



Company Name: Yummylooks Sdn Bhd

Address

Unit 27, 3A-01, Glo Damansara 699 Jalan Damansara TTDI, Kuala Lumpur

Phone

+6 03 - 29359191

Whatsapp

+6 017 279 5502

Email / Web

client@medrux.com www.medrux.com



Product Name: ATOMX

Product Type:

Sterile Latex Surgical Gloves

1. DESCRIPTION AND MATERIALS

Product: Gamma Ray / EtO Sterilized Powder Free Latex Surgical Gloves, Hand specific; curved fingers; natural; textured surface;

USP grade absorbable corn starch *Materials*: 100% Rubber Latex

Cuff: Beaded

Sizes: Extra-Small; Small; Medium; Large and Extra-Large

Colour: White

Compliance: CE, ASTM D3577, EN455, ISO13485



Product

ATOMX - Sterile Latex Surgical Gloves

2. PERFORMANCE REQUIREMENTS

Gloves are sampled at random and inspected in accordance with ISO2859-1:1999 based on batch size. The inspection levels and Acceptance Quality Levels (AQL) shall conform to specification as shown below or as agreed between the purchaser and the supplier.

Samples are inspected/tested as per ASTM D3577 and EN 455 Standards

Storage	The gloves shall maintain their properties when stored in a dry condition at temperature not higher than 30° C.
Moisture Content	Below 0.8% per glove.
Shelf-life	5 years from the date of manufacturing.

3. DIMENSIONS

Dimension	Standards			
	MEDRUX	ASTM D3577	EN455	
Length(mm)	Min 280	Min 245 (size 5.5) Min 265 (size 6-9)	Min. 250 (size 5-5.5) Min. 260 size 6-6.5) Min. 270 (size 7-8) Min. 280 (size 8.5-9.5)	
Width(mm) • 5.5 • 6.0 • 6.5 • 7.0 • 7.5 • 8.0 • 8.5 • 9.0	71 ± 5 77 ± 5 83 ± 5 89 ± 5 95 ± 5 102 ± 5 108 ± 5 115 ± 5	70 ± 6 76 ± 6 83 ± 6 89 ± 6 95 ± 6 102 ± 6 108 ± 6 114 ± 6	72 ± 4 77 ± 5 83 ± 5 89 ± 5 95 ± 5 102 ± 6 108 ± 6 114 ± 6	
Thickness - single wall (mm) Fingers Palm Cuff	Min 0.10 Min 0.10 Min 0.10	Min 0.10 Min 0.10 Min 0.10	N/A	

Product Type:

ATOMX - Sterile Latex Surgical Gloves

4. PHYSICAL PROPERTIES

Size: *All sizes*

Property	ASTM D3577	EN455
Elongation At Break% Before Aging After Aging	min 750 min 560	N/A
Tensile Strength(MPa) Before Aging After Aging	min 24 min 18	N/A
Force at Break (N) Before Aging After Aging	N/A	Median 9 Median 9

5. FREEDOM FROM HOLES

Gloves shall meet requirements as stipulated in ASTM D3577 and EN 455.

6. POWDER RESIDUE

Powder Residue is tested as per ASTM D 6124-06. HLRI Powder residue shall be > 2mg/glove.

7. FUNCTIONAL BENEFITS

- Extra strength provides additional protection from surgical debris.
- Fully anatomical design to reduce hand fatigue.
- Softness provides superior comfort and natural fit.
- Micro-roughened surface provides excellent wet and dry grip.
- Easy donning and helps prevent rolling back.
- High strength and elasticity.

Product Type: ATOMX - Sterile Latex Surgical Gloves

8. PACKAGING

Pouch: 1 pair

Inner Box: 50 pairs

Outer Carton: 200 pairs (4 inner boxes)

9. MARKING

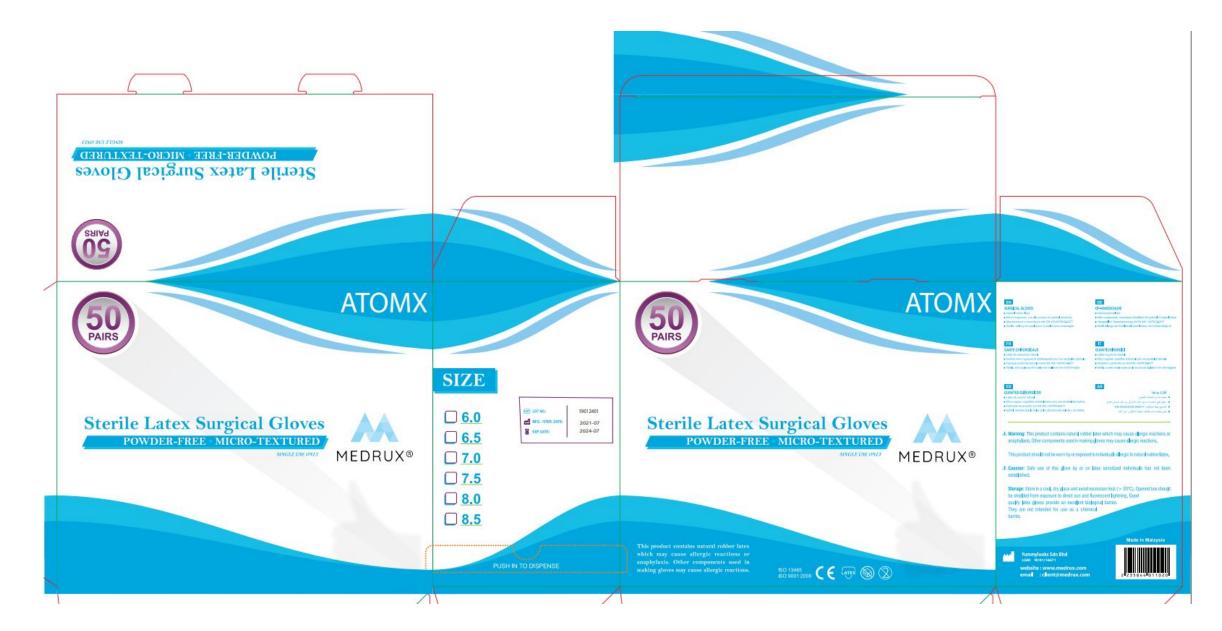
The dispenser and outer cartons shall have the following information/prints:

- Product description and Brand including size and net quality of gloves.
- Name and country of origin of manufacturer or Distributor.
- Single Use only or the symbol for symbol for single use.
- Other instructions on storage.
- Manufacturer's or Distributor's identification i.e. Lot Number; Bar Codes; Reorder Number.

Artwork

Pouch MEDRUX® **ATOMX** POWDER-FREE STERILE LATEX SURGICAL GLOVES, SINGLE USE ONLY Content: One Pair (2 gloves)

Box



Carton



Product Photos









Certifications

Certificate of Compliance

This certificate of compliance is here by issued to the below applicant

Applicant

Address

- YUMMYLOOKS SDN BHD

Kuala Lumpur Malaysia

27, 3A-01, Glo Damansara, TTDI, 6000,



Manufacturer

- Medrux

Product

Latex and Nitrile Gloves

Trade Name

YUMMYLOOKS SDN BHD

Applicable Directive(s) - Medical Devices Directive -93/42/EEC

Test standard

__ EN 455 Part 1:2000 / EN 455 Part 2:2015/

EN 455 Part 3:2015

Test Report no

__ CRSSA/200845255-CA45230

Test Laboratory name ___ SGS (MALAYSIA) SDN BHD

This Certificate of Compliance is issued under following conditions:

- 1 The product is declared by the applicant as complying with the
- applicable directives. 2 - EA has performed a review of the technical information of the
- 3 The applicant is required to inform EA of any changes to its product design and technical documentation.
- 4 The CE mark may be used by the applicant, for this product, under the sole responsibility of the applicant*.

Certificate Number: 21507

Initial Registration Date Date of Certificate Issue 1st Surveillance Audit 2nd Surveillance Audit 26/01/2023 Certificate Expiry*

Harshavardhan Reddy

EURO ASSESSMENTS & CERTIFICATION LTD Kemp House, 160 City Road, London, ECIV 2NX, United Kingdom

"Validity of the certificate is subjected to successful completion of surveillance audit on or before of due date (in case surveillance audit is not allowed to be conducted, this certificate

Certificate Verification: Please verify certificate at https://www.euroassessments.co.uk
This certificate is the property of Euro Assessments & Certification Ltd and shall be returned

immediately when demanded.

"The product Sabilty reds with the manufacturer is accordance with their committed specifications and contrac-tual obligations, including applicable standards. The CE mark shown above is for reference only and does not indi-cate accreditation. Euro Assessmente discount accept any bakilty arising out of this certificate.





CERTIFICATE

This is to Certify that the Management System of

YUMMYLOOKS SDN BHD

3A-01A, Glo Damansara TTDI, Kuala Lumpur, Malaysia

has been found to conform to the Medical Devices - Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope of operations:

"Latex and Nitrile Examination Gloves (Powdered and Powder-free)"

Certificate No.: MY91540H

Date of initial registration

03 February 2021

03 February 2021

Date of this Certificate Surv. audit on or before/ Certificate expiry

02 February 2022

Recertification Due

This Certificate remains valid subject to satisfactory surveillance audits.



Director

ning the present certificate visit to www.lmscert.com This Certificate is the property of LMS Certification Limited and shall be returned immediately when demanded.





LMS Certification Limited Labrynth Business Centre, 43 Middle Hill Gate, Stockport, Great Manchester, England-SK1 3DG Phone :+44 208 935 5094 Company No.: 11029176 E-mail :- info@imscert.com



02 February 2024

Certifications



Certificate of Registration

This is to certify that

YUMMYLOOKS SDN BHD

27, 3A-01, GLO DAMANSARA, TTDI, 6000, KUALA LUMPUR MALAYSIA

> has been independently assessed by QRO and is compliant with the requirement of:

> > ISO 9001:2015

Quality Management System

For the following scope of activities:

LATEX AND NITRILE EXAMINATION GLOVES (POWDERED AND POWDER FREE)

Date of Initial Registration: 05th March 2021 Date of this Certificate: 05th March 2021

Certificate Expiry: 04th March 2022 Recertification Due: 04th March 2024

Certificate Number: 305021030505Q









Validity of this certificate is subject to annual surveillance audits to be done successfully on or before 365 days from date of the audit. (In case surveillance audit is not allowed to be conducted; this certificate shall be suspended / withdrawn). The Validity of this certificate can be verified at www.qrocert.org

This certificate of registration remains the property of QRO Certification LLP, and shall be returned immediately upon request.

India Office : QRO Certification LLP

142, IInd Floor, Avtar Enclave, Near Paschim Vihar West Metro Station, Delhi-110063, (INDIA) Website: www.qrocert.org, E-mail: info@qrocert.org



Certificate of Conformity

Certificate No : CE-12506

Manufacturer

Name

: YUMMYLOOKS SDN BHD

Address

: 27, 3A-01, GLO DAMANSARA, TTDI, 6000, KUALA

LUMPUR MALAYSIA.

Products

: LATEX AND NITRILE EXAMINATION GLOVES

(POWDERED AND POWDER FREE)

: Medrux Trade Name

Applicable Directive

: Medical Devices Directive - 93/42/EEC

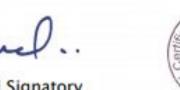
This certificate is issued under the following conditions:

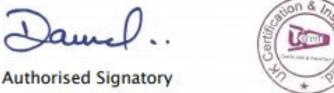
- 1. It applies only to the quality system maintained in the manufacture of above referenced scope / activities.
- 2. The certificate remains valid until the manufacturing conditions or the quality
- 3. are changed and is subject to continuous surveillance according to the FDA
- The certificate validity is conditioned by positive results or surveillance audits

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Certification 06th March 2021 05th March 2022 1st Surveillance Audit Due 05th March 2023 2nd Surveillance Audit Due 05th March 2024 Certificate Expiry (subject to the company maintaining its

system to the required standard)





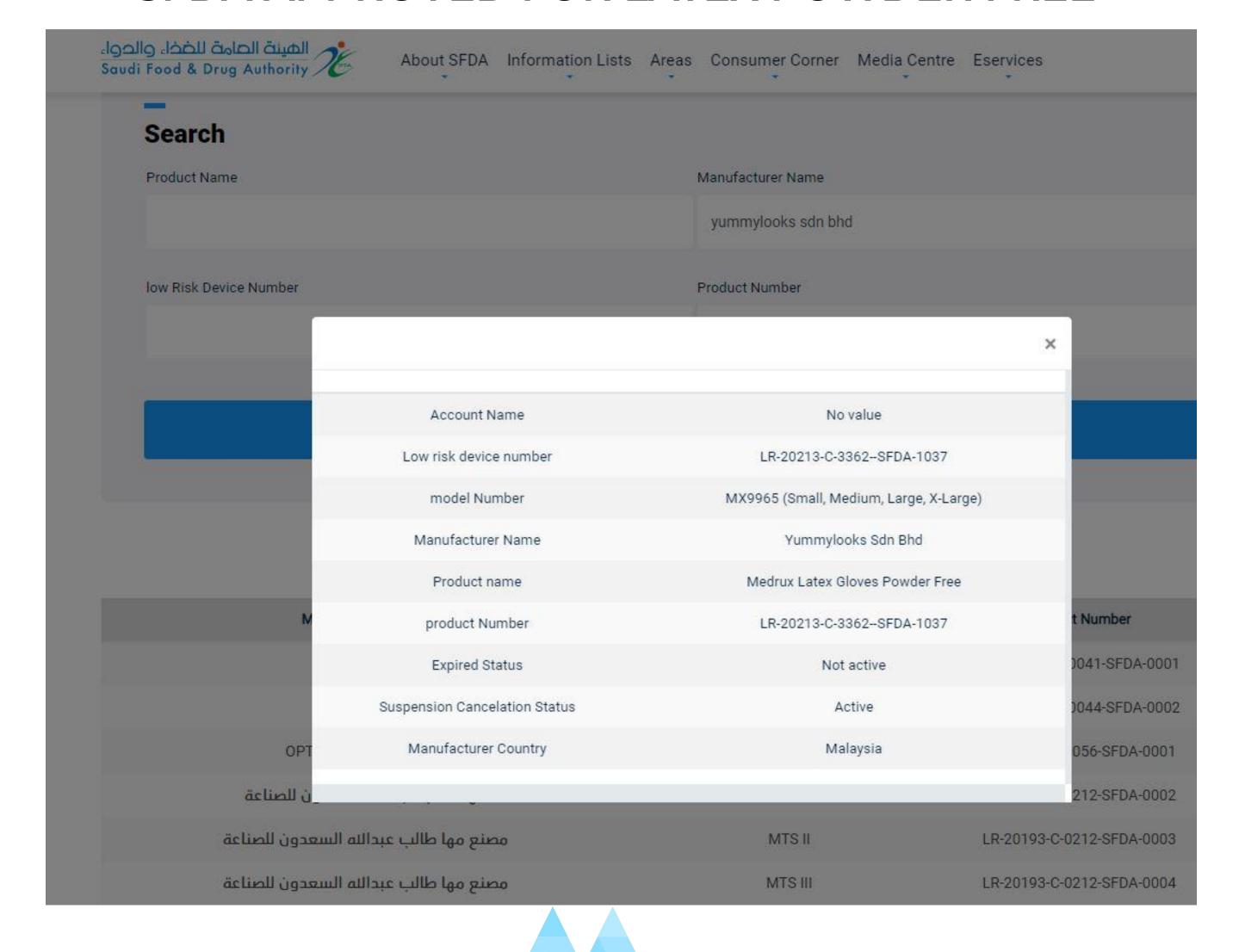
This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request. 71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom Website:- www.akcertifications.org.uk, email:- info@ukcertifications.org.ak

Certifications

الهيئة الصامة للضذاء والدواء

Saudi Food & Drug Authority

SFDA APPROVED FOR LATEX POWDER FREE



Check Here

Business Registration & Rubber License



SALINAN PEMOHON



LESEN

NO. SIRI:036553 LGM/BEPL/W/01/3/018/2020

AKTA LEMBAGA GETAH MALAYSIA (PERBADANAN) 1996 PERATURAN-PERATURAN LEMBAGA GETAH MALAYSIA (PELESENAN DAN PERMIT) 2014

[Peraturan 5(1)]

NO. LESEN: W/01/16671

Mengikut Peraturan-Peraturan Lembaga Getah Malaysia (Pelesenan dan Permit) 2014 dan tertakluk kepada syarat-syarat yang dikenakan pada lesen ini, Lembaga mengeluarkan lesen yang berikut:

Aktiviti Yang Dibenarkan Aktiviti Tambahan Jenis Lesen

Mengeksport Sarung Tangan Getah

Mengeksport Sarung Tangan

menjalankan aktiviti atas nama

YUMMYLOOKS SDN BHD (1245512 - W)

bagi tempoh 24/08/2020 hingga 23/08/2021 di premis yang berikut :

YUMMYLOOKS SDN BHD 3A-01, GLO DAMANSARA, 699, JALAN DAMAI TAMAN TUN DR ISMAIL 60000 KUALA LUMPUR WILAYAH PERSEKUTUAN

Catatan : Syarat-syarat yang dikenakan pada lesen ini adalah seperti berikut

ilvice & ili ,i

Pegawai Yang Diberi Kuasa

*Sila lihat sebelah

OTHER DETAILS

LOCATION

Malaysia

PAYMENT

50% down payment & 50% after inspection at warehouse

PRODUCTION DURATION

21-30 DAYS

CERTIFICATIONS

CE / LGM / ISO13485/ ISO9001 / DOC

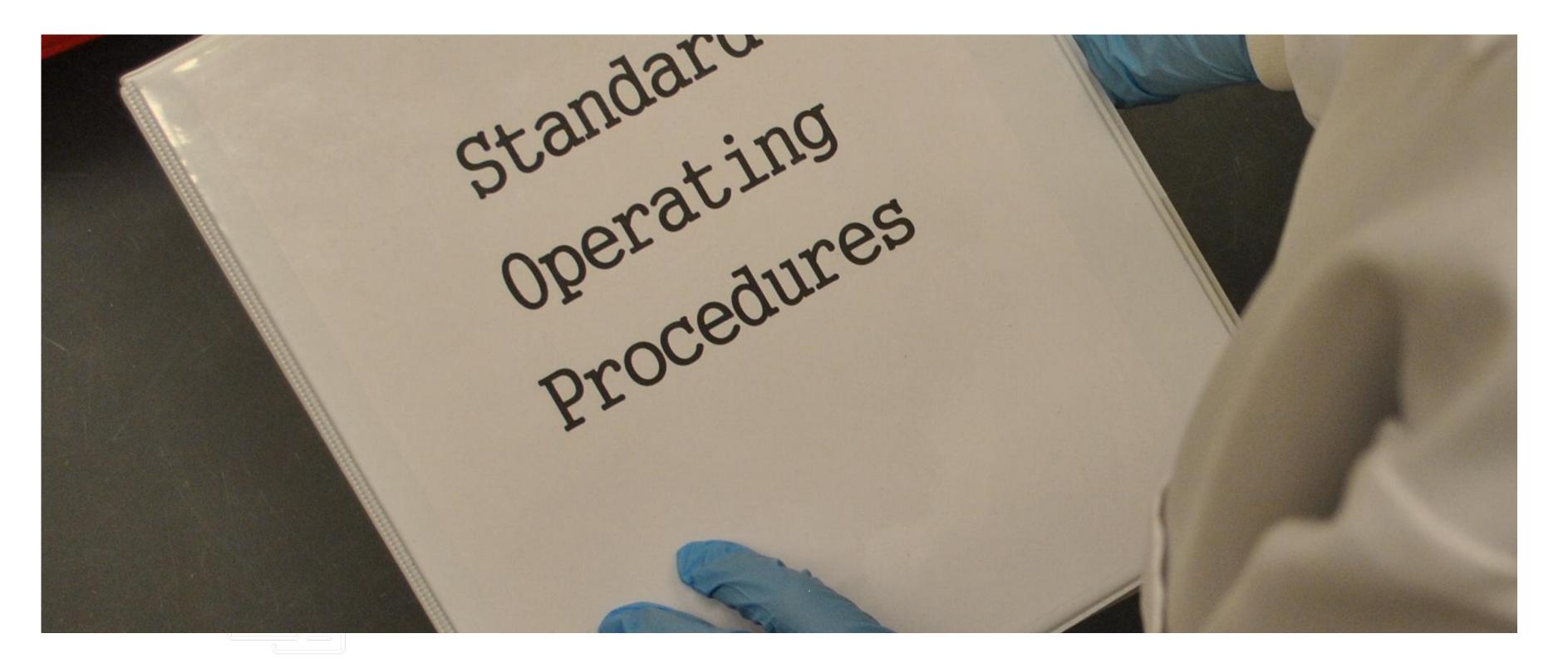
Quality Inspection

At Warehouse

BRAND

MEDRUX





- 1. MEDRUX® issues an offer to buyer
- 2. Purchase Order (PO) from buyer to be presented to MEDRUX.
- 3. After buyer acceptance, MEDRUX issues sales and purchase agreement (SPA).
- 4. Buyer signs the (SPA)
- 5. MEDRUX issues Invoice.
- 6. Payment terms 50% TT upfront and 50% after quality inspection at the warehouse.

- 8. Shipping to be arranged by MEDRUX or buyer.
- 9. Shipment to port

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