gloveon 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 · 2 · 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

Hartalega

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E: info@hartalega.com.my

Protection Always On

Visit us at
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Gloveon Models COATS

gloveon COATS®

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MANUFACTURING ACCREDITATIONS

ISO 9001
ISO 13485
EN ISO 13485
ISO 14001
OHSAS 18001

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Protection Always On

Visit us at
gloveonglobal.com

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

Hartalega

gloveen COATS™

Colloidal Oatmeal System

XS-L: 100 Gloves
XL: 90 Gloves
By Weight

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

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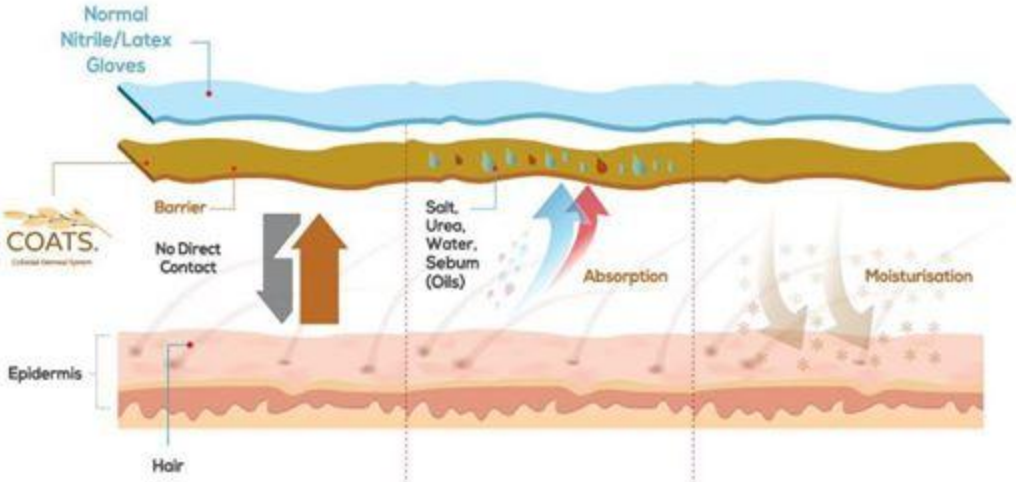
- Ambidextrous
- Standard cuff
- Dawn blue colour

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.

HEALTH, SAFETY AND ENVIRONMENTAL POLICY

Hartalega is an industry leader in Glove Manufacturing and is committed to sustainable work and work practices in order to protect the health, safety and environment, at the same time taking care the needs and expectation of its interested parties.

To be a social responsible organization, Hartalega is committed to continually improve, adapt and monitor its operations to create a safe, healthy and clean work environment by complying with the followings:

- Complying with all applicable health, safety, environmental, legal and other requirements.
- Committing to continually improving the health, safety and environmental performance to prevent ill health, injury, pollution and minimizing environmental impact.
- Designing, operating and maintaining all plants and machineries in a manner that protects the health, safety and environment of our employees and the public.
- Promoting health, safety and environmental consciousness and discipline.
- Committing to efficient usage of natural resources and energy.
- Establishing and maintaining contingency procedures to minimize harm from accident, in the unlikely event that it might occur.
- Continuously monitoring and measuring health, safety and environmental performance.

RESPONSIBILITIES

Each Head of Department is accountable for implementing this policy in their areas of responsibility.

Management is responsible for:

- Instilling health, safety and environmental awareness to all parties involved directly or indirectly to the organization.
- Developing, promoting and implementing Health, Safety and Environmental policies and procedures.
- Ensuring that all hazardous materials and wastes that are used and produced are properly managed and do not pollute the environment in any way.
- Preventing any types of environmental pollution and to report the pollution if any.

Employees, contractors and visitors are to:

- Give full cooperation to the management by following all instructions pertaining to health, safety and environment.
- Report all known or observed hazards, incidents, injuries, near misses and environmental pollutions.

APPLICATION OF THE POLICY

This policy is applicable to Hartalega in all its operations and functions including those situations where employees, suppliers, contractors, customers and visitors are required to work off site.

Kuan Mun Leong
Managing Director
Date : 26th October 2017

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

Innovation & Quality

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Selangor Darul Ehsan,
Malaysia

with European Representative
Medical Device Safety Service (MDSS)
Schiffgraben 41, 30175 Hannover,
Germany

Declares that the new PPE described hereafter
Category III (Type C)
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

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

Kuan Eu Jin
Quality Management Representative

HARTALEGA HOLDINGS BERHAD

(741883-X)

Hartalega and Social Accountability

Hartalega ("Hartalega" or "The Corporation") as a corporation or Group of companies is committed towards developing, maintaining and applying socially acceptable practices and a social accountability framework which complies with all the relevant International Labour Organization Conventions, United Nations Conventions, Universal Declaration of Human Rights, applicable local labour laws, rules and regulations. The Corporation shall continually review periodically the social accountability aspects and these policies and practices shall be applied, communicated and be accessible to all employees globally.

To this end, Hartalega will always endeavor to maintain the following policy and practices:

- Hartalega will not engage or support the use of child labour and complies with Malaysian or local labour laws on minimum age and requirements
- Hartalega does not engage or support the use of forced or compulsory labour and shall not require staff to lodge "deposits" or identity papers upon commencing employment with Hartalega; in this respect, the terms and conditions of employment will be communicated to all staff prior to recruitment who shall be provided with the Employee Handbook.
- Hartalega shall provide a safe, healthy and conducive environment and shall take effective steps to prevent potential health and safety incidents and occupational injury or illness arising or occurring in the course of work. Hartalega has appointed a manager and department in charge of Health, Safety and Environment as its representative responsible for all staff and accountable for implementation of health, safety and environment standards
- Hartalega shall provide personal protective equipment and first aid at all times to all staff and guests when necessary
- Hartalega shall provide to all employees on a regular basis effective health and safety training including on-site and job-specific training. Such training shall be repeated for new and reassigned staff when incidents have occurred and when changes in technology and new machinery present new risks and designated and qualified trainer(s) shall be engaged in-house for this purpose
- Hartalega shall establish documented procedures to respond to potential risks to health, safety and environment and maintain written records of all health and safety incidents
- Hartalega respects the freedom of association and right to collective bargaining – Hartalega enables representative(s) of employees to have access and engage with management
- Hartalega shall ensure that an environment always exists that all staff and stakeholders are treated with respect and dignity. The workforce shall be able to work in a professional atmosphere promoting teamwork and attainment of Hartalega's objectives and vision. Illegal and improper interference with employee work shall be taken seriously and dealt with

HARTALEGA HOLDINGS BERHAD

(741883-X)

- Hartalega shall not engage in or support discrimination in hiring, remuneration, access to training, promotion, termination or retirement based on race, national or territorial or social origin, caste, birth, religion, disability, gender, sexual orientation, family responsibilities, marital status, political opinions, age or any other condition that could give rise to discrimination; Hartalega encourages diversity of workforce and talents at the Board and Corporation level regardless of gender, race, nationality, belief and religion
- Hartalega shall not allow any personnel behavior that is threatening, abusive, exploitative or sexually coercive, including gestures, language and physical contact in its premises or during work hours
- Hartalega shall remunerate employees with wages, salaries and benefits that meet or exceed the legally required minimum. Hartalega will not dock or withhold remuneration for disciplinary or punitive reasons. Hartalega will treat all employees with dignity and respect. The Corporation shall not engage in or tolerate the use of corporal punishment, harsh or inhumane treatment, mental or physical coercion or verbal abuse of employees
- Hartalega will comply with all local labour laws, applicable rules and industry standards on working hours and time of work. The normal work week, not including overtime, shall not exceed 48 hours. All overtime work shall be voluntary, shall not exceed 12 hours per week and shall not be requested on a regular basis. Hartalega undertakes to ensure that workers will not work excessive hours
- Hartalega is committed to providing internship, graduate placement, youth development and apprenticeship programmes to nurture young talents
- Hartalega will set aside annual budget for provision of internal and/or external training programmes for the personal development and training of human resource
- Hartalega will perform a risk assessment and analysis prior to any major projects to be undertaken - employee welfare will be a paramount consideration in any risk assessment of major projects
- Management of Hartalega and relevant staff shall participate in workshops or meetings on labour standards and human resource best practices and be committed to continuous development and improvement on human resource best practices
- Hartalega shall provide ready access and avenues for whistleblowing and grievances to all employees and make known such availability

HARTALEGA HOLDINGS BERHAD

(741883-X)

- As a public listed company, Hartalega prohibits all bribery and corruption practices in any form or guise. Decisions related to the activities of the Corporation are made exclusively for the benefit of the Corporation and not to the benefit of any individual person. If any of these policies have been violated, the offending party will be investigated and may be disciplined for non-compliance with penalties up to and including removal from office or dismissal. Such penalties may include written notices to the individual involved that a violation has been determined, a reprimand or censure, demotion or re-assignment of the individual or suspension. Violation of anti-bribery and anti-corruption policy may also constitute violation of law and may result in criminal penalties and civil liabilities for the covered party and the Corporation. All parties involved are expected to cooperate in internal investigation of misconduct
- Todate as at 30th September 2015, Hartalega has met and qualified for ISO 9001: 2008 for quality management system, ISO 14001: 2004 for environment management system and various other medical equipment standards
- Hartalega shall continuously review the social accountability policies and practices to ensure that they are in line with and adhere to the latest changes and developments in international conventions, rules, regulations and frameworks on labour and human resources

MATERIAL SAFETY DATA SHEET

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 28, 2016
PRODUCT DESCRIPTION GloveOn Comfort Touch	**PRODUCT CATEGORY** Examination gloves
COMMON NAME (USED ON LABEL) Latex Powdered Examination Gloves	**CHEMICAL FAMILY** Natural Rubber Latex
RECOMMENDED USE Healthcare and food environments	**RESTRICTIONS ON USE** Not to be swallowed

SECTION 2: HAZARDOUS INGREDIENTS

HAZARDOUS COMPONENT	CAS NUMBER	% (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.
Natural Rubber Latex, Potassium Hydroxide, Ammonium Laurate, Chemical Composite, Titanium Dioxide, Filler, Wax Emulsion

SECTION 4: FIRST AID MEASURES

This product contains natural rubber latex, which may cause allergic reactions. Components used in the making of these gloves may cause allergic reactions in some people. Do not expose this product to any persons known or suspected to be latex sensitive before consultation with a physician. Do not use in latex-free areas or on patients with spina bifida.

SECTION 5: FIRE FIGHTING MEASURES

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

EXTINGUISHING MEDIA

Water, Carbon Dioxide, chemical foam and dry powder and Halon™ fire extinguisher media may be used

FIRE FIGHTING

Use standard procedures for combustion material fires, including approved self-contained breathing apparatus

FIRE/EXPLOSION HAZARD

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

SECTION 6: ACCIDENTAL RELEASE MEASURES

BIOCOMPATIBILITY

The chemical formulation of the gloves and surface lubrication materials do 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

Latex powdered examination 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	SKIN PROTECTION
Not necessary under conditions of intended use	Not necessary under conditions of intended use
RESPIRATORY PROTECTION	**VENTILATION**
Not necessary under conditions of intended use	Not necessary under conditions of intended use

STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED

These products are solid particles and are not subject to leaks or spills

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Ambidextrous, beaded cuff, textured, powdered, natural colour

DIMENSIONS	X-SMALL	SMALL	MEDIUM	LARGE	X-LARGE
Length (mm)	Minimum 230 (same for all)				
Width (mm)	76±4	84±4	94±4	105±4	114±4

THICKNESS (mm) – SINGLE WALL MEASUREMENT (SAME FOR ALL)	
Finger (mm)	0.13±0.03
Palm (mm)	0.11±0.03

TENSILE PROPERTIES	UNAGED	AGED
Tensile Strength (MPa)	Min. 18.0 MPa	Min. 16.0 MPa
Ultimate Elongation (%)	Min. 650%	Min. 500%

SECTION 10: STABILITY AND REACTIVITY

BOILING POINT	VAPOUR PRESSURE (mm Hg)	VAPOUR DENSITY (AIR=1)
N/A	N/A	N/A
SPECIFIC GRAVITY (WATER=1)	**SOLUBILITY IN WATER**	**% VOLATILE BY VOLUME**
N/A	Insoluble	N/A
EVAPORATION RATE	**VISCOSITY**	
N/A	N/A	

SECTION 11: TOXICOLOGICAL INFORMATION

STABILITY	CONDITIONS TO AVOID
Stable	Does not apply

INCOMPATIBILTY (MATERALS TO AVOID)

Gloves are easily contaminated while in contact with copper content materials

HAZARDOUS DECOMPOSITION PRODUCTS

In a fire, these products may produce black smoke

HAZARDOUS POLYMERISATION

Will not occur

SECTION 12: ECOLOGICAL INFORMATION

N/A

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL

Dispose of in accordance with all local, state and federal regulations. All empty packaging should be disposed of in accordance with local, state, and federal regulations or recycled/reconditioned at an approved facility.

SECTION 14: TRANSPORT INFORMATION

N/A

SECTION 15: REGULATORY INFORMATION

N/A

SECTION 16: OTHER INFORMATION

RECOMMENDED USE AND RESTRICTIONS

This Latex powder free glove is a single use device. Shelf life claim for this product is 3 years.

No.	Test	Method	Purpose of Testing	Result Summary
1	Watertight Test	EN 455-1 ASTM D5151	To detect holes in gloves.	Pass
2	Physical Property Test	EN 455-2 ASTM D6319	To determine the tensile strength and elongation at break of gloves.	Pass
3	Particulate Residue Test	EN 455-3 ASTM D6124-06	To determine the amount of residual powder (or filtered-mass) found on medical gloves.	Pass. Less than 2mg/glove
4	PPE Certification	PPE (EU) 2016/425 EN ISO 374-1	There are several testing methods under PPE certification as shown below:	-
	Chemical Permeation Test	ISO 16523-1	To evaluate the resistance to permeation by chemicals.	Pass
	Penetration (Air & Water Leak) Test	EN 374-2	To determine penetration resistance of gloves that protect against dangerous chemicals and/or organisms.	Pass
	Degradation Test	EN 374-4	To determine resistance of protective glove materials to degradation caused by dangerous chemicals with continuous contact.	Pass
	Protective Gloves (pH & PAH) Test	EN 420	Design and Construction: To evaluate if gloves can perform hazard related activity normally while enjoying appropriate protection at the highest possible level. Testings include sizing and measurement of hands (hand circumference and hand length) and sizing and measurement of glove (length).	Pass
			pH Value : To determine the pH value of glove.	Pass
			Dexterity : To evaluate the ability to perform its task	Pass
	Viral Penetration Test	EN ISO 374-5	To measure resistance of gloves used against penetration by blood-borne pathogens.	No penetration < 1 PFU/ml
5	Chemical Permeation Test (Chemotherapy Drugs)	ASTM D6978	To assess resistance of gloves to permeation by potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	All selected drugs meet breakthrough time of more than 240 minutes
6	Food Contact	EC 1935/2004 EU 10/2011	To evaluate if gloves release their constituents into food at a level harmful to human health.	Pass according to German Recommendation BfR XXI
7	Food Contact	Japan Sanitation Law	To evaluate if gloves release their constituents into food at a level harmful to human health.	Pass
8	Food Contact	21 CFR 177.2600	To evaluate if gloves release their constituents into food at level harmful to human health.	Pass
9	Viral Penetration Test	ASTM F1671	To measure resistance of gloves against penetration by blood-borne pathogens.	No penetration < 1 PFU/ml

Table 3. AMG Antimicrobial Glove Performance According to Globally Recognised Standards.

BIOCOMPATIBLE

AMG glove is suitable for different applications as it has been tested safe for use against various contacts such as skin and oral contact. Some of these tests confirm that the AMG glove is:

- **Non-irritating**
  It does not cause primary skin irritation like redness (erythema) or slight swelling (edema).
- **Non-sensitising**
  It does not contain any substance that will induce skin allergy.
- **Non-toxic**
  No toxic effects occurring following oral administration.
- **Non-cytotoxic**
  It does not display destructive action on cells.
- **Non-sensitising & low dermatitis potential**
  Modified Draize Test shows the gloves do not cause allergic reaction in normal tissue after exposure.

No.	Test	Method	Purpose of Testing	Result Summary
1	Modified Draize-95 Test	FDA	To determine whether gloves contain residual chemical additives at a level that may induce Type IV allergy.	No sensitiser detected
2	Acute Toxicity Oral	ISO 10993-11	To evaluate toxic potential of substance that leaches out of gloves by determining adverse effect occurring within short term exposure via oral route.	No toxic effects
3	Cytotoxicity Test	ISO 10993-5	To determine if gloves contain significant quantities of harmful extractables and their effect on cellular components.	Non-cytotoxic at 10% extract
4	Primary Skin Irritation	ISO 10993-10	To determine whether exposure to gloves may produce skin irritation	Non-irritating
5	Dermal Sensitisation Study	ISO 10993-10	To assess potential of gloves to cause delayed hypersensitivity (Type IV) or allergic reaction stimulated by the immune system.	Non-sensitising
6	Accelerator Extraction Test	Malaysian Rubber Board (MRB) In-House Method	To quantify the amount of extractable accelerators in gloves.	Non-detectable for accelerators

Table 2. List of Biocompatibility Test Results for AMG Antimicrobial Gloves.

UNCOMPROMISED GLOVE PROPERTIES

Apart from medical settings, AMG glove has been proven safe for use in different applications and industries. Its safety and effectiveness are proven to ensure it befits its intended use.

i. Medical

Tested for impermeability and glove strength, AMG glove is effective in preventing contamination between patient and healthcare practitioner, as well as for handling various chemotherapy drugs. All tests conducted are in accordance to recognised international standards such as ASTM D6319, EN 455 and ISO 11193 part 1.

ii. Personal Protective Equipment (PPE)

The glove is tested to protect users from substances and mixtures that are hazardous to health, and harmful biological agents that may cause very serious consequences or damage to health. Tests conducted are in accordance to the harmonised standard [*refer Table 3.*] which complies with PPE Regulation. Some countries may require further registration.

iii. Food Contact

The glove is tested safe for food contact according to the standards of U.S. FDA, BfR XXI German Recommendation and Japan Food sanitation. It is tested in various types of simulants representing different types of food that are acidic, alcoholic and fatty in content. Some countries may require further registration with biocidal agencies such as BPR and EPA.

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

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,

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
Cyclophospliamide (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.

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TÜV SÜD
Product Service

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Certificate

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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

Stefan Preiß

Date, 2018-09-19

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

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

KUAN EU JIN
DIRECTOR-TECHNICAL
RESEARCH & DEVELOPMENT