

Nomi Biotech Corporation sp. z o.o. Mr. Jakub Urbanski YouNick Technology Park ul. Krzemowa 1, Zlotniki **62-002 SUCHY LAS** Poland

Your notice of 25-05-2020

Your reference

Date 11-08-2020

Analysis Report 20.03109.01

Required tests : ISO 16603 (2004)

Resistance to penetration by blood and body fluids

Sample id	Information given by the client	Date of receipt
T2011129	PRO-TEX 3010 medical gown	25-05-2020
T2011130	PRO-TEX 7050 coverall	25-05-2020

Offeren

Christine Remi Order responsible

This report may be reproduced, as long as it is presented in its entire form, without written permission of Centexbel. The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples. In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.





CENTEXBEL • textile competence centre • www.centexbel.be • www.vkc.be

GENT • Technologiepark 70 • BE-9052 Zwijnaarde, Belgium • phone +32 9 220 41 51 • fax +32 9 220 49 55 • gent@centexbel.be GRÂCE-HOLLOGNE • Rue du Travail 5 • BE-4460 Grâce-Hollogne, Belgium • phone +32 4 296 82 00 • g-h@centexbel.be KORTRIJK • Etienne Sabbelaan 49 • BE-8500 Kortrijk, Belgium • phone +32 56 29 27 00 • fax +32 56 29 27 01 • info@vkc.be VAT BE 0459.218.289 • IBAN BE44 2100 4729 6545 • BIC GEBABEBB

6



Reference: T2011129 - PRO-TEX 3010 medical gown

Resistance to penetration by blood and body fluids

Date of ending the test Standard used Product standard

15-07-2020 ISO 16603 (2004) EN 14126 (2003) + AC (2004)

Dimension of the test specimens7.5 cm x 7.5 cmNumber of test specimens3Paraffin-sealed edgesNoSampling1 test specimen per gownTest specimens conditioning $21 \pm 5^{\circ}$ C and $60 \pm 10\%$ RHThe sample is not tested in conditioned area but directly after conditioning.SterilizationNonePre treatment performedNoneBody fluid usedSynthetic bloodSide in contact with the syntheticOuter sidebloodProcedure usedTest procedure usedProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	Type of sample	White non woven with a coated side
Paraffin-sealed edgesNoSampling1 test specimen per gownTest specimens conditioning $21 \pm 5^{\circ}$ C and $60 \pm 10\%$ RHThe sample is not tested in conditioned area but directly after conditioning.SterilizationNonePre treatment performedNoneBody fluid usedSynthetic bloodSide in contact with the synthetic bloodOuter sideProcedure usedProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	Dimension of the test specimens	7.5cm x 7.5cm
Sampling1 test specimen per gownTest specimens conditioning $21 \pm 5^{\circ}C$ and $60 \pm 10\%$ RHThe sample is not tested in conditioned area but directly after conditioning.SterilizationNonePre treatment performedNoneBody fluid usedSynthetic bloodSide in contact with the synthetic bloodOuter sideProcedure usedProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	Number of test specimens	3
Test specimens conditioning $21 \pm 5^{\circ}C$ and $60 \pm 10\%RH$ The sample is not tested in conditioned area but directly after conditioning.SterilizationNonePre treatment performedNoneBody fluid usedSynthetic bloodSide in contact with the syntheticOuter sidebloodProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	Paraffin-sealed edges	No
Image: The sample is not tested in conditioned area but directly after conditioning.SterilizationNonePre treatment performedNoneBody fluid usedSynthetic bloodSide in contact with the synthetic bloodOuter sideBody fluid usedProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	Sampling	1 test specimen per gown
Sterilizationafter conditioning.Pre treatment performedNoneBody fluid usedSynthetic bloodSide in contact with the syntheticOuter sidebloodTest procedure usedProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	Test specimens conditioning	$21 \pm 5^{\circ}$ C and $60 \pm 10\%$ RH
SterilizationNonePre treatment performedNoneBody fluid usedSynthetic bloodSide in contact with the syntheticOuter sidebloodProcedure usedTest procedure usedProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting		The sample is not tested in conditioned area but directly
Pre treatment performedNoneBody fluid usedSynthetic bloodSide in contact with the synthetic bloodOuter sideTest procedure usedProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting		after conditioning.
Body fluid usedSynthetic bloodSide in contact with the synthetic bloodOuter sideTest procedure usedProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	Sterilization	None
Side in contact with the synthetic bloodOuter sideTest procedure usedProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	Pre treatment performed	None
bloodTest procedure usedProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	Body fluid used	Synthetic blood
Test procedure usedProcedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5 kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	Side in contact with the synthetic	Outer side
kPa + 5 min 7 kPa + 5 min 14kPa + 5 min 20kPa - With screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	blood	
screen)Retaining screen specificationsMetal square mesh screen (open area >50%), limiting	Test procedure used	Procedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5
Retaining screen specifications Metal square mesh screen (open area >50%), limiting		$kPa + 5 \min 7 kPa + 5 \min 14kPa + 5 \min 20kPa$ - With
the definition of the general to < 5.0	Retaining screen specifications	
the deflection of the sample to ≤ 5.0 mm		the deflection of the sample to $\leq 5.0 \text{ mm}$
Method used to improve the None	-	None
visualisation		
Surface tension of synthetic blood $0.042 \pm 0.002 \text{ N/m}$	-	
Temperature during the test 23°C	Temperature during the test	23°C

in

f

0



<u>Results</u>

Pass / Fail results

Test specimen	Sampling area	0 kPa	1.75 kPa	3.5 kPa	7 kPa	14 kPa	20 kPa
#1	gown n°1 -	Pass	Pass	Pass	Pass	Pass	Pass
	right sleeve						
#2	gown n°2 -	Pass	Pass	Pass	Pass	Pass	Pass
	stomach	_	_	_	_	_	_
#3	gown n°3 -	Pass	Pass	Pass	Pass	Pass	Pass
	left sleeve						

Pass = no penetration of synthetic blood Fail = synthetic blood penetration

Performed under accreditation in the microbiological lab under the responsibility of Yvette Rogister

in

f



Reference: T2011130 - PRO-TEX 7050 coverall

Resistance to penetration by blood and body fluids

Date of ending the test Standard used Product standard

15-07-2020 ISO 16603 (2004) EN 14126 (2003) + AC (2004)

Type of sample	White non woven with a coated side
Dimension of the test specimens	7.5cm x 7.5cm
Number of test specimens	3
Paraffin-sealed edges	No
Sampling	1 test specimen per coverall
Test specimens conditioning	$21 \pm 5^{\circ}$ C and $60 \pm 10\%$ RH
	The sample is not tested in conditioned area but
	directly after conditioning.
Sterilization	None
Pre treatment performed	None
Body fluid used	Synthetic blood
Side in contact with the synthetic	Outer side
blood	
Test procedure used	Procedure D (5 min 0kPa + 5 min 1.75 kPa + 5 min 3.5
	$kPa + 5 \min 7 kPa + 5 \min 14kPa + 5 \min 20kPa$ - With
	screen)
Retaining screen specifications	Metal square mesh screen (open area >50%), limiting the deflection of the sample to ≤ 5.0 mm
Method used to improve the	** For test specimen #1, one absorbent paper was
visualisation	rubbed at the surface sample to confirm the visual
	detection.
Surface tension of synthetic blood	$0.042 \pm 0.002 \ \mathrm{N/m}$
Temperature during the test	23°C

Performed under accreditation in the microbiological lab under the responsibility of Yvette Rogister

in

f

0)



<u>Results</u>

Pass / Fail results

Test	Sampling	0 kPa	1.75	3.5	7 kPa	14	20	Time *
specimen	area		kPa	kPa		kPa	kPa	
#1	coverall n°1 - stomach	Pass	Pass	Fail	/	/	/	* *
#2	coverall n°2 - thigh	Pass	Pass	Pass	Pass	Pass	Pass	/
#3	coverall n°3 - sleeve	Pass	Pass	Fail	/	/	/	as soon as the pressure
								increases

Time * = Time for drop appearance

Pass = no penetration of synthetic blood Fail = synthetic blood penetration

**Remark : Not possible to indicate clearly a time. Penetration confirmed at the end of the 5 minutes by an absorbent paper.

in

f