

GUANTE DE NITRILO SIN POLVO EUROGLOVES



Guante desechable de examen fabricado en carboxilato de acrilonitrilo, no estéril, sin polvo y 100% sintético. Indicado para todas aquellas prácticas clínicas sin protocolo de esterilidad y que requieran protección al haber un contacto entre el personal sanitario y el paciente. Producto desechable, un solo uso. 100% libre de látex.

CARACTERISTICAS

Composición: Nitrilo (NBR)

Color: Azul violáceo

Interior: Sin polvo

Exterior: Microtexturado en dedos

Terminación: Borde enrollado

Caducidad: 3 años

Diseño: Ambidiestro

Látex: No

Envase: N° de talla en caja y embalaje

GTIN128: Impreso en caja y embalaje

Certificado categoría: CE Cat. III. Clase I

AQL: $\leq 1,5$



DIMENSIONES

TALLA	ANCHO PALMA (acorde EN 455-2)	GRAMAJE	LONGITUD (acorde EN 455-2)	ESPESOR		
				Puño	Palma	Dedo
XS	$\leq 80\text{mm}$	3g/m^2	$\geq 240\text{mm}$	0.08mm	0.10mm	0.10mm
S	$80 \pm 10\text{mm}$					
M	$95 \pm 10\text{mm}$					
L	$110 \pm 10\text{mm}$					
XL	$\geq 110\text{mm}$					

BENEFICIOS

- ' Buena alternativa al látex
- ' Adaptable a la mano gracias a su elasticidad y el puño con reborde, que impide la caída del mismo.
- ' Resistentes y seguros.
- ' Dedos microtexturizados para ofrecer un mejor agarre y manejo del material médico.
- ' Residuo de polvo $\leq 2\text{mg/guante}$ de acuerdo con EN 455-3.

PROPIEDADES FÍSICAS

PROPIEDAD	VALOR
FUERZA DE ROTURA (N) (acorde EN 455-2)	≥ 6
TENSIÓN DE ROTURA (Mpa) (acorde ASTM D 6319)	≥ 14
ELONGACIÓN DE ROTURA (%) (acorde ASTM D 6319)	≥ 400

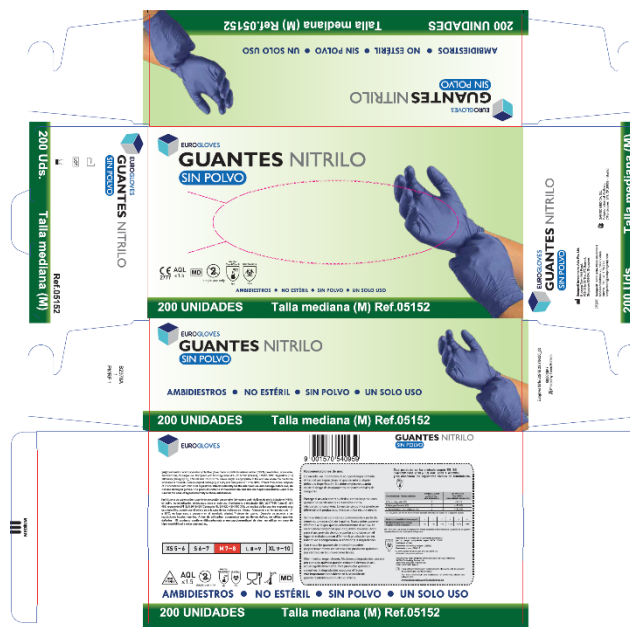
REFERENCIAS Y CÓDIGO DE BARRAS

	REFERENCIA	UDS.	EAN13
XS	05150	200	8432229270223
		2000	8432229370220
S	05151	200	8432229270230
		2000	8432229370237
M	05152	200	8432229270247
		2000	8432229370244
L	05153	200	8432229270254
		2000	8432229370251
XL	05154	200	8432229270261
		2000	8432229370268

NORMATIVAS

- Producto Clase I según el Reglamento UE 2017/745 de productos sanitarios.
- Producto Categoría III según el Reglamento (UE) 2016/425 para EPI. Certificado nº: 2777/11466-01/E00-00
- UNE EN 455-1, 2, 3 y 4: Guantes médicos para un solo uso.
- UNE EN 374-1, 2, 4 y 5: Guantes de protección contra los productos químicos y microorganismos. (ASTM F1671)
- UNE EN 16523-1: Resistencia a la permeación de productos químicos.
- UNE EN 420:2003+A1:2009: Guantes de protección, requisitos generales y métodos de ensayo.
- Calidad certificada acorde ISO 9001, ISO 13485 e ISO 14001.

EMPAQUETADO





EUROGLOVES

GUANTES DE NITRILO

SIN POLVO



VINILO



LÁTEX



NITRILO



QUIRÚRGICO



GUANTE PARA EXAMEN DE USO DUAL. GUANTE SANITARIO (PS) Y DE PROTECCIÓN (EPI)

CAT. III

Niveles de prestación Químicos:

Permeación: K. Hidróxido Sódico - Nivel 6

Tiempo de paso (min)	> 10	> 30	> 60	> 120	> 240	> 480
Nivel de prestación	1	2	3	4	5	6

Degradación: K. Hidróxido Sódico -3.5%

Prestación contra microorganismos y virus que le son aplicables.



K
ISO 374-5:2016



VIRUS



Guantes para examen no estériles. Producto de un solo uso, desechable. Exentos de látex.

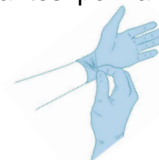
RECOMENDACIONES PARA COLOCACIÓN

- Realizar la apertura de la caja por la zona preparada para ello.
- Los guantes poseen un diseño ambidiestro por lo que cada unidad se adecúa tanto a la mano derecha como a la izquierda.
- Sacar un guante y colocar en una de las manos.
- Sacar una segunda unidad y colocar en la otra mano.



RECOMENDACIONES PARA RETIRADA

- Pellizcar uno de los guantes por la zona externa del puño.



- Retirar el guante totalmente envolviéndolo sobre sí mismo sin tocar la piel.



- Sujetar dicho guante con la mano aún enguantada.

- Retirar el segundo guante con la mano libre introduciendo un dedo entre guante y piel.



- Retirar el guante desde la parte interna envolviéndolo sobre sí mismo.

- Desechar en el contenedor adecuado.

Condiciones de mantenimiento y almacenaje:

- Evitar la exposición directa a luz solar.
- Almacenar en un lugar seco alejado de humedad.
- Mantener a temperaturas entre 5°C a 40°C

Fecha de caducidad:

- En dichas condiciones, vida útil de 5 años.
- Sustituir en caso de que se aprecie algún deterioro en el EPI.



GRUPO UNIDIX

Polígono Industrial Vicálvaro
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info@garricmedica.com

DECLARATION OF CONFORMITY

MEDICAL DEVICE DIRECTIVE 93/42/EEC

PERSONAL PROTECTIVE EQUIPMENT DIRECTIVE 89/686/EEC

Legal Manufacturer:

Semperit Investments Asia Pte Ltd
8 Jurong Town Hall Road
#29-03/04/05/06 JTC Summit
Singapore 609434
<http://www.sempermed.com>
E-mail: sempermed@semperitgroup.com

Authorized representative in the EC:

Semperit Technische Produkte Gesellschaft m.b.H
Modcenterstraße 22
1030 Vienna, Austria

This certificate is valid for the following product:

Non-sterile examination and protective glove for single use

Classification: class I according to MD Directive; category III according to PPE Directive

semperguard sapphire blue (200 pcs)

Sizes	X-Small	Small	Medium	Large	X-Large
Art. No.		3000006815	3000006816	3000006817	3000006818

We hereby declare under sole responsibility that the CE marked product described above conforms to the essential requirements (Annex I) of the directive for medical devices 93/42/EEC.

The conformity assessment is based on Annex VII. Classification according to rule 5, Annex IX.

Applied standards: EN 455-1:2000, EN 455-2:2009+A2:2013 & EN 455-2:2015, EN 455-3:2006 & EN 455-3:2015, EN 455-4:2009, ISO 10993-1:2013, EN ISO 15223-1:2017, EN 1041:2013, EN ISO 14971:2013, DIN ISO 2859-1:2014, , EN ISO 13485:2016

We hereby certify that the CE 0321 marked product described above conforms with the applicable provisions of the directive for personal protective equipment 89/686/EEC and is identical to the personal protective equipment which is the subject of the EC certificate of conformity No. 8430 issued by

SATRA Technology Centre, Wyndham way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom, ID No. 0321

and is subject to the procedure set out in article 11A of Directive 89/686/EEC under the supervision of

SATRA Technology Centre, Wyndham way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom, ID No. 0321

Applied standards: EN 420:2003+A1:2009, EN 374-1:2003, EN 374-2:2015, EN 374-3:2003, EN 388:2003


Andreas Wöss
Director


Released by: Johann Glantschnig
Regulatory Affairs Manager Sempermed

Issued: Singapore, 2018-11-01

Expires: 2023-04-20

DECLARACIÓN DE CONFORMIDAD

REGLAMENTO (UE) 2017/745 DE PRODUCTOS MEDICINALES
REGLAMENTO (UE) 2016/425 PARA EQUIPAMIENTOS PERSONALES

Fabricante

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
#29-03 to 06 The JTC Summit,
Singapore 609434, Singapore
sempermed@semperitgroup.com
SRN: SG-MF-000001645

Representante de la UE

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Brand owner

Garric Medica,
Polígono Industrial Vicálvaro. C/Fundiciones, S/N.
CP:28052 - Madrid

El presente certificado es válido para los siguientes productos:

Guante de exploración y protección no estéril para un solo uso

Clasificación: Clase I según el Reglamento de Productos Medicinales (EU) 2017/745
Categoría III según el Reglamento EPI (UE) 2016/425

Basic UDI-DI: 9001570N*F-030VB-N-3RB

Eurogloves Nitrile 030VB

Tamaños	X-Small	Small	Medium	Large	X-Large
Número de artículo	3000013431	3000013432	3000013433	3000013434	3000013435

Por la presente confirmamos bajo nuestra exclusiva responsabilidad que los productos con marcado CE cumplen con los requisitos del Reglamento (UE) 2017/745 sobre productos sanitarios.

Declaración basada en el anexo IV. Clasificación según la norma 5 del anexo VIII. La evaluación de la conformidad se basa en el anexo II.

Normas aplicadas: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Por la presente confirmamos, bajo nuestra exclusiva responsabilidad, que los productos arriba mencionados con la marca CE cumplen con las disposiciones pertinentes del Reglamento (UE) 2016/425 para equipos de protección personal y están sujetos al Certificado de examen de tipo n°. 2777/11466-01/E00-00 expedido por:

SATRA Technology Europe Ltd, ID No. 2777

Bracetown Business Park, Clonree, Dublin D15 YN2P Ireland

Los productos están sujetos a los procedimientos establecidos en el anexo VII (módulo C2) del Reglamento bajo la supervisión de

SATRA Technology Europe Ltd, ID No. 2777

Bracetown Business Park, Clonree, Dublin D15 YN2P Ireland

Normas aplicadas: EN 420:2003+A1:2009, ISO 374-1:2016/AMD 1:2018, EN 374-2:2014, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016, ISO 2859-1:1999 AMD 1:2011

Expedido el: Singapore, 2022-01-10

Válido hasta: 2024-01-09



PPE REGULATION (EU) 2016/425 MODULE C2 CERTIFICATE

Issued to:

Semperit Technische Produkte GmbH
Modecenterstrasse 22
A-1030 VIENNA
Austria

This is to certify that the following products tested under SATRA reports referenced: *STE0305488 & CHM0305784/2049/JH* have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/11466-01/E00-00	NOF-030VB	Disposable Nitrile powder free medium extra light	EN ISO 374-1:2016 Type B & EN ISO 374-5:2016

Dated: 12th May 2021

This certificate is
valid until:

January 2022

Signed By (Alan Weston)

For and on behalf of SATRA Technology
Europe Limited

The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.

SATRA Technology Europe Limited. Bracetown Business Park Clonree Dublin 15 D15 YN2P. Republic of Ireland.
(Notified Body number 2777)

Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com

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Date 5-4-2018
Page 1 of 8

Ref.no.: 49716
Doc.no: 56050

Semperit Technische Produkte Gesellschaft m.b.H.
Attn. Mr. Weinert
Triester Bundesstrasse 26
A-2632 Wimpassing
Austria

Subject: NOF-035VB
Your reference: Email 08-11-2017
Contact person: W.E.M. Boomaars

Dear Mr. Weinert,

At the request of Semperit Technische Produkte Gesellschaft m.b.H. (your reference Email 08-11-2017) ProQares performed permeation tests with industrial chemicals on protective materials. The tests were performed according to NEN-EN 16523-1:2015 with the deviations (see Annex 2) mentioned in the email d.d. 08-11-2017. The details of the received samples are presented in Table 1 and all test results, including the observations directly after testing (wet) and after drying (dry), are presented in Table 2 to 5 and Figure 1 to 3. The detailed description of the test procedures is presented in the Annex. Note that the test results are only applicable to the tested materials, mentioned in Table 1. The tests were performed between 18-12-2017 and 19-02-2018.

Table 1: Received samples

Sample code ProQares	Description by customer	Received
17PQ2643	NOF-035VB, Lot No: 16011A C39 01 019 0440	14-12-2017

Table 2: Permeation test with **Sodium hydroxide (40%)**, $T = 22.0^{\circ}\text{C}$

Sample code	Thickness (mm)			Average Thickness (mm)	Weight (g/m ²)	Breakthrough time (min)	Observed physical changes on the material (wet/dry)
						1.0*	
17PQ2643A	0.06	0.07	0.06	0.06	64	> 480	None
17PQ2643B	0.05	0.06	0.06	0.06	62	> 480	None
17PQ2643C	0.06	0.07	0.07	0.06	63	> 480	None
Total average				0.06	63	> 480	

* Time point at which the permeation reaches the permeation rate of 1.0 µg/cm²/min

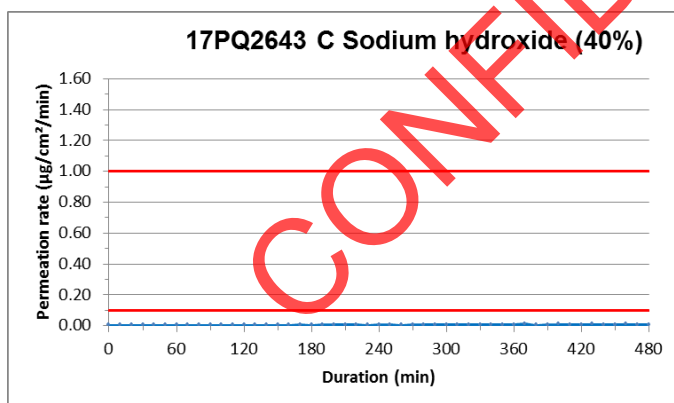
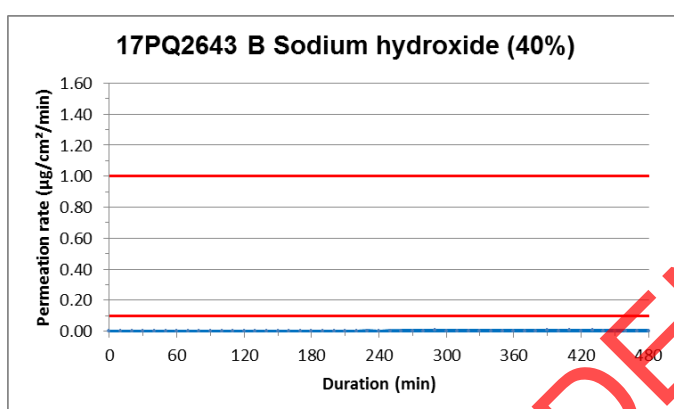
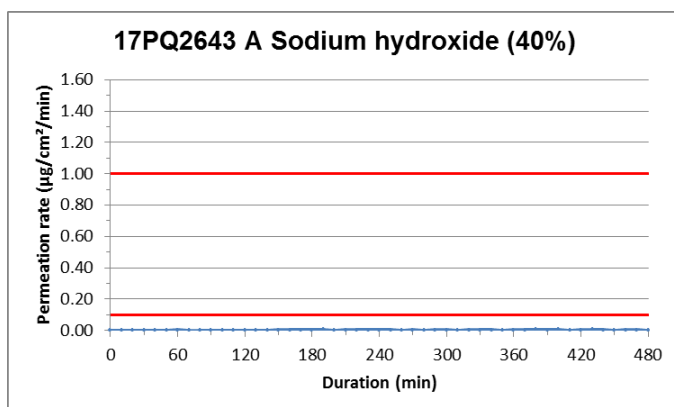


Figure 1 A, B and C Results Sodium hydroxide (40%)

Table 3: Permeation test with **Hydrogen peroxide (30%)**, $T = 23.3^{\circ}\text{C}$

Sample code	Thickness (mm)			Average Thickness (mm)	Weight (g/m ²)	Breakthrough time (min)	Observed physical changes on the material (wet/dry)
	1.0*						
17PQ2643A	0.06	0.07	0.06	0.06	66	> 480	None
17PQ2643B	0.06	0.06	0.05	0.06	66	> 480	None
17PQ2643C	0.06	0.06	0.07	0.06	69	> 480	None
	Total average			0.06	67	> 480	

* Time point at which the permeation reaches the permeation rate of $1.0 \mu\text{g}/\text{cm}^2/\text{min}$

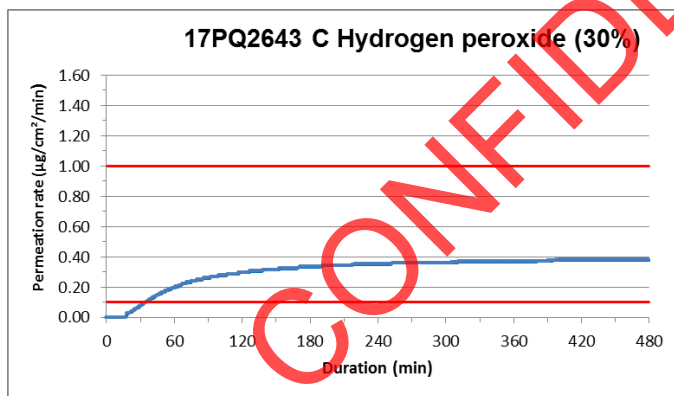
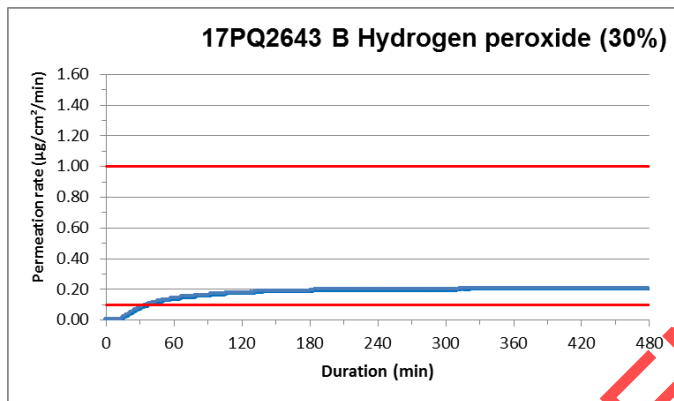
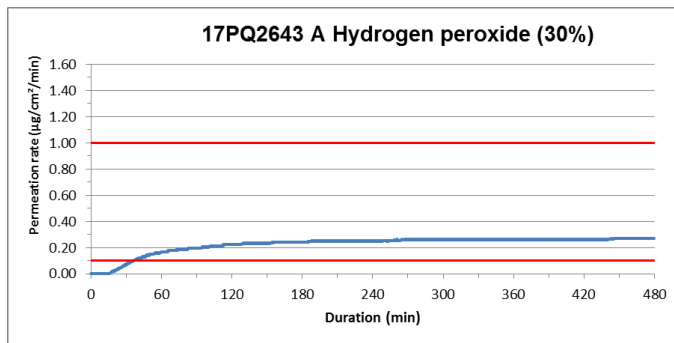


Figure 2 A, B and C Results Hydrogen peroxide (30%)

Table 4: Permeation test with **Formaldehyde (37%)**, $T = 22.6^{\circ}\text{C}$

Sample code	Thickness (mm)			Average Thickness (mm)	Weight (g/m ²)	Breakthrough time (min)	Observed physical changes on the material (wet/dry)
						1.0*	
17PQ2643A	0.06	0.06	0.05	0.06	61	> 480	None
17PQ2643B	0.06	0.06	0.05	0.06	58	> 480	None
17PQ2643C	0.06	0.06	0.06	0.06	60	> 480	None
Total average				0.06	60	> 480	

* Time point at which the permeation reaches the permeation rate of 1.0 µg/cm²/min

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Date 5-4-2018
Page 4 of 8

Ref.no.: 49716
Doc.no: 56050

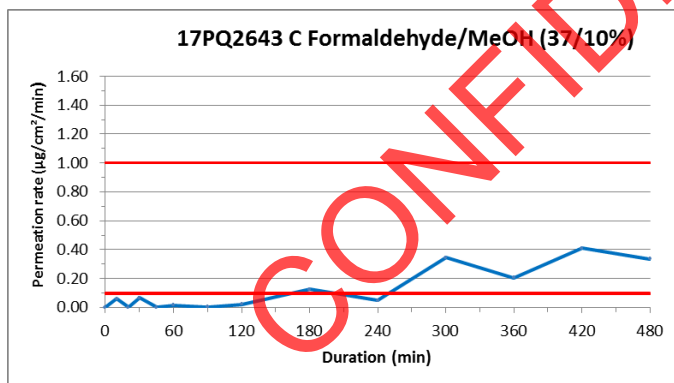
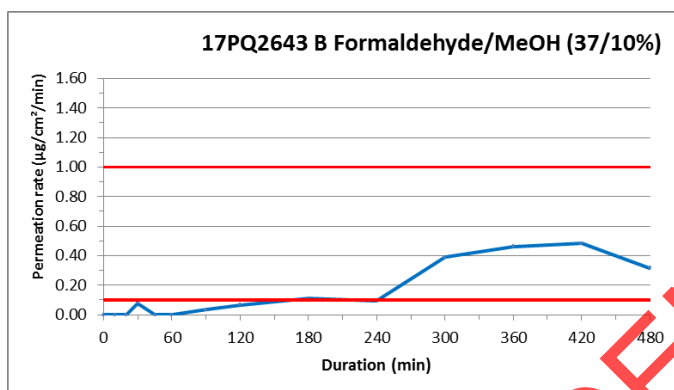
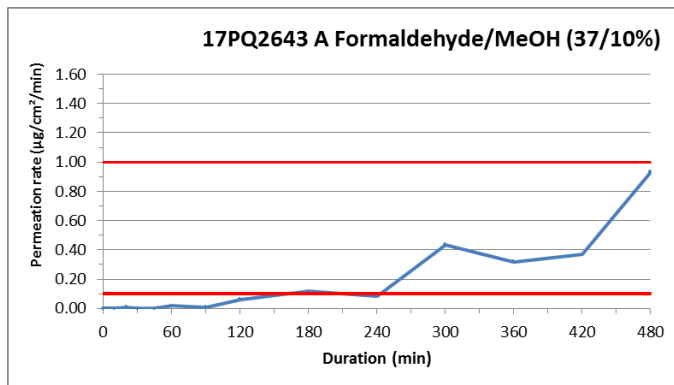


Figure 3 A, B and C Results Formaldehyde (37%)

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Date 5-4-2018
Page 5 of 8

Ref.no.: 49716
Doc.no: 56050

Table 5: Normalized breakthrough and overall result of the test.

Sample code	Chemical	%	Cas number	Breakthrough time (min) 1.0*	Lowest result of test** (min)	Detection limit (µg/cm²/min)
17PQ2643A	Sodium hydroxide	40	1310-73-2	> 480	> 480	0.05
17PQ2643B	Sodium hydroxide	40	1310-73-2	> 480		
17PQ2643C	Sodium hydroxide	40	1310-73-2	> 480		
17PQ2643A	Hydrogen peroxide	30	7722-84-1	> 480	> 480	0.05
17PQ2643B	Hydrogen peroxide	30	7722-84-1	> 480		
17PQ2643C	Hydrogen peroxide	30	7722-84-1	> 480		
17PQ2643A	Formaldehyde	37	50-00-0	> 480	> 480	0.05
17PQ2643B	Formaldehyde	37	50-00-0	> 480		
17PQ2643C	Formaldehyde	37	50-00-0	> 480		

** If the 3 tests breakthrough time results are within 20% of their mean the lowest results is defined as the result of the test.

We trust all things are clear to you. In case of any questions, please do not hesitate to contact us.

Kind regards,



W.E.M. Boomaars
Author

Direct dialling: +31 88 7766908
Direct fax: +31 88 7766999
Email: wendy.boomaars@proqares.com



Mr. C. Jansen
Managing director a.i.

ANNEX 1

DESCRIPTION OF TEST METHODS

Quantitative permeation test with industrial chemicals according to NEN-EN 16523-1:2015

Sodium hydroxide

Parameter	units	specification
Test cell		Alternative, validated cell
Contamination surface	cm ²	30.7
Closed/Open loop system		Closed
Collection medium		H ₂ O
Homogenisation		Stirring during experiment
Method of detection		Conductivity
Temperature	(°C)	23
Humidity	(%RH)	--
Test duration, max	(min)	480
Sampling interval	(min)	1/10
Calculation		Based on interpolation
Result reported	(min)	Breakthrough time
Accuracy	(%)	10*

Date 5-4-2018

Page 6 of 8

Ref.no.: 49716

Doc.no: 56050

The weight and thickness of each swatch is measured before mounting in the test cell. The swatch is mounted in the cell. The test cell is placed in a thermostatic cupboard at 23°C. The chemical permeating through the material is collected and analyzed with conductivity.

* Breakthrough times less than 10 minutes have more variation in the accuracy of the reported values.

Hydrogen peroxide

Parameter	units	specification
Test cell		Alternative, validated cell (EN cell)
Contamination surface	cm ²	4.9
Closed/Open loop system		Open
Collection medium		Air
Flow rate collection medium		> 5 cell volume changes per minute
Method of detection		Electrochemical sensor
Temperature	(°C)	23
Humidity	(%RH)	--
Test duration, max	(min)	480
Sampling interval	(min)	1/10
Calculation		Based on interpolation
Result reported	(min)	Breakthrough time
Accuracy	(%)	10*

The weight and thickness of each swatch is measured before mounting in the test cell. The swatch is mounted in the cell. The test cell is placed in a thermostatic cupboard at 23°C. The chemical permeating through the material is collected and analyzed with a Electrochemical sensor.

* Breakthrough times less than 10 minutes have more variation in the accuracy of the reported values.

Formaldehyde

Parameter	units	specification
Contamination surface	cm ²	20.3
Closed/Open loop system		Closed
Collection medium		H ₂ O
Homogenisation		Stirring during experiment
Method of detection		HPLC
Temperature	(°C)	23
Humidity	(%RH)	--
Test duration, max	(min)	480
Sampling interval	(min)	Variable
Calculation		Based on interpolation
Result reported	(min)	Breakthrough time
Accuracy	(%)	10*

The weight and thickness of each swatch is measured before mounting in the test cell. The swatch is mounted in the cell. The test cell is placed in a thermostatic cupboard at 23°C. The chemical permeating through the material is collected and analyzed by HPLC.

* Breakthrough times less than 10 minutes have more variation in the accuracy of the reported values.

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ANNEX 2

DEVIATIONS FROM THE STANDARD

Parameter	units	specification
Sample points	min	0, 10, 20, 30, 45, 60, 90, 120, 150, 180, 240, 300, 360, 420, 480

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Date 5-4-2018

Page 8 of 8

Ref.no.: 49716

Doc.no: 56050

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DK-8464 Galten
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Fax +45 70 22 42 75
eurofins@eurofins.dk
www.eurofins.dk

Test report

Resistance to degradation by chemicals
EN 374-4

NOF-035VB

Lot Nr.: 0001306277

November - December 2017

Client: Semperit Technische Produkte GmbH
Triester Bundesstraße 26
2632 Wimpassing
AUSTRIA

Att.: Alexander Weinert

Date: 21 December 2017

Performed by: Eurofins Product Testing A/S
Smedeskovvej 38
8464 Galten
Denmark



Nikolaj Røjkjær Andersen
Analytical Chemist

Sample material

Sample identification	Chemical protective material: Sample identification: NOF-035VB Lot no.: 0001306277 Figure 1 shows a picture of the sample
Test Chemical	392-2017-00410127: Sodium hydroxide, 40 % (CAS: 1310-73-2) 392-2017-00410128: Hydrogen peroxide, 30 % (CAS: 7722-84-1) 392-2017-00410129: Formaldehyde, 37 % (CAS: 50-00-0) in 10% methanol
Receipt of samples	15/11/2017
Analytical period	15/11/2017 – 21/12/2017

Applied methods

Method	Principle	Parameter	Uncertainty ¹ (U _m)
EN 374-4:2013	The degradation is determined by measuring the puncture resistance change of the material after continuous contact with test chemical. All samples are measured in triplicate.	Degradation as a percentage of non-exposed reference sample	10 %

¹The expanded uncertainty U_m equals 2 x RSD. The uncertainty is determined using a nitrile material as protective glove against methanol as challenge chemical. Other combinations of protective material and challenge chemical might be associated with higher uncertainty. The overall measurement uncertainty can be estimated from the standard deviation of the three replicates.

Figure 1. Picture of the material



Results

Test results are shown in the table below.

Table 1. Test results, summary.

NOF-035VB Lot no.: 0001306277	EN 374-4 (2013)	
	DR (average)	- 4.3 %
Sodium hydroxide, 40 % (CAS: 1310-73-2)	DR ₁	19 %
	DR ₂	9.1 %
	DR ₃	- 41 %
	SD	32 %
	Post-test condition	No change
	DR (average)	18 %
Hydrogen peroxide, 30 % (CAS: 7722-84-1)	DR ₁	11 %
	DR ₂	13 %
	DR ₃	30 %
	SD	10 %
	Post-test condition	No change
	DR (average)	28 %
Formaldehyde, 37 % (CAS: 50-00-0) in 10% methanol	DR ₁	29 %
	DR ₂	41 %
	DR ₃	14 %
	SD	13 %
	Post-test condition	No change
	DR (average)	28 %

DR: Average degradation (Overall test result), DR_x: Degradation of glove specimen x; SD: Standard deviation

Customer details: Semperit Technische Produkte GmbH
Modecenterstrasse 22
A-1030 VIENNA
Austria

SATRA reference: SPC0272329 /1825 /5

Your reference:

Date of report: 12 July 2018

Samples received: 20 June 2018

For the attention of: Christoph Hafenscher

Date(s) work carried out: 04 July 2018

TECHNICAL REPORT

Subject: Testing of gloves identified as Sempercare Nitrile Skin² (NOF-035VB) in accordance with EN 420:2003+A1:2009 clause 5 Sizing and dexterity

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked \neq fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides for a confidence level of approximately 95%.

Report signed by: Sue Clayton
Position: Technologist
Department: Safety Product Testing

(Page 1 of 5)



Work Requested

Samples of gloves, see Table 1, were received by SATRA for testing in accordance with EN 420:2003+A1:2009 Protective gloves - General requirements and test methods, clauses 5.1 Sizing and 5.2 Dexterity only.

Table 1 – Samples received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
Sempercure Nitrile Skin ² (NOF-035VB)	XS, S, M, L, XL	Mauve	Size: XS Weight: 2.9 g



Conclusion

Standard	Clause / Property	Result
EN 420:2003+A1:2009	5.1 Sizing	See Note ■
	5.2 Dexterity	Level 5

Note ■ – Where gloves do not meet the minimum length requirements specified in Table 1 of EN 420:2003 + A1:2009, the standard therefore requires that the manufacturer shall clearly state in the user instructions the intended application of the gloves and the reason why the gloves do not conform to the minimum length requirements

Testing

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity. Testing was carried out within the same environment.

Requirements

Table 2 – Requirements for EN 420:2003 + A1:2009 Clause 5 Size and Dexterity

Glove size	6	7	8	9	10	11
Minimum length / mm	220	230	240	250	260	270

Performance level	1	2	3	4	5
Diameter of dexterity pin /mm	11.0	9.5	8.0	6.5	5.0

Test Results

Table 3 - EN 420:2003 + A1:2009 Test results for gloves identified as Sempercare Nitrile Skin² (NOF-035VB)

Clause / Test	Test Results	UoM	Result
5.1 Glove length, comfort and fit	Size Length /mm	± 0.3 mm	See Note ■
	Left Right		
	XS / 6 243 240		
	Comments on fit: Satisfactory		
	S / 7 238 236		
	Comments on fit: Satisfactory		
	M / 8 250 242		
	Comments on fit: Satisfactory		
	L / 9 249 241		
	Comments on fit: Satisfactory		
5.2 Dexterity	Size Minimum pin diameter / mm	N/A	Level 5
	XS / 6 5.0		
	S / 7 5.0		
	M / 8 5.0		
	L / 9 5.0		
	XL / 10 5.0		

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

- 1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- 1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- 1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing
- 1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.
- 1.5 All references in these terms and conditions to:
 - (a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
 - (b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
 - (c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).
- 1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.
- 1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

- 2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- 2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.
- 2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- 2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.
- 2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- 2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.
- 2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- 3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.
- 3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- 3.4 The Client agrees and acknowledges that SATRA retains any and all proprietary rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- 3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 1998. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Client's failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

- 5.1 Reports are issued on the basis of information, documents and/or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:
 - (a) death or personal injury caused by its negligence or the negligence of its employees or agents;
 - (b) fraud or fraudulent misrepresentation;
 - (c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
 - (d) defective products under the Consumer Protection Act 1987; or
 - (e) any other liability which cannot be limited or excluded by applicable law.
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- 5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

- 6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- 6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
- 6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- 6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- 7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.
- 7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.
- 7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

- 8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

- 9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.
10. **PROVISION OF SERVICES**
- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.
- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- 10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.
- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.
- Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.
- Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.
- 10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.
- 10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.
- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.
11. **CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES**
- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.
12. **DELIVERY AND NON-DELIVERY OF GOODS**
- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- 12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.
- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- 12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- 12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).
13. **RISK/TITLE OF GOODS**
- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
- b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when: -
- a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
- b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- a) hold the Goods as SATRA's bailee;
- b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
- c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right of remedy SATRA may have:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
- c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
14. **PATENTS**
- 14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.
15. **WARRANTY OF GOODS**
- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.
16. **DEFECTIVE GOODS**
- 16.1 Subject to clauses 16.6 and 16.7 if:
- a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 16.1 that the Goods do not comply with the warranty in that clause; and
- b) SATRA is given a reasonable opportunity of examining such Goods; and
- c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
- b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
- c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
- b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – December 2016



TEST REPORT

Report No. : CH:TX:9420024842

DATE : 18/05/2018



SEMPERIT TECHNISCHE PRODUKTE GMBH
TRIESTER BUNDESSTRASSE 26 A-2630 WIMPASSING
A/C F580101 SGS (MALAYSIA) SDN. BHD.

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

PRODUCT DESCRIPTION

GLOVES
NOF-035VB
VIOLET BLUE
040001656924

COLOUR

COUNTRY OF DESTINATION

GERMANY

COUNTRY OF ORIGIN

MALAYSIA

SAMPLE RECD ON

15-May-18

TESTING PERIOD : 15/05/2018 - 18/05/2018

RESULT SUMMARY

TESTS	PASS	FAIL	REMARKS
PH - TEXTILE			
1	X		

per pro SGS India Private Ltd.

P.PONSUNDARAJ

EXECUTIVE

Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

JOE No. : 1842813711

Page 1 of 3

Control No.:9425025951

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SGS India Pvt. Ltd. Consumer and Retail, 28 B/1 (SP), 28 B/2 (SP), Second Main Road, Ambattur Industrial Estate, Ambattur, Chennai-600 058 Phone:91-44-66081600, Fax:91-44-66081700

Member of the SGS Group (SGS SA)



TEST REPORT

Report No. : CH:TX:9420024842

DATE : 18/05/2018



R E S U L T S

REQ

COMPONENT LIST /LIST OF MATERIALS

SAMPLE NO.	MATERIAL NO.	COMPONENT	MATERIAL	COLOR	FIBER TYPE*	REMARK
1	1	GLOVE	SYNTHETIC	VIOLET BLUE		

* This fiber type identification is for the selection of azo dye testing procedure.

Note:

Type A = Textile contains natural fibers only and/or regenerated fibers exclude the group of acetate.

Type B = Textile contains polyester fibers only.

Type C = Textile contains man-made fibers and/or man-made blended fibers (except polyester fibers).

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JOE No. : 1842813711

Page 2 of 3

Control No.:9425025951

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TEST REPORT

Report No. : CH:TX:9420024842

DATE : 18/05/2018



R E S U L T S

REQ

PH - TEXTILE

ISO 3071

1
RESULT

6.7

pH value of extraction medium : 5.0 - 7.5
Temperature of the extraction solution : 22±2°C

Req. : 3.5 - 9.5

Remark: Requirements given as per EN 420:2003 +A1:2009 (Clause: 4.3.2).

***** End of Report *****

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JOE No. : 1842813711

Page 3 of 3

Control No.: 9425025951

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Viral Penetration ASTM Method F 1671 GLP Report

Test Article: NOF-035VB
Study Number: 1047055-S01
Study Received Date: 07 May 2018
Testing Facility: Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
Test Procedure(s): Standard Test Protocol (STP) Number: STP0062 Rev 16
Deviation(s): None

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 $21 \pm 5^\circ\text{C}$ 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.

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: 2.2, per sponsor
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	3.6×10^8	2.2×10^8	$<1^a$	None Seen	Pass
Negative Control	3.6×10^8	2.2×10^8	$<1^a$	None Seen	Acceptable
Positive Control	3.6×10^8	2.2×10^8	TNTC ^b	Yes	Acceptable

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

^b TNTC = PFUs were too numerous to count.



Study Director

Jennifer Jorgenson, B.S.

Study Completion Date

18 May 2018



1047055-S01

Test Method Acceptance Criteria: The negative control must be negative for viral penetration. The positive control must be positive for viral penetration. The post challenge titer must be $\geq 1.0 \times 10^8$ PFU/mL.

Procedure: The test articles were loaded into the test cells and the bolts were torqued to 13.6 Newton meters (120 inch pounds) in a criss-cross technique. Test articles were challenged with the maximum test cell capacity of approximately 56-60 mL of a Φ X174 bacteriophage suspension for 5 minutes at atmospheric pressure, 1 minute at 2.0 psig (13.8 kPa), then 54 minutes at atmospheric pressure or until liquid penetration was observed. At the conclusion of the test procedure, the bacteriophage suspension was drained from the test cell and collected to determine the post Φ X174 bacteriophage concentration. The observed side of the test article was rinsed with 5 mL of a sterile assay medium and then recovered from the surface of the test article with a sterile pipette. The collected fluid was assayed for the presence of the Φ X174 bacteriophage. The fluid was plated in duplicate using 0.5 mL aliquots. The surface tension of the challenge suspension and the assay medium was adjusted to approximately 40-44 dyn/cm using surfactant-type Tween[®] 80 at a final concentration of approximately 0.01% by volume.

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Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	09 May 2018
Phase Inspected by Quality Assurance: Sample Preparation	11 May 2018
Audit Results Reported to Study Director	16 May 2018
Audit Results Reported to Management	17 May 2018

Scientists	Title
Sarah Smit	Supervisor
Jennifer Jorgensen	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Melissa Avalos
Quality Assurance

21 May 2018
Date

TEST REPORT

Report No. : CH:TX:9420031718

DATE : 28/06/2018



SEMPERIT TECHNISCHE PRODUKTE GMBH
TRIESTER BUNDESSTRASSE 26,
A-2630 WIMPASSING
A/C F580101 SGS (MALAYSIA) SDN. BHD.
CONTACT PERSON : --

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION GLOVES
NOF-035VB
COLOUR VIOLET BLUE
BRAND SEMPERCARE NITRILE SKIN²
COUNTRY OF DESTINATION GERMANY
COUNTRY OF ORIGIN MALAYSIA
PHOTO APPENDIX.



SAMPLE RECD ON 18/06/2018 TESTING PERIOD : 18/06/2018 - 28/06/2018

Summary of Test Results/Conclusion

Test Method / Standard	Clause/Test Name	Status / Performance Level
EN 374-2:2014	Protective gloves against chemicals and micro-organisms:Determination of resistance penetration	
	Clause 4.1 – Air leak test	Pass
	Clause 4.2 – Water leak test	Pass

Per pro SGS India Private Ltd.

K. Pachaiyappan

K. PACHAIYAPPAN
ASST. MANAGER

Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

TEST REPORT

Report No. : CH:TX:9420031718

DATE : 28/06/2018



RESULTS

EN 374-2 : 2014 Protective gloves against chemicals and micro-organisms – Part-2: Determination of resistance penetration

Clause	Test Name	Test Results		Performance level
4.1	Air leak Test (Air Pressure Used : 0.5 kPa)	Specimen #	Leakage	Pass
		1	No Leakage	
		2	No Leakage	
		3	No Leakage	
		4	No Leakage	
4.2	Water leak test	Specimen #	Leakage	Pass
		1	No Leakage	
		2	No Leakage	
		3	No Leakage	
		4	No Leakage	

***** End of report*****

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Recommendation on Chemical Resistance – Cytostatics

Sempermed gloves for single use have been tested in accordance with ASTM D6978 "Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs" by independent accredited test institutes.

Classification:
Not suitable
Suitable if changed before permeation breakthrough
Suitable for longer surgeries*

Permeation Rate:
The tests were performed according to ASTM D6978

Caution: Damaged or swelling gloves shall be changed immediately!

*For reason of precaution it is recommended to change gloves after 2 hours!

TEST RESULTS by:

- ARDL Akron Rubber Development Laboratory, Ohio, USA
- ProQares, Rijswijk, NETHERLANDS

Breakthrough Detection Time (BDT) = Minutes (min)*

Chemotherapy Drug	mg/ml	Sempercare® Green	Sempercare® Shine / Silk	Sempercare® Velvet	Sempercare® Skin? / Aloe	Sempercare® Shine+	Sempercare® Nitrile	Sempercare® Nitrile sterile	Sempercare® Safe+
		NCF-035GR	NCF-035WH	NOF-030VB	NOF-035	NOF-039WH	NOF-047	NOF-047	NOF-065RB
		Nitrile – NBR	Nitrile - NBR	Nitrile - NBR	Nitrile – NBR	Nitrile – NBR	Nitrile - NBR	Nitrile - NBR	Nitrile NBR
		BDT	BDT	BDT	BDT	BDT	BDT	BDT	BDT
5-Fluorouracil	50,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Carmustine (BiCNU)	3,3	22	14	13	23	14	46	46	14
Cisplatin	1,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Cyclophosphamide (Cytosan)	20,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Cytarabine	100,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Dacarbazine (DTIC)	10,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Daunorubicin HCl	5,0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Doxorubicin HCl	2,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Epirubicin	2,0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Etoposide	20,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Ifosfamid	50,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Methotrexate (Amethopterin Hydrate)	25,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Mitomycin C	0,5	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Mitoxantrone HCl	2,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	n/a
Oxaliplatin	5,0	n/a	n/a	n/a	> 240	n/a	> 240	> 240	> 240
Paclitaxel (Taxol)	6,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Thio-Tepa	10,0	27	13	14	47	13	38	38	58
Vincristine sulfate	1,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240

*Concentration: according instruction leaflet

n/a not available

IMPORTANT NOTE: The latest chemical resistance list can be found at www.sempermed.com. Please note that the product characteristics are directly dependent on the conditions of use and on the purity of the chemical substances concerned. The chemical resistance has been assessed under laboratory conditions and cannot reflect all actual conditions. When working with materials that are harmful to the skin, please always inspect the glove for any holes or tears prior to use. In principle, tests and certificates may only be regarded as general indications and do not exempt the user from the responsibility of making sure that the glove affords the protection requirements for the intended purpose prior to use. The chemical resistance recommendations do not form part of the specifications.

CAUTION: Failure to observe this information, in particular with regard to (chemical) resistance, frequency of use and tolerability of the gloves, can result in personal injury and/or material damage. Semperit does not accept any liability for incorrect use of the gloves. In case of doubt, obtain expert advice before use.

This document was issued electronically and is therefore valid without signature and has a validity of up to one year.

Date of Issue: 29.01.2021

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.


i.A. Larissa Millionig
Product Manager


i.A. Sameera Kaur
Product Manager

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 $21 \pm 5^\circ\text{C}$ 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.

Study Director

Jennifer Jorgenson, B.S.



865892-S01

P.O. Box 571830 | Murray, UT 84157-1830 U.S.A. • 6280 South Redwood Road | Salt Lake City, UT 84123-6600 U.S.A.
www.nelsonlabs.com • Telephone 801 290 7500 • Fax 801 290 7998 • sales@nelsonlabs.com



15 Jan 2016
Study Completion Date

idb

FRT0062-0001 Rev 7

Page 1 of 1

EU Type-Examination Certificate

Certificate number: 2777/11466-01/E16-01

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

Eurogloves Nitrile 3.0VB

Description:

Disposable nitrile powder-free gloves.

Sizes: XS-XL**Classification:****EN ISO 374-1:2016/Type B**

Sodium Hydroxide 40%

Formaldehyde 37%

Hydrogen Peroxide 30%

Level

6

4

6

EN 374-4:2013 Degradation %

-9.5

51

44

EN ISO 374-5:2016

Protection against bacteria & fungi

Protection against viruses

Pass

Pass

Standards/Technical specifications applied:

EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016; EN 374-4: 2013; EN 420: 2003+A1: 2009

Technical reports/Approval documents:

SATRA: CHM0245658/1619/SPT, CHM0245658/1619/EN/Final. CHM0245658/1619/SPT

SGS: CH:TX:6420077189, CH:TX:9420024840

proQuares: 56047

eurofins: 0001095942

Nelson Labs: 897899-S01

Signed on behalf of SATRA:



Gabriela Zajac



Quincey Brown

Date of issue: 28/07/2020**Expiry date:** 29/10/2023



The mark of
responsible forestry

Certificate number: TT-COC-005099

Issue number: 2019-01

Certificate start date: 5 September 2019

Certificate expiry date: 4 September 2024

Date of initial certification: 5 September 2014

CERTIFICATE OF REGISTRATION

This is to certify that

Team Printers Sdn. Bhd.
(Company No.: 73890-T)

1260, Jalan Baru,
13700 Perai,
Penang,
Malaysia.

has been audited and found to meet the requirements of standard(s) **FSC-STD-40-004 (Version 3.0) EN** and **FSC-STD-50-001 (Version 2.0) EN** for **FSC® Chain of Custody Certification**

Scope of certification

Manufacture of Printed Paper Boxes and Printed Paper Products

Products:

P5.1 Cardboard Packaging

Karen Prendergast
Divisional Director - Certification
BM TRADA

Issuing Office: Warringtonfire Testing and Certification Limited t/a bmtrada Chiltern House, Stocking Lane, High Wycombe, Buckinghamshire, HP14 4ND, UK
Registered Office: 10 Lower Grosvenor Place, London, United Kingdom, SW1W 0EN Reg.No. 11371436

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TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.