Paloma gloveon

Nitrile Exam Gloves Powder Free, Standard Cuff

Like the purity of a white Dove, **Paloma**, our white nitrile gloves offers the elegance of touch and feel with strength and dexterity needed for the delicate procedure and jobs.

NON STERILE · LATEX · 2 · EN 374 · EN 374 · CE

	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	1.50
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	≤ 2mg/glove

Chemotherapy Drugs and Concentration (Tested for Resistance to Permeation by Chemotherapy Drugs as per ASTM D6978-05 Test Report PN 116668)	Minimum Breakthrough Detection Time (minutes)
Carmustine (BCNU), 3.3mg/ml (3,300 ppm)	15.1 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)	15.4 minutes
Vincristine Sulfate, 1.0mg/ml (1,000 ppm)	>240 minutes

WARNING: Carmustine and Thiotepa, at the tested concentration, degraded Paloma nitrile glove at 15.1 minutes and 15.4 minutes, respectively. The safe use of gloves in chemotherapy treatment is solely the decision of clinicians authorised to make such decision.

REORDER CODE

NTR51XS	X-SMALL
NTR51SS	SMALL
NTR51MM	MEDIUM
NTR51LL	LARGE
NTR51XL	X-LARGE

FEATURES

- Fingertip textured
- Powder free
- Not made with natural rubber latex
- Chemo drugs tested
- Lab chemical tested
- Ambidextrous
- Standard cuff
- White colour

PACKAGING

200 gloves per box for XS to L
180 gloves per box for XL
10 boxes per carton

REGULATORY COMPLIANCE

TGA - ARTG 164563, FDA 510(k), MDD 93/42/EEC, REACH, ROHS Directive 2002/95/EC, EC 10/2011, REGULATION (EC) No 1935/2004, PPE 89/686/EEC

STANDARDS

ASTM D6319, EN 455 part 1, 2, 3 & 4 , EN 1186, EN 13130, CEN/TS 14234, EN 420, EN 374 part 1, 2 & 3

MANUFACTURING ACCREDITATIONS

ISO 9001:2008
ISO 13485:2003
EN ISO 13485:2003

gloveen

Nitrile Exam Gloves Powder Free, Standard Cuff

Like the purity of a white Dove, **Paloma**, our white nitrile gloves offers the elegance of touch and feel with strength and dexterity needed for the delicate procedure and jobs.

NON STERILE | LATEX | 2 | EN 374 | EN 374 | CE

ASTM D3578

Physical Dimensions	
Glove Length (mm)	≥ 230
Palm Thickness (mm)	0.07 ± 0.02
Finger Thickness (mm)	0.09 ± 0.02

Physical Properties		
Test	Before Aging	After Aging
Tensile strength (MPa)	≥ 18.0	≥ 16.0
Elongation (%)	≥ 500	≥ 400

EN 455

Physical Dimensions	
Median glove length (mm)	≥ 240
Median palm thickness (mm)	0.07 ± 0.02
Median finger thickness (mm)	0.09 ± 0.02

Physical Properties		
Test	Before Aging	After Aging
Median Force at break (N)	≥ 6	≥ 6

Regulatory Compliance

FDA 510(k), MDD 93/42/EEC, REACH, ROHS Directive 2002/95/EC, EC 10/2011, EC 1935/2004, PPE 89/686/EEC

Standards

ASTM D6319, ASTM 6978, EN455 part 1, 2, 3 & 4, EN 1186, EN 13130, CEN/TS 14234, EN 420, EN 374 part 1, 2 & 3

Classification

Class I (FDA), Class I (MDD 93/42/EEC), Category 3 (BfR XXI), Category III (PPE 89/686/EEC)

Patent

7,691,436; 7,718,240; 7,740,622; 8,075,965; 8,458,818

Application Settings

Low risk - medical, dental, procedures, chemotherapy drugs, pathology lab and food handling. Coated with FDA recognised skin protectant. Clinically proven to help protect and moisturise your skin from dry and irritated skin from prolonged glove use and hand wash.

Colour

Dawn blue, white

A brand by
mun
www.munglobal.com
Mun Australia
Toll free: 1800 456 837 (GLOVES)
info.au@munglobal.com

Birthing Kit Foundation Australia
Proud Supporter of
Birthing Kit Foundation (Australia)

Protection Always On

MATERIAL SAFETY DATA SHEET

Hartalega

SECTION 1: PRODUCT IDENTIFICATION

Hartalega Sdn. Bhd.	C-G-9, Jalan Dataran SD1, Dataran SD, PJU 9, Bandar Sri Damansara, 52200 Kuala Lumpur
TELEPHONE NUMBER (603) 6277 1733	**DATE PREPARED** October 15, 2014
COMMON NAME (USED ON LABEL) Nitrile Powder Free Examination Gloves	**CHEMICAL FAMILY** Carboxylated Butadiene Acrylonitrile Polymer Latex
APPLICATION Medical and Dental	**TRADENAME & SYNONYM** GLOVEON COATS NITRILE (CTS38) NITRILE POWDER FREE EXAMINATION GLOVES COATS

SECTION 2: HAZARDOUS INGREDIENTS

HAZARDOUS COMPONENT	CAS #	%(WT)	TLV	PEL
N/A	N/A	N/A	N/A	N/A

PEL: Permissible Exposure Limit established by Occupational Safety and Health Administration (OSHA).
TLV: Threshold Limit Value established by the American Conference of Governmental Industrial Hygienists, 1987-1988.

SECTION 3: COMPOSITION/ INFORMATION ON INGREDIENTS

CHEMICAL COMPOSITION
All chemicals used are non-toxic/ non-hazardous.
Butadiene-Acrylonitrile Latex, Sodium Dodecylbenzenesulfonate, Sulphur, Zinc Oxide, Zinc Di-n-butyldithiocarbamate, Titanium Dioxide, Paraffin Wax Emulsion
Coating Ingredient
Colloidal Oatmeal & Constituents, Sodium Benzoate, Processing Aid

SECTION 4: FIRST AID MEASURE

If reaction in the form of skin irritation is noticed, remove gloves immediately and wash affected part with saline water. If there is no relief, seek medical reactions.

SECTION 5: FIRE FIGHTING MEASURE

FLASHPOINT	AUTOIGNITION TEMPERATURE	FLAMMABLE LIMITS IN AIR
N/A	N/A	N/A

EXTINGUISHING MEDIA
Chemical foam and dry chemical may be used.

FIRE-FIGHTING PROCEDURES
Use standard procedures for combustion material fires, including approved self-contained breathing apparatus.

FIRE AND EXPLOSION HAZARDS
No fire or explosion hazards are associated with these products. They will melt at elevated temperatures.

SECTION 6: ACCIDENTAL RELEASE MEASURES

BIOCOMPATABILITY
The chemical formulation of the gloves and surface lubrication materials does not contain any substances normally known to be harmful to the user or to any person with whom the gloves come into contact.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE
Nitrile Powder Free Gloves are not expected to cause any adverse health effects.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE
Store in a dry, cool and ventilated area. Do not store above 104 °F (40 °C). Shield open box from direct sunlight, fluorescent lighting and x-rays. Improper storage will decrease usable life.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

EYE PROTECTION
Not necessary under conditions of intended use.

SKIN PROTECTION
Not necessary under conditions of intended use.

RESPIRATORY PROTECTION
Not necessary under conditions of intended use.

VENTILATION
Not necessary under conditions of intended use.

STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED
These products are solid articles and are not subject to leaks or spills.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/ ODOR
Ambidextrous, Beaded Cuff, Micro-textured, Chlorinated, Powder Free, Coated with Colloidal Oatmeal USP Skin Protectant, Dawn Blue.

DIMENSION	X-SMALL	SMALL	MEDIUM	LARGE	X-LARGE
Length (mm)	Minimum 230 (same for all)				
Width (mm)	76 ± 4	86 ± 4	98 ± 4	107 ± 4	115 ± 4
THICKNESS (mm) - SINGLE WALL MEASUREMENT (same for all)					
Finger (mm) Palm (mm)	0.09 ± 0.02 0.07 ± 0.02				

TENSILE PROPERTIES	UNAGED	AGED
Tensile Strength (Mpa)	Min. 18.0 MPa	Min. 16.0 MPa
Ultimate Elongation (%)	Min. 500%	Min. 400%

SECTION 10: STABILITY AND REACTIVITY

BOILING POINT
N/A

VAPOR PRESSURE (mm Hg)
N/A

VAPOR DENSITY (air=1)
N/A

SPECIFIC GRAVITY (water=1)
N/A

SOLUBILITY IN WATER
Insoluble

% VOLATILE BY VOLUME
N/A

EVAPORATION RATE
N/A

VISCOSITY
N/A

SECTION 11: TOXICOLOGICAL INFORMATION

STABILITY
Stable.

CONDITIONS TO AVOID
Does not apply.

INCOMPATABILITY (MATERIALS TO AVOID)
High polar solvent like methyl ethyl ketone, acetone.

HAZARDOUS DECOMPOSITION PRODUCTS
In a fire, these products may produce a black smoke. Carbon Dioxide, Carbon Monoxide, Oxides of Nitrogen, aromatic/aliphatic hydrocarbons.

HAZARDOUS POLYMERIZATION
Will not occur.

SECTION 12: ECOLOGICAL INFORMATION

N/A

SECTION 13: DISPOSAL CONSIDERATION

WASTE DISPOSAL METHOD
Consult current local, state and federal regulations for proper disposal methods.

SECTION 14: TRANSPORT INFORMATION

N/A

SECTION 15: REGULATORY INFORMATION

N/A

SECTION 16: OTHER INFORMATION

RECOMMENDED USE AND RESTRICTION
The Nitrile Powder Free Gloves is a Single Use device.

The Brand

Leadership | Certifications | Global Locations

Certifications

Certifications

Gloveon's quality standards, management systems and exemplary regulatory compliance, all contribute to the global success of the company. Our capabilities have been assessed and certified by the following international governing bodies.

Management Service ISO 9001:2015

America ISO 13485:2016

EN ISO 13485:2016

Japan Confirmation Letter for GMP Audit

Product Service EC Certificate

ISO 14001:2015

UL Certification

ISEGA Food Contact Test Certification (German)

Registration Certificate for Medical Device

NFPA Certification

510(k) Approval

PPE Cert

ANVISA

SATRA

Notified Body: 2777 SATRA customer number: P0130

EU Type-Examination Certificate

Certificate number: 2777/10648-04/E04-01

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: AS NPF

Description: Nitrile examination powder free gloves

Sizes: 6 (XS) – 10 (XL)

Classification:

EN ISO 374-1:2016/Type B	Level	EN374-4:2013
37% Formaldehyde	6	3.1%
40% Sodium Hydroxide	6	-25.6%
30% Hydrogen Peroxide	2	17.0%

EN ISO 374-5:2016

Resistance to Bacteria and Fungi	Pass
Resistance to Virus	Pass

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHM0265112/1749/EN/A, CHM0265112/1749/EN/B, CHM0265112/1749/SPT, CHM0272621/1826/JS, CHM0275215/1836/LH, CHM0275215/1836/LH/E, CHM0275215/1836/LH/D, CHM0275215/1836/LH/A/Final TUV: 7191143339-CHM16-01-RC

Signed on behalf of SATRA: Hannah Coe Geoff Graham

Date of issue: 17/04/2019 **Expiry date: 25/06/2023**

Page 1 of 2

SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland.

Hartalega

EC Declaration of Conformity

Hartalega

EC Declaration of Conformity

We, the manufacturer

with European Representative

Declares that the new PPE described hereafter

is in conformity with the relevant Union harmonisation legislation

where such is the case, with the national standard transposing harmonised standard number

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/

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 17th February 2020.

Rev 02

Hartalega

EC Declaration of Conformity

We, the manufacturer

with European Representative

Declares that the new PPE described hereafter

is in conformity with the relevant Union harmonisation legislation

where such is the case, with the national standard transposing harmonised standard number

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/

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 17th February 2020.

Rev 02

Hartalega Sdn Bhd
Nurul Kong
Quality Assurance Senior Manager
No. 7, Kawasan Perusahaan Suria
Bestari Jaya, 45600 My

Re: K180644
Trade/Device Name: Nitrile Powder Free Examination Gloves with Colloidal Oatmeal -Lemon Green
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: July 16, 2018
Received: July 23, 2018

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/pmn.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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 03/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K180644

Device Name
Nitrile Powder Free Examination Gloves with Colloidal Oatmeal - Lemon Green

Indications for Use (Describe)
The Nitrile Powder Free Examination Glove with Colloidal Oatmeal - Lemon Green is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner

Type of Use (Select one or both, as applicable)
☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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FORM FDA 3881 (7/17) Page 1 of 1

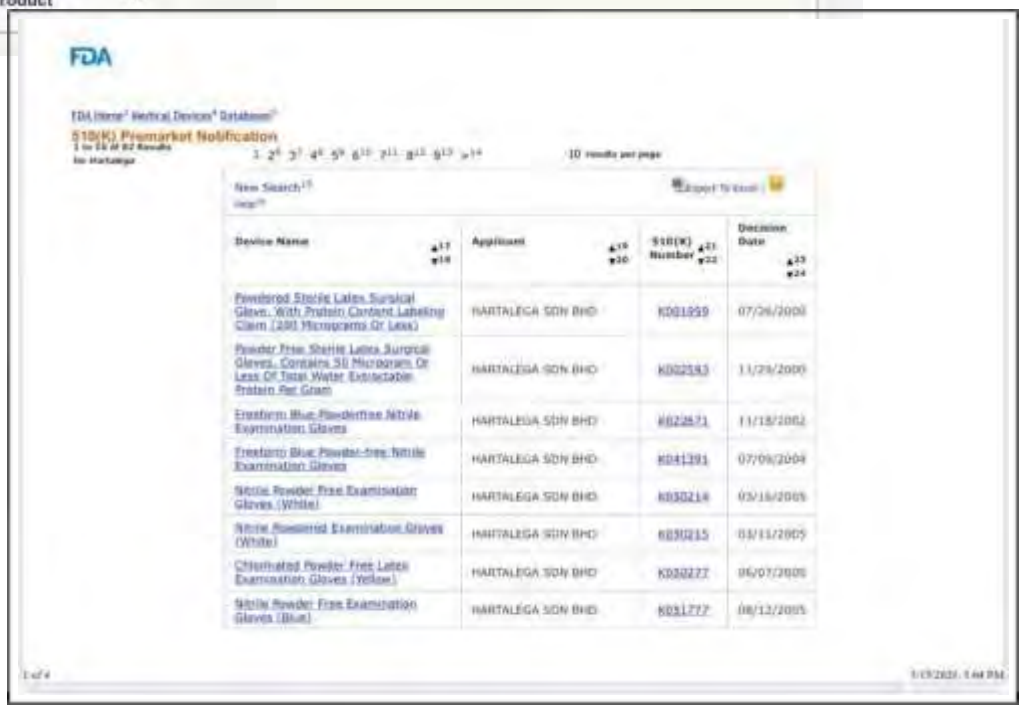
510(k) Premarket Notification

FDA Home • Medical Devices • Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search | Back To Search Results

Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K133956
Device Name	NITRILE POWDER FREE EXAMINATION GLOVE WITH COLLOIDAL OATMEAL USP SKIN PROTECTANT DRUG - WHITE / DAWN BLUE / LEMON GREEN
Applicant	HARTALEGA SDN BHD NO. 7, KAWASAN PERUSAHAAN SURIA Bestari Jaya, Selangor, MY 45600
Applicant Contact	Nurul Aisyah Kong
Correspondent	HARTALEGA SDN BHD NO. 7, KAWASAN PERUSAHAAN SURIA Bestari Jaya, Selangor, MY 45600
Correspondent Contact	Nurul Aisyah Kong
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	12/23/2013
Decision Date	05/28/2014
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No



FDA

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510(K) Premarket Notification

New Search

Device Name	Applicant	510(K) Number	Decision Date
Powdered Sterile Latex Surgical Glove, With Protein Content Labeling Claim (200 Micrograms Or Less)	HARTALEGA SDN BHD	K001959	07/26/2000
Powder Free Sterile Latex Surgical Gloves, Contains 50 Microgram Or Less Of Total Water Extractable Protein Per Gram	HARTALEGA SDN BHD	K002593	11/29/2000
Freeform Blue Powderfree Nitrile Examination Gloves	HARTALEGA SDN BHD	K022871	11/18/2002
Freeform Blue Powder-free Nitrile Examination Gloves	HARTALEGA SDN BHD	K041391	07/09/2004
Nitrile Powder Free Examination Gloves (White)	HARTALEGA SDN BHD	K050214	03/16/2005
Nitrile Powdered Examination Gloves (White)	HARTALEGA SDN BHD	K050215	03/15/2005
Chlorinated Powder Free Latex Examination Gloves (Yellow)	HARTALEGA SDN BHD	K050277	06/07/2005
Nitrile Powder Free Examination Gloves (Blue)	HARTALEGA SDN BHD	K051777	08/12/2005

Testing, Development, Problem Solving.

April 16, 2009

- TEST REPORT -

PN 83672A - Amended

CHEMICAL ANALYTICAL SERVICES

Prepared For [illegible]

Prepared By: [illegible]

Approved By: [illegible]

ISO 9001:2000

[illegible]

Testing, Development, Problem Solving.

[illegible]

SUBJECT: [illegible]

RECEIVED: [illegible]

TESTING CHEMOTHERAPY DRUGS

Table 1. [illegible]

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]

COLLECTION MEDIA

[illegible]

Table 2. [illegible]

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]

MDSS

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

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

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 Wilde
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: Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient 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/pmn.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.

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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

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Silver Spring, MD 20993
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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) 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

Hartalega Attains International Certification on Occupational Health and Safety – OHSAS 18001

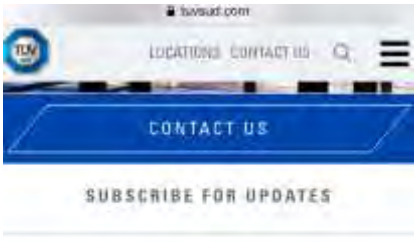
Hartalega has once again proven its commitment to the highest quality standards, as the Group recently attained OHSAS 18001:2007 certification.

Awarded by TUV SUD Asia Pacific TUV SUD Group, an audit and management systems certification body, OHSAS 18001:2007 is an internationally recognised standard which sets the requirements and best practices for occupational health and safety management systems in an organisation. The Group was previously awarded ISO 14001:2004 certification as a result of its outstanding environmental management system.

Mr Kuan Mun Leong, Managing Director of Hartalega said, "The OHSAS is a testament to our group's commitment to the well being of all Hartanians. As we continue to grow our business aggressively, being able to provide a quality work place in the aspects of health and safety is very important."

The OHSAS 18001:2007 certification was achieved through Hartalega's comprehensive range of health and safety measures, which include internal workplace audits, risk assessments, behaviour observations, accident and incident investigations, work permit issuances, training sessions for emergency preparedness and environmental performance monitoring, amongst others.

"As important as it is to focus on productivity and efficiency, it is equally as crucial to ensure that our employees work in a safe environment. We aim to continuously enhance Health, Safety and Environment initiatives throughout the Group for the benefit of our workforce," concluded Kuan.



CRS REF : SAT/18/0248
DATE RECEIVED : MAR 02, 2018
DATE REPORTED: MAR 14, 2018
PAGE: 1 of 1

Report No. : CRSSA/02645/18

TEST REPORT

Product Description	:	Powder Free Nitrile Examination Gloves
Country of Origin	:	Malaysia
Size	:	Medium
Quantity Tested	:	200 pieces
Test Conducted	:	Freedom from holes
Test Method	:	EN455 Part 1:2000
Testing Period	:	02 Mar 2018 – 08 Mar 2018

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5 Accept : 7 Found : 2

Result : Within AQL

Note: Upon Customer's request, this report has been issued in more than one original. Only the first original is a legally binding document and may be used for any legal purpose, including payment. (Original 1-3)

SGS (MALAYSIA) SDN. BHD.

CHEE TUCK CHOON
B.Sc. MMIC
SECTION HEAD

CRS REF : SAT/18/0248
DATE RECEIVED : MAR 02, 2018
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PAGE: 1 of 1

Report No. : CRSSA/02646/18

TEST REPORT

Product Description	:	Powder Free Nitrile Examination Gloves
Country of Origin	:	Malaysia
Size	:	Medium
Quantity Tested	:	13 pieces
Test Conducted	:	Dimensions
Test Method	:	EN 455 Part 2:2015
Testing Period	:	02 Mar 2018 – 08 Mar 2018

Based on submitted samples, the following results obtained :-

Size	M	M	M	M	M	M	M	M	M	M	M	M	M	M	Median
Width	98	98	96	98	98	97	98	97	98	97	96	97	97	97	
Length	250	255	250	255	251	250	252	252	250	254	252	253	252	252	

Note: Upon Customer's request, this report has been issued in more than one original. Only the first original is a legally binding document and may be used for any legal purpose, including payment. (Original 1-3)

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DATE RECEIVED : MAR 02, 2018
DATE REPORTED: MAR 14, 2018
PAGE: 1 of 1

Report No. : CRSSA/02647/18

TEST REPORT

Product Description	:	Powder Free Nitrile Examination Gloves
Country of Origin	:	Malaysia
Size	:	Medium
Quantity Tested	:	13 pieces
Test Conducted	:	Force at Break During Shelf Life and After
Test Method	:	Challenge EN 455 Part 2:2015
Ageing	:	70 ± 2 Deg C for 168 hrs
Testing Period	:	02 Mar 2018 – 14 Mar 2018

		Force at Break, N	
SIZE	**SAMPLE NO.**	**BEFORE AGING**	**AFTER AGING**
M	1	8.2	8.4
	2	8.1	8.2
	3	7.9	6.5
	4	7.3	7.9
	5	8.5	6.6
	6	9.2	9.3
	7	8.7	7.2
	8	8.8	7.4
	9	9.3	7.1
	10	8.0	7.9
	11	9.2	7.3
	12	6.3	7.1
	13	8.1	7.1
Median		8.2	7.3
Requirement		≥ 6.0	≥ 6.0

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PAGE: 1 of 1

Report No. : CRSSA/02648/18

TEST REPORT

Product Description	:	Powder Free Nitrile Examination Gloves
Country of Origin	:	Malaysia
Size	:	Medium
Quantity Tested	:	5 pieces
Test Conducted	:	Powder Content
Test Method	:	EN455 Part 3:2015
Testing Period	:	02 Mar 2018 – 08 Mar 2018

On testing the samples, the following results were obtained:-

SIZE	**Average Powder Mass per Glove**
M	0.26 mg

Note: Upon Customer's request, this report has been issued in more than one original. Only the first original is a legally binding document and may be used for any legal purpose, including payment. (Original 1-3)

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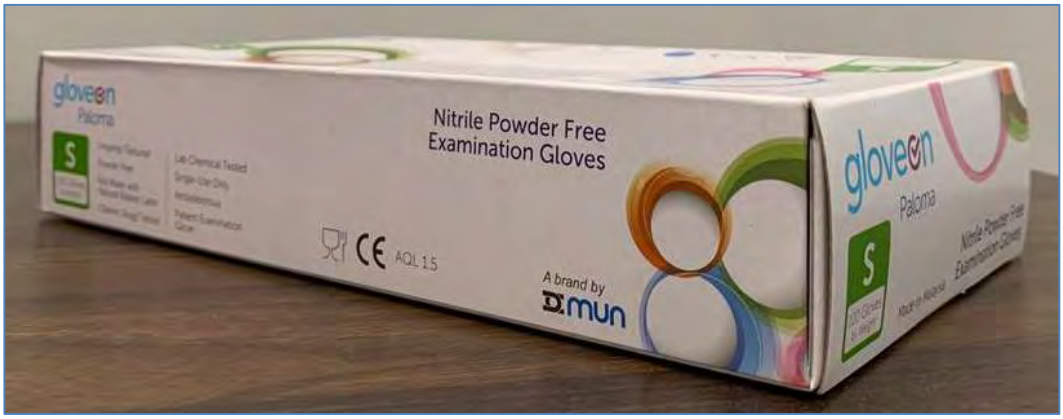
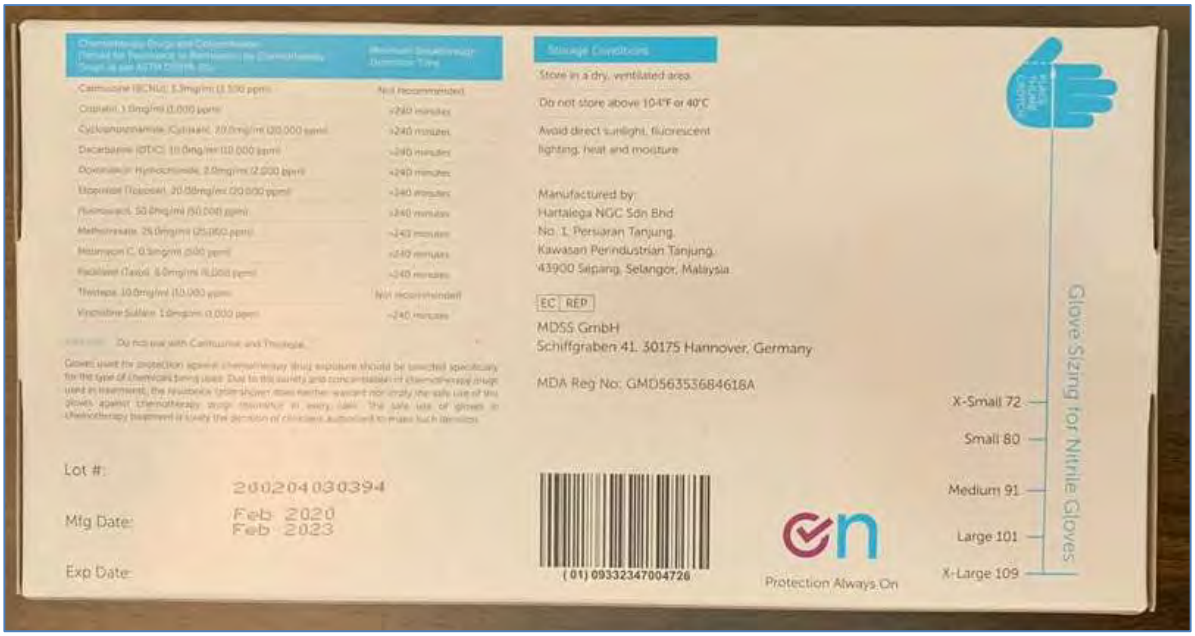
25cm X12.5cm X 5cm. 100 Gloves in 1 box





26cm X 26cm X 26cm. 10 boxes of 100 Gloves in One Carton