sempermed®
A MEMBER OF THE SEMPERIT-GROUP

Viral penetration | Virenbeständigkeit

Semperguard® sapphire *blue*

According to ASTM Method F 1671 / gemäß ASTM Testmethode F 1671

Vienna, July 2016

We / Wir

Semperit Technische Produkte Ges.m.b.H.
Modecenterstrasse 22
A - 1030 Vienna

authorised EC representative of the manufacturer / autorisierter EG Repräsentant

Semperit Investments Asia Ltd,
8 Jurong Town Hall Road
#29-03 to 06 JTC Summit
Singapore 609434,

[EN]

hereby declare that the powder free examination and disposable protective gloves sold under the brand **Semperguard® sapphire *blue*** are equivalent to the powder free nitrile examination gloves known under the specification code **NOF-030VB-N-3CZ** and are produced according to the same production parameters and quality guidelines.

Thus, we herewith confirm that the enclosed analytical test report issued by *NELSON LABORATORIES* on 30 December 2015 and referring to the test article **NOF-030VB-N-3CZ** was carried out with the same glove type offered under the brand name **Semperguard® sapphire *blue.***

[DE]

bestätigen hiermit, dass die puderfreien Untersuchungs- und Einmalschutzhandschuhe der Marke **Semperguard® sapphire *blue*** baugleich den puderfreien Nitriluntersuchungshandschuhen mit dem Produktcode **NOF-030VB-N-3CZ** sind und denselben Qualitätsrichtlinien folgend erzeugt werden.

Somit bestätigen wir hiermit, dass der angefügte Analysereport ausgestellt von *NELSON LABORATORIES* am 30 Dezember 2015 und sich auf den Testartikel **NOF-030VB-N-3CZ** bezieht mit demselben Handschuh durchgeführt wurde, der unter der Marke **Semperguard® sapphire *blue*** angeboten wird.

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Product Manager

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NELSON LABORATORIES

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Viral Penetration ASTM Method F 1671 Final Report

Test Article:	Online Chlorinated Powder Free Nitrile Examination Gloves (3.0gm) NOF-030VB-N-3CZ LOT NO. : 151216A502A001 (1320)
Purchase Order:	4500008955
Study Number:	865892-S01
Study Received Date:	30 Dec 2015
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0062 Rev 14

Summary: This test method was performed to evaluate the barrier performance of protective materials which are intended to protect against blood borne pathogen hazards. Test articles were conditioned for a minimum of 24 hours at 21 ± 5°C and 30-80% relative humidity (RH), and then tested for viral penetration using a ΦX174 bacteriophage suspension. At the conclusion of the test, the observed side of the test article was rinsed with a sterile medium and assayed for the presence of ΦX174 bacteriophage. The viral penetration method complies with ASTM F1671; sampling was at the discretion of the sponsor. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested:	3
Number of Test Articles Passed:	3
Test Article Side Tested:	Outside
Test Article Preparation:	Cut from the Palm at Random
Exposure Procedure:	B (Retaining Screen: Woven Polyester Mesh, with >50% Open Area)
Compatibility Ratio:	1.4
Environmental Plate Results:	Acceptable

Results:

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
1-3	1.5×10^8	1.7×10^8	<1[a]	None Seen	Pass
Negative Control	1.5×10^8	1.7×10^8	<1[a]	None Seen	Acceptable
Positive Control	1.5×10^8	1.7×10^8	5.0×10^1	Yes	Acceptable

[a] A value of <1 plaque forming unit (PFU)/mL is reported for assay plates showing no plaques.

ANAB ACCREDITED ISO 17025 TESTING LABORATORY

Study Director — Jennifer Jorgenson, B.S.

15 Jan 2016
Study Completion Date

865892-S01

idb

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