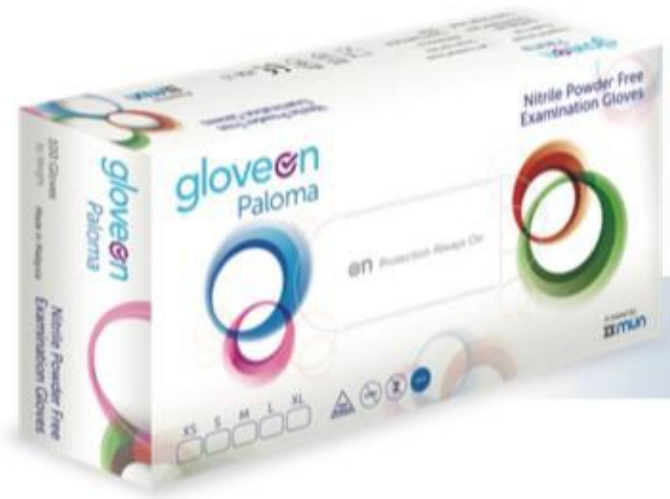

gloveon Paloma

Nitrile Exam Gloves
Powder Free, Standard Cuff

To don **Paloma** is like putting on a second skin. Its absolute tactility commends it to delicate procedures and jobs plus an assured tensile strength and resistance to chemical expected of a nitrile glove. You owe it to yourself to try this exceptional nitrile glove from **GloveOn**.

	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

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

Hartalega

Hartalega Sdn Bhd
T: +603 6277 1733
E: info@hartalega.com.my

Protection Always On

Visit us at
gloveonglobal.com

Certificate of CE-Registration

MDSS
Medical Device Safety Service

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

Ludger Möller
President
MDSS GmbH

MDSS
Medical Device Safety Service

MDSS · Schiffgraben 41 · 30175 Hannover, Germany

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

Schiffgraben 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

Annex A dated January 18, 2019
Manufacturer: Hartalega NGC Sdn. Bhd.

UMDNS Code Description Notified Medical Device Product Name & Catalogue Number	UMDNS Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
Gloves, Examination/Treatment	11-882	I	10	DE/CA09/0170/H13/001-01	N.A.	N.A.
Latex Examination Gloves; Nitrile Examination Gloves; Antimicrobial Nitrile Power Free Examination Gloves						
Latex Powder Free Examination Gloves *Latex Powdered Examination Gloves* *Nitrile Powder Free Examination Gloves* *Antimicrobial Nitrile Power Free Examination Gloves*						

FDA

FDA Home[3] Medical Devices[4] Databases[5]

510(K) Premarket Notification

1 to 10 of 82 Results
for *Hartalega*

1 2[6] 3[7] 4[8] 5[9] 6[10] 7[11] 8[12] 9[13] >[14] 10 results per page

New Search[15]
Help[16]

Export To Excel |

Device Name ▲17 ▼18	Applicant ▲19 ▼20	510(K) Number ▲21 ▼22	Decision Date ▲23 ▼24
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	K022671	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	03/11/2005
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

FDA LIVE LINK

https://www.accessdata.fda.gov/cdrh_docs/pdf18/K180505.PDF

https://fda.report/Company/HARTALEGA+SDN+BHD

510(k) Premarket Notification

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

U.S. FOOD & DRUG ADMINISTRATION

Trade/Device Name: Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP with Low-Dermatitis Potential Claim and Tested For Use with Chemotherapy Drugs (White)

Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: May 15, 2018
Received: May 17, 2018

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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

Indications for Use

Form Approved: OMB No. 0910-0120

See *PRA Statement* below.

Device Name

Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs (White)

Indications for Use *(Describe)*

Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs (White) 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. Is it also tested to be used against Chemotherapy Drugs.

The list of Chemotherapy Drugs tested (with breakthrough times) is as below;

Carmustine (3.3 mg/ml)	17.2 minutes
Cisplatin (1.0 mg/ml)	>240 minutes
Cyclophosphamide (20 mg/ml)	>240 minutes
Dacarbazine (10.0 mg/ml)	>240 minutes
Doxorubicin Hydrochloride (2.0 mg/ml)	>240 minutes
Etoposide (20 mg/ml)	>240 minutes
Fluorouracil (50 mg/ml)	>240 minutes
Methotrexate (25 mg/ml)	>240 minutes
Mitomycin C (0.5 mg/ml)	>240 minutes
Paclitaxel (6.0 mg/ml)	>240 minutes
Thiotepa (10.0 mg/ml)	36.1 minutes
Vincristine Sulfate (1.0 mg/ml)	>240 minutes

Do not use with Carmustine. Do not use with Thiotepa.

Type of Use *(Select one or both, as applicable)*

Prescription Use (Part 21 CFR 801 Subpart D) X 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."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

www.ardl.com
2887 Gilchrist Rd. | Akron, Ohio 44305 | answers@ardl.com
Toll Free (800) 830-ARDL | Worldwide (330) 794-6600 | Fax (330) 794-6610

April 15, 2009

Ms. Nurul Aisyah Kong
Hartalega SDN. BHD

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

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

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 result

Acceptable Quality Limit (AQL) :

Result :

Note: Upon Custome... ...as been issued in more than one original. Only the first original is a legally binding d... ...ay be used for any legal purpose, including payment. (Original 1-3)

SGS (MALAYSIA) SDN. BHD.

CHEE TUCK CHOON
B.Sc. MMIC
SECTION HEAD

EC Declaration of Conformity

We, the manufacturer
Hartalega NGC Sdn. Bhd.,
No. 1, Persiaran Tanjung,
Kawasan Perindustrian Tanjung,
43900 Sepang,
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)
HNGC-TF-PPE-002
Antimicrobial Nitrile Powder Free Examination Gloves
Five fingered, chlorinated, powder free nitrile gloves, with textured fingers and beaded cuff. Thickness ≥2.2mil

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 2777/11723-01/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 NGC Sdn. Bhd. on 11th February 2020.

Kuan Eu Jin
Quality Management Representative

Rev 01

CRS REF : SAT/18/0248
DATE RECEIVED : MAR 02, 2018
DATE REPORTED: MAR 14, 2018
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	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)

SGS (MALAYSIA) SDN. BHD.

CHEE TUCK CHOON
B.Sc. MMIC
SECTION HEAD

TÜV SÜD OHSAS 18001

Occupational Health & Safety
OHSAS 18001

QGWS.MH49134 - Protective Clothing and Ensembles for Emergency Medical Operations

Protective Clothing and Ensembles for Emergency Medical Operations

See General Information for Protective Clothing and Ensembles for Emergency Medical Operations

HARTALEGA SDN BHD MH49134
C-G-9 Jalan Dataran Sd1
Dataran Sd Pju 9
Bandar Sri Damansara
52200 Kuala Lumpur, MALAYSIA
Protective clothing, equipment and [C]BRN ensembles for emergency medical operations in accordance with NFPA 1999 (2018)

Single-use emergency medical examination gloves

Type	Model/Style	UL Certification No.
Nitrile	Glove On Maverick LC	49134010301
Nitrile	HSB 41 (Orange) or GloveOn Vigor	49134010302
Nitrile	HSB 45 (Black)	49134010303
Nitrile	HSB 78 (Orange) or GloveOn Vigor LC	49134010304
Nitrile	HSB 78 (Black) or GloveOn Hammer LC	49134010305
Nitrile	HSB 71	49134010306

Last Updated on 2019-12-23