20 May 2020

STATEMENT

Subject: Effectiveness of MicroGard™ II Filter in laboratory use, including high flows

We, Vyaire Medical GmbH, Leibnizstrasse 7, 97204 Hoechberg, Germany,
declare in relation to our products

part number	consist of amount/ part number
V-892381 MicroGard IIB Box of 50 ea	**50x V-892380 MicroGard IIB Filter**
V-892384 MicroGard IIC Box of 50 ea	**50x V-892383 MicroGard IIC Filter**
V-892386 MicroGard IIB Pack with 25 ea	**25x V-892380 MicroGard IIB Filter**
V-892388 MicroGard II Series Sample Pack	**2x V-892383 2x V-892380 1x V892389 1x V-892390**
V-892391 Filter Kit IIB Box of 80 ea	**80x V-892389 MicroGard IIB Kit**
V-892392 Filter Kit IIC Box of 80 ea	**80x V-892390 MicroGard IIC Kit**

Not all configurations are available in all markets. Please consult your local sales team for availability.

the following:

The filter efficiency of the MicroGard II respiratory filters was tested by senetics healthcare group GmbH&Co KG, Ansbach, Germany in a bio burden test according to DIN EN ISO 11737-1.

In two distinct setups the daily use of the PFT equipment was simulated by:

- 30 minutes of low flow (120 L/min = 2 L/s) equivalent to the expiration in 60 minute tidal breathing as present in bodyplethysmography, N2 washout, He wash-in, Diffusion, and slow spirometry
- 20 times a high flow (720 L/min = 12 L/s) for 5 seconds equivalent to multiple flow/volume trials of 20 subjects

The warm air supply and germ injection setup was validated to deliver a constant high amount of bacteria to the PFT equipment. The amount of bacteria in the PFT equipment was then tested after 90 working days and in a second study after 180 days. The ratio between detected bacteria and infused bacteria was less than 0.001% in all tests and setups. So more than 99.999% of the infused bacteria could not be detected in the PFT system. The results of these bio burden tests justified the prolongation of the cleaning cycles for our PFT systems as reflected in the current hygiene and cleaning instructions.

All designs of the MicroGard II filters (MicroGard II B and MicroGard II C) are tested annually for their bacterial and viral effectiveness at NELSON Laboratories, LLC, Salt Lake City, U.S.A. on behalf of the Vyaire Medical GmbH.

The test results show that the bacterial filter effectiveness is slightly better than viral filter effectiveness. The bacterial effectiveness is not more than 10 times higher than the viral effectiveness.

For the viral filter effectiveness tests, NELSON uses a suspension of Phi X174 bacteriophages as described in the standard test protocols. These have an average size of 30 nm.

For bacterial filter effectiveness tests, NELSON uses Staphylococcus aureus as the challenge organism. These have an average particle size of 3.0 ± 0.3 µm. [1]

According to current knowledge, COVID-19 has a particle size of 80 - 160 nm, significantly larger than the bacteriophages used by NELSON in the effectiveness tests. However, at this point in time we have not conducted any tests of our products against COVID-19 as the challenge organism.

Hoechberg, 2020-05-19

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1. References: https://www.nelsonlabs.com/testing/bacterial-viral-filtration-efficiency-bfe-vfe/

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