VERO Test kit 500	12-1850	1 NIOX VERO sensor 500 + 500 NIOX VERO filters
NIOX VERO Test kit 1000	12-1900	1 NIOX VERO sensor 1000 + 1000 NIOX VERO filters

In accordance with Article 12 of the Medical Device Directive 93/42/EEC, Aerocrine AB hereby states that:

We have verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and have carried out our operations in accordance with these instructions.

We have packaged the procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers.

The whole activity is subjected to appropriate methods of internal control and inspection.

Date and Place of issue

21-NOV-2016, Oxford

Name and signature of authorized person

Steve Harris, CEO