

PRODUCT DETAILS SPECIFICATIONS AND CERTIFICATION

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- KYC/ Know Your Client.
- Supplier Information Sheet
- Production Information
- Production Specification
- Supplier and Product Certification
- Good Quality Management Certification

SUPPLIER JURISTIC CLIENT INFORMATION SHEET

Registered No :	
Registered Type:	
Registered Date :	24/06/2014
Status :	Active Operating
Registered Capital (Baht)	5,000,000.00
Address :	
Industry group in registered document :	24202 : Manufacture of medical and surgical wears
Industrial group in latest financial statement :	24101 : Manufacture and exporter of goods in secondary and consuming form
Fiscal Year (submitted financial statement):	2563 2562 2561 2560 2559 2558
Board of Directors List :	
Authorized director :	
Authorized director No 1 :	
Passport Number:	
Identity card Number:	
E-mail address :	
A SHARMAN POWER TO	

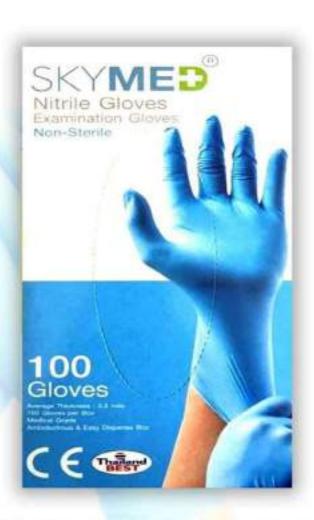


Nitrile Examination Gloves

BRAND: SKYMED

We Strive to supply the best of quality.





All Products are quality tested, certified and cleared before export



PRODUCT STANDARDISATION

Nitrile Powder Free Examination Gloves.

Inspection level and AQL.

Characteristic	Inspection level	AQL
1) Freedom from holes	GI	1.5
2) Physical dimension (Width, length, thickness)	5-2	4.0
3) Physical properties (before and after accelerated aging)	S-2	4.0
4) Powder Amount	N=2	N/A
5) Powder free residue	N=5	N/A
6) Protein content	N=3	N/A

Dimensions and Tolerances

Size	Width (mm)	Minimun length	Minimun length	Thickness (mm)		1)	
	width (mm)	(mm)	(mm)	Finger	Palm	Cuff	
XS	75±5	290 Min	240 Min				
5	85±5	290 Min	240 Min	0,12 Min	0.10 Min	0.07 Min	
M	95±5	290 Min	240 Min				0.07 Min
L	106±5	290 Min	240 Min				
XL	115±5	290 Min	240 Min				

Feature

- -Premium quality
- -Full textured surface and finger textured surface
- -Ambidextrous
- -Single use only





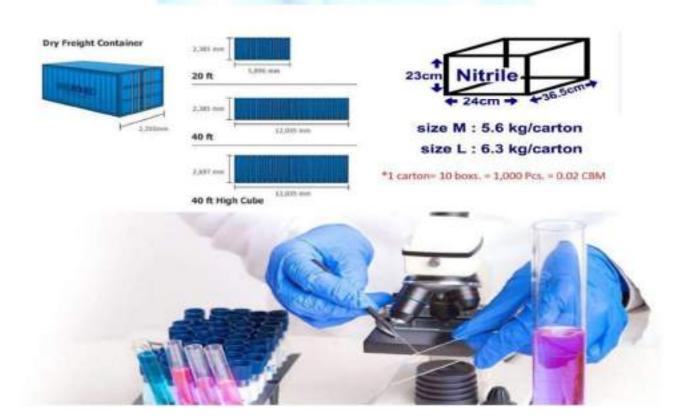
MANAGEMENT AND VALUE

We are committed to providing safe and effective products for healthcare providers and other users. This entails strict and stringent measures in manufacturing process and product quality control as well as a persistent attention to R&D efforts. The ultimate aim is to achieve complete customer satisfaction and ensure minimum risk in using the company's products.

Presently, each manufacturer can produce over 20 million pieces per day for all types of gloves. We all can definitely increase our production capacities to response customers' demands in worldwide.

The core values represent the high degree of quality in the gloves we produce. Being in the middle of numerous rubber plantations and having an extensive amount of raw materials at our fingertips extends us an advantage in producing top quality products.

Manufacturing operations are also accredited with ISO 9001:2008 and EN ISO 13485:2003 under CMDCAS. These qualifications ensure that we adhere to a strict quality management system that guarantees the highest quality of gloves are produced.





Product Properties: Nitrile Powder Free Non-Sterile

Type : Powder-Free

Specification : Non-Sterile, Ambidextrous, Disposable

Cuff : Beaded

Surface : Smooth/Textured

Color : Blue

Main Material : Natural Concentrated Latex

Parameter 1. Silicone-Free 2. Chloride Max. 0.85 mg./g.

3. Amide Non Detectable 4. DOP Non Detectable

Characteristic	Inspection level	AQL
1) Freedom from holes	GI	1.5
2) Physical dimension (Width, length, thickness)	5-2	4.0
3) Physical properties (before and after accelerated aging)	5-2	4.0
1) Powder Amount	N=2	N/A
5) Powder free residue	N=5	N/A
6) Protein content	N=3	N/A

Dimensions and Tolerances

Size	Width (mm)	Minimun length	Minimun length	Thickness (mm)		1)
	widui (min)	(mm)	(mm)	Finger	Palm	Cuff
XS	75±5	290 Min	240 Min	0.12 Min		
5	85±5	290 Min	240 Min		0.10 Min 0	
M	95±5	290 Min	240 Min			0.07 Min
L	106±5	290 Min	240 Min			
XL	115±5	290 Min	240 Min			

Quality : Conformed to ASTM D 3619

And FDA 510(K)

Confirmed to EN455 Part 1-3 and CE

Standard Packing : 100 pcs per box

10 boxes per carton

1200cartons/20ft container



We, the manufacturer, herewith declare that the products

Examination Gloves Non Sterile

UMDNS-Code: 1182

Meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex VII of the Directive 93/42/EEC. It bears the mark



The product concerned has been manufactured under a quality management system according to Annex VII of Directive 93/42/EEC.

Following the procedure relating to the EC Deck Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of conformity and inconnection with the release document for the respective batch of produced devices.





Certificate of Registration



in recognition of the organization's Quality Management System which complies with

EN ISO

The scope of activities covered by this certificate is defined below

Production of Latex, Nitrile, and Vinyl Disposable Examination Gloves Alcohol Swabs, Face Masks, Under Pads, Diapers, Head Covers and Shoe Covers

Certificate Number:

Date of Issue: (Original)

Date of issue:

20 February 2018

20 February 2018 -

sue No:

Expiry Date:

19 February 2021

issued by:



On behalf of the Schemes Manager











GMP CERTIFICATE

Ref. No. Valid until: 15 March 2021



is found to conform to the current Medical Device Good Manufacturing Practice 2005 laid down in accordance with the International Standard Requirements.

Scope : Manufacturing of Examination glove and Surgical glove



Certification Services for Accreditation (Europe) Ltd.



Verification Compliance

This verification of compliance is hereby issued to the below named company issued in cognisance of European Product Safety requirements for Confirming European Standards in the following product:

SAOWAPA GARMENT COMPANY LIMITED

BANG CHAN KHLONG SAM WA BANGKOK

In respect of protective To EN



is documented in line with the requirements as per the declaration of the organisation the product falls within the category.

This certificate of conformity is based on the evaluation of a sample of the above mentioned product. This is to certify that the tested sample is in conformity with all the provisions. The applicant is authorised to use this certificate.

The CE mark as shown below can be used under the responsibility of the applicant as compliance with all relevant EC directives

Valid until DEC 2022



Certificate authorised for issue by:
Chairman and CEO
CSA(E):

MS



Accreditation Certificate Reference:



Certified that the above product /organisation has been registered in with the CSA(E) terms and conditions.

> Certification Services for Accreditation (Europe) Ltd. 94 Peterson Street, Telford, Shropshire, TF3 4DE, U.K.



Report No.: 40162415-01

INSPECTION REPORT

(Special for Epidemic prevention materials)

IMPORTANT INFORMATION REGARDING THE SCOPE AND LIMITATIONS OF THE INSPECTION AND REPORT

The scope of this report is limited to a VISUAL INSPECTION ONLY for the workmanship and basic function check of the product.

T		
To: From:		
T TOTTI.		
SGS File No.:	40162419	Product family view
Buyer:	DEWA CLINIC	
Supplier:		
Manufacturer:		
Style Number: Product description:		560
P.O. Number:	N/A	
SPA Number:	N/A	
Service performed:	FRI	SHEET STATE AND VALUE
Inspection Date:	-	AND THE RESERVE OF THE PERSON
Inspection Location:		
Inspection Criteria		
Reference sample pro		Not Available
Client instruction/spec	cification	Yes
SGS WI number Other		I NI/A
Other		N/A
Overall Inspection	Conclusion:	Conform
Inspection Summary	:	
1. Workmanship appe		Conform
2. Quantity:		Conform
3. Style, Material, Col	lour:	Not Conform Remark #01, 02
4. Data measurement	t / Function/Field tests:	Actual Finding
5. Packing:		Actual Finding
6. Marking / Label:		Actual finding
Problem Remark:		1
Inspector: S		Factory Representative: V

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Report No.:	
	J

- 1. There was no reference sample provided at inspection time.
- 2. Inspector found additional color during inspection:
 - + Booking: only Blue color
 - + Actual finding: 2 color (Blue color & White color).

1. Workmanship Appearance / Functional Inspection Findings: Inspection Method Applied:

Within AQL

ANSI / ASQ Z1.4-2003(R2018), Single sampling plans for normal inspection,

Level: II

Acceptance Quality Limit(AQL) for:

Critical: 0

Major: 2.5

Minor: 4.0

Sample size: 50,000,000 boxes

(50,000,000 boxes /sets selected from packed cartons, 0 pieces/sets selected from finished but unpacked products) Samples selected from carton numbers: 39 cartons without carton number.

Defect description	Critical	Major	Minor
Small stain mark at finger			1
Hole at palm		1	
Tear at finger		1	
Stain mark at palm		1	
Small stain mark at palm			1
Small stain mark at finger			1
Pin hole at finger		1	
Small stain mark at palm			4
Small stain mark at cuff			1
Tear at palm		1	
Small stain mark at palm			1
Fray at cuff		1	
Small stain mark at finger			1
Small stain mark at cuff			1
Stain mark at finger		1	
Small stain mark at palm			1
Stain mark at palm		1	
Fray at cuff		1	
Total defectives:	0	9	12
Maximum allowed:	0	21	21

Inspector:	S	Factory Representative: V	
•			-

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Report No.:40162415-01



Defect photos:



Inspector: Factory Representative:

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Inspector: Factory Representative:	Inspector:	Factory Representative:	
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Minor defect: Small stain mark at palm

Minor defect: Small stain mark at cuff





nspector:	Factory Representative
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2. Quantity:

No	Style / Itam/ Article	Item/ Article P.O. No.	Order Qty.	Inspection Qty. (Presented Qty. for insp.)		Number	of Cartons
	Style / Item/ Article		. No. Order Qty.	Packed	Not Packed	Packed	Not packed
1	SKY MED	N/A	800000	800000	0	800	0
	_	Total:	800000	800000	0	800	0

Inspector:	Factory Representative:	

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Report No.:	

3. Style, Material & Color Conformity

3.1 Style conformity: Subject to client's evaluation

- There was no reference sample provided at inspection time.

3.2 Material conformity (hand feeling): Subject to client's evaluation

- There was no reference sample provided at inspection time.

3.3 Color conformity:

- Inspector found additional color during inspection:

+ Booking: only Blue color

+ Actual finding: 2 color (Blue color & White color).

Remarks: 2 color shade batches could be acceptable for mass production when the difference was grade 4 or above per the gray scale. However, our comment is for indication only and based on the samples selected, and laboratory analysis with standard laboratory facility is recommended at cost.

4. Product-Specific Data Measurement / Field Test:

4.1 Size measurement check on 18 sub samples:

Actual finding

Not Conform

Details please see attached size measurement chart.

Size		3	N	И	l	_
Color	LENGTH	WIDTH	LENGTH	WIDTH	LENGTH	WIDTH
Dive	235	106	240	11.8	245	129
Blue	236	105	-	-	246	127
White	235	105	240	11.8	245	129
wille	-	-	242	11.7	-	-

4.2 Weight check

4.2.1 Product weight check on 9 pcs (unit: gm/pc)

Actual finding

If factory equipment used, calibration record: Yes / No, period:_____

Color/ size		S			М			L	
Blue	3.5	3.5	3.5	3.5	3.5	3.5	4.0	4.0	4.0
White	3.5	3.5	3.5	3.5	3.5	3.5	4.0	4.0	4.0

4.2.	2 Fabric weight check onpcs (unit: g/m2) If factory equipment used, calibration record: Yes / No, pe	Not riod:	Applicable -
4.3	Thickness check 9 pcs	Actu	ual finding
	If factory equipment used, calibration record: Yes / No, period:		

		li .
Inspector:	Factory Representative:	
•		

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0.1/.:	White	Blue	White
Color/size	S	S	S
CUFF	0.064	0.062	0.070
PALM	0.067	0.066	0.077
FINGER	0.090	0.087	0.097
Color/size	Blue	White	Blue
Color/size	M	M	M
CUFF	0.066	0.065	0.067
PALM	0.070	0.069	0.076
FINGER	0.098	0.095	0.095
Color/size	White	White	Blue
Color/size	L	L	L
CUFF	0.065	0.066	0.064
PALM	0.068	0.069	0.067
FINGER	0.099	0.098	0.098

4.4 Function or assembly test:

Conform

If factory equipment used, calibration record: Yes / No, period:_

Check points	Qty	Test Result	Specification/Tolerance
Leakage check	9	Conform	3pcs per size per style
Barcode check	09	Conform	3pcs per size per style
Fitting check	09	Conform	3pcs per size per style
Carton drop test	01	Conform	-

5. Packing

5.1 Individual packing conformity :Each piece / flat	Actual Finding
5.2 Inner packing conformity:100pieces/ solid color/ solid size/ inner box.	Actual Finding
10 inner boxes (i.epieces / sets / pairs) per export carton	
 5.3 Export packing conformity: 03 ply corrugated cardboard carton Sealed by gummed tapes Secured bynylon bands 	Actual Finding
5.4 Packing assortment checked on _39cartons	Conform
Inspector Factory Representative:	

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Deviation (+/- samples)



Size/ style

Carton No.



6. Marking / Label:	
6.1 Bar code:	Conform All readable
6.2 Export Carton Marking:	
A. Shipping mark conformity:	Actual Finding
B. Side mark conformity:	Actual Finding
6.3 Label/Hangtag conformity:	
A. Main label:	Not Applicable
B. Care/Composition Label:	Not Applicable
C. Size Label:	Not Applicable
D. Hangtag:	Not Applicable
E. Polybag printing:	Not Applicable

Color

7. Informative Remark:

7.1 Carton information:

D. Others:

Carton weight: Carton product L: 4.8kgs. carton product size M: 4.3kgs, carton product size S: 4.15kgs (Blue color)

Carton product L: 4.8kgs. carton product size M: 4.35kgs, carton product size S: 4.1kgs (White color)

Carton size: L x W x H = 13 3/8 x 9 x 9 ¼ (Blue color)

 $L \times W \times H = 133/8 \times 9 \times 9 \frac{1}{4}$ (White color)

Carton with Metal Staple: No

Carton with Nylon Band: No

7.2. Grey Scale

Inspector:	Factory Representative:	

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Not Applicable



Report No.:	

Color shading batch checking by grey scale on the samples randomly selected could be applied when applicable at inspection site and subject to client's requirement, the result is just preliminary and indicative only, and subject to the environment, condition and the available facility at site, for more reliable and accurate result, they should be performed by qualified technician in lab under standard environment and equipment. (Please refer to the Working Instruction for Grey Scale Use and On-site Testing Method P-INSP-WI-SL-001-01).

7.3. Notice:

SGS inspector already informed the supplier of samples that we found during inspection, and reminded the supplier to pay attention to assortment during repacking after repairing . Please note repairing of defective samples and repacking is done by the factory without SGS inspector's supervision. Supervision on repairing of defective samples and repacking can be performed by SGS inspector at another working day upon request by client.

7.4. Others.

8. Inspection Environment

Lighting : Daylight

Sufficient

Inspection place : Warehouse Inspection done on: Table

Cleanliness : Clean Weather condition: Dry

Cargo storage: Orderly, easy to count

9. Attachment



Inspector: Factory Representative:

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Inspector:

Factory Representative:

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****** END OF REPORT *******