

DECLARATION UE DE CONFORMITE

Je soussignée, Madame Sandrine COLOMBEL, agissant en qualité de Responsable Qualité de la société **PROMOSAC MEDIPROTEC**, 9 rue du Poitou – 91220 Brétigny sur Orge, déclare que l'équipement de protection individuelle neuf décrit ci-après :

ISOGV308	GANT VINYLE NON POUUDRE PREMIUM - TAILLE S A XL
-----------------	--

Est conforme au modèle de gant ayant fait l'objet de la déclaration UE de conformité de type n° :

2777/14715-03/E00-00

délivrée par l'organisme notifié n°2777 SATRA TECHNOLOGY, Europe Limited, Bracetown Business Park – Clonee – D15YN2P – Republic of Ireland.

Et est soumis à la procédure d'évaluation de la conformité au type sur la base du contrôle interne de la production et de contrôles supervisés du produit à des intervalles aléatoires (Module C2) sous la surveillance de l'organisme notifié N°2777 SATRA TECHNOLOGY, Europe Limited, Bracetown Business Park – Clonee – D15YN2P – Republic of Ireland.

Il est conforme aux dispositions du règlement UE 2016/425. Il est conçu pour la protection contre les risques chimiques et les micro-organismes.

Le gant de protection est fabriqué en conformité avec les normes européennes :

- EN ISO 21420 :2020
- EN ISO 374-1 :2016+A1 :2018
- EN ISO 374-5 :2016

Gant de catégorie III - protection contre les risques mortels ou dommages irréversibles.


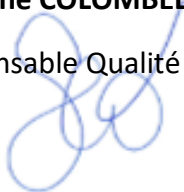
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.

Signé pour et au nom de **PROMOSAC MEDIPROTEC**.

Fait à Brétigny sur Orge, le 26/09/2022.

Sandrine COLOMBEL

Responsable Qualité



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info@mediprotec.com N° TVA intracommunautaire : FR51612040816- APE 4676Z

ANNEXE 1 - IH

ISOGV308-S	LOTS : 2200355, 2200354, 2200482, 2200419, 2200420
ISOGV308-M	LOTS : 2200355, 2200354, 2200484, 2200483, 2200482, 2200418, 2200419, 2200420
ISOGV308-L	LOTS : 2200355, 2200354, 2200484, 2200483, 2200482, 2200419, 2200420
ISOGV308-XL	LOTS : 2200355, 2200354, 2200484, 2200483, 2200482, 2200419, 2200420



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→ Extension de certificat en cours



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2777/11158-01/E01-02

délivrée par l'organisme notifié n°2777 SATRA TECHNOLOGY, Europe Limited, Bracetown Business Park – Clonee – D15YN2P – Republic of Ireland.

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Le gant de protection est fabriqué en conformité avec les normes européennes :

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- EN 374-1 :2016
- EN 374-5 :2016

Gant de catégorie III - protection contre les risques mortels ou dommages irréversibles.


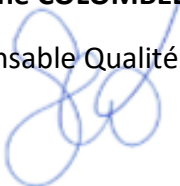
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Signé pour et au nom de **PROMOSAC MEDIPROTEC**.

Fait à Brétigny sur Orge, le 31/05/2022.

Sandrine COLOMBEL


Responsable Qualité



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ANNEXE 1 - WA

ISOGV308-S	LOTS : 18655, 18894, 18895, 18898, 18900, 19277, 19554, 19694, 19697, 19743, 19699, 19772, 19808, 2000077, 2000161, 2000162, 2000274, 2000315, 2000319, 2000198, 2000433, 2000762, 2000761, 2000819, 2000757, 2000824, 2000821, 2000825, 2000936, 2000938, 2000942, 2001038, 2001080, 2001081, 2001082, 2001083, 2001084, 2001085, 2001036, 2001035, 2001037, 2100046, 2001035, 2001037, 2100044, 2100045, 2100198, 2100643, 2100644, 2100755, 2100758, 2100766, 2100765, 2100817, 2100818, 2100819, 2100991, 2100993, 2200055, 2200021, 2200023, 2200024, 2200193
ISOGV308-M	LOTS : 18485, 18654, 18655, 18797, 18894, 18895, 18897, 18898, 18900, 19227, 19277, 19357, 19467, 19554, 19694, 19697, 19743, 19699, 19772, 19808, 19809, 19810, 19905, 19906, 19904, 20058, 2000077, 2000162, 2000166, 2000168, 2000207, 2000275, 2000276, 2000315, 2000319, 2000198, 2000433, 2000646, 2000649, 2000762, 2000761, 2000819, 2000757, 2000759, 2000824, 2000821, 2000825, 2000936, 2000938, 2000942, 2001038, 2001080, 2001081, 2001082, 2001083, 2001084, 2001085, 2001036, 2001035, 2001037, 2100046, 2001035, 2001037, 2100044, 2100045, 2100198, 2100643, 2100644, 2100755, 2100760, 2100758, 2100762, 2100766, 2100765, 2100817, 2100818, 2100819, 2100820, 2101044, 2100993, 2200055, 2100992, 2100991, 2100993, 2200021, 2200019, 2200023, 2200024, 2200193
ISOGV308-L	LOTS : 18485, 18654, 18655, 18797, 18894, 18895, 18897, 18898, 18900, 19227, 19277, 19357, 19553, 19694, 19697, 19743, 19699, 19772, 19808, 19905, 19903, 19904, 20059, 2000077, 2000161, 2000208, 2000275, 2000276, 2000315, 2000319, 2000198, 2000433, 2000646, 2000649, 2000762, 2000761, 2000819, 2000757, 2000759, 2000824, 2000821, 2000825, 2000936, 2000938, 2000942, 2001038, 2001080, 2001081, 2001082, 2001083, 2001084, 2001085, 2001036, 2001035, 2001037, 2100046, 2001035, 2001037, 2100044, 2100045, 2100198, 2100643, 2100644, 2100760, 2100762, 2100766, 2100765, 2100817, 2100818, 2100819, 2100815, 2100820, 2100816, 2101044, 2100993, 2200055, 2100992, 2100991, 2100993, 2200021, 2200019, 2200023, 2200024, 2200193
ISOGV308-XL	LOTS : 18485, 18655, 18797, 18894, 18895, 18898, 18900, 19227, 19277, 19357, 19467, 19553, 19694, 19697, 19743, 19699, 19772, 19905, 20059, 2000077, 2000162, 2000165, 2000168, 2000206, 2000276, 2000315, 2000319, 2000198, 2000433, 2000646, 2000649, 2000761, 2000819, 2000757, 2000824, 2000821, 2000825, 2000936, 2000938, 2000942, 2001038, 2001080, 2001081, 2001082, 2001083, 2001084, 2001085, 2001036, 2001035, 2001037, 2100046, 2001035, 2001037, 2100044, 2100045, 2100198, 2100760, 2100762, 2100766, 2100765, 2100814, 2100817, 2100818, 2100819, 2100815, 2100820, 2100816, 2100993, 2200055, 2100992, 2100991, 2200021, 2200023, 2200024



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Nous changeons d'identité, pas de métier.



Issued to:

Promosac Mediprotec
9 rue du Poitou
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91220 Brétigny Sur Orge
France

Notified Body: 2777

SATRA customer number: P1852

EU Type-Examination Certificate

Certificate number: 2777/11158-01/E01-02

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:

Description:

ISO3GV308
ISO3GV309

Powder free Vinyl gloves non sterile

ISO3GV303
ISO3GV304

Micro powdered Vinyl gloves non sterile

Sizes:

Classification:

Sizes	Classification	Level	EN ISO 374-4:2013	Degradation %
XS	6	EN ISO 374-1 2016 Type C	6	-28.6
S	7	40% Sodium Hydroxide (K)	1	-62.5
M	8	96% Sulphuric Acid (L)		
L	9	EN ISO 374-5: 2016	Level	
XL	10	Protection against bacteria and fungi	Pass	
		Protection against viruses	Pass	

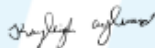
Standards/Technical specifications applied:

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

Technical reports/Approval documents:

SATRA: CHT0272948/1828, CHT0289921/1816/EN/A, CHT0289921/1816/EN/B, CHT0289921/1816/JS/C, CHT0289921/1816/SPT/issue 2, CHT0270813/1819/ issue 3.

Signed on behalf of SATRA:



Kayleigh Aylward



Geoff Graham

Date of issue: 26/11/2018

Expiry date: 28/08/2023

Page 1 of 2

SATRA Technology Europe Limited, Bracktown Business Park, Clonsilla, D15YN2P, Republic of Ireland.

RESULTATS DES TESTS – LOT WA

Réalisés par SATRA TECHNOLOGY

GANTS VINYLES A USAGE UNIQUE

1. EN 420 :2003 + A1 :2009

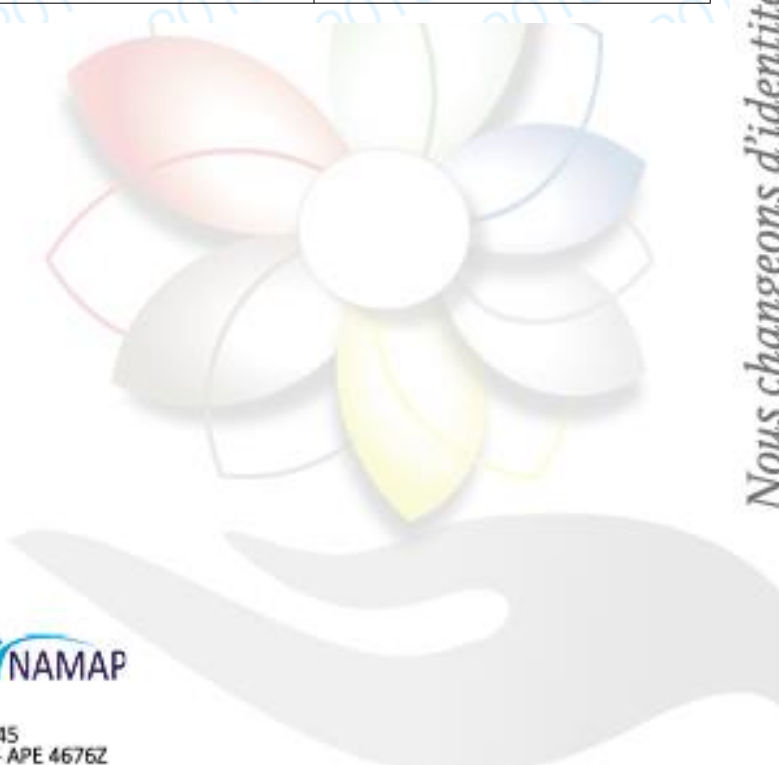
Conclusion

Standard	Clause / Property	Level
EN 420: 2003 + A1: 2009	5.1 Length and fit	PASS
	5.2 Dexterity	Level 5

2. EN 374-2 : 2014 Résistance à la pénétration

Conclusion

Standard	Clause / Property	Result
EN 374-2:2014	7.2 Air leak	PASS
	7.3 Water leak	PASS



Test Results

Table 3 - EN 374-2:2014 Test results for gloves identified as "Disposable vinyl gloves"

Clause / Test	Test Results	UoM	Result
7.2 Air leak test	Total air pressure used: 2.51 kPa		
	Sample size Leaks		
	XS No leaks detected	± 2.8 mmH ₂ O	PASS
	S No leaks detected		
	M No leaks detected		
	L No leaks detected		
XL No leaks detected			
7.3 Water leak test	Sample size Leaks		
	XS No leaks detected	N/A	PASS
	S No leaks detected		
	M No leaks detected		
	L No leaks detected		
	XL No leaks detected		

3. EN 16523-1 : 2015 Résistance à la permeation par des produits chimiques

WORK REQUESTED:

Samples of gloves described as disposable vinyl gloves were received on the 18th April 2018 for testing in accordance with EN 16523-1:2015 and assessment in accordance with the requirements of EN ISO 374-1: 2016.

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016 the samples of gloves described as disposable vinyl gloves achieved the following performance levels:

Chemical	Performance level
Diethylamine (CAS: 109-89-7)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
40% Sodium hydroxide (CAS: 1310-73-2)	6
96% Sulphuric acid (CAS: 7664-93-9)	1

Full results are reported in the following tables.

Test/Property	Sample reference:	Disposable vinyl gloves		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-005 Using stainless steel permeation cells with standardised dimensions	Test information:	Chemical: Diethylamine		The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: GC-FID (periodic measurement)		
		Collection medium: Dry air (open loop)		
		Collection medium flow rate: 335 – 380 ml/min		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)[▲]	
	1	0.15	<1	
	2	0.13	<1	
	3	0.12	<1	
	Test result:	<1		
	UoM:	<1		
Visual appearance of specimens after testing:	Swollen			

Test/Property	Sample reference:	Disposable vinyl gloves		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-009 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 40% sodium hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)	
	1	0.13	>480	
	2	0.13	>480	
	3	0.13	>480	
	Test result:	>480		
	UoM:	<1		
Visual appearance of specimens after testing:	Discoloured			

Nous changeons d'identité, pas de métier.

Test/Property	Sample reference:	Disposable vinyl gloves		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 96% sulphuric acid		Level 1
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)	
	1	0.14	18	
	2	0.14	22	
	3	0.13	24	
		Test result:	18	
	UoM:	<1		
Visual appearance of specimens after testing:	Swollen and delaminated			

4. EN 374-4 : 2013 Résistance à la dégradation des produits chimiques

CONCLUSION:

When assessed in accordance with EN 374-4:2013 the samples of gloves described as disposable vinyl gloves achieved the following degradation results:

Chemical	Mean degradation / %
40% Sodium hydroxide (CAS: 1310-73-2)	-28.6
96% Sulphuric acid (CAS: 7664-93-9)	-62.5
Diethylamine (CAS: 109-89-7)	-45.9

NOTE: The quoted mean degradation values are subject to often significant measurement uncertainties. Please see results tables below for more information

Nous changeons d'identité, pas de métier.

TESTING REQUIRED:

- EN 374-4:2013. Protective gloves against chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

RESULTS:

Sample description:	Disposable vinyl gloves		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-20.0	-19.7	-46.0
Mean degradation (DR) / %:	-28.6		
Standard deviation (σ_{DR}) / %:	15.1		
UoM \diamond / \pm %:	34.2		
Appearance of samples after testing:	Swollen		

Sample description:	Disposable vinyl gloves		
Challenge chemical:	96% Sulphuric acid (CAS: 7664-93-9)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-69.3	-32.0	-86.1
Mean degradation (DR) / %:	-62.5		
Standard deviation (σ_{DR}) / %:	27.7		
UoM \diamond / \pm %:	41.5		
Appearance of samples after testing:	Shrunken and delaminated		



Nous changeons d'identité, pas de métier.

Sample description:	Disposable vinyl gloves		
Challenge chemical:	Diethylamine (CAS: 109-89-7)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-49.3	-24.7	-63.8
Mean degradation (DR) / %:	-45.9		
Standard deviation (σ_{DR}) / %:	19.8		
UoM \diamond / \pm %:	37.4		
Appearance of samples after testing:	Swollen		

\diamond Absolute measurement uncertainty of the mean degradation value; it is therefore inferred that the true degradation value, with 95% confidence, lies within the range (DR \pm UoM) %.

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

5. EN 374-5 : 2016 Résistance de performance pour les risques contre les micro-organismes

TESTING REQUIRED:

- ISO 16604:2004 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage

RESULTS:

Test validity

The positive control sample showed the bacteriophages passed through a microporous PE film whilst the negative control samples showed no passage through the polyester film.

Test specimen	Number of PFU/ml of assay fluid	Pass/Fail results
1	<1 (no penetration)	Pass
2	<1 (no penetration)	Pass
3	<1 (no penetration)	Pass

Pass-no penetration of bacteriophages through the specimen

Test pressure: 14kPa

Compatibility test

Test specimen	Compatibility ratio
1	1.0
2	1.0
3	1.0

Date completed	29 th June 2018
Standard used	ISO 16604 (2004)
Product standard	ISO 374-5 (2016)
Type of sample	White gloves
Dimension of the test specimens	7.5cm x 7.5cm
Number of test specimens	3
Sampling	1 test specimen per glove in the palm of hand
Paraffin-sealed edges	No
Test specimens conditioning	21 ±5°C and 60 ± 10% RH The sample is not tested in conditioned area but directly after conditioning
Sterilization	None
Pretreatment performed	None
Side in contact with the bacteriophage suspension	Outer side
Test procedure used	Procedure B (0kPa 5 min + 14kPa 1 min +0kPa 4 min-with screen)
Retaining screen specifications	Metal square mesh screen (open area >50%) limiting the deflection of the sample to ≤5.0mm
Surface tension of the bacteriophage suspension	0.042±0.002N/m
Used bacteriophage	<i>Bacteriophage Phi-X174 (ATCCC13706-B1)</i>
Host bacteria	<i>Escherichia coli (ATCC 13706)</i>
Deviation from the standard	The measure of the thickness and the mass have not been done on the tested specimens

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Gant de catégorie III - protection contre les risques mortels ou dommages irréversibles.


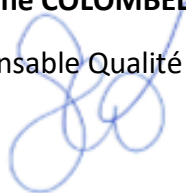
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Signé pour et au nom de **MEDIPROTEC**.

Fait à Brétigny sur Orge, le 17/01/2024.

Sandrine COLOMBEL

Responsable Qualité



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ANNEXE 1 - BJ

ISOGV308-S	Lots : 2100931, 2200027, 2200088, 2200089, 2200141, 2200213, 2300803, 2300804, 2300805
ISOGV308-M	Lots : 2100931, 2200056, 2200027, 2200088, 2200089, 2200141, 2300416, 2300803, 2300804, 2300805
ISOGV308-L	Lots : 2100931, 2200056, 2200027, 2200088, 2200089, 2300548, 2300416, 2300803, 2300804, 2300805
ISOGV308-XL	Lots : 2200027, 2200088, 2200089, 2200213, 2300549, 2300803, 2300804, 2300805



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→ Extension de certificat en cours.



Nous changeons d'identité, pas de métier.

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RESULTATS DES TESTS – LOT BJ

Réalisés par SATRA TECHNOLOGY

GANTS VINYLES A USAGE UNIQUE

1. EN 420 :2003 + A1 :2009

Conclusion

Standard	Clause / Property		Level
EN 420: 2003 + A1: 2009 (Long cuff)	5.1	Length and fit	PASS
	5.2	Dexterity	Level 5
EN 420: 2003 + A1: 2009 (Short cuff)	5.1	Length and fit	See Note A
	5.2	Dexterity	Level 5

2. EN 374-2 : 2014 Résistance à la pénétration

Conclusion

Standard	Clause / Property		Result
EN 374-2: 2014	7.2	Air leak	Pass
	7.3	Water leak	Pass

Nous changeons d'identité, pas de métier.

Test Results

TECHNOLOGY

Table 3 - EN 374-2:2014 Test Results of gloves identified as Disposable vinyl powdered or powder-free examination gloves and Long cuff exam vinyl gloves

Clause / Test	Test Results	UoM	Result
7.2 Air leak test	Total Air Pressure Used	2.87 kPa	± 2.8 mmH ₂ O
	Sample size	Leaks	
	6	No leaks detected	
	7	No leaks detected	
	8	No leaks detected	
	9	No leaks detected	
7.3 Water leak test	Sample size	Leaks	N/A
	6	No leaks detected	
	7	No leaks detected	
	8	No leaks detected	
	9	No leaks detected	
	10	No leaks detected	

3. EN 16523-1 : 2015 Résistance à la permeation par des produits chimiques

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016 the samples of gloves described as Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6
37% Formaldehyde (CAS: 50-00-0)	6
30% Hydrogen peroxide (CAS: 7722-84-1)	5

Nous changeons d'identité, pas de métier.



Test/Property	Sample reference:	Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 40% Sodium Hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
	Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)
1		0.07	>480	
2		0.06	>480	
3		0.06	>480	
		Test result:	>480	
	UoM:	<1		
Visual appearance of specimens after testing:	No change			

Test/Property	Sample reference:	Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 37% Formaldehyde		Level 6
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Spectrophotometry (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
	Test temperature: (23 ± 1) °C			
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)[▼]	
	1	0.08	>480	
	2	0.08	>480	
	3	0.07	>480	
		Test result:	>480	
	UoM:	<1		
Visual appearance of specimens after testing:	Discoloured			

Nous changeons à l'identie, pas de metier.

Test/Property	Sample reference:	Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 30% Hydrogen peroxide		Level 5
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Electrochemical detector (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm) [△]	Breakthrough time (mins) [▽]	
	1	0.07	>480	
	2	0.06	Between 361 to 480	
	3	0.07	>480	
		Test result:	Between 361 to 480	
	UoM:	See below		
Visual appearance of specimens after testing:	Swollen and discoloured			

4. EN 374-4 : 2013 Résistance à la dégradation des produits chimiques

CONCLUSION:

When assessed in accordance with EN 374-4:2013 the samples of gloves described as Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves achieved the following degradation results:

Chemical	Mean degradation / %
Formaldehyde (CAS: 50-00-0)	7.9
40% Sodium hydroxide (CAS: 1310-73-2)	0.4
Hydrogen peroxide (CAS: 7722-84-1)	-12.4

Nous changeons à l'identie, pas de métier.

Sample description:	Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves		
Challenge chemical:	Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	13.0	2.8	7.9
Mean degradation (DR) / %:	7.9		
Standard deviation (σ_{DR}) / %:	5.1		
UoM ♦ / ± %:	49.2		
Appearance of samples after testing:	No change		

Sample description:	Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-5.7	-2.4	9.2
Mean degradation (DR) / %:	0.4		
Standard deviation (σ_{DR}) / %:	7.8		
UoM ♦ / ± %:	51.9		
Appearance of samples after testing:	No change		

Sample description:	Disposable Vinyl Examination Gloves and Long cuff exam Vinyl Gloves		
Challenge chemical:	Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	4.5	-23.6	-18.2
Mean degradation (DR) / %:	-12.4		
Standard deviation (σ_{DR}) / %:	14.9		
UoM ♦ / ± %:	53.8		
Appearance of samples after testing:	No change		

Nous changeons à l'aide, pas de métier.

5. EN 374-5 : 2016 Résistance de performance pour les risques contre les micro-organismes

TESTING REQUIRED:

- ISO 16604:2004 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage

RESULTS:

The positive control sample showed the bacteriophages passed through a microporous film whilst the negative control samples showed no passage through the polyethylene film.

Test specimen	Result	Pass/Fail results
1	No penetration	Pass
2	No penetration	Pass
3	No penetration	Pass

APPENDICES:

Resistance to penetration by blood-borne pathogens-Test method using Phi-X174 bacteriophage

Standard used	ISO 16604 (2004)
Product standard	EN ISO 374-5 (2016)
Dimension of the test specimens	75mm x 75mm
Number of test specimens	3
Test procedure used	Procedure B
Used bacteriophage	<i>Bacteriophage Phi-X174 (ATCC 13706-B1 LOT CNCM 14812)</i>
Penetration survey method	Plaque-forming units (PFU)
Pre-test bacteriophage titre	3.8×10^8
Post-test bacteriophage titre	3.7×10^8

Nous changeons à l'identie, pas de métier.

DECLARATION UE DE CONFORMITE

Je soussignée, Madame Sandrine COLOMBEL, agissant en qualité de Responsable Qualité de la société **PROMOSAC MEDIPROTEC**, 9 rue du Poitou – 91220 Brétigny sur Orge, déclare que l'équipement de protection individuelle neuf décrit ci-après :

ISOGV308	GANT VINYLE NON POUFRE PREMIUM - TAILLE S A XL
-----------------	---

Est conforme au modèle de gant ayant fait l'objet de la déclaration UE de conformité de type n° :
2777/11628-01/E00-00

délivrée par l'organisme notifié n°2777 SATRA TECHNOLOGY, Europe Limited, Bracetown Business Park – Clonee – D15YN2P – Republic of Ireland.

Et est soumis à la procédure d'évaluation de la conformité au type sur la base du contrôle interne de la production et de contrôles supervisés du produit à des intervalles aléatoires (Module C2) sous la surveillance de l'organisme notifié N°2777 SATRA TECHNOLOGY, Europe Limited, Bracetown Business Park – Clonee – D15YN2P – Republic of Ireland.

Il est conforme aux dispositions du règlement UE 2016/425. Il est conçu pour la protection contre les risques chimiques et les micro-organismes.

Le gant de protection est fabriqué en conformité avec les normes européennes :

- EN 420:2003+A1:2009
- EN 374-1 :2016
- EN 374-5 :2016

Gant de catégorie III - protection contre les risques mortels ou dommages irréversibles.


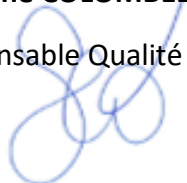
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.

Signé pour et au nom de **PROMOSAC MEDIPROTEC**.

Fait à Brétigny sur Orge, le 27/11/2020.

Sandrine COLOMBEL


Responsable Qualité



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ANNEXE 1 - SS

ISOGV308-S	LOTS : 2000198, 2000197, 2000424
ISOGV308-M	LOTS : 2000198, 2000197, 2000424
ISOGV308-L	LOTS : 2000198, 2000197, 2000424
ISOGV308-XL	LOTS : 2000198, 2000197, 2000424


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Nous changeons d'identité, pas de métier.

RESULTATS DES TESTS – LOT SS

Réalisés par SATRA TECHNOLOGY

GANTS VINYLES A USAGE UNIQUE

1. EN 420 :2003 + A1 :2009

Conclusion

Standard	Clause / Property	Level
EN 420: 2003 + A1: 2009	5.1 Length and fit	PASS
	5.2 Dexterity	Level 5

2. EN 374-2 : 2014 Résistance à la pénétration

Conclusion

Standard	Clause / Property	Result
EN 374-2:2014	7.2 Air leak	PASS
	7.3 Water leak	PASS

Test Results

Table 3 - EN 374-2:2014 Test Results of gloves identified as Disposable vinyl glove

Clause / Test	Test Results	UoM	Result
7.2 Air leak test	Total Air Pressure Used	2.36 kPa	± 2.8 mmH ₂ O
	Sample size	Leaks	
	7	No leaks detected	
	8	No leaks detected	
	9	No leaks detected	
7.3 Water leak test	Sample size	Leaks	N/A
	7	No leaks detected	
	8	No leaks detected	
	9	No leaks detected	
	10	No leaks detected	

3. EN 16523-1 : 2015 Résistance à la permeation par des produits chimiques

WORK REQUESTED:

Samples of gloves described as Vinyl Glove were received on the 24th May 2017 for testing in accordance with the innocuousness requirements of BS EN 420:2003 + A1:2009 and BS EN 16523-1:2015 and assessment in accordance with the requirements of BS EN ISO 374-1:2016.

CONCLUSION:

The samples of gloves described as Vinyl Glove were assessed in accordance with the innocuousness requirements of BS EN 420:2003 + A1:2009 and were found to meet with the requirement for pH value and the REACH annex XVII requirement for PAHs. When assessed in accordance with the requirements of BS EN ISO 374-1:2016 the samples of gloves described as Vinyl Glove achieved the following performance levels:

Chemical	Performance level
Methanol (CAS: 67-56-1)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
40% sodium hydroxide (CAS: 1310-73-2)	6

Test/Property	Sample reference:	Vinyl Glove	Performance
BS EN 16523-1:2015 in accordance with SATRA SOP CAT-005 Using brass alloy permeation cells with standardised dimensions	Test information:	Chemical: Methanol	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
		Normalised permeation rate (NPR): 1 µg/cm ² /min	
		Detection technique: GC-FID (periodic measurement)	
		Collection medium: Dry air (open loop)	
		Collection medium flow rate: 335 – 380 ml/min	
		Test temperature: (23 ± 1) °C	
	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)[^]
	1	0.06	<1
	2	0.06	<1
	3	0.06	<1
	Test result:	<1	
	UoM:	± <1	
Visual appearance of specimens after testing:	No change		

Nous changeons d'identité, pas de métier.

Test/Property	Sample reference:	Vinyl Glove		Performance	
BS EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical:	40% sodium hydroxide		Level 6
		Normalised permeation rate (NPR):	1 µg/cm ² /min		
		Detection technique:	Conductimetry (continuous measurement)		
		Collection medium:	Deionised water (closed loop)		
		Collection medium stirring rate:	45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature:	(23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)		
	1	0.07	>480		
	2	0.07	>480		
	3	0.07	>480		
		Test result:	>480		
	UoM:	± <1			
Visual appearance of specimens after testing:	No change				

4. EN 374-4 : 2013 Résistance à la dégradation des produits chimiques

CONCLUSION:

When assessed in accordance with BS EN 374-4:2013 the samples of gloves described as Vinyl Glove achieved the following degradation results:

Chemical	Mean degradation / %
Methanol (CAS: 67-56-1)	16.4
40% Sodium hydroxide (CAS: 1310-73-2)	-16.2

NOTE: The quoted mean degradation values are subject to often significant measurement uncertainties. Please see results tables below for more information

TESTING REQUIRED:

- BS EN 374-4:2013. Protective gloves against chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

RESULTS:

Sample description:	Vinyl Glove		
Challenge chemical:	Methanol (CAS: 67-56-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	9.9	11.3	27.9
Mean degradation (DR) / %:	16.4		
Standard deviation (σ_{DR}) / %:	10.0		
UoM ♦ / ± %:	42.0		
Appearance of samples after testing:	No change		

Sample description:	Vinyl Glove		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-5.7	-25.1	-17.9
Mean degradation (DR) / %:	-16.2		
Standard deviation (σ_{DR}) / %:	9.8		
UoM ♦ / ± %:	47.5		
Appearance of samples after testing:	No change		

Nous changeons d'identité, pas de métier.

5. EN 374-5 : 2016 Résistance de performance pour les risques contre les micro-organismes

TESTING REQUIRED:

- ISO 16604:2004 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage

RESULTS:

The positive control sample showed the bacteriophages passed through a microporous film whilst the negative control samples showed no passage through the polyethylene film.

Test specimen	Result	Pass/Fail
1	No penetration	Pass
2	No penetration	Pass
3	No penetration	Pass

APPENDICES:

Resistance to penetration by blood-borne pathogens-Test method using Phi-X174 bacteriophage

Standard used	ISO 16604 (2004)
Product standard	EN ISO 374-5 (2016)
Dimension of the test specimens	75mm x 75mm
Number of test specimens	3
Test procedure used	Procedure B
Used bacteriophage	<i>Bacteriophage Phi-X174 (ATCC 13706-B1 LOT CNCM 14812)</i>
Penetration survey method	Plaque-forming units (PFU)
Pre-test bacteriophage titre	6.0x10 ⁸ PFU/ml
Post-test bacteriophage titre	5.8x10 ⁸ PFU/ml

Nous changeons d'identité, pas de métier.

DECLARATION UE DE CONFORMITE

Je soussignée, Madame Sandrine COLOMBEL, agissant en qualité de Responsable Qualité de la société **PROMOSAC MEDIPROTEC**, 9 rue du Poitou – 91220 Brétigny sur Orge, déclare que l'équipement de protection individuelle neuf décrit ci-après :

ISOGV308	GANT VINYLE NON POUVRE PREMIUM - TAILLE S A XL
-----------------	--

Est conforme au modèle de gant ayant fait l'objet de la déclaration UE de conformité de type n° :

BP 60136847 0001 – Rapport n°60222007 001

développée par l'organisme notifié n°0197 TÜV Rheinland LGA Products GmbH – Tillystrabe 2 – 90431 Nürnberg.

Et est soumis à la procédure d'évaluation de la conformité au type sur la base du contrôle interne de la production et de contrôles supervisés du produit à des intervalles aléatoires (Module C2) sous la surveillance de l'organisme notifié N°0197 TÜV Rheinland LGA Products GmbH – Tillystrabe 2 – 90431 Nürnberg.

Il est conforme aux dispositions du règlement UE 2016/425. Il est conçu pour la protection contre les risques chimiques et les micro-organismes.

Le gant de protection est fabriqué en conformité avec les normes européennes :

- EN 420:2003+A1:2009
- EN 374-1 :2016+A1 :2018
- EN 374-5 :2016

Gant de catégorie III - protection contre les risques mortels ou dommages irréversibles.

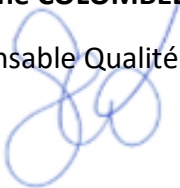
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.

Signé pour et au nom de **PROMOSAC MEDIPROTEC**.

Fait à Brétigny sur Orge, le 17/05/2021.

Sandrine COLOMBEL


Responsable Qualité



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ANNEXE 1 - PW

ISOGV308-S	LOTS : 2001030, 2001031, 2001086, 2001087
ISOGV308-M	LOTS : 2001030, 2001031, 2001086, 2001087
ISOGV308-L	LOTS : 2001030, 2001031, 2001086, 2001087
ISOGV308-XL	LOTS : 2001030, 2001031, 2001086, 2001087



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Nous changeons d'identité, pas de métier.

RESULTATS DES TESTS – LOT PW

Réalisés par TÜV Rheinland

GANTS VINYLES A USAGE UNIQUE

1. EN 374-2 : 2014 Résistance à la pénétration

7.2	Luft-Leck- Prüfung <i>Air leak test</i>																				
4.1	Ein Handschuh wird in Wasser getaucht und sein Innenvolumen mit Luft aufgeblasen. Eine Undichtheit (Leck) wird als Strom aus Luftblasen sichtbar, der sich an der Oberfläche des Handschuhes bildet. <i>A glove is immersed in water, and its interior is pressurised with air. A leak is detected by a stream of air bubbles from the surface of the glove.</i>	<table border="1"> <thead> <tr> <th>Größe/ size</th> <th>Luft-Leck-Prüfung/ Air leakage</th> </tr> </thead> <tbody> <tr> <td>(6,5/S)</td> <td>keine/ no Leakage</td> </tr> <tr> <td>(7,5/M)</td> <td>keine/ no Leakage</td> </tr> <tr> <td>(8,5/L)</td> <td>keine/ no Leakage</td> </tr> <tr> <td>(9/XL)</td> <td>keine/ no Leakage</td> </tr> </tbody> </table>	Größe/ size	Luft-Leck-Prüfung/ Air leakage	(6,5/S)	keine/ no Leakage	(7,5/M)	keine/ no Leakage	(8,5/L)	keine/ no Leakage	(9/XL)	keine/ no Leakage	<table border="1"> <tr> <td>P</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>F</td> <td><input type="checkbox"/></td> </tr> <tr> <td>N/A</td> <td><input type="checkbox"/></td> </tr> <tr> <td>N/T</td> <td><input type="checkbox"/></td> </tr> </table>	P	<input checked="" type="checkbox"/>	F	<input type="checkbox"/>	N/A	<input type="checkbox"/>	N/T	<input type="checkbox"/>
Größe/ size	Luft-Leck-Prüfung/ Air leakage																				
(6,5/S)	keine/ no Leakage																				
(7,5/M)	keine/ no Leakage																				
(8,5/L)	keine/ no Leakage																				
(9/XL)	keine/ no Leakage																				
P	<input checked="" type="checkbox"/>																				
F	<input type="checkbox"/>																				
N/A	<input type="checkbox"/>																				
N/T	<input type="checkbox"/>																				
Tab. 1	<table border="1"> <thead> <tr> <th>Nennstärke der Handschuhe (e) nach Angaben des Herstellers mm <i>Nominal glove thickness (e) mm As provided by the manufacturer</i></th> <th>Luftdruck (X) <i>Air pressure (X)</i> kPa</th> </tr> </thead> <tbody> <tr> <td>e < 0,3</td> <td>0,5</td> </tr> <tr> <td>0,3 < e < 0,5</td> <td>2,0</td> </tr> <tr> <td>0,5 < e < 1,0</td> <td>5,0</td> </tr> <tr> <td>e > 1,0</td> <td>6,0</td> </tr> </tbody> </table>	Nennstärke der Handschuhe (e) nach Angaben des Herstellers mm <i>Nominal glove thickness (e) mm As provided by the manufacturer</i>	Luftdruck (X) <i>Air pressure (X)</i> kPa	e < 0,3	0,5	0,3 < e < 0,5	2,0	0,5 < e < 1,0	5,0	e > 1,0	6,0	Verwendeter Luftdruck / air pressure used: 0,5 kPa									
Nennstärke der Handschuhe (e) nach Angaben des Herstellers mm <i>Nominal glove thickness (e) mm As provided by the manufacturer</i>	Luftdruck (X) <i>Air pressure (X)</i> kPa																				
e < 0,3	0,5																				
0,3 < e < 0,5	2,0																				
0,5 < e < 1,0	5,0																				
e > 1,0	6,0																				
7.3	Wasser-Leck-Prüfung <i>Water leak test</i>																				
4.2	Ein Handschuh wird mit Wasser gefüllt. Eine Undichtheit wird durch das Auftreten von Wassertröpfchen an der Außenseite des Handschuhes festgestellt. <i>A glove is filled with water. A leak is detected by the appearance of water droplets on the outside of the glove.</i>	<table border="1"> <thead> <tr> <th>Größe/ size</th> <th>Luft-Leck-Prüfung/ Air leakage</th> </tr> </thead> <tbody> <tr> <td>(6,5/S)</td> <td>keine/ no Leakage</td> </tr> <tr> <td>(7,5/M)</td> <td>keine/ no Leakage</td> </tr> <tr> <td>(8,5/L)</td> <td>keine/ no Leakage</td> </tr> <tr> <td>(9/XL)</td> <td>keine/ no Leakage</td> </tr> </tbody> </table>	Größe/ size	Luft-Leck-Prüfung/ Air leakage	(6,5/S)	keine/ no Leakage	(7,5/M)	keine/ no Leakage	(8,5/L)	keine/ no Leakage	(9/XL)	keine/ no Leakage	<table border="1"> <tr> <td>P</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>F</td> <td><input type="checkbox"/></td> </tr> <tr> <td>N/A</td> <td><input type="checkbox"/></td> </tr> <tr> <td>N/T</td> <td><input type="checkbox"/></td> </tr> </table>	P	<input checked="" type="checkbox"/>	F	<input type="checkbox"/>	N/A	<input type="checkbox"/>	N/T	<input type="checkbox"/>
Größe/ size	Luft-Leck-Prüfung/ Air leakage																				
(6,5/S)	keine/ no Leakage																				
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(8,5/L)	keine/ no Leakage																				
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P	<input checked="" type="checkbox"/>																				
F	<input type="checkbox"/>																				
N/A	<input type="checkbox"/>																				
N/T	<input type="checkbox"/>																				

Nous changeons d'identité, pas de métier.

2. EN 16523-1 : 2015 Résistance à la permeation par des produits chimiques



Leistungsstufen gegen Permeation <i>Permeation performance levels</i>		/*3		P	<input checked="" type="checkbox"/>	
Tab. 1	Gemessene Durchbruchzeit/ <i>Measured breakthrough time</i> [min]	Schutzindex / <i>Permeation performance level</i>	Prüf-chemikalie / <i>Chemical</i>	Durchbruchzeit / <i>Measured breakthrough time</i> [min]	F	<input type="checkbox"/>
	> 10	Klasse / <i>class</i> 1	Natriumhydr oxid 40 % / <i>Sodium hydroxide</i> 40 %	480	N/A	<input type="checkbox"/>
	> 30	Klasse / <i>class</i> 2			N/T	<input type="checkbox"/>
	> 60	Klasse / <i>class</i> 3			Level 6	
	> 120	Klasse / <i>class</i> 4			Typ/ <i>type</i>	
	> 240	Klasse / <i>class</i> 5			C	
	> 480	Klasse / <i>class</i> 6				
<p>Die Prüfchemikalie(n) muss / (müssen) aus der Liste der Prüfchemikalien in Tabelle 2 genommen werden. Abhängig von der Anwendung der Handschuhe könnten andere Prüfchemikalien verwendet werden.</p> <p><i>The test chemical(s) shall be taken from the list of test chemicals in Table 2. Other test chemicals could be used depending on the application of the gloves.</i></p>						

3. EN 374-4 : 2013 Résistance à la dégradation des produits chimiques

5.3.4	Darstellung der Ergebnisse <i>Expression of results</i>	/*2		P	<input checked="" type="checkbox"/>
	<p>Die Degradation ist an jedem der drei Handschuhprüfmuster gegen jede spezifische Chemikalie oder jedes Chemikaliengemisch zu bestimmen.</p> <p>Die Degradation des Prüfmusters durch die beanspruchende Chemikalie ist zu ermitteln.</p> <p>Die Standardabweichung (SD) der Degradation der drei Handschuhe ist zu bestimmen.</p> <p>Veränderungen wie Aufquellen, Schrumpfen, Versprödung, Verhärtung, Erweichung, Schuppenbildung, Auflösung, Farbveränderung/ Ausbleichen, Delaminieren sind anzugeben.</p> <p><i>Determine the degradation for each of the three glove specimens against each specific chemical or chemical mixture.</i></p> <p><i>Determine the degradation of the sample against the challenge chemical.</i></p> <p><i>Determine the standard deviation (SD) of the degradation for the three gloves.</i></p> <p><i>Any changes such as swelling, shrinking, brittleness, hardening, softening, flaking, disintegration, colour change/bleeding, delaminating shall be noted and described for information.</i></p>	Chemikalie/ <i>chemical</i> :	NaOH	F	<input type="checkbox"/>
		Reinheit/ <i>purity</i> :	40%	N/A	<input type="checkbox"/>
		DR1	4,5	N/T	<input type="checkbox"/>
		DR2	19,4	DR = 14%	
		DR3	17,4		
		DR	13,7		
		SD	7,1		
Veränderungen / <i>changes</i> : keine / <i>none</i>		Prüfdatum / <i>date of the test</i> : 21.08.2017			

Nous changeons d'identité, pas de métier.

4. EN 374-5 : 2016 Résistance de performance pour les risques contre les micro-organismes

6.3	Kennzeichnung von Handschuhen, die vor Viren, Bakterien und Pilze schützen <i>Marking of gloves protecting against viruses, bacteria and fungi</i>									
	<p>Schutzhandschuhe die vor Viren schützen, müssen den Anforderungen aus EN 374-5 6.2 entsprechen und dürfen gemäß ISO 16604 Verfahren B kein nachweisbarer Transfer (<1 PFU/ml) des Phi-X174 Bakteriophagen bei der Titer Untersuchung aufweisen.</p> <p><i>Protective gloves against virus have to comply with the requirements of EN 374-5 6.2 and shall be tested according to ISO 16604 Procedure B and shall exhibit no detectable transfer (<1 PFU/ml) of the Phi-X174 bacteriophage in the assay titre.</i></p> <p>ISO 374-5:2016</p> <div style="display: flex; align-items: center;">   </div> <p>VIRUS</p>	<table style="border: none;"> <tr><td>P</td><td><input type="checkbox"/></td></tr> <tr><td>F</td><td><input type="checkbox"/></td></tr> <tr><td>N/A</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>N/T</td><td><input type="checkbox"/></td></tr> </table>	P	<input type="checkbox"/>	F	<input type="checkbox"/>	N/A	<input checked="" type="checkbox"/>	N/T	<input type="checkbox"/>
P	<input type="checkbox"/>									
F	<input type="checkbox"/>									
N/A	<input checked="" type="checkbox"/>									
N/T	<input type="checkbox"/>									



Nous changeons d'identité, pas de métier.

DECLARATION UE DE CONFORMITE

Je soussignée, Madame Sandrine COLOMBEL, agissant en qualité de Responsable Qualité de la société **MEDIPROTEC**, 9 rue du Poitou – 91220 Brétigny sur Orge, déclare que l'équipement de protection individuelle neuf décrit ci-après :

ISOGV308	GANT VINYLE NON POUDRE PREMIUM - TAILLE S A XL
-----------------	---

Est conforme au modèle de gant ayant fait l'objet de la déclaration UE de conformité de type n° :
2777/16200-01/E02-01

délivrée par l'organisme notifié n°2777 SATRA TECHNOLOGY, Europe Limited, Bracetown Business Park – Clonee – D15YN2P – Republic of Ireland.

Et est soumis à la procédure d'évaluation de la conformité au type sur la base du contrôle interne de la production et de contrôles supervisés du produit à des intervalles aléatoires (Module C2) sous la surveillance de l'organisme notifié N°2777 SATRA TECHNOLOGY, Europe Limited, Bracetown Business Park – Clonee – D15YN2P – Republic of Ireland.

Il est conforme aux dispositions du règlement UE 2016/425. Il est conçu pour la protection contre les risques chimiques et les micro-organismes.

Le gant de protection est fabriqué en conformité avec les normes européennes :

- EN ISO 21420:2020
- EN ISO 374-1 :2016
- EN ISO 374-5 :2016

Gant de catégorie III - protection contre les risques mortels ou dommages irréversibles.

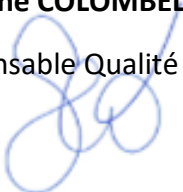
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.

Signé pour et au nom de **MEDIPROTEC**.

Fait à Brétigny sur Orge, le 08/02/2024.

Sandrine COLOMBEL

Responsable Qualité



ANNEXE 1 - AQ

ISOGV308-S	LOTS : 2200281, 2200285, 2200284, 2200283, 2200866, 2300078, 2300151, 2300478, 2300479, 2300480, 2300417, 2300448, 2300575, 2300692, 2300273, 2300275, 2300274, 2300788
ISOGV308-M	LOTS : 2200281, 2200285, 2200284, 2200283, 2200799, 2200866, 2200870, 2200868, 2200865, 2200863, 2200869, 2200871, 2200872, 2300078, 2300080, 2300089, 2300087, 2300083, 2300151, 2300154, 2300153, 2300152, 2300447, 2300301, 2300478, 2300479, 2300480, 2300477, 2300417, 2300448, 2300575, 2300634, 2300636, 2300692, 2300273, 2300275, 2300274, 2300345, 2300576, 2300633, 2300693, 2300694, 2300788, 2300797
ISOGV308-L	LOTS : 2200285, 2200284, 2200283, 2200696, 2200799, 2200866, 2200866, 2200863, 2200869, 2200872, 2200871, 2300023, 2300078, 2300080, 2300089, 2300087, 2300083, 2300154, 2300153, 2300152, 2300348, 2300447, 2300478, 2300479, 2300480, 2300477, 2300417, 2300448, 2300575, 2300634, 2300636, 2300692, 2300273, 2300275, 2300274, 2300633, 2300693, 2300694, 2300788, 2300797
ISOGV308-XL	LOTS : 2200285, 2200284, 2200283, 2300348, 2300301, 2300478, 2300479, 2300480, 2300222, 2300575, 2300273, 2300275, 2300692, 2300274, 2300693, 2300694, 2300788, 2300797



Nous changeons d'identité, pas de métier.



Issued to:

Médiprotec
9 rue du Poitou
ZAC Maison Neuve
91220 Brétigny-sur-Orge
France

Notified Body: 2777

SATRA customer number: P20291

EU Type-Examination Certificate

Certificate number: 2777/16200-02/E02-01

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. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product reference:
Powdered: ISOGV303-S-XL
Powder Free: ISOGV308-S-XL

Description:
Disposable vinyl gloves
Colour: clear

Sizes:	Classification:	Level	EN ISO 374-4:2019 Degradation %
S(6-7)	EN ISO 374-1:2016+A1:2018/Type B		
M(7-8)	(K) Sodium hydroxide 40%	6	-23.7
L(8-9)	(P) Hydrogen peroxide 30%	6	-12.0
XL(9-10)	(T) Formaldehyde 37%	6	-29.9
	EN ISO 374-5:2016		
	Protection against Bacterial and Fungi	Pass	
	Protection against Viruses	Pass	

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0306078/2050/Issue 2, CHM0306604/2052/LC/A/Issue 2, CHM0306604/2052/LC/B/Issue 2, CHT0328078/2211

Signed on behalf of SATRA:



Geoff Graham

Date of issue: 24/10/2022
Expiry date: 29/03/2026

Page 1 of 2

SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland.

Nous changeons d'identité, pas de métier.

www.mediprotec.com

9 rue du Poitou - ZAC Maison Neuve
91220 Brétigny-sur-Orge - France



Tel : (33) 1 60 49 15 15 S.A.S au capital de 1 000 000 €
Fax : (33) 1 60 49 15 10 RCS Evry B 612 040 816- Siret 612 040816 00045
info@mediprotec.com N° TVA Intracommunautaire : FR51612040816- APE 4676Z

RESULTATS DES TESTS – LOT AQ

Réalisés par SATRA TECHNOLOGY

GANTS VINYLES A USAGE UNIQUE

1. EN 374-2 : 2014 Résistance à la pénétration

Table 4 – EN ISO 374-2: 2019 Test Results

Clause / Test	Test Results		UoM (See note ♣)	Result
7.2 Air leak test	Total air pressure used	3.0 kPa	N/A	Pass
	Sample size	Leaks		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	10	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		

2. EN 16523-1 : 2015 Résistance à la permeation par des produits chimiques

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as DISPOSABLE VINYL GLOVES, POWDERED AND POWDER FREE achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6
30% Hydrogen peroxide (CAS: 7722-84-1)	6
37% Formaldehyde (CAS: 50-00-0)	6

Nous changeons d'identité, pas de métier.

Test/Property	Sample reference:	DISPOSABLE VINYL GLOVES, POWDERED AND POWDER FREE		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 40% Sodium hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
	Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)
1 (White)		0.16	>480	
2 (Clear)		0.14	>480	
3 (Blue)		0.15	>480	
		Test result:	>480	
	UoM:	<1		
Visual appearance of specimens after testing:	Discoloured			

Test/Property	Sample reference:	DISPOSABLE VINYL GLOVES, POWDERED AND POWDER FREE		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 30% Hydrogen peroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: Electrochemical detector (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
	Test temperature: (23 ± 1) °C			
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)[▼]	
	1 (Clear)	0.16	>480	
	2 (White)	0.15	>480	
	3 (Cream)	0.14	>480	
		Test result:	>480	
	UoM:	<1		
Visual appearance of specimens after testing:	No change			

Nous changeons d'identité, pas de métier.

Test/Property	Sample reference:	DISPOSABLE VINYL GLOVES, POWDERED AND POWDER FREE		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 37% Formaldehyde		Level 6
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: HPLC-DAD (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm) ^Δ	Breakthrough time (mins) [▼]	
	1 (Blue)	0.20	>480	
	2 (White)	0.16	>480	
	3 (Cream)	0.17	>480	
		Test result:	>480	
	UoM:	<1		
Visual appearance of specimens after testing:	Swollen and discoloured			

3. EN 374-4 : 2013 Résistance à la dégradation des produits chimiques

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as DISPOSABLE VINYL GLOVES, POWDERED AND POWDER FREE achieved the following degradation results:

Chemical	Mean degradation / %
40% Sodium hydroxide (CAS: 1310-73-2)	-23.7
30% Hydrogen peroxide (CAS: 7722-84-1)	-12.0
37% Formaldehyde (CAS: 50-00-0)	-29.9

RESULTS:

Sample description:	DISPOSABLE VINYL GLOVES, POWDERED AND POWDER FREE		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-26.7	-21.1	-23.3
Mean degradation (DR) / %:	-23.7		
Standard deviation (σ_{DR}) / %:	2.8		
UoM / ± %:	15.0		
Appearance of samples after testing:	No change		

Sample description:	DISPOSABLE VINYL GLOVES, POWDERED AND POWDER FREE		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-19.9	-32.6	16.7
Mean degradation (DR) / %:	-12.0		
Standard deviation (σ_{DR}) / %:	25.6		
UoM / ± %:	14.9		
Appearance of samples after testing:	Slightly swollen		

Sample description:	DISPOSABLE VINYL GLOVES, POWDERED AND POWDER FREE		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-32.9	-22.7	-34.2
Mean degradation (DR) / %:	-29.9		
Standard deviation (σ_{DR}) / %:	6.3		
UoM / ± %:	13.4		
Appearance of samples after testing:	Slightly swollen		

Nous changeons d'identité, pas de métier.

4. EN 374-5 : 2016 Résistance de performance pour les risques contre les micro-organismes

Table 1 – Resistance to penetration by blood-borne pathogens results

Sample description: Disposable clear vinyl gloves, powder free referenced as ASPF101						
Test method	Specimen	Step 1 (0 kPa, 5 min)	Step 2 (14 kPa, 1min)	Step 3 (0kPa, 4min)	Titre of phage Phi-X174 (PFU /mL)	Comment
ISO 16604: 2004 Procedure B Using retaining screen	+ control	Penetration	Penetration	Penetration	Penetration	Acceptable
	- control	No penetration	No penetration	No penetration	< 1	Acceptable
	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass

Sample description: Disposable blue vinyl gloves, powdered referenced as ASPP102						
Test method	Specimen	Step 1 (0 kPa, 5 min)	Step 2 (14 kPa, 1min)	Step 3 (0kPa, 4min)	Titre of phage Phi-X174 (PFU /mL)	Comment
ISO 16604: 2004 Procedure B Using retaining screen	+ control	Penetration	Penetration	Penetration	Penetration	Acceptable
	- control	No penetration	No penetration	No penetration	< 1	Acceptable
	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass

Sample description: Disposable creamy stretch vinyl gloves, powdered referenced as ASPP203						
Test method	Specimen	Step 1 (0 kPa, 5 min)	Step 2 (14 kPa, 1min)	Step 3 (0kPa, 4min)	Titre of phage Phi-X174 (PFU /mL)	Comment
ISO 16604: 2004 Procedure B Using retaining screen	+ control	Penetration	Penetration	Penetration	Penetration	Acceptable
	- control	No penetration	No penetration	No penetration	< 1	Acceptable
	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass

Nous changeons d'identité, pas de métier.

DECLARATION UE DE CONFORMITE

Je soussignée, Madame Sandrine COLOMBEL, agissant en qualité de Responsable Qualité de la société **PROMOSAC MEDIPROTEC**, 9 rue du Poitou – 91220 Brétigny sur Orge, déclare que l'équipement de protection individuelle neuf décrit ci-après :

ISOGV308	GANT VINYLE NON POWDRE PREMIUM - TAILLE S A XL
-----------------	---

Est conforme au modèle de gant ayant fait l'objet de la déclaration UE de conformité de type n° :
2777/17971-02/E00-00

délivrée par l'organisme notifié n°2777 SATRA TECHNOLOGY, Europe Limited, Bracetown Business Park – Clonee – D15YN2P – Republic of Ireland.

Et est soumis à la procédure d'évaluation de la conformité au type sur la base du contrôle interne de la production et de contrôles supervisés du produit à des intervalles aléatoires (Module C2) sous la surveillance de l'organisme notifié N°2777 SATRA TECHNOLOGY, Europe Limited, Bracetown Business Park – Clonee – D15YN2P – Republic of Ireland.

Il est conforme aux dispositions du règlement UE 2016/425. Il est conçu pour la protection contre les risques chimiques et les micro-organismes.

Le gant de protection est fabriqué en conformité avec les normes européennes :

- EN 21420:2020
- EN 374-1 :2016
- EN 374-5 :2016

Gant de catégorie III - protection contre les risques mortels ou dommages irréversibles.


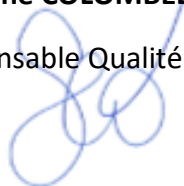
La présente déclaration de conformité est établie sous la seule responsabilité du fabricant.

Signé pour et au nom de **PROMOSAC MEDIPROTEC**.

Fait à Brétigny sur Orge, le 31/05/2022.

Sandrine COLOMBEL

Responsable Qualité



9, rue du Poitou
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91220 Brétigny-Sur-Orge - France



Tel : (33) 1 60 49 15 15 S.A.S au capital de 1 000 000 €
Fax : (33) 1 60 49 15 10 RCS Evry B 612 040 816- Siret 612 040816 00045
info@mediprotec.com N° TVA Intracommunautaire : FR51612040816- APE 4676Z

ANNEXE 1 - RH

ISOGV308-S	LOTS : 2100019, 2100020, 2100021, 2100207, 2100933, 2101069, 2200018, 2101069
ISOGV308-M	LOTS : 2100019, 2100020, 2100021, 2100207, 2100933, 2101069, 2200018, 2101069
ISOGV308-L	LOTS : 2100019, 2100020, 2100021, 2100207, 2100933, 2101069, 2200018, 2101069
ISOGV308-XL	LOTS : 2100019, 2100020, 2100021, 2100207, 2200018



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R.C.S. Evry B 612 040 816
Tél. 01 60 49 15 15 - Fax 01 60 49 15 10

→ Extension de certificat en cours.

RESULTATS DES TESTS – LOT RH

Réalisés par SATRA TECHNOLOGY

GANTS VINYLES A USAGE UNIQUE

5. EN 374-2 : 2014 Résistance à la pénétration

Conclusion

Standard	Clause / Property	Result
EN 374-2:2014	7.2 Air leak	PASS
	7.3 Water leak	PASS

Test Results

Table 3 - EN 374-2:2014 Test Results of gloves identified as Disposable vinyl glove

Clause / Test	Test Results	UoM	Result
7.2 Air leak test	Total Air Pressure Used	2.36 kPa	± 2.8 mmH ₂ O
	Sample size	Leaks	
	7	No leaks detected	
	8	No leaks detected	
	9	No leaks detected	
7.3 Water leak test	Sample size	Leaks	N/A
	7	No leaks detected	
	8	No leaks detected	
	9	No leaks detected	
	10	No leaks detected	

WORK REQUESTED:

Samples of gloves described as Vinyl Glove were received on the 24th May 2017 for testing in accordance with the innocuousness requirements of BS EN 420:2003 + A1:2009 and BS EN 16523-1:2015 and assessment in accordance with the requirements of BS EN ISO 374-1:2016.

CONCLUSION:

The samples of gloves described as Vinyl Glove were assessed in accordance with the innocuousness requirements of BS EN 420:2003 + A1:2009 and were found to meet with the requirement for pH value and the REACH annex XVII requirement for PAHs. When assessed in accordance with the requirements of BS EN ISO 374-1:2016 the samples of gloves described as Vinyl Glove achieved the following performance levels:

Chemical	Performance level
Methanol (CAS: 67-56-1)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
40% sodium hydroxide (CAS: 1310-73-2)	6

Test/Property	Sample reference:	Vinyl Glove		Performance	
BS EN 16523-1:2015 in accordance with SATRA SOP CAT-005	Test information:	Chemical:	Methanol		The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
		Normalised permeation rate (NPR):	1 µg/cm ² /min		
		Detection technique:	GC-FID (periodic measurement)		
		Collection medium:	Dry air (open loop)		
		Collection medium flow rate:	335 – 380 ml/min		
		Test temperature:	(23 ± 1) °C		
Using brass alloy permeation cells with standardised dimensions	Specimen	Thickness (mm)^Δ	Breakthrough time (mins)[▲]		
		1	<1		
		2	<1		
		3	<1		
			Test result:	<1	
	UoM:	± <1			
Visual appearance of specimens after testing:		No change			

Test/Property	Sample reference:	Vinyl Glove		Performance	
BS EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical:	40% sodium hydroxide		Level 6
		Normalised permeation rate (NPR):	1 µg/cm ² /min		
		Detection technique:	Conductimetry (continuous measurement)		
		Collection medium:	Deionised water (closed loop)		
		Collection medium stirring rate:	45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature:	(23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)_Δ	Breakthrough time (mins)		
	1	0.07	>480		
	2	0.07	>480		
	3	0.07	>480		
		Test result:	>480		
	UoM:	± <1			
Visual appearance of specimens after testing:	No change				

7. EN 374-4 : 2013 Résistance à la dégradation des produits chimiques

CONCLUSION:

When assessed in accordance with BS EN 374-4:2013 the samples of gloves described as Vinyl Glove achieved the following degradation results:

Chemical	Mean degradation / %
Methanol (CAS: 67-56-1)	16.4
40% Sodium hydroxide (CAS: 1310-73-2)	-16.2

NOTE: The quoted mean degradation values are subject to often significant measurement uncertainties. Please see results tables below for more information

TESTING REQUIRED:

- BS EN 374-4:2013. Protective gloves against chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

RESULTS:

Sample description:	Vinyl Glove		
Challenge chemical:	Methanol (CAS: 67-56-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	9.9	11.3	27.9
Mean degradation (DR) / %:	16.4		
Standard deviation (σ_{DR}) / %:	10.0		
UoM ♦ / ± %:	42.0		
Appearance of samples after testing:	No change		

Sample description:	Vinyl Glove		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	-5.7	-25.1	-17.9
Mean degradation (DR) / %:	-16.2		
Standard deviation (σ_{DR}) / %:	9.8		
UoM ♦ / ± %:	47.5		
Appearance of samples after testing:	No change		

8. EN 374-5 : 2016 Résistance de performance pour les risques contre les micro-organismes

TESTING REQUIRED:

- ISO 16604:2004 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage

RESULTS:

The positive control sample showed the bacteriophages passed through a microporous film whilst the negative control samples showed no passage through the polyethylene film.

Test specimen	Result	Pass/Fail
1	No penetration	Pass
2	No penetration	Pass
3	No penetration	Pass

APPENDICES:

Resistance to penetration by blood-borne pathogens-Test method using Phi-X174 bacteriophage

Standard used	ISO 16604 (2004)
Product standard	EN ISO 374-5 (2016)
Dimension of the test specimens	75mm x 75mm
Number of test specimens	3
Test procedure used	Procedure B
Used bacteriophage	<i>Bacteriophage Phi-X174 (ATCC 13706-B1 LOT CNCM 14812)</i>
Penetration survey method	Plaque-forming units (PFU)
Pre-test bacteriophage titre	6.0x10 ⁸ PFU/ml
Post-test bacteriophage titre	5.8x10 ⁸ PFU/ml

DECLARATION DE CONFORMITE UE

Selon le règlement DM 2017/745

Fabricant

PROMOSAC MEDIPROTEC
SRN : FR-MF-000002420

Adresse : 9 rue du Poitou
ZAC Maison Neuve
91220 BRETIGNY SUR ORGE – Franc
e

Produits

ISOGV308 PREMIUM
GANT VINYLE PREMIUM NON POUFRE - TAILLE S A XL
Marque : **MEDIPROTEC**
UDI-DI de base : /

Classification

Classe I selon l'annexe VIII, règle 1 du règlement DM 2017/745 (UE).

Normes applicables :

- EN 455-1
- EN 455-2

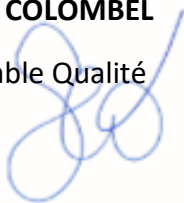
PROMOSAC MEDIPROTEC déclare que le produit mentionné ci-dessus est conforme aux dispositions du règlement 2017/745 sur les dispositifs médicaux, et aux exigences des normes applicables.

Cette déclaration est établie sous la seule responsabilité du fabricant.

Fait à Brétigny sur Orge, le 18/05/2021.

Sandrine COLOMBEL

Responsable Qualité



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