



Colloidal Oatmeal System

Nitrile Exam Gloves Powder Free, Standard Cuff

COATS® (an acronym for colloidal oatmeal system) is a patented and unique nitrile glove technology. COATS® utilises the powerful benefits of all-natural oats, an FDA-recognised skin protectant, as a coating that forms a natural, moisturising barrier between the glove and skin. This acts as a preventative measure against skin irritation, and eliminates many of the uncomfortable and irritating conditions experienced when wearing normal gloves. Users who suffer from dry and itchy skin due to constant hand washing and glove usage can now rely on COATS® to soothe and nurture the skin, and protect their hands while they work.



COATS® Nitrile		
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
Colloidal Oatmeal Content	N = 5	≥ 5mg/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)	Not recommended
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)	Not recommended
Vincristine Sulfate, 1.0mg/ml (1,000 ppm)	>240 minutes

WARNING: Gloves used for protection against chemotherapy drug exposure should be selected specifically for the type of chemicals being used. Due to the variety and concentration of chemotherapy drugs used in treatments, the resistance table shown does neither warrant nor imply the safe use of the gloves against chemotherapy drugs resistance in every case. The safe use of gloves in chemotherapy treatment is solely the decision of clinicians authorised to make such decision.

FEATURES

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

PACKAGING

100 gloves per box (XS-L)

90 gloves per box (XL)

10 boxes per carton

REGULATORY COMPLIANCE

TGA - ARTG 164563, FDA 510(k),
MDD 93/42/EEC, REACH, EC 10/2011,
EC 1935/2004

STANDARDS

ASTM D6319, ASTM D412, ASTM D573,
ASTM D5151, ASTM D6124,
EN 455 part 1, 2, 3 & 4,
EN 1186, EN 13130, CEN/TS 14234

PATENTS

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

MANUFACTURING ACCREDITATIONS

ISO 9001
ISO 13485
EN ISO 13485
ISO 14001
OHSAS 18001

Nitrile



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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

MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION



COMMON NAME (USED ON LABEL)

Nitrile Powder Free Examination Gloves

APPLICATION

Medical and Dental

CHEMICAL FAMILY

Carboxylated Butadiene Acrylonitrile Polymer Latex

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-butylthiocarbamate, 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)			0.09 ± 0.02		
Palm (mm)			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.
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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
TECHNOLOGY

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:	Description:
AS NPF	Nitrile examination powder free gloves

Sizes:	Classification:	EN ISO 374-1:2016/Type B	Level	EN374-4:2013
6 (XS) – 10 (XL)	EN ISO 374-1:2016/Type B 37% Formaldehyde 40% Sodium Hydroxide 30% Hydrogen Peroxide	6 6 2	3.1% -25.6% 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/E/N/A, CHM0265112/1749/E/N/B, CHM0265112/1749/I/P/T, CHM0272621/1826/U/S, CHM0275215/1836/L/H, CHM0275215/1836/L/H/E, CHM0275215/1836/L/H/D, CHM0275215/1836/L/H/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

SATRA Technology Europe Limited, Braehead Business Park, Clones, D151YGP, Republic of Ireland

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Hartalega Innovation & Quality

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 A)
HSB-TF-006
Nitrile Powder Free Examination Glove – Blue (SBLU)
Powder free blue Nitrile disposable five fingered glove

In is 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 Europe with Notified Body Number of 2777 performed the EU type-examination (Module B) and issued the EU type-examination certificate 2777/10475-03/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 Europe with Notified Body Number of 2777.

Done at Hartalega Sdn. Bhd. on 11th February 2020.

Kuan Eu Jin
Quality Management Representative

Hartalega Holdings Berhad (4118815)
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Bandar Sri Damansara
59100 Kuala Lumpur, Malaysia
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Hartalega Sdn. Bhd. (1088414)
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45600 Bestari Jaya
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Rev 02
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Innovation & Quality

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 B)
HSB-TF-005
≥ 2.5 mil Powder Free Nitrile disposable five fingered glove
Available in a standard minimum 240mm length or a longer cuff variant of 280mm
Available in sterile and non-sterile

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 2777/11755-02/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 11th February 2020.

Kuan Eu Jin
Quality Management Representative

Hartalega Holdings Berhad (414881-U)
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Innovation & Quality

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 B)
HSB-TF-009
Nitrile Powder Free Glove with Colloidal Oatmeal USP Skin Protectant

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 2777/10783-02/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 11th February 2020.

Kuan Eu Jin
Quality Management Representative

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Rev 01
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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/cfpnn/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

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K180644

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, 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 -S

For Tina Xiang, Ph.D.
Acting Director
Division of Anesthesia,
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
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number (if known)

K180644

Device Name

Nitrile Powder Free Examination Glove 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.

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New Search	Applicant	510(k) Number	Decision Date
Biodegradable Nitrile Powder Free Examination Gloves Tested For Like With Chemotherapy Drugs And Feminist Gloves (Blue)	Hartalega NGC SDN. BHD.	K180581	04/29/2020
Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs And Feminist, Chaste (Blue)	Hartalega NGC Sdn. Bhd.	K180019	04/06/2020
Nitrile Powder Free Examination Gloves With Colloidal Oatmeal (Blue)	Hartalega NGC Sdn. Bhd.	K182221	11/09/2019
Nitrile Powder Free Surgical Gloves With Protein Labeling	Hartalega Ngt Sdn. Bhd.	K180444	06/26/2019
Nitrile Powder Free Surgical Gloves With Protein Labeling Grams Of 50 Microgram Or Less Per Gram Of Gloves	Hartalega Ngt Sdn. Bhd.	K185536	06/16/2019
Polysulfone Powder Free Surgical Gloves, Polyisobutylene	Hartalega NOC Sdn. Bhd.	K185388	06/29/2019
Powder Free Examination Gloves With Colloidal Oatmeal (Blue)	Hartalega Sdn. Bhd.	K180445	11/16/2018
Sterile Nitrile Powder Free Examination Gloves Tested For Use With Chemotherapy Drugs (Blue) (White)	HARTALEGA SDN. BHD.	K180736	11/02/2018
Nitrile Powder Free Examination Gloves With Colloidal Oatmeal (Blue)	Hartalega Sdn. Bhd.	K177509	06/17/2018
Nitrile Powder Free Examination Gloves With Colloidal Oatmeal (Blue)	Hartalega Sdn Bhd	K180644	06/10/2018

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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

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for Hartalega

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Device Name ^{▲17} ^{▼18}	Applicant ^{▲19} ^{▼20}	510(K) ^{▲21} ^{▼22} Number ^{▲23} ^{▼24}	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

1 of 4

5/15/2020, 5:04 PM



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April 15, 2009

TEST REPORT

PN 83672A - Amended

CHEMICAL ANALYTICAL SERVICES

Prepared For:
Hartalega SDN. BHD
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. Barbour, M.S.
Manager, Chemical & Pharmaceutical Services

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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), 3.3 mg/ml (3.300 ppm)	Sigma, Lot# 038K4008, Expiration 12/2009
Cisplatin, 1.0 mg/ml (1,000 ppm)	Sigma, Lot# 59H3657, Expiration 09/2009
Cyclophosphamide (Cytosan)	Sigma, Lot# 068K1131, Expiration 1/2010
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Hospira, Lot# U022223AA, Expiration 06/2010
Doxorubicin Hydrochloride	Teva, Lot# 07N625, Expiration 10/2009
Etoposide (Toposar)	Teva, Lot# 3130397B8, Expiration 9/2011
Fluorouracil	APP, Lot# 203867, Expiration 03/2010
Mitomycin C	Sigma, Lot# 048K1130, Expiration 05/2010
Methotrexate	Hospira, Lot# 024497AA, Expiration 05/2010
Paclitaxel (Taxol)	Dubur Oncology, Lot# PA08H0701, Exp. 05/2010
Thiotepa	Sigma, Lot# 78K1526, Expiration 12/2009
Vincristine Sulfate	Hospira, Lot# U037139A, 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 (Cytosan), 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 (25,000 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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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/cfpmpn/cfpmpn.cfm> identifies combination product submissions. This database provides information on the Act's submission 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

U.S. Food & Drug Administration
10901 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

2K200581 - Nurul Kong

Page

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 1 Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-1-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
DHT4-Division of Infection Control
Office of Medical Devices
OHT4-Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

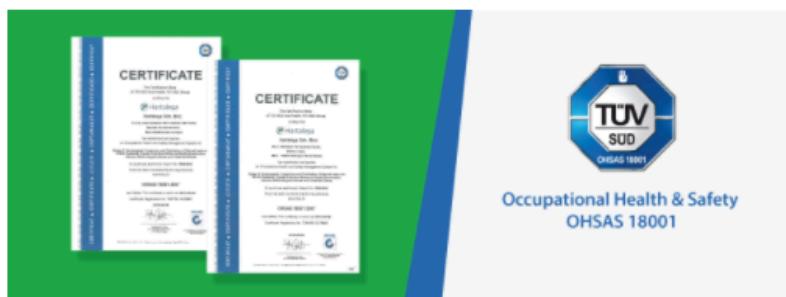
DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration		Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2020 See PRA Statement below.
510(k) Number (if known) K200581		
Device Name Biodegradable Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl 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 (3.2 mg/ml)	>21.4	
Cisplatin (1.0 mg/ml)	>240	
Cyclophosphamide (2.0 mg/ml)	>240	
Dacarbazine (10.0 mg/ml)	>240	
Doxorubicin Hydrochloride (2.0 mg/ml)	>240	
Etoposide (2.0 mg/ml)	>240	
Fluorouracil (50.0 mg/ml)	>240	
Methotrexate (25.0 mg/ml)	>240	
Mitomycin (0.5 mg/ml)	>240	
Pelitaxel (0.0 mg/ml)	>240	
Thiotepa (1.0 mg/ml)	67.2	
Vincristine Sulfate (1.0 mg/ml)	>240	
Vinorelbine (25.0 mg/ml)	>240	
Carboplatin (10.0 mg/ml)	>240	
Docetaxel (10 mg/ml)	>240	
Epirubicin (2.0 mg/ml)	>240	
Gencitabine (38 mg/ml)	>240	
Leucovorin (10 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 Fentanyl Citrate Injection (100 mcg/2ml) Type of Use (Select one or both, as applicable) <input type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input checked="" type="checkbox"/> Over-The-Counter Use (21 CFR 801 Subpart C)		
CONTINUE ON A SEPARATE PAGE IF NEEDED.		
FORM FDA 3881 (7/17) Page 1 of 2 www.accessdata.fda.gov		

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FORM FDA 3881 (7/17) Page 2 of 2

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 TÜV SUD Asia Pacific TÜV 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.

A screenshot of the TÜV SUD website homepage. At the top, there is a navigation bar with links for 'LOCATIONS', 'CONTACT US', and a search icon. Below the navigation is a large blue button labeled 'CONTACT US'. Further down, there is a section titled 'SUBSCRIBE FOR UPDATES'.

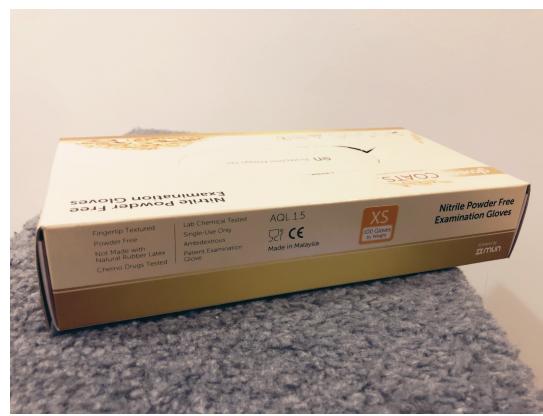
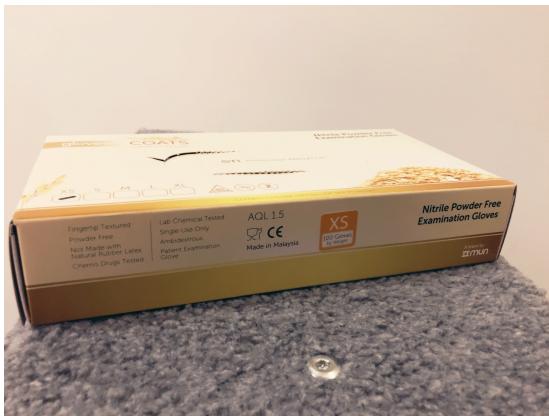
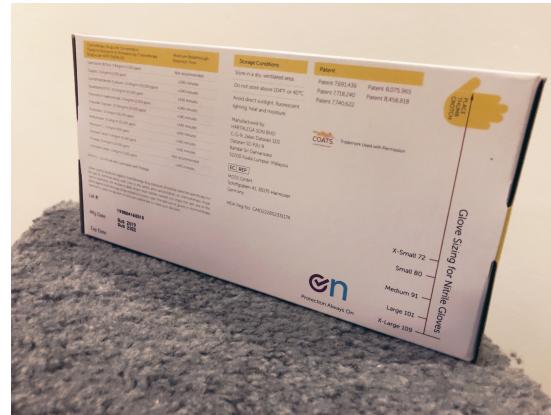
A screenshot of a QM Certificate document titled 'Q5 055298 0020 Rev. 02'. The document contains detailed information about the certification, including the type (QM Certificates), type name (QM System ISO 13485), certification body (TÜV SUD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany), holder of certificate (HARTALEGA SDN. BHD.), product (Gloves, Design and Development, Production and Distribution of Natural Latex and Nitrile Powdered, Powder-Free Non-Sterile and Sterile Examination Gloves and Sterile Surgical Gloves), date (14.04.2020), and status (Valid). The document is presented in a clean, professional layout with a blue header and footer.



The voluntary certification mark with the statement "Type tested" is issued for products and components. The certification mark demonstrates that the product or component has been tested according to the applicable standard and has been found to meet the required safety and performance criteria.

A second screenshot of a QM Certificate document titled 'Q5 055298 0020 Rev. 02'. This document is identical in structure to the first one, showing the same details about the QM System ISO 13485 certification for HARTALEGA SDN. BHD. for gloves. It includes the same information about the type, product, date, and status.

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



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

