PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST
Nitrilové rukavice NITRIL DIAMOND 3

ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné a vyšetřovací rukavice
Materiál:	100% syntetický nitril
Barva:	oranžová
Provedení:	pravolevé, diamantový vzor, korálková manžeta
Pudr:	není přidán
Skladování:	rukavice neztrácejí své vlastnosti při skladování v suchu při teplotě od 10 do 30 °C
Životnost:	5 let od data výroby při dodržení podmínek skladování
Balení:	100 ks v krabičce, 10 krabiček v kartonu

ČÁST II: SPECIFIKACE PRODUKTU

Délka (mm):	min. 240
Šířka (mm):	XS – 77 ± 10 S – 85 ± 10 M – 95 ± 10 L – 110 ± 10 XL – 120 ± 10
Tloušťka (mm):	prsty: 0.12 ± 0.05 (typická hodnota 0.11 – 0.14) dlaň: 0.25 ± 0.05 (typická hodnota 0.23 – 0.25)
Prodloužení do přetržení (%):	min. 500
Pevnost v tahu (MPa):	min. 6
AQL:	1.5

ČÁST III: NORMY A NAŘÍZENÍ

Tímto potvrzujeme, že výše uvedený výrobek je v souladu s:

Obecné:	PPER (EU) 2016/425 Cat. III EN420 EN 1186-2,9:2002 EN 10130-1:2004 EN 388:2016+A1:2018 EN ISO 374-1,5:2016+A1:2018 EN ISO 374-2,4:2019
Potravinářství:	EC 1935/2004 EU 10/2011 * Vyhovuje pro všechny simulanty kromě 3% kyseliny octové. Tento produkt je vhodný pro manipulaci s potravinami, kromě kyselých potravin (testováno 2 hodiny při 40 ° C)

ČÁST IV: POLOŽKY

Pol. č.	Velikost	Hmotnost (g)	Rozměry (mm)	Kvalita (g)	EAN
100165	M	860	240x140x110	8.0 ± 0.3	8594177201626
100166	L	890	240x140x110	8.3 ± 0.3	8594177201633
100167	XL	920	240x140x110	8.6 ± 0.3	8594177201640

ČÁST V: NÁHLED PRODUKTU

ČÁST VI: PŮVOD PRODUKTU

Výrobce:
INTCO Medical Technology Co., Ltd, No. 29 Zhangliu Road, Zibo, Shandong, China

Distributor:
Espeon s.r.o., U větrolamu 1212/53, 184 00 Praha 8, info@espeon.cz , www.espeon.cz

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0248

Customer details: SATRA Technology Services (Dongguan) Ltd
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Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM0330968/2219/JL
Your reference: CHT0328812
Date of report: 17th May 2022
Samples received: 11th April 2022
Date(s) work carried out: 14th to 16th May 2022

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Shandong Intco Medical Products Co Ltd
Qiwang Road, Naoshan Industrial Park
Qingzhou
Shandong
262506
China

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Nitrile gloves, colour: orange, black.

Report signed by: Jennifer Lewis
Position: Technical Administrator
Department: Chemical & Analytical Technology

TECHNICAL REPORT

0248

WORK REQUESTED:

Samples of gloves described as Nitrile gloves, colour: orange, black were received on the 11th April 2022 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:

Sample described as Nitrile gloves, colour: orange, black.

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Nitrile gloves, colour: orange, black achieved the following degradation results:

Chemical	Mean degradation / %
40% Sodium hydroxide (CAS: 1310-73-2)	-7.1
25% Ammonium hydroxide (CAS: 1336-21-6)	27.0
37% Formaldehyde (CAS: 50-00-0)	17.7
30% Hydrogen peroxide (CAS: 7722-84-1)	27.1
96% Sulphuric acid (CAS: 7664-93-9)	100.0

TESTING REQUIRED:

- EN ISO 374-4:2019. Protective gloves against dangerous chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

RESULTS:

Sample description:	Nitrile gloves, colour: orange, black		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	-12.1	-14.6	5.3
Mean degradation (DR) / %:	-7.1		
Standard deviation (σ_{DR}) / %:	10.8		
UoM / ± %:	5.6		
Appearance of samples after testing:	No change		

Sample description:	Nitrile gloves, colour: orange, black		
Challenge chemical:	25% Ammonium hydroxide (CAS: 1336-21-6)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	31.7	17.5	32.0
Mean degradation (DR) / %:	27.0		
Standard deviation (σ_{DR}) / %:	8.3		
UoM / ± %:	6.6		
Appearance of samples after testing:	Slightly swollen and discoloured		

Sample description:	Nitrile gloves, colour: orange, black		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	21.5	12.1	19.3
Mean degradation (DR) / %:	17.7		
Standard deviation (σ_{DR}) / %:	4.9		
UoM / ± %:	6.2		
Appearance of samples after testing:	No change		

Sample description:	Nitrile gloves, colour: orange, black		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	34.4	19.3	27.7
Mean degradation (DR) / %:	27.1		
Standard deviation (σ_{DR}) / %:	7.6		
UoM / ± %:	7.9		
Appearance of samples after testing:	Swollen and discoloured		

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

Sample description:	Nitrile gloves, colour: orange, black		
Challenge chemical:	96% Sulphuric acid (CAS: 7664-93-9)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	100.0	100.0	100.0
Mean degradation (DR) / %:	100.0		
Standard deviation (σ_{DR}) / %:	<1		
UoM / ± %:	N/A		
Appearance of samples after testing:	Softened, swollen, disintegrated and discoloured		

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

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23671

Customer details: Shandong Intco Medical Products Co Ltd
Qiwang Road, Naoshan Industrial Park
Qingzhou
Shandong
China
262506

SATRA reference: CHT0328812 /2212/A

Your reference:

Date of report: 12 April 2022

Samples received: 26 March 2022

Date(s) work carried out: 4 April 2022

TECHNICAL REPORT

Subject: EN 388: 2016+ A1: 2018 abrasion, blade cut, tear and puncture test on nitrile gloves, colour: orange, black, sizes M7, L8, XL9, XXL10.

Report signed by: Adam Zhang
Position: Technologist
Department: China Testing

Adam Zhang

TECHNICAL REPORT

23671

WORK REQUESTED

Samples described as nitrile gloves, colour: orange, black, sizes M7, L8, XL9, XXL10 were received by SATRA on 26 March 2022 for testing in accordance with EN 388:2016+A1:2018.

SAMPLE SUBMITTED

Nitrile gloves

TESTING REQUESTED

EN 388:2016 +A1:2018 Clause 6.1 – Abrasion resistance
EN 388:2016 +A1:2018 Clause 6.2 – Blade cut resistance
EN 388:2016 +A1:2018 Clause 6.4 – Tear Resistance
EN 388:2016 +A1:2018 Clause 6.5 – Puncture Resistance

CONCLUSION

The samples described as nitrile gloves, colour: orange, black, sizes M7, Lv8, XL9, XXL10 vwere found to achieve the following results:

EN 388:2016+A1:2018 Clause 6.1 – Level 0
EN 388:2016+A1:2018 Clause 6.2 – Level 0
EN 388:2016+A1:2018 Clause 6.4 – Level 0
EN 388:2016+A1:2018 Clause 6.5 – Level 0

Detailed results are included on the following page(s)

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 23671

TESTING

Testing was carried out in accordance with EN 388:2016+A1:2018.

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity.

REQUIREMENTS

Table 1 – Requirements for EN 388:2016 +A1:2018 Levels of performance

Performance Level	1	2	3	4	5
6.1Abrasion resistance (number of rubs)	100	500	2000	8000	-
6.2 Coupe test Blade cut resistance (index)	1.2	2.5	5.0	10	20
6.4 Tear resistance (N)	10	25	50	75	-
6.5Puncture resistance (N)	20	60	100	150	-

TEST RESULTS

Table 2 – EN 388:2016+A1:2018 Test Results

Clause / Test	Test Results					UoM (See note ♠)	Level
6.1 Abrasion resistance	Sample	Failure between / cycles	Physical change observed at end point			± 5 %	Level 0
	1	105-150	Hole				
	2	10-20	Hole				
	3	1-10	Hole				
	4	105-150	Hole				
	Abradant-Klingspor PL31B Gritt 180 Tape-3M 465 Abrasion machine compliant with EN 388:2016 +A1:2018 Clause 6.1.3						
6.2 Blade cut resistance	Sample	C_n Control specimen	Test specimen	C_{n+1} Control specimen	Cut Index	± 0.64	Level 0
	Left	0.8	0.1	1.1	1.11		
		1.1	0.1	0.8	1.11		
		0.8	0.1	0.8	1.13		
		0.8	0.1	0.8	1.13		
		0.8	0.1	1.1	1.11		
	Mean				1.11		
	Right	0.8	0.1	0.8	1.13		
		0.8	0.1	0.8	1.13		
		0.8	0.1	1.1	1.11		
		1.1	0.1	0.8	1.11		
		0.8	0.1	1.1	1.11		
	Mean				1.11		
	OLFA ® RB 45 mm blades used N° 14861 cotton canvas used from Tenthorey De La Plaine						
6.4 Tear resistance	Sample	Peak force / N				± 1.8 N	Level 0
	1	2.0					
	2	1.4					
	3	0.9					
	4	1.0					
6.5 Puncture resistance	Sample	Peak force / N				± 1.9 N	Level 0
	1	21.3					
	2	13.5					
	3	17.8					
	4	20.1					

ADDITONAL INFORMATION /NOTES

Note ♠ – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard.

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

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Customer details: SATRA Technology Services (Dongguan) Ltd
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523079

SATRA reference: CHM0329706/2215/CC
Your reference: CHT0328812
Date of report: 25th April 2022
Samples received: 11th April 2022
Date(s) work carried out: 11th to 25th April 2022

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Shandong Intoo Medical Products Co Ltd
Qiwang Road, Naoshan Industrial Park
Qingzhou
Shandong
262506
China

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Nitrile gloves, colour: orange, black.

Report signed by: Chelsea Craig
Position: Technical Administrator
Department: Chemical & Analytical Technology

TECHNICAL REPORT

0248

WORK REQUESTED:

Samples of gloves described as Nitrile gloves, colour: orange, black were received on the 11th April 2022 for testing in accordance with EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

SAMPLES SUBMITTED:

Samples described as Nitrile gloves, colour: orange

Samples described as Nitrile gloves, colour: black

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Nitrile gloves, colour: orange, black achieved the following performance levels:

Chemical	Performance level
n-Heptane (CAS: 142-82-5)	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
25% Ammonium hydroxide (CAS: 1336-21-6)	6
30% Hydrogen peroxide (CAS: 7722-84-1)	4
37% Formaldehyde (CAS: 50-00-0)	5

Full results are reported in the following tables.

TESTING REQUIRED:

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

RESULTS AND REQUIREMENTS:

EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Performance levels are based on the lowest individual result achieved per chemical.

TECHNICAL REPORT

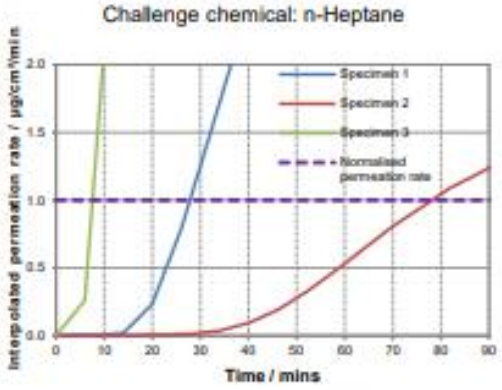
0248

Test/Property	Sample reference:	Nitrile gloves, colour: orange, black		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-005 Using stainless steel permeation cells with standardised dimensions	**Test information:**	Chemical: n-Heptane		**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 – Orange	0.28	27	
	2 – Black	0.24	78	
	3 – Orange	0.26	7	
	4 - Orange	0.25	53	
	5 – Black	0.24	42	
	6 - Orange	0.27	71	
		Test result:	**7**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Severely swollen		

In accordance with clauses 8.5.1.2 and 8.5.1.4, the test results were outside the defined range and required an additional 3 specimens to be tested. All 6 results have been reported and the sample was found to not meet with the minimum breakthrough time for a performance level 1 to be achieved.

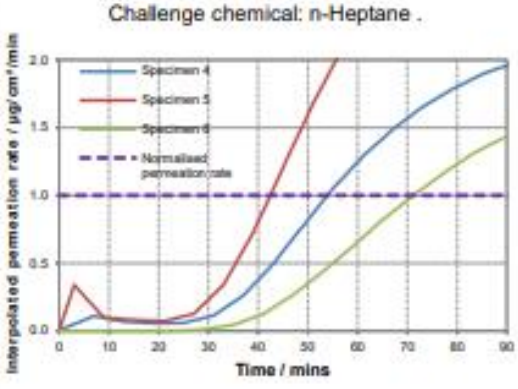
PERMEATION RATE GRAPHS

Challenge chemical: n-Heptane



PERMEATION RATE GRAPHS

Challenge chemical: n-Heptane .



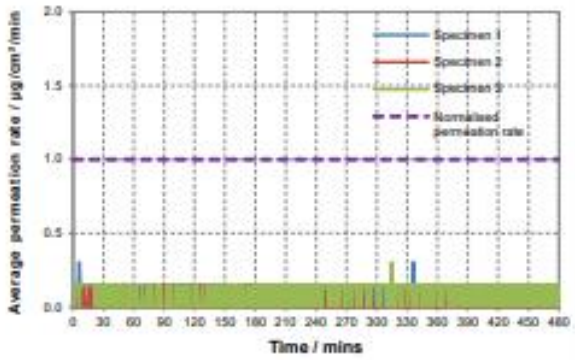
TECHNICAL REPORT

0248

Test/Property	Sample reference:	Nitrile gloves, colour: orange, black		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 – Orange	0.26	>480	
	2 – Black	0.29	>480	
	3 - Orange	0.24	>480	
		Test result:	**>480**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Slightly Swollen and slightly discoloured		

PERMEATION RATE GRAPHS

Challenge chemical: 40% Sodium Hydroxide .



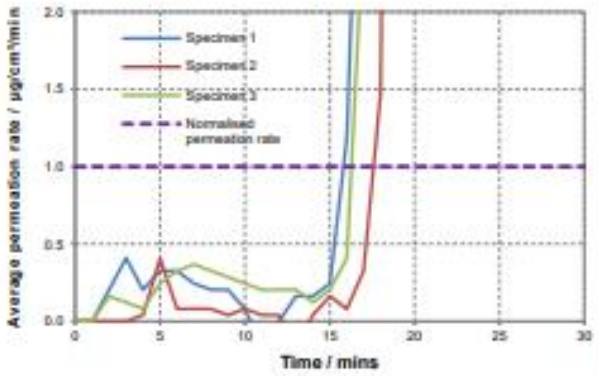
TECHNICAL REPORT

0248

Test/Property	Sample reference:	Nitrile gloves, colour: orange, black		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009 Using PTFE permeation cells with standardised dimensions	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		
	Specimen	**Thickness (mm)△**	**Breakthrough time (mins)**	
	1 – Orange	0.23	16	
	2 – Black	0.23	18	
	3 - Orange	0.29	17	
		Test result:	**16**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Swollen and discoloured		

PERMEATION RATE GRAPHS

Challenge chemical: 96% Sulphuric Acid .



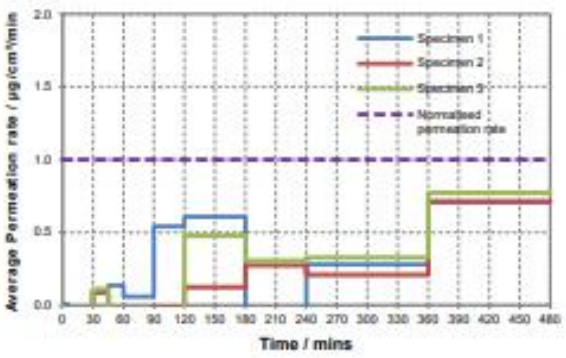
TECHNICAL REPORT

0248

Test/Property	Sample reference:	Nitrile gloves, colour: orange, black		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 25% Ammonium hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Ion Chromatography with conductivity 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 – Orange	0.27	>480	
	2 – Black	0.25	>480	
	3 – Orange	0.26	>480	
		Test result:	**>480**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Swollen and discoloured		

PERMEATION RATE GRAPHS

Challenge chemical: 25% Ammonium Hydroxide.



Ammonium Hydroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

TECHNICAL REPORT

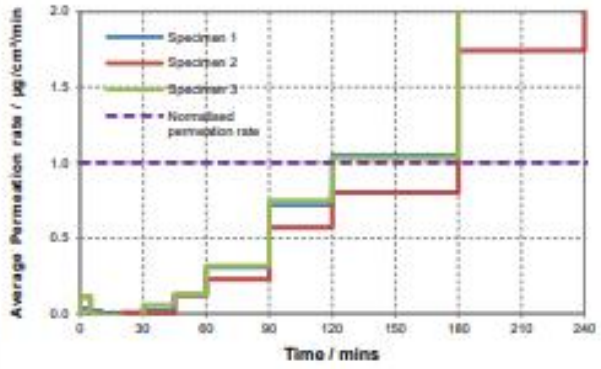
0248

Test/Property	Sample reference:	Nitrile gloves, colour: orange, black		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 4
		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 – Orange	0.28	Between 121 to 180	
	2 – Black	0.27	Between 181 to 240	
	3 – Orange	0.28	Between 121 to 180	
		Test result:	**Between 121 to 180**	
		UoM:	**See below**	
Visual appearance of specimens after testing:		Swollen and discoloured		

For SOP CAT-025, where both the P1 and Pu are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

PERMEATION RATE GRAPHS

Challenge chemical: 30% Hydrogen Peroxide.



Hydrogen peroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

TECHNICAL REPORT

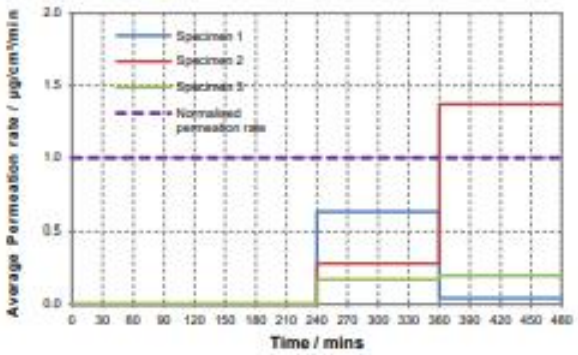
0248

Test/Property	Sample reference:	Nitrile gloves, colour: orange, black		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 5**
		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 – Orange	0.25	>480	
	2 – Black	0.25	Between 361 to 480	
	3 – Orange	0.27	>480	
		Test result:	**Between 361 to 480**	
		UoM:	**See below**	
Visual appearance of specimens after testing:		Swollen and discoloured		

For SOP CAT-025, where both the P1 and Pu are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

PERMEATION RATE GRAPHS

Challenge chemical: 37% Formaldehyde.



Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

△ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.

▲ The collection medium from each cell is analysed once every 6 minutes. Due to the complexity of the detection technique, the minimum sampling frequency for final results ≤ 60 minutes as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible. Breakthrough time is calculated using linear interpolation between the discrete sampling points.

▼ Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

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Customer details: Shandong Intco Medical Products Co Ltd
Qiwang Road, Naoshan Industrial Park
Qingzhou
Shandong
China
262506

SATRA reference: CHT0328812 /2212 /B

Your reference:

Date of report: 25 April 2022

Samples received: 26 March 2022

Date(s) work carried out: 2-14 April 2022

TECHNICAL REPORT

Subject: EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak, EN ISO 374-5: 2016 viruses test on nitrile gloves, colour: orange, black, sizes M7, L8, XL9, XXL10.

Report signed by: Adam Zhang
Position: Technologist
Department: China Testing

Adam Zhang

TECHNICAL REPORT

23671

WORK REQUESTED

Samples described as nitrile gloves, colour: orange, black, sizes M7, L8, XL9, XXL10 were received by SATRA on 26 March 2022 for testing in accordance with EN ISO 21420: 2020, EN ISO 374-2: 2019 and EN ISO 374-5: 2016.

SAMPLE SUBMITTED

Nitrile gloves

TESTING REQUESTED

EN ISO 21420: 2020 Clause 5.1 – Sizing and measurement of gloves
EN ISO 21420: 2020 Clause 5.2 – Dexterity
EN ISO 374-2: 2019 Clause 7.2 – Air leak
EN ISO 374-2: 2019 Clause 7.3 – Water leak
≠EN ISO 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 16604: 2004 Procedure B)
≠EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves

CONCLUSION

The samples described as nitrile gloves, colour: orange, black, sizes M7, L8, XL9, XXL10 were found to achieve the following results:

EN ISO 21420: 2020 Clause 5.1 – See below table
EN ISO 21420: 2020 Clause 5.2 – Level 5
EN ISO 374-2: 2019 Clause 7.2 – Pass
EN ISO 374-2: 2019 Clause 7.3 – Pass
≠EN ISO 374-5: 2016 Clause 5.3 – Pass
≠EN ISO 21420: 2020 Clause 4.2 – Pass pH value and PAHs

Detailed results are included on the following page(s)

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TESTING

Testing was carried out in accordance with EN ISO 21420:2020 and EN ISO 374-2: 2019

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity.

REQUIREMENTS

Table 1 – Requirements for EN ISO 21420: 2020 Clause 5.2 Dexterity

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

Table 2 – Requirements for EN ISO 374-2: 2019

Clause 7.2 Air leak	No leak to be detected
Clause 7.3 Water leak	No leak to be detected

TEST RESULTS

Table 3 – EN ISO 21420:2020 Test Results

Clause / Test	Requirement	Test Results				UoM (See note ♠)	Result
5.1 Glove length, comfort and fit	N/A	Size	Length /mm 1	2	3	± 1.10 mm	N/A
		7	248	250	250		
		Comfortable on fit					
		8	242	242	242		
		Comfortable on fit					
		9	253	252	253		
		Comfortable on fit					
		10	259	259	263		
		Comfortable on fit					
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm			N/A	Level 5
		7	5.0				
		8	5.0				
		9	5.0				
		10	5.0				

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

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total air pressure used	2.9 kPa	± 0.25 kPa	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	NA	Pass
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		

ADDITIONAL INFORMATION / NOTES

Note ♣ – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard

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PROTECTION AGAINST VIRUSES TEST RESULTS

Testing was conducted at a third-party laboratory and reported under their reference 220074309. The laboratory is CNAS accredited to ISO 17025: 2017 with ISO 16604: 2004 included in their accreditation schedule.

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

Sample description:		Nitrile gloves, colour: orange				
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:		Nitrile gloves, colour: black				
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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INNOCUOUSNESS TEST RESULTS

Testing was conducted at a third-party laboratory and reported under their reference A220402048001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	Orange nitrile gloves	Gloves	1
I002	Black nitrile gloves	Gloves	2

pH Value - EN ISO 21420:2020

Test Method I : With reference to EN ISO 4045:2018, analyzed by pH meter.
Test Method II: With reference to ISO 3071:2020, analyzed by pH meter.

Requirement:	3.5-9.5

-	Unit	Result	
Test Item(s)	-	**I001**	**I002**
Test Method	-	**II**	**II**
Parameter	-	-	-
pH Value of Extracting Solution	-	6.11	6.11
Temp. of Aqueous Extract	deg. C	25.1	25.1
pH Value of Aqueous Extract	-	6.6	6.5
Difference Figure	-	-	-
Conclusion	-	PASS	PASS

Note / Key : deg. C = degree Celsius (°C) Temp. = Temperature
Remark: Result(s) was (were) reported the average value from two trials.
Tested part(s) was/were specified by client.

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Polycyclic Aromatic Hydrocarbons (PAHs) Content - EN ISO 21420:2020

Test Method : With reference to test method PD CEN ISO/TS 16190:2013

Maximum Allowable Limit:	**Each of all listed PAHs: 1.0 mg/kg**

Tested Item(s)	Result			Conclusion
	Detected Analyte(s)	Conc.	Unit	
I001+I002	ND	ND	mg/kg	PASS

Note / Key : ND = Not detected(<Detection Limit) Detection Limit (mg/kg) : Each : 0.2;
mg/kg = milligram per kilogram = ppm = part per million

Remark: The list of polycyclic aromatic hyrdocarbons is summarized in table of Appendix.
Tested part(s) was/were specified by client.
Composite testing(s) was/were specified by client.

APPENDIX

List of Polynuclear Aromatic Hydrocarbons:

No.	Name of Analytes	CAS-No.	No.	Name of Analytes	CAS-No.
1	Chrysene	218-01-9	5	Dibenzo (a,h) anthracene	53-70-3
2	Benzo (a) pyrene	50-32-8	6	Benzo (b) fluoranthene	205-99-2
3	Benzo (e) pyrene	192-97-2	7	Benzo (j) fluoranthene	205-82-3
4	Benzo (a) anthracene	56-55-3	8	Benzo (k) fluoranthene	207-08-9

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

Test Report

No. TAOHG2203886501 Date: 15 Jun 2022 Page 1 of 5

Client Name : SHANDONG INTCO MEDICAL PRODUCTS CO., LTD

Client Address : NO.9888,QIWANG ROAD,NAOSHAN INDUSTRY PARK,QINGZHOU,SHANDONG,CHINA

Sample Name : DIAMOND TEXTURED NITRILE GLOVES

The above sample(s) and information were provided by the client.

SGS Job No. : QDHL2205007192CW - QD

Date of Sample Received : 01 Jun 2022

Testing Period : 01 Jun 2022 - 15 Jun 2022

Test Requested : Selected test(s) as requested by the client.

Test Method(s) : Please refer to next page(s).

Test Result(s) : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Council of Europe Resolution AP (2004) 4 -Overall migration	PASS
Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 -Sensorial examination odour and taste test	PASS
Council of Europe Resolution AP (2004) 4 -Specific migration of primary aromatic amine	PASS
Council of Europe Resolution AP (2004) 4 -Specific migration of nitrosamine and nitrosatable substances	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

Wang Bo, Claire
Approved Signatory

scan to see the report

TAOHG2203886501

Test Result(s) :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TAO22-038865.001	Orange rubber glove	Nitrile rubber

Remarks :

(1) mg/dm² = milligram per square decimeter
(2) mg/kg = milligram per kilogram
(3) °C= degree Celsius
(4) < = less than
(5) MDL = Method Detection Limit
(6) ND = Not Detected (< MDL)

Council of Europe Resolution AP (2004) 4 -Overall migration

Test Method : With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods;
EN 1186-9: 2002 aqueous food simulants by article filling method;
EN 1186-2: 2002 olive oil by total immersion method;

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 001 Overall Migration	Conclusion
3% Acetic acid (W/V) aqueous solution	0.5hr(s)	40°C	10mg/dm²	8.2mg/dm²	PASS
10% Ethanol (V/V) aqueous solution	0.5hr(s)	40°C	10mg/dm²	6.6mg/dm²	PASS
Rectified olive oil	0.5hr(s)	40°C	10mg/dm²	3.5mg/dm²	PASS
Area/Volume			-	10.0dm²/kg	

Notes :

(1) Analytical tolerance of aqueous simulants is 2 mg/dm² or 12 mg/kg.
(2) Analytical tolerance of fatty food simulants is 3 mg/dm² or 20mg/kg.
(3) Test condition & simulant were specified by client.
(4) Report the first migration result.
(5) The test of rectified olive oil simulant was subcontracted to SGS Ningbo chemical lab.

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 -Sensorial examination odour and taste test

Test Method : With reference to DIN 10955: 2004
Test media: Distilled water
No. of panelist: 6

Test Item(s)	Limit	*001*
Test time (hr)	-	0.5
Temperature (°C)	-	40
Sensorial examination odour (Point scale)	2.5	0.0
Sensorial examination taste (Point scale)	2.5	0.0
Conclusion		**PASS**

Notes :

Intensity scale (rounded at 0.5):
0 – no perceptible difference
1 – just perceptible difference
2 – slight difference
3 – marked difference
4 – strong difference

Council of Europe Resolution AP (2004) 4 -Specific migration of primary aromatic amine

Test Method : With reference to EN 13130-1: 2004, analysis was performed by UV-Vis.

Sample 001

Simulant Used : 3% Acetic acid (W/V) aqueous solution
Test Condition : 40 °C 0.5 hr(s)

Test Item(s)	Max. Permissible Limit	Unit	MDL	Test result
Migration times	-	-	-	First
Area/volume	-	dm²/kg	-	6.0
Specific migration of primary aromatic amine	ND	mg/kg	0.01	ND
Conclusion				**PASS**

Notes :

(1) Test condition & simulant were specified by client.

Council of Europe Resolution AP (2004) 4 -Specific migration of nitrosamine and nitrosatable substances

Test Method : With reference to EN 13130-1: 2004, analysis was performed by GC-MS.

Sample 001

Simulant Used : 3% Acetic acid (W/V) aqueous solution
Test Condition : 40 °C 0.5 hr(s)

Test Item(s)	Max. Permissible Limit	Unit	MDL	Test result
Migration times	-	-	-	First
Area/volume	-	dm²/kg	-	6.0
Specific migration of Nitrosamines	0.01	mg/kg	0.01	ND
Specific migration of Nitrosatable substances	0.1	mg/kg	0.1	ND
Conclusion				**PASS**

Notes :

(1) Nitrosamines tested: N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA), N-nitrosodipropylamine (NDPA), N-nitrosodibutylamine (NDBA), N-nitrosopiperidine (NPIP), N-nitrosopyrrolidine (NPYR), N-nitrosomorpholine (NMOR), N-nitrosodibenzylamine (NDBzA), N-nitroso-N-methyl-N-phenylamine (NMPhA), N-nitroso-N-ethyl-N-phenylamine (NEPhA), N-nitrosodiisononylamine (NDiNA) and N-Nitrosodiisobutylamine (NDiBA)
(2) Test condition & simulant were specified by client.
(3) The test was subcontracted to SGS Ningbo chemical lab.
Unless otherwise stated, the decision rule for conformity reporting is based on Binary Statement for Simple Acceptance Rule (w=0) stated in ILAC-G8:09/2019.

Sample photo:

TAO22-038865.001

SGS authenticate the photo on original report only

*** End of Report ***