18 March 2020

STATEMENT

Subject: Effectiveness of MicroGard™ II Filter in relation of COVID-19

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

MicroGard II (item-no.: V-892381, V-892386, V-892384, V-892388) and
Filter Kit MicroGard II (item-no.: V-892391, V-892392)

the following:

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. All tests performed so far confirm the effectiveness against cross-contamination specified by Vyaire. This is:

viral filter efficiency	=	99,995 %
bacterial filter efficiency	=	99,999 %

For 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, 2020-03-18

Dr. Juergen Reinstaedtler, Clinical SME

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

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