MEDIPROTEC
Protège l'Homme et son environnement

www.mediprotec.com

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 13/04/2026.

Sandrine COLOMBEL

Responsable Qualité

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S.A.S au capital de 1 000 000 €
RCS Evry B 612 040 816- Siret 612 040 816 00045
N° TVA Intracommunautaire : FR51612040816 - APE 4676Z

ANNEXE 1 - AQ

ISOGV308-S	LOTS : 2200281, 2200285, 2200284, 2200283, 2200866, 2300078, 2300151, 2300478, 2300479, 2300480, 2300417, 2300448, 2300575, 2300692, 2300273, 2300275, 2300274, 2300788, 2300790, 2300789,2400203, 2400021, 2400518, 2400519, 2400612, 2400613, 2400614, 2400651, 2400300, 2400301, 2400450, 2400452, 2400451, 2400653, 2400852, 2400853, 2400854, 2401006, 2500316, 2500613, 2500673, 2500738, 2500798, 2500862, 2500907
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, 2300790, 2300789,2400203, 2400021, 2400651, 2400718, 2400300, 2400301, 2400450, 2400451, 2400452, 2400518, 2400519, 2400612, 2400613, 2400614, 2400653, 2400719, 2400852, 2400853, 2400854, 2400855, 2400857, 2401006, 2500317, 2500318, 2500319, 2500316, 2500616, 2500671, 2500737, 2500798, 2500957, 2500863
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, 2300790, 2300789,2400203, 2400021, 2400450, 2400451, 2400452, 2400518, 2400519, 2400612, 2400613, 2400614, 2400651, 2400653, 2400718, 2400300, 2400301, 2400719, 2400852, 2400853, 2400854, 2400855, 2400857, 2401006, 2401154, 2500317, 2500318, 2500319, 2500316, 2500538, 2500617, 2500799, 2500737, 2500798, 2500862, 2500907, 2500953
ISOGV308-XL	LOTS : 2200285, 2200284, 2200283, 2300348, 2300301, 2300478, 2300479, 2300480, 2300222, 2300575, 2300273, 2300275, 2300692, 2300274, 2300693, 2300694, 2300788, 2300797, 2300790, 2300789,2400203, 2400021, 2400651, 2400718, 2400300, 2400301, 2400450, 2400451, 2400452, 2400518, 2400519, 2400612, 2400613, 2400614, 2400653, 2400719, 2400852, 2400853, 2400854, 2400855, 2400857, 2401006, 2401154, 2500317, 2500318, 2500319, 2500316, 2500613, 2500673, 2500799, 2500737, 2500863, 2500953

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:
S(6-7)
M(7-8)
L(8-9)
XL(9-10)

Classification:

EN ISO 374-1:2016+A1:2018/Type B	Level	EN ISO 374-4:2019 Degradation %
(K) Sodium hydroxide 40%	6	-23.7
(P) Hydrogen peroxide 30%	6	-12.0
(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, CHT0328076/2211

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.

→ **Renouvellement en cours**

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		
	9	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

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 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 40% Sodium hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/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		
	Specimen	**Thickness (mm)⌂**	**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 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 30% Hydrogen peroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Electrochemical detector (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		
	Specimen	**Thickness (mm)⌂**	**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		

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 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 37% Formaldehyde		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: HPLC-DAD (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		
	Specimen	**Thickness (mm)⌂**	**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		

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

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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 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° :

2777/14715-03/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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91220 BRÉTIGNY SUR ORGE
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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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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 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° :

2777/11158-01/E01-02

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 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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SATRA TECHNOLOGY

Issued to:

Promosac Mediprotec
9 rue du Poitou
ZAC Maison Neuve
91220 Bretigny 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:
ISOGV308 ISOGV309	Powder free Vinyl gloves non sterile
ISOGV303 ISOGV304	Micro powdered Vinyl gloves non sterile

Sizes:

XS	6
S	7
M	8
L	9
XL	10

Classification:

EN ISO 374-1 2016 Type C	Level	EN ISO 374-4:2013	Degradation %
40% Sodium Hydroxide (K)	6	-28.6	
96% Sulphuric Acid (L)	1	-62.5	

EN ISO 374-5: 2016	Level
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, CHT0269921/1816/EN/A, CHT0269921/1816/EN/B, CHT0269921/1816/JS/C, CHT0269921/1816/SPT/ issue 2, CHT0270613/1819/ 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. Bracetown Business Park. Clonee. 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	± 2.8 mmH_20	PASS
	Sample size	Leaks		
	XS	No leaks detected		
	S	No leaks detected		
	M	No leaks detected		
	L	No leaks detected		
	XL	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	PASS
	XS	No leaks detected		
	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/cm²/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)⌂**	**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/cm²/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		
	Specimen	**Thickness (mm)⌂**	**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		

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/cm²/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)⌂**	**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

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 ♦ / ± %:	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 ♦ / ± %:	41.5		
Appearance of samples after testing:	Shrunken and delaminated		

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 ♦ / ± %:	37.4		
Appearance of samples after testing:	Swollen		

♦ 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 ± 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	29th 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	*Bacteriophage Phi-X174 (ATCCC13706-B1)*
Host bacteria	*Escherichia coli (ATCC 13706)*
Deviation from the standard	The measure of the thickness and the mass have not been done on the tested specimens

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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° :

2777/11331-02/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 420:2003+A1:2009
- 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 06/11/2025.

Sandrine COLOMBEL

Responsable Qualité

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ANNEXE 1 - BJ

ISOGV308-S	Lots : 2100931, 2200027, 2200088, 2200089, 2200141, 2200213, 2300803, 2300804, 2300805, 2300906, 2300908, 2300905, 2300907, 2400989, 2400988
ISOGV308-M	Lots : 2100931, 2200056, 2200027, 2200088, 2200089, 2200141, 2300416, 2300803, 2300804, 2300805, 2300906, 2300908, 2300905, 2300907, 2400989, 2400988
ISOGV308-L	Lots : 2100931, 2200056, 2200027, 2200088, 2200089, 2300548, 2300416, 2300803, 2300804, 2300805, 2300906, 2300908, 2300905, 2300907, 2400989, 2400988, 2500493
ISOGV308-XL	Lots : 2200027, 2200088, 2200089, 2200213, 2300549, 2300803, 2300804, 2300805, 2300906, 2300908, 2300905, 2300907, 2400989, 2400988

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→ Extension de certificat en cours.

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

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Test Results

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_20	Pass
	Sample size	Leaks		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	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		

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

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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/cm²/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)⌂	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/cm²/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)⌂	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		

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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/cm²/min		
		Detection technique: Electrochemical detector (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)⌂**	**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

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		

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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	*Bacteriophage Phi-X174 (ATCC 13706-B1 LOT CNCM 14812)*
Penetration survey method	Plaque-forming units (PFU)
Pre-test bacteriophage titre	3.8×10^8
Post-test bacteriophage titre	3.7×10^8

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 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° :

2777/11628-01/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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Nous changeons d'identité, pas de métier.

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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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 mmH2O	Pass
	Sample size	Leaks		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	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/cm²/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)⌂**	**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		

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/cm²/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)⌂	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		

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	*Bacteriophage Phi-X174 (ATCC 13706-B1 LOT CNCM 14812)*
Penetration survey method	Plaque-forming units (PFU)
Pre-test bacteriophage titre	6.0×10^8 PFU/ml
Post-test bacteriophage titre	5.8×10^8 PFU/ml

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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 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° :

BP 60136847 0001 – Rapport n°60222007 001

délivrée 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

promosac mediprotec
9, rue du Poitou
91220 BRÉTIGNY SUR ORGE
R.C.S. Evry B 612 040 816
Tél. 01 60 49 15 15 - Fax 01 60 49 15 10

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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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 *Air leak test*		
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. *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.*	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 ☒ F ☐ N/A ☐ N/T ☐
Tab. 1	Nenndicke der Handschuhe (*e*) nach Angaben des Herstellers mm *Nominal glove thickness (e) mm As provided by the manufacturer* / Luftdruck (*X*) *Air pressure (X) 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	

7.3	Wasser-Leck-Prüfung *Water leak test*		
4.2	Ein Handschuh wird mit Wasser gefüllt. Eine Undichtheit wird durch das Auftreten von Wassertröpfchen an der Außenseite des Handschuhes festgestellt. *A glove is filled with water. A leak is detected by the appearance of water droplets on the outside of the glove.*	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 ☒ F ☐ N/A ☐ N/T ☐

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

	Leistungsstufen gegen Permeation *Permeation performance levels*			
Tab. 1	Gemessene Durchbruchzeit/ *Measured breakthroug time* [min]	Schutzindex / *Permeation perfomance level*	/*3 Prüf-chemikalie / *Chemical* / Durchbruchzeit / *Measured breakthrough time* [min] Natriumhydroxid 40 % / *Sodium hydroxide 40 %* / 480	P ☒ F ☐ N/A ☐ N/T ☐ Level 6 Typ/ *type C*
	> 10	Klasse / *class* 1		
	> 30	Klasse / *class* 2		
	> 60	Klasse / *class* 3		
	> 120	Klasse / *class* 4		
	> 240	Klasse / *class* 5		
	> 480	Klasse / *class* 6		
	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. *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.*			

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

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

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 *Marking of gloves protecting against viruses, bacteria and fungi*		
	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. *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.* ISO 374-5:2016  VIRUS	---	P ☐ F ☐ N/A ☒ N/T ☐

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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° :

2777/11030-04/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 **MEDIPROTEC.**

Fait à Brétigny sur Orge, le 03/12/2024.

Sandrine COLOMBEL

Responsable Qualité

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S.A.S au capital de 1 000 000 €
RCS Evry B 612 040 816- Siret 612 040 816 00045
N° TVA Intracommunautaire : FR51612040816 - APE 4676Z

ANNEXE 1 - IJ

ISOGV308-S	LOTS : 2400200, 2401014, 2401015, 2401012
ISOGV308-M	LOTS : 2400200, 2401014, 2401015, 2401012
ISOGV308-L	LOTS : 2400200, 2401014, 2401015, 2401012
ISOGV308-XL	LOTS : 2400200, 2401014, 2401015, 2401012

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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 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° :

2777/17971-02/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

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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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→ 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 mmH2O	Pass
	Sample size	Leaks		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		

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N° TVA Intracommunautaire FR 51612040816 - APE 4676Z - N° EORI FR612040816

FRAEOF00164807

6. 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/cm²/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)⌂**	**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		

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/cm²/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)⌂**	**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.

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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		

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N° TVA Intracommunautaire FR 51612040816 - APE 4676Z - N° EORI FR612040816

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	*Bacteriophage Phi-X174 (ATCC 13706-B1 LOT CNCM 14812)*
Penetration survey method	Plaque-forming units (PFU)
Pre-test bacteriophage titre	6.0×10^8 PFU/ml
Post-test bacteriophage titre	5.8×10^8 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 POUDRE - TAILLE S A XL
Marque : **MEDIPROTEC**
UDI-DI de base : 322117GV308

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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