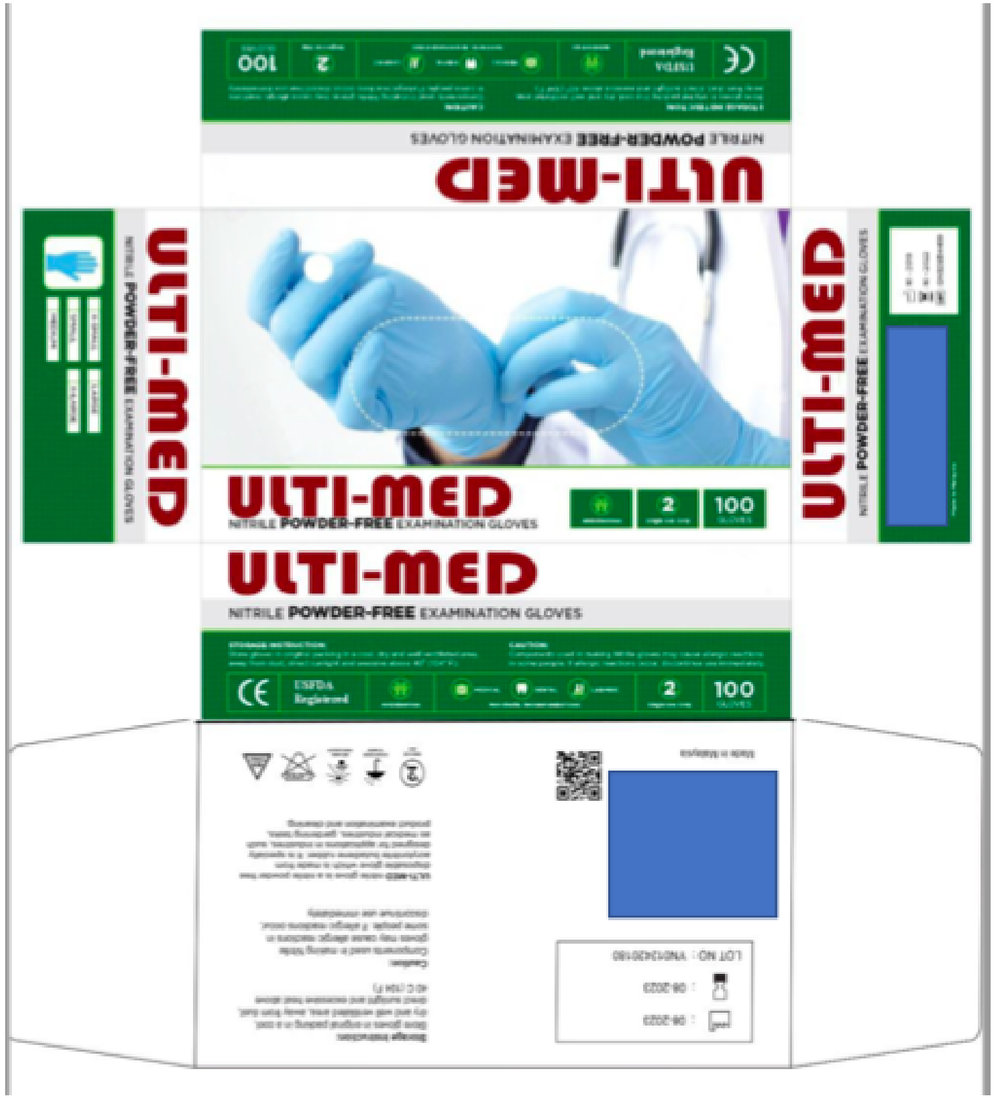
NITRILE GLOVES

100 PER BOX

APPENDIX A: PACKAGING



APPENDIX B: PHYSICAL DIMENSIONS

Gloves Physical Dimensions

Dimensions	Standards		
	Gloves	ASTM D3578	EN 455
Length (mm)	Min 230 Min 240 300 ± 10	Min 220 (XS , S) Min 230 (M, L , XL)	Min 240
Palm width (mm)			
• XS	76 ± 3	70 ± 10	≤80
• S	84 ± 3	80 ± 10	80 ± 10
• M	94 ± 3	95 ± 10	95 ± 10
• L	105 ± 3	110 ± 10	110 ± 10
• XL	113 ± 3	120 ± 10	≥110
Thickness: Single wall (mm)			
• Finger	0.09±0.02	± 0.07	N/A
• Palm	0.07±0.02	± 0.07	N/A

Properties	ASTM D6319	EN 455
Tensile Strength (MPa)		
• Before Aging	Min 14	N/A
• After Aging	Min 14	N/A
Elongation at Break (%)		
• Before Aging	Min 500	N/A
• After Aging	Min 400	N/A
Median Force at Break (N)		
• Before Aging	N/A	Min 6
• After Aging	N/A	Min 6

TEST REPORT:

Date: 09 JAN 2014 Tel: +65 68851312 Fax: +65 67784301

Client's Ref: 221403179Rev1 Email: zhou.xiao@tuv-sud-psb.sg

PSB Singapore

Choose certainty. Add value.

SUBJECT

Overall Migration Test for "Powder Free Nitrile Exam Gloves" Sample

CLIENT

SAMPLE SUBMISSION DATE

16 Oct 2013 & 30 Oct 2013

DESCRIPTION OF SAMPLE

A packet of sample labelled as follows was received. The tests were confirmed to be analysed on 13 Dec 2013.

Glove Type	Code	Lot No.	Size
Powder Free Nitrile Exam Gloves	N28FFB	TUV141013-01	M

DATE OF ANALYSIS

18 Dec 2013 – 06 Jan 2014

METHOD OF TEST

The sample was analysed for the following tests according to Commission Regulation (EU) No 10/2011.

1. **Preparation of Test Specimen**

   Only the exterior of the glove sample was performed for the test.

2. **Overall Migration Content with Aqueous Food Simulant (10% Ethanol, 3% Acetic Acid, 20% Ethanol & 50% Ethanol)**

   According to BS EN 1186-9:2002 – Test Methods for overall migration into aqueous food simulants by article filling.

3. **Overall Migration Content with Fatty Food Simulant (Olive Oil)**

   According to BS EN 1186-8:2002 – Test Methods for overall migration into olive oil by article filling.

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

Phone : +65-6885 1333
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Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
3 Science Park Drive, #04-01/05
The Franklin, Singapore 118223

RESULTS

Table 1 : Overall Migration Content with Food Simulants for the "Powder Free Nitrile Exam Gloves, N28FFB, Lot No.:TUV141013-01" Sample

Type of Simulant	Testing Condition	Surface Area (dm^2)	Volume of Extractant (ml)	Overall Migration (mg/dm^2)	Commission Regulation (EU) No 10/2011 Requirement for Overall Migration Content (mg/dm^2)
1. 10% Ethanol	40 °C, 2 hours	5.14	250	<1.0	<10
2. 3% Acetic Acid	40 °C, 2 hours	5.08	250	1.6	<10
3. 20% Ethanol	40 °C, 2 hours	5.11	250	<1.0	<10
4. 50% Ethanol	40 °C, 2 hours	5.12	250	2.6	<10
5. Vegetable Oil (Olive Oil)	40 °C, 2 hours	5.06	250	<1.0	<10

Based on the above results, the "Powder Free Nitrile Exam Gloves, N28FFB, Lot No.: TUV141013-01" sample met the overall migration requirements under Commission Regulation (EU) No 10/2011 – "Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams of total constituents released per dm^2 of food contact surface (mg/dm^2) (overall migration limit)".

MS TAN SER LING
TECHNICAL EXECUTIVE

DR XIAO ZHOU
PRODUCT MANAGER
MICROCONTAMINATION DIAGNOSIS
CHEMICAL & MATERIALS

Cc: YTY Industry (Manjung)Sdn Bhd

TEST REPORT:
09 JAN 2014

PSB Singapore

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 TUV SUD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TUV SUD 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. TUV SUD 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 TUV SUD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TUV SUD PSB or to the report or results furnished by TUV SUD PSB in any advertisements or sales promotion.

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

July 2011

Product Certificates

SGMP Company Limited
บริษัท เอสจีเอ็มพี จำกัด

181 Moo 6, Tambol Kampaengphet, Amphur Rattaphum, Songkhla 90180 Thailand. Tel: (074) 894065-6, Fax: (074) 498595
เลขที่ 181 หมู่ที่ 6 ตำบลคำแพงพระ อำเภอรัตภูมิ จังหวัดสงขลา 90180 โทร. (074) 894065-6 แฟกซ์ (074) 498595

DECLARATION OF CONFORMITY

Product Name	:	Nitrile Examination Gloves (Non-Sterile)
Type	:	Ambidextrous Powder-Free Black, White & Blue
Manufacturer's Name	:	S G M P Company Limited
Manufacturer's Address	:	181 Moo 6, Tambol Kampaengphet Amphur Rattaphum, Songkhla 90180 Thailand
Document No.	:	SGMP-CE-DC-NITRILE-001
Classification	:	Class I
Brand	:	Sunrise Nitrile Examination Gloves Sunrise Latex Examination Gloves

I, the undersign, hereby declare that the medical device(s) specified above conforms to the Essential Requirements listed in Annex VII of Medical Devices Directive (MDD) 93/42/ECC and bears the mark

CE

This Declaration of Conformity is valid in connection with the release document for the respective batch produced devices. The above-mentioned declaration of conformity is under the responsibility of Manufacturer.

Danny Chiong
RAQA Officer

SGMP Company Limited
26 June 2020

For use in contact with aqueous foods:

Extractants	Test Condition	RL (mg/Inch²)	Result (mg/inch²) M002	Permissible Limit (mg/Inch²)
Distilled Water	Reflux temperature for 7 hours	0.1	0.7	20
	Succeeding 2 hours of extraction	0.1	0.2	1
Comment	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	RL (mg/Inch²)	Result (mg/inch²) M002	Permissible Limit (mg/Inch²)
n-Hexane	Reflux temperature for 7 hours	0.1	0.4	175
	Succeeding 2 hours of extraction	0.1	n.d.	4
Comment	--	--	Pass	--

For use in contact with aqueous foods:

Extractants	Test Condition	RL (mg/Inch²)	Result (mg/inch²) M003	Permissible Limit (mg/Inch²)
Distilled Water	Reflux temperature for 7 hours	0.1	0.7	20
	Succeeding 2 hours of extraction	0.1	n.d.	1
Comment	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	RL (mg/Inch²)	Result (mg/inch²) M003	Permissible Limit (mg/Inch²)
n-Hexane	Reflux temperature for 7 hours	0.1	0.4	175
	Succeeding 2 hours of extraction	0.1	n.d.	4
Comment	--	--	Pass	--

For use in contact with aqueous foods:

Extractants	Test Condition	RL (mg/Inch²)	Result (mg/inch²) M004	Permissible Limit (mg/Inch²)
Distilled Water	Reflux temperature for 7 hours	0.1	0.8	20
	Succeeding 2 hours of extraction	0.1	n.d.	1
Comment	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	RL (mg/Inch²)	Result (mg/inch²) M004	Permissible Limit (mg/Inch²)
n-Hexane	Reflux temperature for 7 hours	0.1	0.4	175
	Succeeding 2 hours of extraction	0.1	n.d.	4
Comment	--	--	Pass	--

Abbreviation: n.d. denotes Not Detected (<RL)
RL denotes Reporting Limit
mg/inch² denotes Milligram per square inch

Test No.	T003		T004	
Material No.	M003		M004	
Tested no.	Force at break Before ageing (N)	Force at break After ageing (N)	Force at break Before ageing (N)	Force at break After ageing (N)
1	99.13	7.97	6.71	5.20
2	7.32	7.32	7.37	5.83
3	7.15	7060	6.57	5.49
4	8.16	7085	7.70	5.37
5	9.04	7072	7.16	5.57
6	8.59	7.84	6.40	5.34
7	7.86	7.33	7.70	4.48
8	8.33	8.29	5.73	4.68
9	7.74	7.39	7.05	5.85
10	9.65	9.11	7.58	4.45
11	7.89	9.26	7.27	5.33
12	7.84	6.87	6.35	4.58
13	9.59	7.73	8.26	5.73
Median result	8.33	7.87	7.06	5.22
Conclusion	Pass	Pass	Pass	Pass

Abbreviation: N denotes Newton

Remark:
1. Median values of force at break

Force at Break (newton)		
a)	b)	c)
≥ 9.0	≥ 6.0	≥ 3.0

a) Requirements for all surgical gloves
b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene)
c) Requirements for gloves made from thermoplastic materials (e.g. Polyvinylchloride, Polyethylene)

Proteins extraction

Test method: With reference to EN 455-3: 2015 (E), Annex A.

Test result:

Test No.	Material No.	Test parameter	Unit	MDL	Test result
T001	M001	Proteins	µg/g	3	n.d.
T002	M002	Proteins	µg/g	3	n.d.
T003	M003	Proteins	µg/g	3	n.d.
T004	M004	Proteins	µg/g	3	n.d.

Abbreviation: µg/g denotes Microgram per gram
MDL denotes Method Detection Limit

Remark: The leachable protein level shall be "As Low As Reasonable Practicable" (ALARP)

US FDA 21 CFR 177.2600 (Rubber Articles) – Determination of Amount of Extractives

Test Method: With reference to US FDA 21 CFR 177.2600.

For use in contact with aqueous foods:

Extractants	Test Condition	RL (mg/inch²)	Result (mg/inch²)	Permissible Limit (mg/inch²)
			M001	
Distilled Water	Reflux temperature for 7 hours	0.1	0.5	20
	Succeeding 2 hours of extraction	0.1	n.d.	1
Comment	--	--	Pass	--

For use in contact with fatty foods:

Extractants	Test Condition	RL (mg/inch²)	Result (mg/inch²)	Permissible Limit (mg/inch²)
			M001	
n-Hexane	Reflux temperature for 7 hours	0.1	0.2	175
	Succeeding 2 hours of extraction	0.1	n.d.	4
Comment	--	--	Pass	--

Test No.:	T003		T004	
Material No.:	M003		M004	
Tested no.	Length (mm)	Width (mm)	Length (mm)	Width (mm)
1	245	110	245	116
2	246	110	244	116
3	245	110	245	119
4	245	110	244	116
5	245	110	245	116
6	245	110	245	115
7	245	111	245	116
8	246	110	244	117
9	245	110	245	116
10	246	110	245	116
11	245	110	245	116
12	245	110	245	116
13	245	111	245	116
Median result	245	110	245	116
Conclusion	Pass	Pass	Pass	Pass

Abbreviation: mm denotes millimeter

Remark: Dimension limit reference to table

Size	Median length (mm)	Median width (mm)
Extra small	≥ 240	≤ 80
Small		80±10
Medium		95±10
Large		110±10
Extra large		≥ 110

Products

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Force at break

Test method: EN 455-2: 2015

Test results:

Test No.	T001		T002	
Material No.	M001		M002	
Tested no.	Force at break Before ageing (N)	Force at break After ageing (N)	Force at break Before ageing (N)	Force at break After ageing (N)
1	6.31	6.33	10.11	10.98
2	7.22	6.81	9.45	8.67
3	6.47	5.92	9.75	10.57
4	7.46	6.72	8.33	9.41
5	5.56	5.35	10.80	8.94
6	5.47	5.93	8.48	10.75
7	6.18	6.70	8.80	9.46
8	6.32	4.80	10.00	8.65
9	5.72	6.21	9.95	9.83
10	6.71	5.87	9.12	9.58
11	6.45	6.68	9.11	8.90
12	5.87	5.95	11.02	8.40
13	6.53	6.52	8.97	10.54
Median result	6.33	6.14	9.53	9.59
Conclusion	Pass	Pass	Pass	Pass

TÜV Rheinland Thailand Ltd. · Global Technology Assessment Center Bangkok (GTAC BKK) Ladkrabang Industrial Estate 123/1,
Soi Chalongkung 31, Lamplatew, Ladkrabang, Bangkok 10520 Thailand
Tel.: +66 (0) 2326-1333 Fax.: +66 (0) 2326-1334-5 Email: info@tha.tuv.com · Web:www.tuv.com

Freedom from holes

Test method: With reference to EN 455-1: 2000

Test result:

Gloves Size	Tested samples	No. of samples for Non-compliance	Conclusion
S	200 pcs.	1	Pass
M	200 pcs.	0	Pass
L	200 pcs.	0	Pass
XL	200 pcs.	0	Pass

Remark:

1. All samples were selected and supplied by the client.
2. The batch size of the gloves supplied was not stated by the client. In accordance with BS EN 455-1, a batch size between 35,001 to 150,000 was chosen, and therefore 50 gloves per stage were tested for perforations using General Inspection Level I at an AQL of 1.5%. with reference to table;

Stage No.	Cumulative no. tested	Accept	Reject
First	50	0	4
Second	100	1	6
Third	150	3	8
Fourth	200	5	9
Fifth	250	9	19

Dimension test

Test method: EN 455-2: 2015

Test results:

Test No.:	T001		T002	
Material No.:	M001		M002	
Tested no.	Length (mm)	Width (mm)	Length (mm)	Width (mm)
1	246	85	244	94
2	246	86	244	94
3	245	85	246	94
4	246	85	246	94
5	245	85	245	94
6	245	85	244	93
7	245	84	245	94
8	245	85	245	94
9	245	85	244	94
10	244	82	244	94
11	245	85	244	94
12	243	85	244	95
13	244	85	244	94
Median result	245	85	245	94
Conclusion	Pass	Pass	Pass	Pass

Product Certificates

SGS

Test Report No. 4605024 Date : 23-May-2020 Page 3 of 3

SAMPLE/ATTACHMENT PICTURE

---------- End of Report ----------

4306737

Products

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Test Report No.: 60393368-001 Page 2 of 11

Sampling Information:

Inspection Method: No inspection, submitted sample by client
Inspection level: N/A
AQL: N/A
Sample size: N/A

Material list:

Material No.	Material	Color	Location
M001	Nitrile Glove	Purple	Size S
M002	Nitrile Glove	Blue	Size M
M003	Nitrile Glove	Blue	Size L
M004	Nitrile Glove	Blue	Size XL

Product Certificates

FDA

FDA Home[3] Medical Devices[4] Databases[5]

510(k) Premarket Notification

510(k)[7] | DeNovo[8] | Registration & Listing[9] | Adverse Events[10] | Recalls[11] | PMA[12] | HDE[13] | Classification[14] | Standards[15]

CFR Title 21[16] | Radiation-Emitting Products[17] | X-Ray Assembler[18] | Medsun Reports[19] | CLIA[20] | TPLC[21]

New Search | Back To Search Results

Device Classification Name	Polymer Patient Examination Glove[22]
510(K) Number	K000868
Device Name	NON-STERILE POWDER-FREE, BLUE NITRILE EXAMINATION GLOVES
Applicant	SGMP CO., LTD. 181 MOO 6, TAMBOL KAMPAENGPETCH, RATTAPHUM Songkhla, TH 90180
Applicant Contact	Cheah Chor Hee
Correspondent	SGMP CO., LTD. 181 MOO 6, TAMBOL KAMPAENGPETCH, RATTAPHUM Songkhla, TH 90180
Correspondent Contact	Cheah Chor Hee
Regulation Number	880.6250[23]
Classification Product Code	LZA[24]
Date Received	03/17/2000
Decision Date	04/20/2000
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm

Product Certificates

SGS

ilac-MRA

Test Report No. 4605024 Date : 23-May-2020

Client :

The following sample(s) was/were submitted and identified by client as:

Sample Name	: Disposble Rubber Glove
Color	: White (Nature)
Manufacturer/Vendor	: SAS Rubber Product Co.,Ltd.
Country of Origin	: Thailand
Country of Destination	: Around the world

The following sample(s) was/were identified by SGS as:

SGS Sample No.	: 4778104
Sample Condition	: Sample is contained in a plastic bag.
Quantity Submitted	: 1 pair
Sample Receiving Date	: 19-May-2020
Testing Period	: 19-May-2020 to 23-May-2020
Test Method & Results	: Please refer to next page(s).

Test Requested & Result Summary

Test Requested : Please refer to the result summary (Test parameter(s) was/were selected by client).

Result Summary:

Test Requested	Conclusion
US FDA 21 CFR 177.2600 (Rubber Articles)-	--
Determination of Amount of Extractives	
- Distilled Water Extractants	PASS
- n-Hexane Extractants	PASS

Remark:Test results in this report are applicable for the item tested and reflects the tested sample as received.

Signed for and on behalf of
SGS (Thailand) Limited

Rutchuporn Moungsom
Laboratory manager - Toy and Hardgood

4306737

Product Certificates

Indications for Use

510(k) Number (if known): K042879

Device Name: NON-STERILE, POWDER-FREE BLUE NITRILE EXAMINATION GLOVES WITH VANILLA SCENTING

Indications For Use: **This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.**

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K042879

Product Certificates

FDA U.S. Food & Drug Administration

FDA Home[3] Medical Devices[4] Databases[5]

510(k) Premarket Notification

(510(k)[7]|DeNovo[8]|Registration & Listing[9]|Adverse Events[10]|Recalls[11]|PMA[12]|HDE[13]|Classification[14]|Standards[15] CFR Title 21[16]|Radiation-Emitting Products[17]|X-Ray Assembler[18]|Medsun Reports[19]|CLIA[20]|TPLC[21])

New Search | Back To Search Results

Device Classification Name	Polymer Patient Examination Glove[22]
510(K) Number	K020317
Device Name	NON-STERILE POWDER FREE GREEN BARRIER-PRO SYNTHETIC BUTADIENE COPOLYMER EXAMINATION GLOVE, COLOR: BLUE
Applicant	SGMP CO., LTD. 198 AVENUE DE LA D'EMERALD Sparks, NV 89434
Applicant Contact	Janna Tucker
Correspondent	SGMP CO., LTD. 198 AVENUE DE LA D'EMERALD Sparks, NV 89434
Correspondent Contact	Janna Tucker
Regulation Number	880.6250[23]
Classification Product Code	LZA[24]
Date Received	01/30/2002
Decision Date	02/14/2002
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary[25]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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9. /scripts/cdrh/cfdocs/cfRL/rl.cfm

Product Certificates

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2005

SGMP Company Limited
C/O Ms. Janna P. Tucker
Official Correspondent
Tucker & Associates
198 Avenue De La D' Emerald
Sparks, Nevada 89434-9550

Re: K042879
Trade/Device Name: Non-Sterile, Powder-Free Blue Nitrile Examination Gloves with Vanilla Scenting
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: December 31, 2004
Received: January 4, 2005

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Product Certificates

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Product Certificates

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

Applicant : SGMP Company Limited

510K NUMBER: K072400

Device Name : Non-Sterile, Powder Free Black Nitrile Examination Gloves

Indication For Use :

The Non-sterile Powder Free Black Nitrile Examination Gloves , is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use ..... **AND / OR** **Over-The-Counter.....✓**
(Part 21 CFR 801.Subpart D) **21 CFR 801 Subpart C**

Concurrence of CDRH , Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072400

Product Certificates

FDA

FDA Home[3] Medical Devices[4] Databases[5]

510(k) Premarket Notification

(510(k)[7] DeNovo[8] Registration & Listing[9] Adverse Events[10] Recalls[11] PMA[12] HDE[13] Classification[14] Standards[15] CFR Title 21[16] Radiation-Emitting Products[17] X-Ray Assembler[18] Medsun Reports[19] CLIA[20] TPLC[21]

New Search Back To Search Results

Device Classification Name	Polymer Patient Examination Glove[22]
510(K) Number	K042879
Device Name	NON-STERILE POWDER-FREE BLUE NITRILE EXAMINATION GLOVES, WITH VANILLA SCENTING
Applicant	SGMP CO., LTD. 198 AVENUE DE LA D'EMERALD Sparks, NV 89434
Applicant Contact	Janna P Tucker
Correspondent	SGMP CO., LTD. 198 AVENUE DE LA D'EMERALD Sparks, NV 89434
Correspondent Contact	Janna P Tucker
Regulation Number	880.6250[23]
Classification Product Code	LZA[24]
Date Received	10/18/2004
Decision Date	01/13/2005
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary[25]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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Product Certificates

K042879

JAN 13 2005

APPENDIX L

510(k) SUMMARY

SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR POWDER-FREE BLUE NITRILE EXAMINATION WITH VANILLA SCENTING

Submitted For : SGMP Company Limited, 181 Moo 6, Tambol Kampaengpetch, Rattaphum, Songkhla 90180, Thailand.

Submitted By: Tucker & Associates
Official Correspondent for SGMP Co Ltd
Janna P. Tucker, President – CEO
198 Avenue de la D'emerald, Sparks, NV 89434-9550
Phone No : 775-342-2612 Fax No : 775-342-2613
E-mail: Tuckerjan@aol.com

Equivalent Predicate Device: POWDER FREE NITRILE EXAM GLOVES which was granted a 510 (k) # K000868 as shown in APPENDIX M

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Device Information:
Trade Name – NON-STERILE POWDER FREE BLUE NITRILE EXAMINATION GLOVES WITH VANILLA SCENTING
Common Name - Exam gloves
Classification Name - Patient examination glove (per 21 CFR 880.6250)
Classification Information - Class I nitrile patient examination glove 80LZA, powder free and meeting all the requirements of ASTM-D6319-00aE1 Standard Specification for Nitrile Examination Gloves for Medical Application.

Device Description:
Class I nitrile patient examination gloves 80LZA, powder free and meeting all the requirements of ASTM-D6319-00aE1 Standard Specification for Nitrile Examination Gloves for Medical Application.

Intended Use of Device:
A medical glove to be worn on the hand of the health care and similar personnel to prevent contamination between health care personnel and patient.

Product Certificates

K072400

Conclusion:

The data presented indicate the Non-sterile Powder-Free Black Nitrile Examination Glove meets the following Standards:

1. ASTM D6319-00aE3, Standard Specification For Nitrile Gloves.
2. ISO 2859-1, Standard for Water Leak Test and/or ASTM D5151-06, Standard Test Method for Detection of Holes in Medical Gloves.
3. ASTM D6124-06, Standard Test Method for Residual Powder on Medical Gloves.
4. Biocompatibility Testing on White rabbits and Guinea Pigs.
5. Labeling meets FDA Specifications
6. Except for Color, this glove is equivalent to K000868.

APPENDIX K

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Product Certificates

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2008

SGMP Company, Limited
C/O Ms. Janna P. Tucker
Official Correspondent/ United States Agent
Tucker & Associates
198 Avenue De La D' Emerald
Sparks, Nevada 89434-9550

Re: K072400
Trade/Device Name: Non-Sterile, Powder Free Black Nitrile Examination Gloves
Regulation Number: 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: March 11, 2008
Received: March 13, 2008

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Product Certificates

FDA

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510(k) Premarket Notification

[510(k)[7]|DeNovo[8]|Registration & Listing[9]|Adverse Events[10]|Recalls[11]|PMA[12]|HDE[13]|Classification[14]|Standards[15]
CDRH SuperSearch
CFR Title 21[16]|Radiation-Emitting Products[17]|X-Ray Assembler[18]|Medsun Reports[19]|CLIA[20]|TPLC[21]]

New Search | Back To Search Results

Device Classification Name	Polymer Patient Examination Glove[22]
510(K) Number	K072400
Device Name	NON-STERILE, POWDER-FREE, BLACK NITRILE EXAMINATION GLOVES
Applicant	SGMP CO., LTD. 198 AVENUE DE LA D'EMERALD Sparks, NV 89434
Applicant Contact	Janna P Tucker
Correspondent	SGMP CO., LTD. 198 AVENUE DE LA D'EMERALD Sparks, NV 89434
Correspondent Contact	Janna P Tucker
Regulation Number	880.6250[23]
Classification Product Code	LZA[24]
Date Received	08/27/2007
Decision Date	03/27/2008
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary[25]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
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10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
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13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
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Product Certificates

MAR 2 7 2008 APPENDIX K

510(k) SUMMARY K072400

SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR NON-STERILE, POWDER FREE BLACK NITRILE EXAMINATION GLOVES

Submitted For : SGMP Company Limited, 181 Moo 6, Tambol Kampaengpetch, Rattaphum, Songkhla 90180, Thailand

Submitted By: Tucker & Associates
Official Correspondent for SGMP Co Ltd
Janna P. Tucker, President – CEO
198 Avenue de la D'emerald, Sparks, NV 89434-9550
Phone No : 775-342-2612 Fax No : 775-342-2613
E-mail: Tuckerjan@aol.com

Equivalent Predicate Device: POWDER FREE BLUE NITRILE EXAM GLOVES which was granted a 510(k) # K000868

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Device Information:
Trade Name – Non-Sterile, Powder Free Black Nitrile Examination Gloves

Common Name - Exam gloves
Classification Name - Patient examination glove (per 21 CFR 880.6250)
Classification Information - Class I Nitrile examination glove 80LZA, powder free and meeting all the requirements of ASTM D6319-00aE3 Standard Specification for Nitrile Examination Gloves for Medical Application.

Device Description:
Class I Nitrile examination gloves 80LZA, powder free and meeting all the requirements of ASTM D6319-00aE3 Standard Specification for Nitrile Examination Gloves for Medical Application.

Intended Use of Device:
A medical glove to be worn on the hand of the health care and similar personnel to prevent contamination between health care personnel and patient.

Product Certificates

K101822

CONCLUSION:

The data presented indicates the Powder-Free, Blue Nitrile Examination Gloves, Tested for Use With Chemotherapy Drugs Labeling Claim, (Non-Sterile), K101822 is equivalent to K082957, Non-Sterile, Powder-free Nitrile Examination Gloves, Blue with Polymer Coating, Tested for use with Chemotherapy Drugs.

It should be noted that testing for use with two chemotherapy drugs had extremely low permeation times as follows: CARMUSTINE (BCNU) @ 0.49 minutes, and THIOTEPA @ 2.61 minutes. Therefore, these gloves are not approved for use when using those chemo drugs.

These gloves do meet the following recognized standards unless otherwise noted:

ASTM D6319-00a00A(2005), Standard Specification for Nitrile Gloves

ISO 2859-1, Standard for Water Leak Test and/or ASTM D5151-06, Test Method for Detection of Holes in Medical Gloves

ASTM D6124-06, Standard Test Method for Residual Powder on Medical Gloves.

Biocompatibility Testing on White Rabbits and Guinea Pigs

Labeling meets FDA requirement

Substantially equivalent to Siam Sempermed Corp. Ltd. K082957

ASTM D6978-05 Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs.

Product Certificates

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SGMP Company, Limited
C/O Ms. Janna P. Tucker
Tucker & Associates
198 Avenue De La D'Emerald
Sparks, Nevada 89434

NOV 19 2010

Re: K101822
Trade/Device Name: Non-Sterile, Powder Free Blue Nitrile Examination Gloves
Tested for use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA/LZC
Dated: October 22, 2010
Received: October 21, 2010

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Product Certificates

K101822

8. Substantial Equivalence Discussion :

Characteristic and Parameter	SGMP Company Limited Non-sterile , Powder-free Blue Nitrile Examination Gloves. Tested for use with Chemotherapy Drugs	Siam Sempermed Corp.Ltd. Non-sterile , Powder-free Nitrile Examination Glove , Blue with Polymer Coating, Tested for use with Chemotherapy Drugs 510 K # K082957	Substantial Equivalence (SE)
Devise Class	I	I	SE
Product Code	LZA	LZA	SE
Glove Color	Blue	Blue	SE
Dimensions	Meets ASTM D6319-00a-05	Meets ASTM D6319-00a-05	SE
Physical Properties	Meets ASTM D6319-00a-05	Meets ASTM D6319-00a-05	SE
Freedom From Pinholes	Meets ASTM D6319-00a-05	Meets ASTM D6319-00a-05	SE
Powder-free Residue	Meets ASTM D6124-06	Meets ASTM D6124-06	SE

Product Certificates

K101822

Biocompatibility Test	Passes Primary Skin Irritation in Rabbits	Passes Primary Skin Irritation in Rabbits	SE
	Passes Guinea Pig Maximization	Passes Guinea Pig Sensitization	SE
Chemotherapy Drugs Tests	Meets ASTM D6978-05 Cisplatin > 240 mins Cyclophosphamide > 240 mins Doxorubicin Hydrochloride > 240 mins Etoposide > 240 mins Flurouracil > 240 mins Paclitaxel > 240 mins Vencristine Sulfate > 240 mins Dacarbazine > 240 mins Methotrexate > 240 mins	Meets ASTM D6978-05 Cisplatin > 240 mins Cyclophosphamide > 240 mins Doxorubicin Hydrochloride > 240 mins Etoposide > 240 mins Flurouracil > 240 mins Paclitaxel > 240 mins Vencristine Sulfate > 240 mins Dacarbazine > 240 mins Methotrexate > 240 mins	SE

Product Certificates

K101822

510 (k) SUMMARY APPENDIX M

(As Required by 21 section 807.92 (c))

NOV 19 2010

1. **Submitted For :**
   SGMP Company Limited
   181 Moo 6, Tambol Kampaengphet ,
   Rattaphum , Songkhla 90180 Thailand,

2. **Submitted By :**
   Tucker & Associates
   Official Correspondent for SGMP Company Limited
   Janna P.Tucker , President – CEO
   198 , Avenue de la D'emerald , Sparks,
   NV 89434-9550
   Phone No : 775-342-2612
   Fax No : 775-342-2613
   Email : Tuckerjan@aol.com

3. **Device Trade or Proprietary Name :**
   Non-sterile , Powder-free Blue Nitrile Examination Gloves, Tested for use with Chemotherapy Drugs.

4. **Device Common Name :**
   Examination Gloves

5. **Device Classification Name :**
   Patient Examination Gloves (per 21CFR 880.6250)

6. **Device Description :**
   Non-sterile , Powder-free Blue Nitrile Examination Gloves , Tested for use with Chemotherapy Drugs.

7. **Intended Use of Device :**
   A disposable medical glove to be worn on the hand of the healthcare and similar personnel to prevent contamination between healthcare personnel and patient.

ATCH 2
APPENDIX M revised 10-12-10, Janna Tucker
Now shows Equivalence to K082957

Product Certificates

K101822

The Non-sterile Powder Free Blue Nitrile Examination Gloves Tested for use with Chemotherapy Drugs , is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Chemotherapy Drug Permeation (Breakthrough Detection Time) in Minutes
The following chemical have been tested with these gloves.

Test Chemotherapy Drug	Average Breakthrough Detection Time (Minutes)
***Carmustine (BCNU)**	**0.49 minutes**
Cisplatin	>240 minutes
Cyclophosphamide (Cytoxan)	>240 minutes
Doxorubicin Hydrochloride	>240 minutes
Etoposide (Toposar)	>240 minutes
Flurouracil	>240 minutes
Paclitaxel (Taxol)	>240 minutes
***Thiotepa**	**2.61 minutes**
Vincristine Sulfate	>240 minutes
Dacarbazine (DTIC)	>240 minutes
Methotrexate	>240 minutes

*Please note that Carmustine (BCNU) and Thiotepa have extremely low permeation times of 0.49 and 2.61 minute only.

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Product Certificates

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CERTIFICATE

No. QS5 18 06 52111 005

Certificate Holder: SGMP Company Limited
181 Moo 6,Tambol Kampaengphet
Amphur Rattaphum,Songkhla Pro. 90180
THAILAND

Certification Mark:

Scope of Certificate: Design and Development, Production and Distribution of Non-sterile Powdered and Powder Free Examination Gloves

Standard(s): ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: M2930

Effective Date: 2018-06-13
Expiry Date: 2021-06-01

Manuel Bradaric
MHS Certification Manager

Page 1 of 1

TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

UCB_F_12.04 2012-02

Product Certificates

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CERTIFICATE

No. QS6 18 06 52111 004

Certificate Holder: SGMP Company Limited
181 Moo 6,Tambol Kampaengphet
Amphur Rattaphum,Songkhla Pro. 90180
THAILAND

Certification Mark:

Scope of Certificate: Design and Development, Production and Distribution of Non-sterile Powdered and Powder Free Examination Gloves

Standard(s): ISO 13485:2016

Regulatory Authority: Health Canada.
See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website
http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: 66-072-9989
Effective Date: 2018-06-02
Expiry Date: 2021-06-01

Manuel Bradaric
MHS Certification Manager

Page 1 of 2

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UCB_F_12.02 2012-02

Product Certificates

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America

CERTIFICATE

No. QS6 18 06 52111 004

Audit/Certification Criteria

Canada

- **Medical Device Regulations SOR/98-282, Part 1**

Effective Date: 2018-06-02
Expiry Date: 2021-06-01

Manuel Bradaric
Certification Manager MHS

UCIL_F_12.02 2013-02

TÜV SÜD AMERICA INC • 10 Centennial Drive • Peabody, MA 01960 USA • www.TUVamerica.com

TÜV®

Product Certificates

SATRA TECHNOLOGY

Issued to:

SGMP Company Limited
181 Moo6
Tambol Kampaenghet
Amphur Rattaphum
Songkhla 90180
Thailand

Notified Body: 2777

SATRA customer number: P1643

EU Type-Examination Certificate

Certificate number: 2777/14166-01/E00-00

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:

PF NBR 8mil

Description:

Powder free Nitrile Glove, 8mil with Pattern texture available in Black, Orange, Green and Yellow colours.

Sizes:

Medium – 5558PF-M
Large – 5558PF-L
X-Large – 5558PF-XL
XX-Large – 5558PF-XXL

Classification:

EN ISO 374-1:2016/ Type C	Level	EN 374-4: 2013 Degradation %
n-Heptane (J)	2	27
40% Sodium Hydroxide (K)	6	-58.7
96% Sulphuric Acid (L)	0	100.0

EN ISO 374-5: 2016	Result
Protection against bacteria and fungi	Pass
Protection against viruses	N/A

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN 388:2016+A1:2018; EN ISO 374-1:2016+A1:2018

Technical reports/Approval documents:
SATRA: SPC0247447/1626/2, CHM0247460/1626/EN/B, CHM0260647/1731/EN, CHM0262288/1738/SMcD/B, SPC0262693/1740, CHM0262288/1738/SMcD/A

Signed on behalf of SATRA: Besjana Pilinci Quincey Brown

Date first issued: 26/02/2020
Date of issue: 26/02/2020

Expiry date: 26/02/2025

SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YNCP, Republic of Ireland.