Hartalega

gloveen COATS™

Colloidal Oatmeal System

Made in Malaysia by Hartalega Sdn Bhd.

Nitrile Examination Glove

Features a patented and unique glove technology. Contains a coating of all-natural oats that forms a natural, moisturising barrier to prevent skin irritation.

AQL 1.5

ASTM D6319, EN 455 part 1, 2, 3 & 4

EN 1186, EN 13130, CEN/TS 14234

EN 420, EN 374 part 1, 2 & 3

MD Directive 93/42/EEC

TGA - ARTG 164563,

FDA 510(k)

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

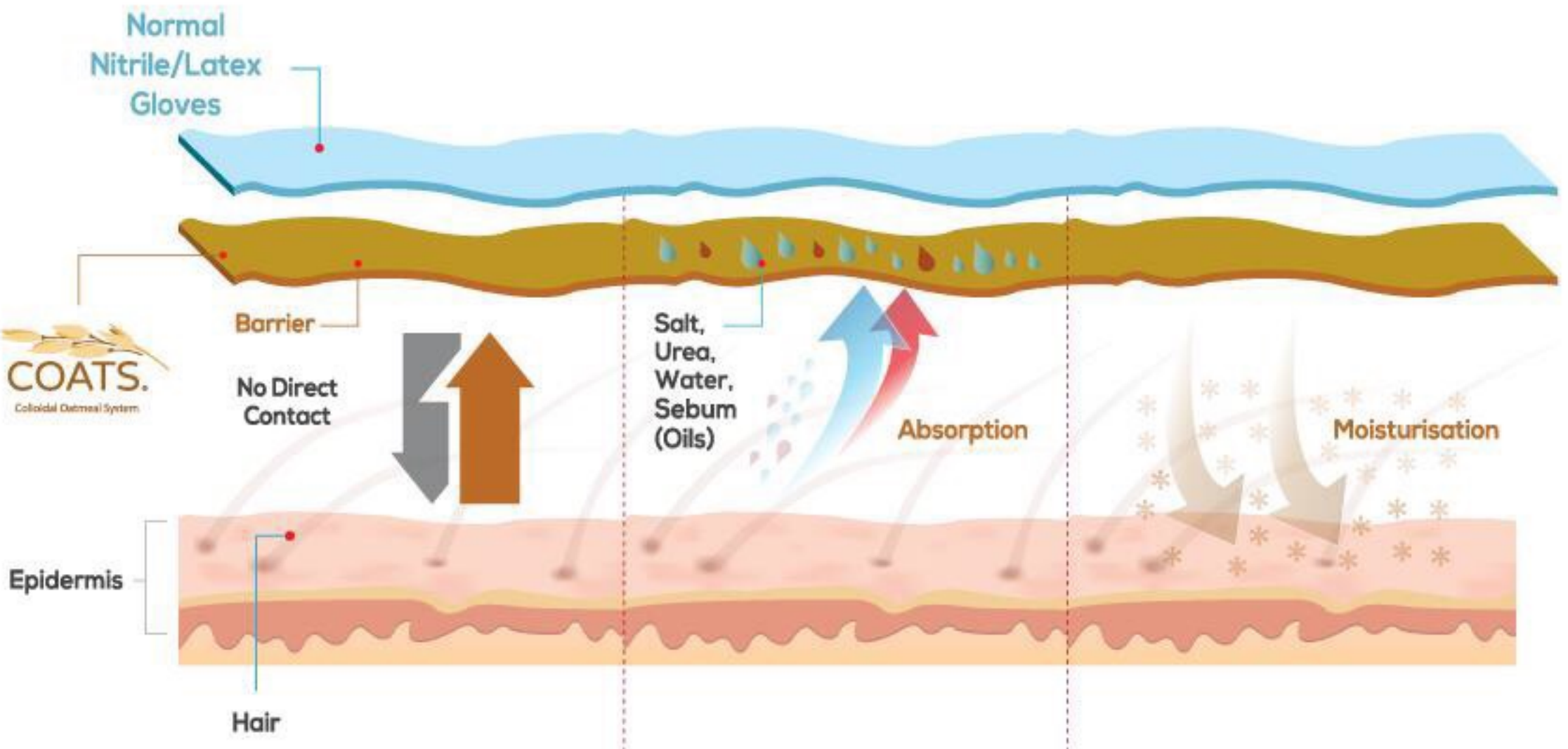
AUSTRALIAN DENTAL ASSOCIATION ADA SEAL OF APPROVAL

FEATURES

- Fingertip textured
- Powder Free
- Not made with natural rubber latex
- Chemo drugs tested
- Lab chemical tested
- Ambidextrous
- Standard cuff
- Dawn blue colour

Actual Dimension in millimetres (mm)

HOW COATS® GLOVE WORKS



1 Barrier

COATS creates a physical barrier between glove and skin, hence preventing direct irritation from glove film.

2 Absorption

COATS absorbs water, urea and salt excretions that cause irritation.

3 Moisturisation

COATS penetrates quickly into skin to keep it moisturised.

COATS® Colloidal Oatmeal Coated Nitrile Powder Free 2.5 Mil

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Hartalega

Hartalega Sdn. Bhd.

C-G-9, Jalan Dataran SD1, Dataran SD PJU9, Bandar Sri Damansara,
52200 Kuala Lumpur
Malaysia

Scope of application:

Distribution of Natural Latex and Nitrile Powdered
and Powder-Free Non-Sterile and Sterile Examination Gloves,
Sterile Surgical Gloves and Industrial Gloves

Hartalega Sdn. Bhd.

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

Scope of application:

Design and Development, Production and Distribution
of Natural Latex and Nitrile Powdered and Powder-Free Non-Sterile
and Sterile Examination Gloves, Sterile Surgical Gloves
and Industrial Gloves

has established and applies
a Quality Management System.

An audit was performed, Order No. **721423945**.

Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled. The certificate is valid from **2020-02-29** until **2023-02-27**.

Certificate Registration No.: **12 100 25208 TMS**.

Product Compliance Management
Munich, 2020-02-03

IAF DAkkS

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 089752 0007 Rev. 00

Holder of Certificate: **Hartalega NGC Sdn. Bhd**
No.1, Persiaran Tanjung
Kawasan Perindustrian Tanjung
43900 Sepang, Selangor Darul Ehsan
MALAYSIA

Facility(ies):
Hartalega NGC Sdn. Bhd
No.1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Natural Latex and Nitrile Powdered and Powder Free Non-Sterile Examination Gloves**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: MYQMH0418038Rev1-721419970

Valid from: 2018-09-19
Valid until: 2020-11-26

Date, 2018-09-19

Stefan Preiß

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200581

Device Name
Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)

Indications for Use *(Describe)*
Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) 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. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.

These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (3.3 mg/ml)	21.4
Cisplatin (1.0 mg/ml)	>240
Cyclophosphamide (20.0 mg/ml)	>240
Dacarbazine (10.0 mg/ml)	>240
Doxorubicin Hydrochloride (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	67.2
Vincristine Sulfate (1.0 mg/ml)	>240
Azacytidine (25.0 mg/ml)	>240
Carboplatin (10.0 mg/ml)	>240
Docetaxel (10 mg/ml)	>240
Epirubicin (2.0 mg/ml)	>240
Gemcitabine (38 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan (20 mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Oncovin (1.0 mg/ml)	>240
Oxaliplatin (5 mg/ml)	>240
Vinorelbine (10 mg/ml)	>240

Please note that Carmustine and Thiotepa have extremely low permeation times of 21.4 minutes and 67.2 minutes respectively.
Warning: Do not use with Carmustine

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection (100 mcg/2ml)	>240

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.

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

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200581

Device Name
Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue)

Indications for Use *(Describe)*
Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate (Blue) 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. It is also tested to be used against Chemotherapy Drugs and Fentanyl Citrate.

These gloves were tested for use with chemotherapy drugs and Fentanyl Citrate as per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (3.3 mg/ml)	21.4
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Doxorubicin Hydrochloride (2.0 mg/ml)	>240
Etoposide (20.0 mg/ml)	>240
Fluorouracil (50.0 mg/ml)	>240
Methotrexate (25.0 mg/ml)	>240
Mitomycin C (0.5 mg/ml)	>240
Paclitaxel (6.0 mg/ml)	>240
Thiotepa (10.0 mg/ml)	67.2
Vincristine Sulfate (1.0 mg/ml)	>240
Azacytidine (25.0 mg/ml)	>240
Carboplatin (10.0 mg/ml)	>240
Docetaxel (10 mg/ml)	>240
Epirubicin (2.0 mg/ml)	>240
Gemcitabine (38 mg/ml)	>240
Ifosfamide (50 mg/ml)	>240
Irinotecan (20 mg/ml)	>240
Mitoxantrone (2.0 mg/ml)	>240
Oncovin (1.0 mg/ml)	>240
Oxaliplatin (5 mg/ml)	>240
Vinorelbine (10 mg/ml)	>240

Please note that Carmustine and Thiotepa have extremely low permeation times of 21.4 minutes and 67.2 minutes respectively.
Warning: Do not use with Carmustine

Fentanyl Citrate and Concentration	Minimum Breakthrough Detection Time in Minutes
Fentanyl Citrate Injection (100 mcg/2ml)	>240

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.

510(k) Premarket Notification

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

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

FDA

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

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 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
Cyclophospharnide (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

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*						

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

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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

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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

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

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

April 15, 2009

· TEST REPORT ·

PN 83672A - Amended

CHEMICAL ANALYTICAL SERVICES

Prepared For:
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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

Ludger Möller
President
MDSS GmbH

MDSS

Medical Device Safety Service

MDSS · Schiffgraben 41 · 30175 Hannover, Germany

Hartalega NGC Sdn. Bhd.
Khairunnisa Warsito
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30175 Hannover, Germany

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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

MATERIAL SAFETY DATA SHEET

Hartalega

SECTION 1: PRODUCT IDENTIFICATION

NAME Hartalega Sdn. Bhd.	**ADDRESS** 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.