PharmacyGo™
MEDICAL SUPPLIES

Gloves

NITRILE

- ✓ **On the ground availability**
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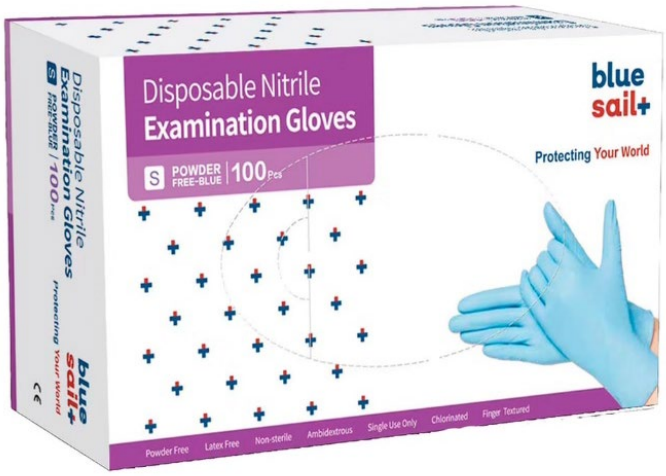
- ✓ **Ocean Freight also available**
- ✓ **HEALTH CANADA APPROVED**
- ✓ **Quantities and large volumes available**



Health Canada Licence No: 102741

- Powder-Free
- Disposable
- Medical Examination gloves
- Latex-free
- Sizes: XS/ S/ M/ L/ XL
- Colours: White, blue, black, cobalt blue, blue purple

Health Canada License Listing

Français

Government of Canada | Gouvernement du Canada

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Home → Drugs & Health Products → Medical Devices → Medical Devices Active Licence Listing

Active licence listing by company

From Health Canada

Archived Licence Search

New search

Revision date: 2020-10-23

[redacted]

Licence No.: 102741

Type: Device Family
Device class: 2
Device first issue date: 2019-04-15
Licence name: POWDER FREE NITRILE EXAMINATION GLOVES

Device details

Device first issue date	Device name	Identifier first issue date	Device identifier
2019-04-15	POWDER FREE NITRILE EXAM GLOVES	2019-04-15	0102016-BLUE-XS
		2019-04-15	0102017-BLUE-S
		2019-04-15	0102018-BLUE-M
		2019-04-15	0102019-BLUE-L
		2019-04-15	0102020-BLUE-XL
		2019-04-15	0102026-VIOLET-XS
		2019-04-15	0102027-VIOLET-S
		2019-04-15	0102028-VIOLET-M
		2019-04-15	0102029-VIOLET-L
		2019-04-15	0102030-VIOLET-XL
		2019-04-15	0102036-COBALT-XS
		2019-04-15	0102037-COBALT-S
		2019-04-15	0102038-COBALT-M
		2019-04-15	0102039-COBALT-L
		2019-04-15	0102040-COBALT-XL

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 062837 0012 Rev. 02

Holder of Certificate: [redacted]

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of Disposable Vinyl Examination Gloves, Disposable Nitrile Examination Gloves.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ19924043

Valid from: 2019-11-12
Valid until: 2022-07-31

Date, 2019-11-12

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Test Report No. 7191233436-EEC20/01-WBH
dated 13 Apr 2020

PSB Singapore

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Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Powder Free Nitrile Examination Gloves submitted by Blue Sail Medical Co., Ltd. on 05 Mar 2020.

TESTED FOR:

[redacted]

TEST DATE:

09 Mar 2020 to 09 Apr 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Powder-Free Examination Gloves	BS 020-N01	Blue	01254511	XS	60	Blue Sail Medical Co., Ltd.
				01254512	S	60	
				01264711	M	60	
				01264712	L	60	
				01264921	XL	400	

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

1. EN 455-1:2000 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes

2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation

PSB Singapore

RESULTS:

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N01, Blue

Table 1: Results for EN 455-1:2000

Clause	Tests	Size	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	XS	Shall not leak	10	315	0	Passed
		S		10	315	1	Passed
		M		10	315	1	Passed
		L		10	315	1	Passed
		XL		10	315	1	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	XS	≥ 240	13	243	Passed
		S		13	246	Passed
		M		13	242	Passed
		L		13	242	Passed
		XL		13	250	Passed
	b) Width (mm)	XS	≤ 80	13	80	Passed
		S	80 ± 10	13	84	Passed
		M	95 ± 10	13	95	Passed
		L	110 ± 10	13	105	Passed
		XL	≥ 110	13	115	Passed
5	Strength a) Force at break (N)	XS	For nitrile examination gloves: ≥ 6.0	13	10.8	Passed
		S		13	8.7	Passed
		M		13	8.0	Passed
		L		13	10.9	Passed
		XL		13	10.8	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	XS	For nitrile examination gloves: ≥ 6.0	13	9.6	Passed
		S		13	8.7	Passed
		M		13	8.0	Passed
		L		13	10.3	Passed
		XL		13	10.8	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N01, Blue

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks		Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is powder-free glove, based on client's declaration letter version 2019001		NA
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients		NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'		NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	XS	0.04 mg per glove	Passed
			S	0.17 mg per glove	Passed
			M	0.51 mg per glove	Passed
			L	0.14 mg per glove	Passed
			XL	0.18 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Non-natural rubber latex glove		NA

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

PSB Singapore

REMARKS:

1. Freedom from holes test for XS, S, M and L sizes were tested in manufacturer's site, witnessed by TÜV SÜD Certification and Testing (China) Co., Ltd. Beijing Branch on 04 Apr 2020.

2. Labelling requirements are assessed based on submitted packaging artwork together with client's declaration letter version number 2019001.

3. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

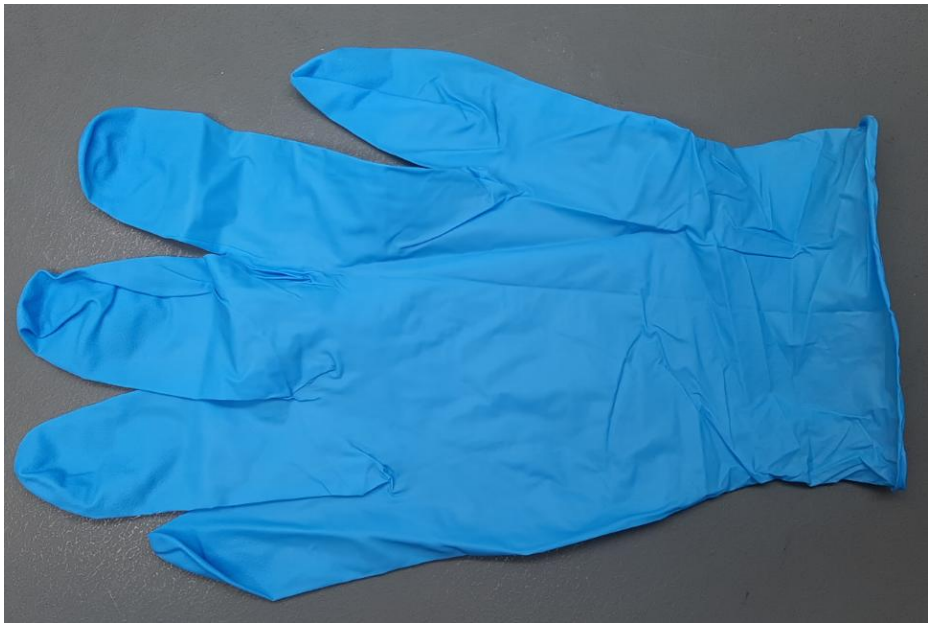

Photo : Disposable Nitrile Powder-Free Examination Gloves, BS 020-N01, Blue

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Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

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5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011

Test Report No. 7191233436-EEC20/03-WBH
dated 13 Apr 2020

PSB Singapore

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SUBJECT:

Testing of Powder Free Nitrile Examination Gloves submitted by Blue Sail Medical Co., Ltd. on 05 Mar 2020.

TESTED FOR:

[redacted]

TEST DATE:

09 Mar 2020 to 09 Apr 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Powder-Free Examination Gloves	BS 020-N03	Blue Purple	02153711	XS	60	Blue Sail Medical Co., Ltd.
				02163811	S	60	
				02153922	M	60	
				02164612	L	60	

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

1. EN 455-1:2000 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes

2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
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Singapore 118221

Phone : +65-6885 1333
Fax : +65-6776 8670
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www.tuv-sud-psb.sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221

RESULTS:

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N03, Blue Purple

Table 1: Results for EN 455-1:2000

Clause	Tests	Size	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	XS	Shall not leak	10	315	0	Passed
		S		10	315	1	Passed
		M		10	315	0	Passed
		L		10	315	1	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	XS	≥ 240	13	240	Passed
		S		13	242	Passed
		M		13	248	Passed
		L		13	248	Passed
	b) Width (mm)	XS	≤ 80	13	80	Passed
		S	80 ± 10	13	85	Passed
		M	95 ± 10	13	96	Passed
		L	110 ± 10	13	104	Passed
5	Strength a) Force at break (N)	XS	For nitrile examination gloves: ≥ 6.0	13	7.2	Passed
		S		13	6.6	Passed
		M		13	6.4	Passed
		L		13	6.3	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	XS	For nitrile examination gloves: ≥ 6.0	13	6.8	Passed
		S		13	6.9	Passed
		M		13	6.3	Passed
		L		13	6.9	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N03, Blue Purple

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks		Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is powder-free glove, based on client's declaration letter version 2019001		NA
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients		NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'		NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	XS	0.02 mg per glove	Passed
			S	0.06 mg per glove	Passed
			M	0.27 mg per glove	Passed
			L	0.24 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Non-natural rubber latex glove		NA

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
			Inferred results: Passed

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REMARKS:

1. Freedom from holes test for XS, S, M and L sizes were tested in manufacturer's site, witnessed by TÜV SÜD Certification and Testing (China) Co., Ltd. Beijing Branch on 04 Apr 2020.

2. Labelling requirements are assessed based on submitted packaging artwork together with client's declaration letter version number 2019001.

3. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

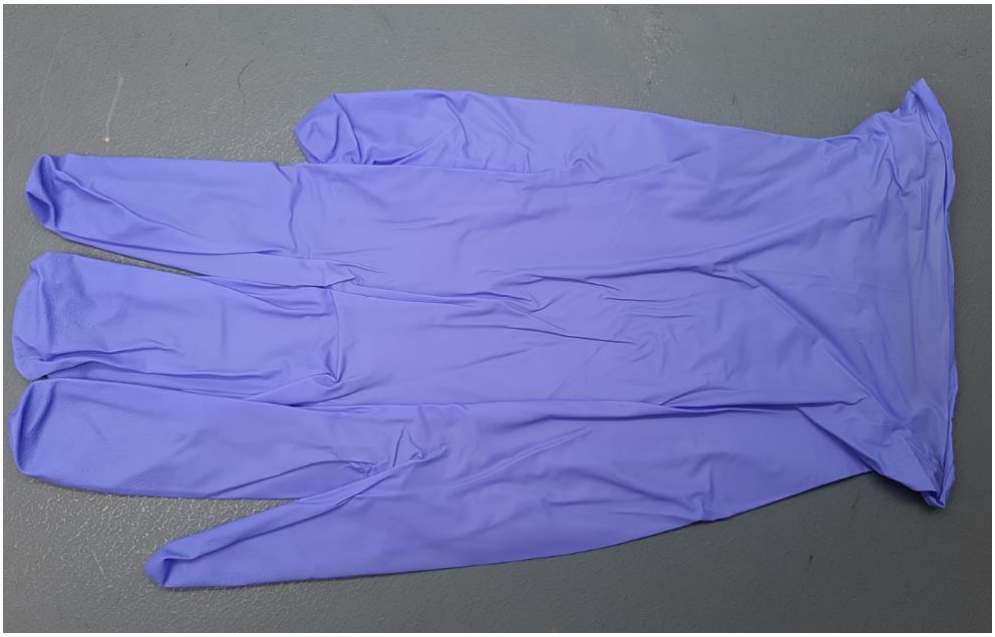

Photo: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N03, Blue Purple

PSB Singapore

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July 2011

Test Report

No. TAOHG1900588501 Date: 28 Feb 2019 Page 1 of 4

[redacted]

The following sample(s) was/were submitted and identified on behalf of the clients as : POWDER FREE NITRILE EXAMINATION GLOVES, BLUE

SGS Job No. :	QDHL1902002781OT - QD
Item No. :	M
Date of Sample Received :	18 Feb 2019
Testing Period :	18 Feb 2019 - 28 Feb 2019
Test Requested :	Selected test(s) as requested by client.
Test Method :	Please refer to next page(s).
Test Results :	Please refer to next page(s).

Result Summary :

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

Conclusion : The tested parameters comply with the requirement stated in Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004.

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

Wang Bo, Claire
Approved Signatory

QDHL1902002781OT

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86–532) 68999888 f (86–532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TAO19-005885.001	Blue rubber gloves	Rubber

Remarks :

(1) mg/dm² = milligram per square decimeter
(2) mg/kg = milligram per kilogram
(3) ℃= 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	2.0hr(s)	70℃	10mg/dm²	<3.0mg/dm²	PASS
10% Ethanol (V/V) aqueous solution	2.0hr(s)	70℃	10mg/dm²	<3.0mg/dm²	PASS
Rectified olive oil	2.0hr(s)	70℃	10mg/dm²	<3.0mg/dm²	PASS

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) The test data is obtained by considering the articles intended for repeated use as per described in Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex V. Report the 3rd extractive result.
(5)The rectified olive oil simulant test was subcontracted to SGS Shanghai chemical lab.

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℃ 2.0hr(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	0.01	mg/kg	0.01	ND
Conclusion				**PASS**

Notes :
(1)Test condition & simulant were specified by client.
(2)The test was subcontracted to SGS Shanghai chemical lab.

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℃ 2.0hr(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 Shanghai chemical lab.

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
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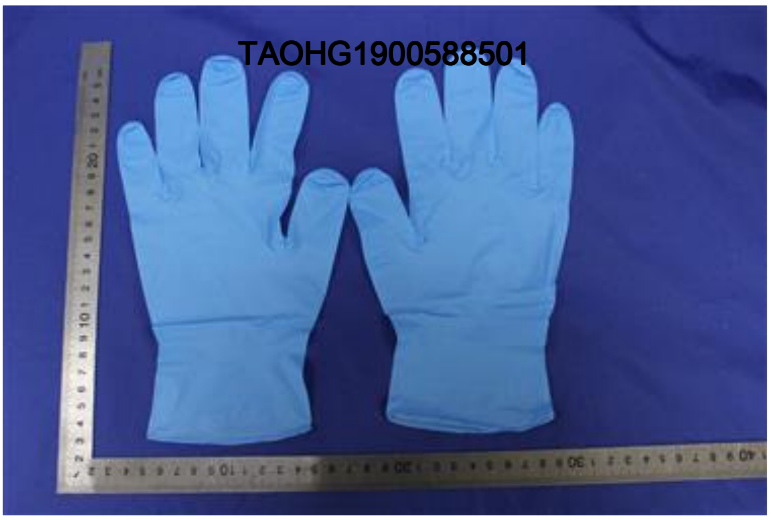
e sgs.china@sgs.com

Sample photo:



TAO19-005885.001

SGS authenticate the photo on original report only

*** End of Report ***

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