



# Hartalega

Malaysian Reserve

# Products

Hartalega offers a range of products, superior in quality, and critical protection. There is no compromise in our manufacturing standards, in fact we are proud to consistently exceed international quality standards. This is why we are known and trusted, worldwide.

## Gloves by Market Segment

Whether you are in manufacturing, healthcare or laboratory environment; you can enjoy comfort, protection, hygiene and cost-effectiveness in Hartalega's range of gloves.



Industrial



Healthcare



Laboratory



Food



### Nitrile Gloves

Since 2002, Hartalega has been in the forefront of Nitrile gloves production. That's over a decade of producing the world's best Nitrile gloves, along with the introduction of major technological improvements in Nitrile glove manufacturing that has cemented our reputation the world over.

[Read More](#)



### Latex Gloves

Before Hartalega focused primarily on producing nitrile gloves, we were already known for our exceptional quality latex gloves. In fact, our latex gloves were considered to be the 'gold standard' in terms of quality and consistency, and still are to this very day.

[Read More](#)

# gloveon

## gloveon®

The premium name in hand protection. GloveOn gloves are engineered with the greatest precision, reliability and attention to detail only because protection is never compromised.

### mun

Focused on high quality care giving for all, Mun is the global platform for premium health care brands. We come empowered with knowledge, expertise and experience gained from developing some of the best and most cutting edge products in the health care industry. Our goal is to share and provide the best quality health care products for the betterment of humanity.

### Hartalega

Mun is birthed from a culture of excellence and innovation – the foundation to Hartalega's global success. This is proven by Hartalega's many unprecedented technological achievements in both process and product development. The same values of quality, passion, integrity, innovation, reliability and dedication found in Hartalega are embedded in the DNA of Mun.



## Paloma

Nitrile, Powder Free, Standard Cuff,  
Non-Sterile, Fingertip Textured

Product Code	-	NTR 51 (Size)
Product Description	-	Nitrile, Powder Free, Standard Cuff, Non-Sterile, Fingertip Textured
Colour	-	White
Material	-	Synthetic Nitrile Rubber
Product Conformance	-	ASTM D6319
Packing Method	-	100 pcs per box by weight 10 boxes per carton (180 pcs per box for XL)

## Specifications

### Glove Length (mm)

Length (mm)	$\geq 230$
-------------	------------

### Glove Size (Palm Width) mm

Extra Small	$76 \pm 4$
Small	$86 \pm 4$
Medium	$98 \pm 4$
Large	$107 \pm 4$
Extra Large	$115 \pm 4$

### Thickness Measurements mm

Palm (Centre of Palm)	$0.07 \pm 0.02$
Finger (13mm $\pm$ 3mm from tip)	$0.09 \pm 0.02$

### Physical Properties

	Before Ageing	After Ageing
Tensile Strength (Mpa)	$\geq 18$	$\geq 16$
Elongation (%)	500	400

### Inspection Levels & AQL

	Inspection Level	AQL
Watertightness	G1	1.50
Physical Dimensions	S2	4.00
Tensile Strength	S2	4.00
Visual Inspection (Major)	S4	2.50
Visual Inspection (Minor)	S4	4.00
Particulate Residue	N = 5	$\leq 2\text{mg/glove}$



# Nitrile Examination Glove Powder Free



**100  
Gloves**  
By Weight



XS S M L XL  
72 80 91 101 109

Actual Dimension in millimetres (mm)

Made in Malaysia by Hartalega Sdn Bhd

GloveOn Paloma		
Length (mm)	≥ 230	
Thickness Measurements (mm)		
Palm (centre of Palm)	0.07 ± 0.02	
Finger (13mm ± 3mm from tip)	0.09 ± 0.02	
Physical Properties	Before Ageing	After Ageing
Tensile Strength (MPa)	≥ 18	≥ 16
Elongation (%)	≥ 500	≥ 400
Inspection Levels & AQL	Inspection Level	AQL
Watertightness	G1	1.5
Physical Dimensions	S2	4.0
Physical Properties	S2	4.0
Visual Inspection (Major)	S4	2.5
Visual Inspection (Minor)	S4	4.0
Particulate Residue	N = 5	≤ 2mg/glove

Chemotherapy Drugs and Concentration (Tested for Resistance to Permeation by Chemotherapy Drugs as per ASTM D6978-05)	Minimum Breakthrough Detection Time (minutes)
Carmustine (BCNU), 3.3mg/ml (3,300 ppm)	16.2 minutes
Cisplatin, 1.0mg/ml (1,000 ppm)	>240 minutes
Cyclophosphamide (Cytoxan), 20.0mg/ml (20,000 ppm)	>240 minutes
Dacarbazine (DTIC), 10.0mg/ml (10,000 ppm)	>240 minutes
Doxorubicin Hydrochloride, 2.0mg/ml (2,000 ppm)	>240 minutes
Etoposide (Toposar), 20.00mg/ml (20,000 ppm)	>240 minutes
Fluorouracil, 50.0mg/ml (50,000 ppm)	>240 minutes
Methotrexate, 25.0mg/ml (25,000 ppm)	>240 minutes
Mitomycin C, 0.5mg/ml (500 ppm)	>240 minutes
Paclitaxel (Taxol), 6.0mg/ml (6,000 ppm)	>240 minutes
Thiotepa, 10.0mg/ml (10,000 ppm)	28.4 minutes
Vincristine Sulfate, 1.0mg/ml (1,000 ppm)	>240 minutes

**WARNING:** Carmustine and Thiotepa, at the tested concentration, degraded Paloma nitrile glove at 16.2 minutes and 28.4 minutes, respectively. The safe use of gloves in chemotherapy treatment is solely the decision of clinicians authorised to make such a decision.

## FEATURES

- Fingertip textured
- Powder free
- Not made with natural rubber latex
- Chemo drugs tested
- Lab chemical tested
- Ambidextrous
- Violet blue colour
- Food Safe

## PACKAGING

100 gloves per box  
10 boxes per carton

## REGULATORY COMPLIANCE

FDA 510(k), MDD 93/42/EEC,  
REACH, ROHS Directive 2002/95/EC,  
EC 10/2011, EC 1935/2004

## STANDARDS

ASTM D6319, ASTM D412, ASTM D573,  
ASTM D5151, ASTM D6124,  
EN455 part 1, 2, 3 & 4, EN 1186,  
EN 13130, CEN/TS 14234

## MANUFACTURING ACCREDITATIONS

ISO 9001  
ISO 13485  
EN ISO 13485



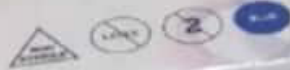
gloveen  
Paloma

EN Protection Always On

Nitrile Powder Free  
Examination Gloves

A brand by  
IMUN

XS S M L XL



Nitrile Powder Free  
Examination Gloves

gloveen  
Paloma

Fingertip Textured  
Powder Free  
Not Made with  
Natural Rubber Latex  
Chemo Drugs Tested

Lab Chemical Tested  
Single-Use Only  
Ambidextrous  
Patient Examination  
Glove



A brand by  
IMUN

## EC Declaration of Conformity

**We, the manufacturer**

Hartalega Sdn. Bhd.,  
No. 7, Kawasan Perusahaan Suria,  
45600 Bestari Jaya,  
Selangor Darul Ehsan,  
Malaysia

**with European Representative**

Medical Device Safety Service (MDSS)  
Schiffgraben 41, 30175 Hannover,  
Germany

**Declares that the new PPE described hereafter**

Category III (Type C)  
HSB-TF-005  
≥ 2.0 mil Powder Free Nitrile disposable five fingered glove  
Available in a longer cuff variant

**is in conformity with the relevant Union harmonisation legislation**

PPE Regulation (EU) 2016/425

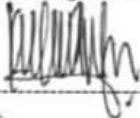
**where such is the case, with the national standard transposing harmonized standard number**

EN 420: 2003+A1: 2009  
EN ISO 374 – 1:2016  
EN ISO 374 – 5:2016

The notified body SATRA Technology Centre with Notified Body Number of 2777 performed the EU type-examination (Module B) and issued the EU type-examination certificate 2777/13926-02/E00-00.

The PPE is subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the Notified body SATRA Technology Centre with Notified Body Number of 2777.

Done at Hartalega Sdn. Bhd. on 31<sup>st</sup> January 2020.



Kuan Eu Jin  
Quality Management Representative





MDSS - Schiffgroben 41 - 30175 Hannover, Germany

Hartalega NGC Sdn Bhd.  
Khairunnisa Warsito  
No. 1, Persiaran Tanjung  
Kawasan Perindustrian Tanjung  
43900 Sepang, Selangor  
MALAYSIA

Schiffgroben 41  
30175 Hannover, Germany

Tel: + 49 - 511 - 62 62 86 30  
Fax: + 49 - 511 - 62 62 86 33

eMail: info@mdss.com  
Internet: www.mdss.com

2019.01.18

### Confirmation of CE Registration

Dear Khairunnisa,

It is our pleasure to enclose the new Certificate of CE-Registration for your product.

Please note that registration was performed under § 25 MPG (Medizinproduktegesetz). This is the *Federal Republic of Germany's national interpretation of Medical Device Directive 93/42/EEC*. Registration is therefore in accordance with EU legislation. We remind you that all products must meet the applicable provision of the European and national regulation before they may be placed on the market.

We are looking forward to continuing our good business relationship and wish you a successful product launch in Europe.

Best regards,

Juan Monferrer Tena  
Administrative Assistant  
Medical Device Safety Service GmbH

Encl.

1 Certificate of CE-Registration

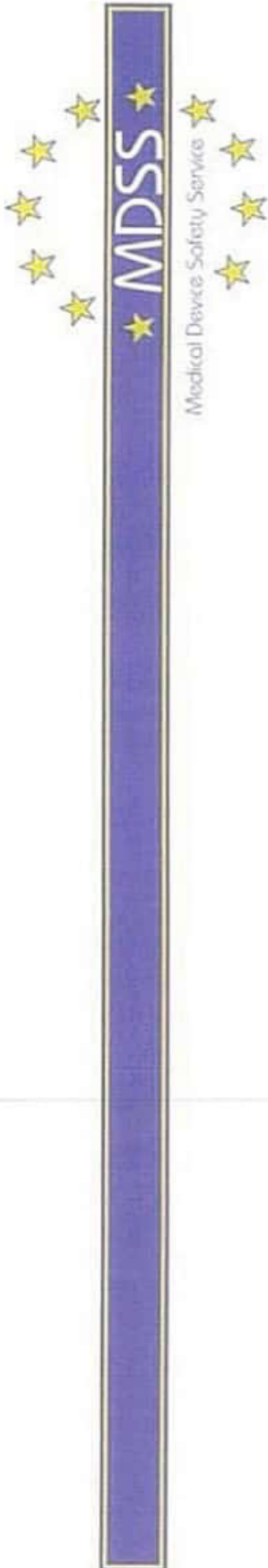
1 Annex A

MDSS - Medical Device Safety Service GmbH  
Handelsregister Hannover HRB 57318 - USt-IdNr. DE 177346163 - Geschäftsführer: Ludger Möller

Bankverbindungen  
Sparkasse Hannover  
S.W.I.F.T.: SPHHD22H  
IBAN: DE24 2505 0180 0910 0792 77

Commerzbank AG, Hannover  
S.W.I.F.T.: COBADE33  
IBAN: DE67 2504 0066 0338 8816 00





# Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Hartalega NGC Sdn. Bhd.  
No. 1, Persiaran Tanjung  
Kawasan Perindustrian Tanjung  
43900 Sepang, Selangor  
MALAYSIA

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

**Annex A dated January 18, 2019**

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2019-01-18

  
Lüdger Möller  
President  
MDSS GmbH



April 25, 2020

Hartalega NGC SDN. BHD.  
Nurul Kong  
Senior Manager- Quality Assurance  
Kawasan Perindustrian Tanjung  
Sepang, Selangor 43900  
Malaysia

Re: K200581

Trade/Device Name: Paloma Nitrile Powder Free Examination Gloves (Blue)  
Regulation Number: 21 CFR 880.6250  
Regulation Name: Paloma Powder Free Examination Glove  
Regulatory Class: Class I, reserved  
Product Code: LZA, LZC, QDO  
Dated: February 27, 2020  
Received: March 5, 2020

Dear Nurul Kong:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm> identifies combination product submissions. 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,  
Elizabeth F.  
Claverie -S



CAPT Elizabeth Claverie, M.S.  
Assistant Director  
DHT4B: Division of Infection Control  
and Plastic Surgery Devices  
OHT4: Office of Surgical  
and Infection Control Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

April 15, 2009

# • TEST REPORT •

PN 83672A - Amended

## CHEMICAL ANALYTICAL SERVICES

Prepared For:  
Hartalega SDN. BDH  
Ms. Nurul Aisyah Kong  
No. 7 Kawasan Perusahaan Suria  
Bestari Jaya  
Selangor, 45600  
Malaysia

Prepared By:   
Tiffany L. Heller  
Chemical Technician

Approved By:   
Ana C. Barbur, M.S.  
Manager, Chemical & Pharmaceutical Services

An A2LA Accredited Testing Laboratory — Certificate Numbers 255.01 & 255.02  
ISO 9001:2000 Registered  
Member of ACIL: The American Council of Independent Laboratories



ISO 9001:2000  
Registered



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Toll Free (800) 830-ARDL | Worldwide (330) 794-6600 | Fax (330) 794-6610

## Testing. Development. Problem Solving.

April 15, 2009

Ms. Nurul Aisyah Kong  
Hartalega SDN. BHD

Page 1 of 3 – PN 83672A - Amended

**SUBJECT:** Permeation testing per ASTM D 6978-05 on sample submitted by the above company. Wire Transfer.

**RECEIVED:** Glove sample identified as Nitrile Powder Free Examination Gloves (Blue) Code: ABLU.

### TESTING CHEMOTHERAPY DRUGS:

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU)	Sigma; Lot# 038K4008; Expiration 12/2009
Cisplatin	Sigma; Lot# 59H3657; Expiration 09/2009
Cyclophosphamide (Cytoxan)	Sigma; Lot# 068K1131; Expiration 1/2010
Dacarbazine (DTIC)	Hospira; Lot# U022223AA; Expiration 06/2010
Doxorubicin Hydrochloride	Teva; Lot#07N625; Expiration 10/2009
Etoposide (Toposar)	Teva; Lot# 31303976B; Expiration 9/2011
Fluorouracil	APP; Lot# 203867; Expiration 03/2010
Mitomycin C	Sigma, Lot# 048K1086; Expiration 01/2010
Methotrexate	Hospira; Lot# U024457AA; Expiration 05/2010
Paclitaxel (Taxol)	Dabur Oncology; Lot# PA08H00701; Exp. 05/2010
Thiotepa	Sigma; Lot#078K1526; Expiration 12/2009
Vincristine Sulfate	Hospira, Lot# U037139AA; Expiration 12/2009

### COLLECTION MEDIA:

The collection media, which were selected, are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

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Toll Free (800) 830-ARDL | Worldwide (330) 794-6600 | Fax (330) 794-6610

**TESTING CONDITIONS:**

Standard Test Method Used:	ASTM D 6978-05
Deviation From Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm <sup>2</sup>
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area
Comments/Other Conditions:	Magnetic stir bar was used in the sampling chamber

**DETECTION METHOD OF CHEMICAL PERMEATION; UV/VIS ABSORPTION SPECTROMETRY:**

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm)	200
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

**SAMPLE CHARACTERISTICS:**

Table 4. Thickness characteristics for the tested specimens: Nitrile Powder Free Examination Gloves (Blue) Code: ABLU.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m <sup>2</sup> )
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.080	0.084	0.082	<b>0.082</b>	79.2
Cisplatin	0.086	0.082	0.088	<b>0.085</b>	79.2
Cyclophosphamide (Cytosan)	0.087	0.083	0.081	<b>0.084</b>	79.2
Dacarbazine (DTIC)	0.086	0.080	0.084	<b>0.083</b>	79.2
Doxorubicin Hydrochloride	0.087	0.084	0.082	<b>0.084</b>	79.2
Etoposide (Toposar)	0.085	0.088	0.090	<b>0.088</b>	79.2
Fluorouracil	0.082	0.082	0.094	<b>0.086</b>	79.2
Methotrexate	0.081	0.084	0.087	<b>0.084</b>	79.2
Mitomycin C	0.082	0.082	0.084	<b>0.083</b>	79.2
Paclitaxel (Taxol)	0.086	0.081	0.082	<b>0.083</b>	79.2
Thiotepa	0.084	0.083	0.087	<b>0.085</b>	79.2
Vincristine Sulfate	0.088	0.084	0.082	<b>0.085</b>	79.2

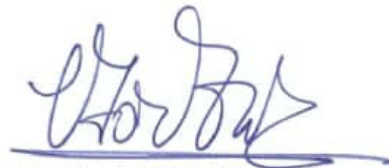
**RESULTS:**

Table 5. Permeation Test Results on: Nitrile Powder Free Examination Gloves (Blue) Code: ABLU.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) ( $\mu\text{g}/\text{cm}^2/\text{minute}$ )	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	35.80 (45.31,30.46,31.63)	1.24 (1.36,1.16,1.20)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	85.48 (105.33,75.52,75.60)	1.32 (1.33,1.32,1.32)	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation



Tiffany L. Heller  
Chemical Technician, Chemical Services  
AKRON RUBBER DEVELOPMENT LABORATORY, INC.



Ana C. Barbur, M.S.,  
Chemical and Pharmaceutical Services



## 510(k) Premarket Notification

FDA Home Medical Devices Databases

1 to 10 of 82 Results

Applicant: *Hartalega* Decision Date To: 05/27/2020

1 2 3 4 5 6 7 8 9 >

Results per Page 10

New Search <a href="#">Export to Excel</a>   <a href="#">Download Files</a>   <a href="#">More About 510(k)</a>			
Device Name	Applicant	510(K) Number	Decision Date
<a href="#">Biodegradable Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue)</a>	Hartalega NGC SDN. BHD.	<a href="#">K200581</a>	04/25/2020
<a href="#">Nitrile Powder Free Examination Glove Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue), Nitrile Powder Free Examination Glove Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Black)</a>	Hartalega NGC Sdn. Bhd.	<a href="#">K200019</a>	04/06/2020
<a href="#">Nitrile Powder Free Examination Glove With Low Dermatitis Potential Claim (White)</a>	Hartalega NGC Sdn. Bhd.	<a href="#">K192232</a>	11/08/2019
<a href="#">Nitrile Powder Free Examination Glove Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue), Nitrile Powder Free Examination Glove Tested For Use With Chemotherapy Drugs And Fentanyl Citrate (Blue) - Extended Cuff</a>	Hartalega Ngc Sdn. Bhd.	<a href="#">K190454</a>	09/26/2019
<a href="#">Latex Powder Free Surgical Glove With Protein Labeling Claim Of 50 Microgram Or Less Per Gram Of Glove</a>	Hartalega Ngc Sdn. Bhd.	<a href="#">K183536</a>	08/16/2019
<a href="#">Polyisoprene Powder Free Surgical Glove, Polyisoprene Powder Free Surgical Underglove</a>	Hartalega NGC Sdn. Bhd.	<a href="#">K183389</a>	06/28/2019
<a href="#">Powder Free Examination Gloves With Colloidal Oatmeal Usp And Tested For Use With Chemotherapy Drugs - (Lemon Green)</a>	Hartalega Sdn Bhd	<a href="#">K180645</a>	11/16/2018
<a href="#">Sterile Nitrile Powder Free Examination Glove Tested For Use With Chemotherapy Drugs Aqua Blue (Ablu), Sterile Nitrile Powder Free Examination Glove Tested For Use With Chemotherapy Drugs Violet Blue (Vblu) - Extended Cuff</a>	HARTALEGA SDN. BHD.	<a href="#">K180786</a>	11/02/2018
<a href="#">Biodegradable Nitrile Powder Free Examination Glove (Blue)</a>	Hartalega Sdn. Bhd.	<a href="#">K173509</a>	08/17/2018
<a href="#">Nitrile Powder Free Examination Gloves With Colloidal Oatmeal - Lemon Green</a>	Hartalega Sdn Bhd	<a href="#">K180644</a>	08/10/2018

Page Last Updated: 05/25/2020

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gloveen

Paloma

Nitrile Po  
Examination

Fingertip Textured  
Powder Free  
Not Made with  
Natural Rubber Latex  
Chemo Drugs Tested

Contains:  
100 gloves x 10 boxes (by weight)

AQL 1.5

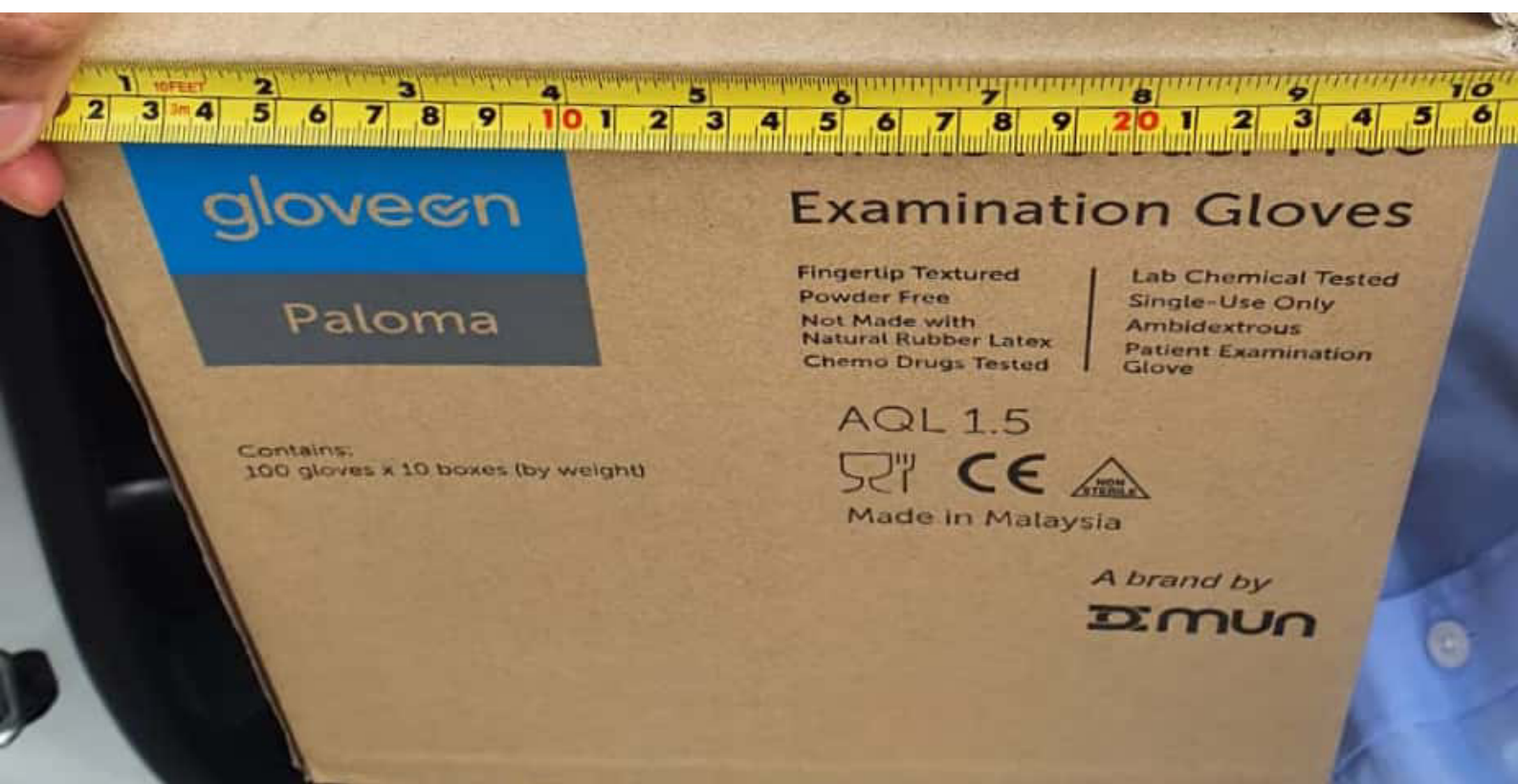


Made in Mala

**PALOMA 100-MY**

- EXTRA SMALL
- SMALL
- MEDIUM
- LARGE
- EXTRA LARGE

10 FEET  
2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 20 1 2 3 4 5 6



gloveen

Paloma

### Examination Gloves

Fingertip Textured  
Powder Free  
Not Made with  
Natural Rubber Latex  
Chemo Drugs Tested

Lab Chemical Tested  
Single-Use Only  
Ambidextrous  
Patient Examination  
Glove

Contains:  
100 gloves x 10 boxes (by weight)

AQL 1.5



Made in Malaysia

A brand by  
**DMUN**

gloveen

Paloma

# Nitrile Powder Free Examination Gloves

Fingertip Textured  
Powder Free  
Not Made with  
Natural Rubber Latex  
Chemo Drugs Tested

Lab Chemical Tested  
Single-Use Only  
Ambidextrous  
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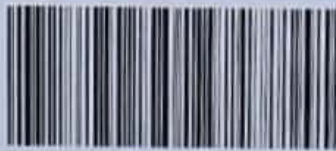


Made in Malaysia

A brand by

**DMUN**

S



(01) 89332347004762(17)238419(10)0732

Gross wt	3.7 Kg	Exp. Date	Apr-2023	PD No	MD0161
Nett wt	2.9 Kg	Barcode No		Ctn No	00279

# **HARTALEGA : GloveOn PALOMA**

Dimension of Carton box  
26cm(L) x 26cm(W) x  
26cm(H)

Weight in Carton box :  
Size S at 3.7kg  
Size M at 4.1kg  
Size L at 4.4kg

20GP FCL  
at 13,000 boxes

One carton 10 boxes  
One box 100 pieces