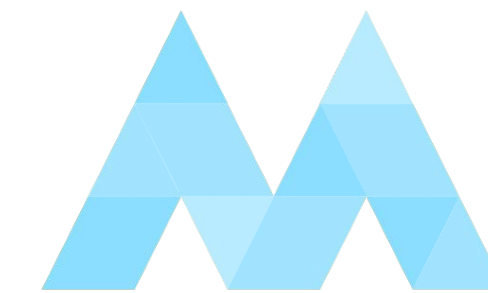




MEDRUX[®]

PRODUCT GUIDE

Yummylooks Sdn Bhd



MEDRUX[®]

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 Type:

Powder Free Nitrile Examination Gloves M= 3.5 ± 0.2gm

1. DESCRIPTION AND MATERIALS

Product : Powder Free Nitrile Gloves, Non-sterile. Micro-textured Finish; Ambidextrous; Disposable

Materials : Acrylonitrile Butadiene Synthetic Rubber Latex

Cuff : Beaded

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

Standard : Meet the requirements of ASTM D6319-10 (Standard Specification for Nitrile Examination Gloves)



Spec Sheet

Product Type:

Powder Free Nitrile Examination Gloves M= 3.5 ± 0.2gm

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 D6319-10.

Characteristic	Inspection Level	AQL
Dimension	S-2	4.0
Freedom from holes	G-1	1.5
Physical Properties	S-2	4.0
Visual Defects:		
Major	G-1	2.5
Minor	G-1	4.0
Packaging & Labeling	S-2	4.0

3. DIMENSIONS

Weight (gm):

Size	Weight (gm)	Range (gm)
XS	3.5 ± 0.2	3.3 – 3.7
S	3.6 ± 0.2	3.5 – 3.7
M	3.8 ± 0.2	3.6 – 4.0
L	4.1 ± 0.2	3.9 – 4.1
XL	4.2 ± 0.2	4.0 – 4.4

Palm Width (mm):

Size	X-Small	Small	Medium	Large	X-Large	Tolerance
ASTM D6319-10	70	80	95	110	120	±10
Medrux Nominal	76	84	94	105	113	±3

Length (mm):

ASTM D6319-10 : 230mm minimum (all sizes)

HLRI nominal : 230mm minimum (all sizes) range : 220-230mm

Thickness (single wall (mm)):

ASTM D6319-10 : 0.05 minimum for palm and finger

HLRI nominal (all sizes) : Cuff : 0.05mm minimum

Palm :0.05mm minimum

Finger:0.05mm minimum

Spec Sheet

Product Type:

Powder Free Nitrile Examination Gloves M= 3.5 ± 0.2gm

4. PHYSICAL PROPERTIES

Size: All sizes

	Before Ageing		After Accelerated Ageing 166±2 hours @70±2°C	
	Tensile Strength (Mpa)	Elongation %	Tensile Strength (Mpa)	Elongation %
ASTM D6319-10	14 min	500 min	14 min	400 min

5. FREEDOM FROM HOLES

Gloves shall meet requirements as stipulated in ASTM D6319-10. Method of test shall be in accordance with ASTM D 5151-06.

6. POWDER RESIDUE

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

7. PACKAGING

The unit of packaging is 100 pieces gloves (by weight) per dispenser box. 10 dispensers per carton. Other presentation or packaging mode materials used be agreed between Purchaser and supplier.

Example (L Size):

1 box is 400grams = 100 pcs

1 carton = 10 boxes

Net Weight = 4 kg / carton

Gross weight = 5 kg/carton

Carton Dimensions: 335 x 265 x 255

Typically one 40ft container can fit 35,000 boxes.

8. 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.



Product Type:

Powder Free Latex Examination Gloves

1. DESCRIPTION AND MATERIALS

Product : Powder Free Latex Gloves, Non-sterile. Micro-textured Finish; Ambidextrous; Disposable

Materials : 100% Rubber Latex

Cuff : Beaded

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

Colour : Black & White

Compliance: CE, FDA, ISO13485



Spec Sheet

Product Type:

Powder Free Latex Examination 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 D6319-10.

Characteristic	Inspection Level	AQL
Dimension	S-2	4.0
Freedom from holes	G-1	1.5
Physical Properties	S-2	4.0
Visual Defects:		
Major	G-1	2.5
Minor	G-1	4.0
Packaging & Labeling	S-2	4.0

3. DIMENSIONS

Weight (gm):

Size	Weight (gm)	Range (gm)
XS	4.6 ± 0.2	4.4 – 4.8
S	4.8 ± 0.2	4.6 – 5.0
M	5.0 ± 0.2	4.8 – 5.2
L	5.2 ± 0.2	5.0 – 5.4
XL	5.4 ± 0.2	5.2 – 5.6

Palm Width (mm):

Size	X-Small	Small	Medium	Large	X-Large	Tolerance
ASTM D6319-10	70	80	95	110	120	±10
Medrux Nominal	76	84	94	105	113	±3

Length (mm):

ASTM D6319-10 : 230mm minimum (all sizes)

HLRI nominal : 230mm minimum (all sizes) range : 220-230mm

Thickness (single wall (mm)):

ASTM D6319-10 : 0.05 minimum for palm and finger

HLRI nominal (all sizes) : Cuff : 0.05mm minimum

Palm :0.05mm minimum

Finger:0.07mm minimum

Product Type:

Powder Free Latex Examination Gloves

4. PHYSICAL PROPERTIES

Size: All sizes

	Before Ageing	
	Tensile Strength (Mpa)	Elongation %
ASTM D6319-10	14 min	500 min

5. FREEDOM FROM HOLES

Gloves shall meet requirements as stipulated in ASTM D6319-10. Method of test shall be in accordance with ASTM D 5151-06.

6. POWDER RESIDUE

Powder Residue is tested as per ASTM D 6124-06. HLRI Powder residue shall be $\leq 2\text{mg/glove}$.

7. PACKAGING

The unit of packaging is 100 pieces gloves (by weight) per dispenser box. 10 dispensers per carton. Other presentation or packaging mode materials used be agreed between Purchaser and supplier.

Example (L Size):

1 box is 550grams = 100 pcs

1 carton = 10 boxes

Net Weight = 5.5 kg / carton

Gross weight = 6.5 kg/carton

Box Dimensions: (L)22cm x (W)12.5cm x (H) 7cm

Carton Dimensions: (L)36cm x (W)26cm x (H)24cm

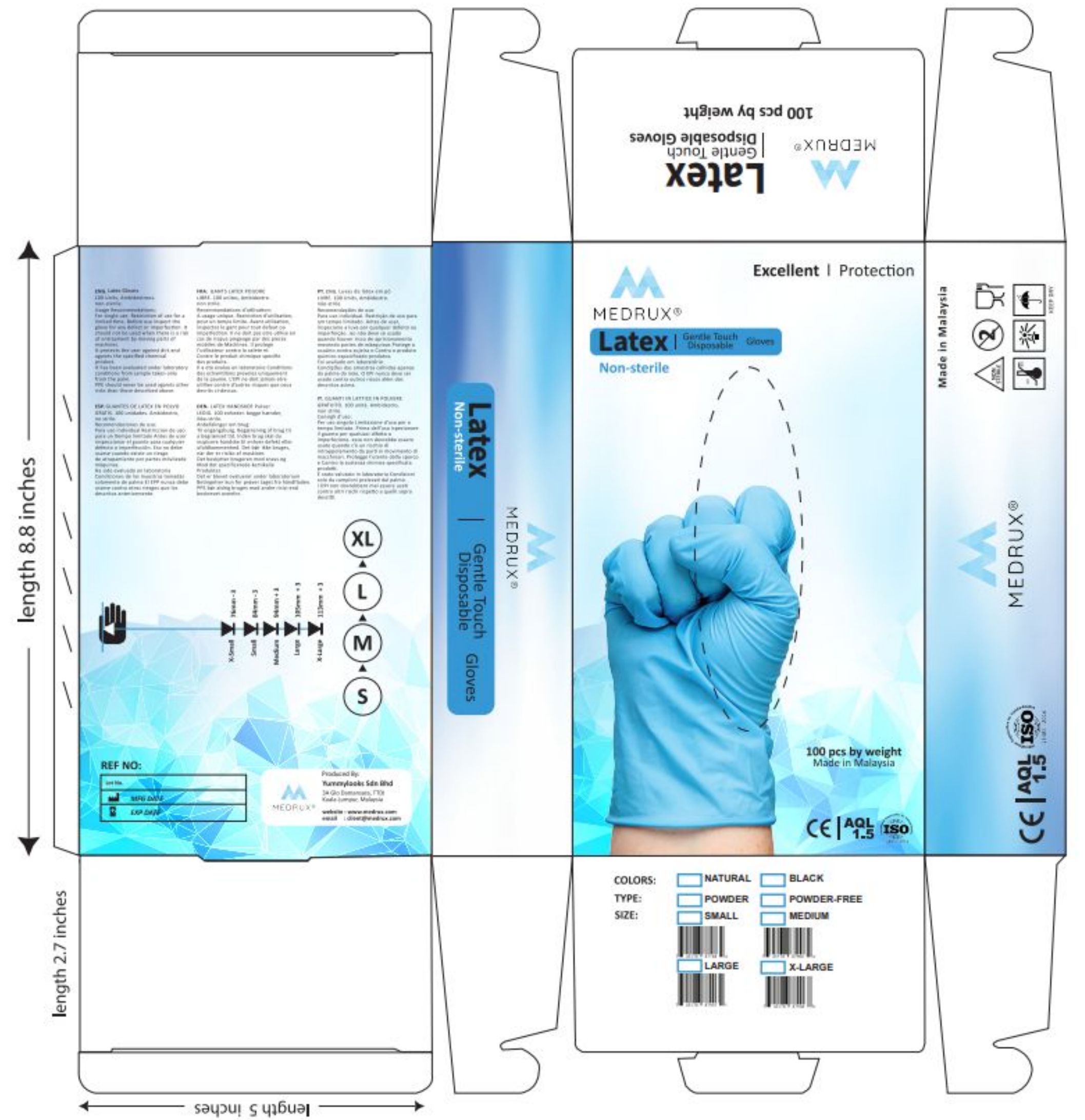
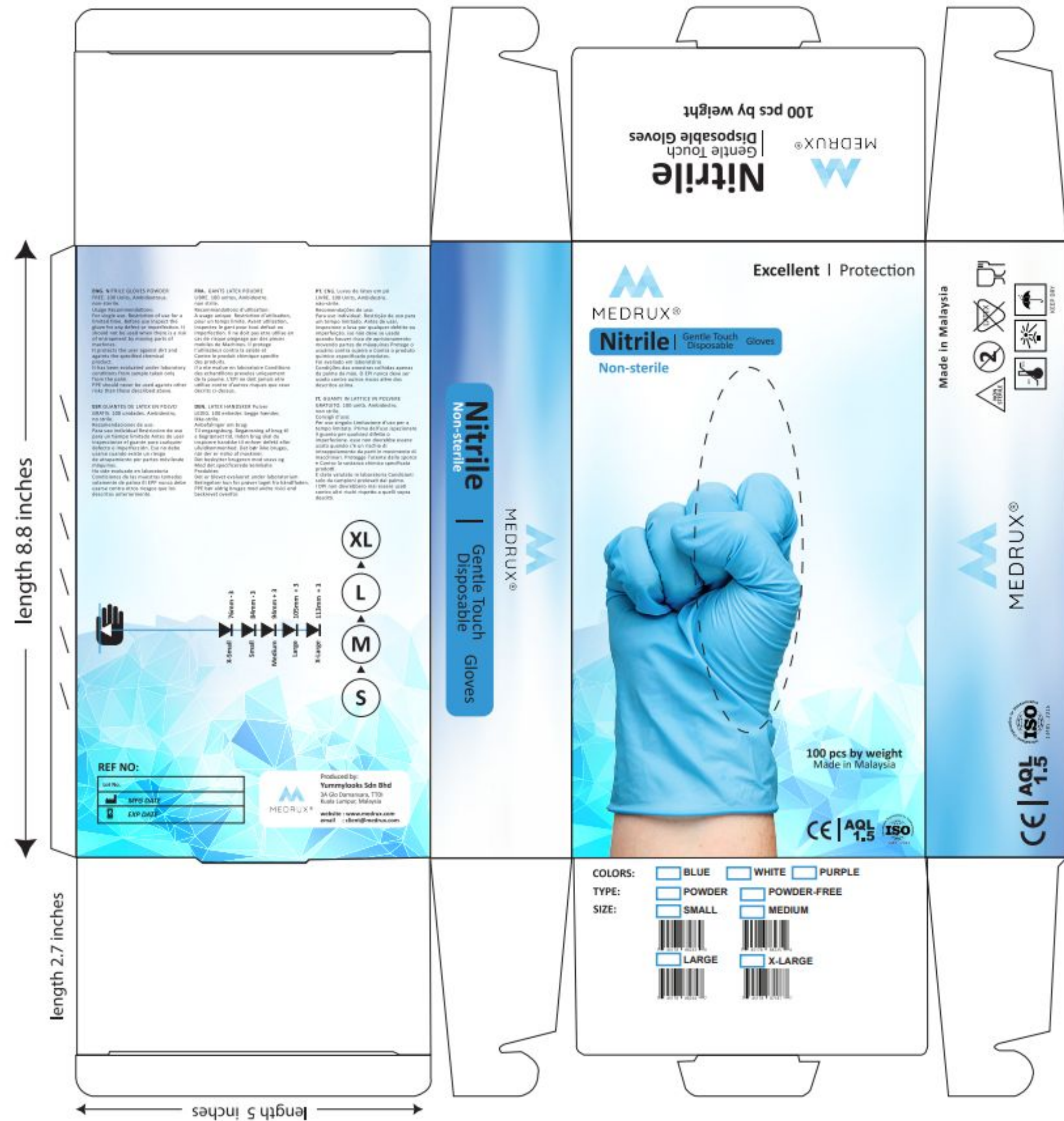
Typically one 40ft container can fit 33,000 boxes.

8. 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*

Artwork



Product Photos



Certifications

CE COMPLIANCE

Certificate of Compliance

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

Applicant — YUMMYLOOKS SDN BHD

Address — 27, 3A-01, Glo Damansara, TTDI, 6000, Kuala Lumpur Malaysia

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 product.
- 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 : 25/01/2021
 Date of Certificate Issue : 28/01/2021
 1st Surveillance Audit : 27/01/2022
 2nd Surveillance Audit : 26/01/2023
 Certificate Expiry* : 25/01/2024


Harshavardhan Reddy
 (Director)

EURO ASSESSMENTS & CERTIFICATION LTD
 Kemp House, 160 City Road, London, ECTV 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 shall be suspended/withdrawn).

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 liability rests with the manufacturer in accordance with their committed specifications and contractual obligations, including applicable standards. The CE mark shown above is for reference only and does not indicate accreditation. Euro Assessments does not accept any liability 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	Date of this Certificate	Surv. audit on or before/ Certificate expiry	Recertification Due
03 February 2021	03 February 2021	02 February 2022	02 February 2024

This Certificate remains valid subject to satisfactory surveillance audits.


Director

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



ACCREDITED
Management Systems
Certification Body
MSCB132



MEMBER OF MULTILATERAL
RECOGNITION ARRANGEMENT

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



LMS Certifications Private Limited

LMS/PM00/MDQ/REV06





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 Certificate Expiry: 04th March 2022
Date of this Certificate: 05th March 2021 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, 11nd 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)

Trade Name : Medrux

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 systems
3. are changed and is subject to continuous surveillance according to the FDA Guidelines
4. The certificate validity is conditioned by positive results or surveillance audits

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

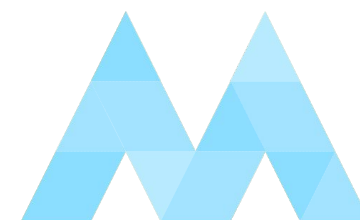
Date of Certification	06th March 2021
1 st Surveillance Audit Due	05th March 2022
2 nd Surveillance Audit Due	05th March 2023
Certificate Expiry (subject to the company maintaining its system to the required standard)	05th March 2024



Authorised Signatory



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.ukcertifications.org.uk, email:- info@ukcertifications.org.uk



SFDA APPROVED FOR LATEX POWDER FREE

The screenshot shows the SFDA website interface. At the top, there is a navigation menu with links: About SFDA, Information Lists, Areas, Consumer Corner, Media Centre, and Eservices. Below the menu is a search bar with fields for Product Name, Manufacturer Name, low Risk Device Number, and Product Number. The Manufacturer Name field contains 'yummylooks sdn bhd'. A search result modal is displayed in the center, showing the following details:

Account Name	No value
Low risk device number	LR-20213-C-3362--SFDA-1037
model Number	MX9965 (Small, Medium, Large, X-Large)
Manufacturer Name	Yummylooks Sdn Bhd
Product name	Medrux Latex Gloves Powder Free
product Number	LR-20213-C-3362--SFDA-1037
Expired Status	Not active
Suspension Cancelation Status	Active
Manufacturer Country	Malaysia

Below the modal, a table lists additional product entries:

مصنع مها طالب عبدالله السعدون للصناعة	MTS II	LR-20193-C-0212-SFDA-0003
مصنع مها طالب عبدالله السعدون للصناعة	MTS III	LR-20193-C-0212-SFDA-0004

[Check Here](#)



Business Registration & Rubber License



OTHER DETAILS

LOCATION

Malaysia

PRODUCTION DURATION

40 DAYS

Quality Inspection

At Warehouse

PAYMENT

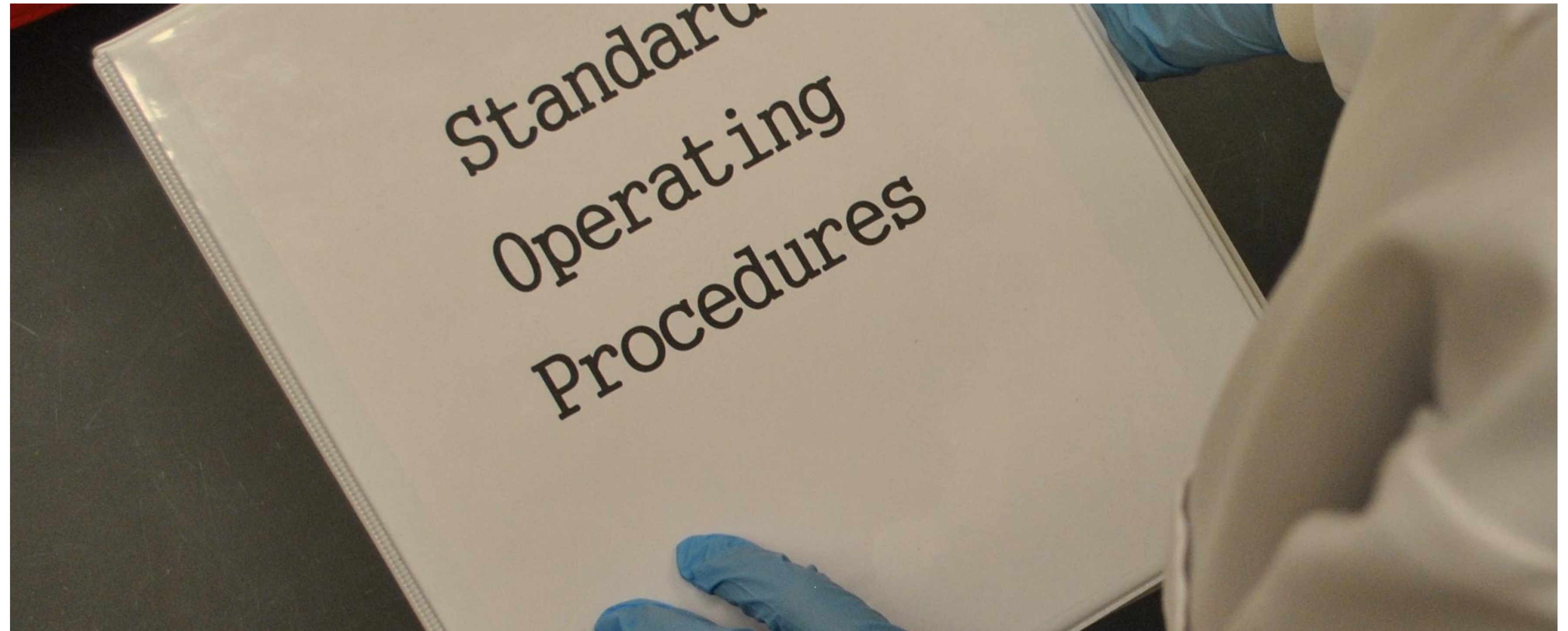
50% down payment & 50% after
inspection at warehouse

CERTIFICATIONS

CE / LGM / ISO13485/ ISO9001 / DOC

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

Company Name:
Yummylooks Sdn Bhd
Address

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

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MEDRUX®