gloveen COATS®

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.

NON STERILE · LATEX · CE

	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 chemotherapytreatment 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

Previous | Next

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 IDENTIFI

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

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:
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/AFinal
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

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-008
Nitrile Powder Free Examination Glove – Blue (SBLU)
Powder free blue Nitrile disposable five fingered glove

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 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 (701683-X)
C-G-9, Jalan Dataran SD1, Dataran SD PJU 9
Bandar Sri Damansara
52200 Kuala Lumpur, Malaysia
Tel: +603 - 6277 7733 Fax: +603 - 6280 2533
www.hartalega.com.my

Hartalega Sdn Bhd (753384-X)
No.7, Kawasan Perusahaan Suria
45600 Bestari Jaya
Selangor Darul Ehsan, Malaysia
Tel: +603 - 3280 3888 Fax: +603 - 3271 0135

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 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 (741883-X)
C-G-9, Jalan Dataran SD1, Dataran SD PJU 9
Bandar Sri Damansara
52200 Kuala Lumpur, Malaysia
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45600 Bestari Jaya
Selangor Darul Ehsan, Malaysia
Tel: +603 - 3280 3888 Fax: +603 - 3271 0135

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 B)
HSB-TF-009
Nitrile Powder Free Gloves 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

Hartalega Holdings Berhad (741883-X)
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U.S. FOOD & DRUG ADMINISTRATION

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: 06/30/2020
See PRA Statement below.

Indications for Use

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.

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

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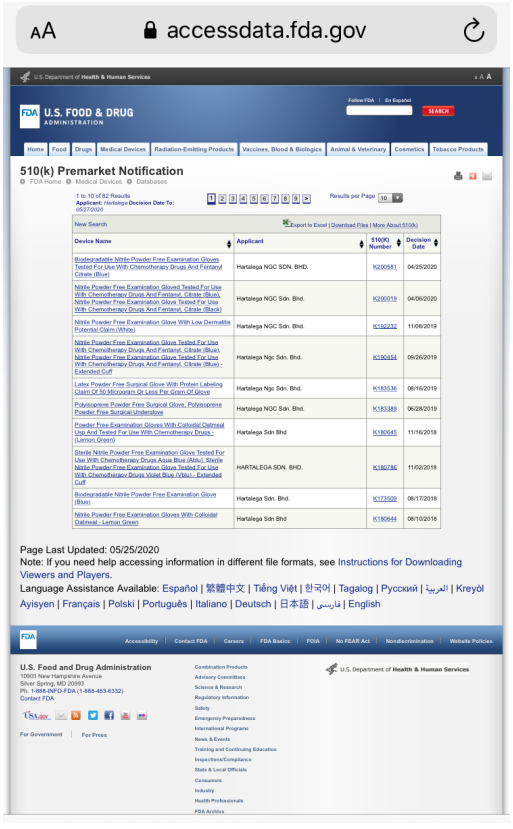

510(k) Premarket Notification

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

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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	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

Testing. Development. Problem Solving.

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

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

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Testing. Development. Problem Solving.

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

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

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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

MDSS
Medical Device Safety Service

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

U.S. FOOD & DRUG ADMINISTRATION

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

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

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

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.

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

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"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."

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

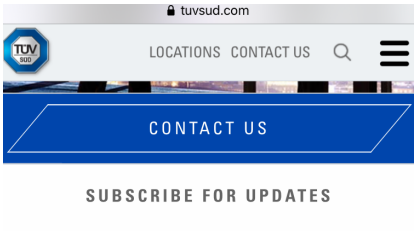
Hartalega has once again proven its commitment to the highest quality standards, as the Group recently attained OHSAS 18001:2007 certification.

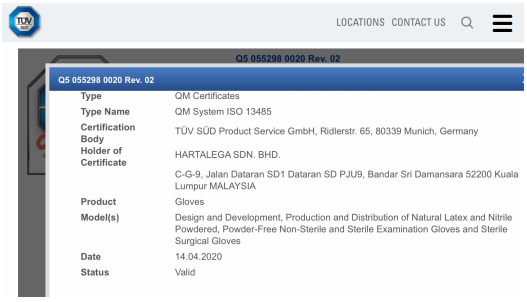
Awarded by TUV SUD Asia Pacific TUV SUD Group, an audit and management systems certification body, OHSAS 18001:2007 is an internationally recognised standard which sets the requirements and best practices for occupational health and safety management systems in an organisation. The Group was previously 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.





The voluntary certification mark with the statement "Type tested" is issued for products and components. The certification mark demonstrates that the

Familiar from ho
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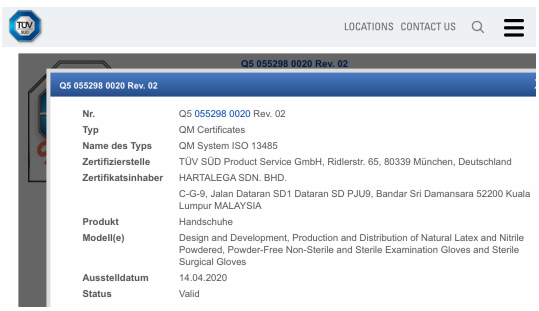
safety according to



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
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	M	Median
Width	98	98	96	98	98	97	98	97	98	97	96	97	97	97	97
Length	250	255	250	255	251	250	252	252	250	254	252	253	252	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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CRS REF : SAT/18/0248
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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B.Sc. MMIC
SECTION HEAD

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

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SGS (MALAYSIA) SDN. BHD.

CHEE TUCK CHOON
B.Sc. MMIC
SECTION HEAD

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

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