

gloveen



Nitrile Exam Gloves Powder Free, Standard Cuff

Made from 100% all natural oats, **COATS** is a patented glove coating technology recognised by the FDA as a skin protectant. Users who often suffer from dry and itchy skin due to constant hand washing and glove use can now rely on **COATS** colloidal oatmeal glove to help maintain the natural moisture barrier as they work with their hands.



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GloveOn COATS		
Length (mm)	≥ 240	
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	1.50
Physical Dimensions	S2	4.00
Tensile Strength	S2	4.00
Visual Inspection (Major)	S4	2.50
Visual Inspection (Minor)	S4	4.00
Particulate Residue	N = 5	≤ 2mg/glove
Colloidal Oatmeal Content	N = 5	≥ 5mg/glove

REORDER CODE

CTS38XS	X-SMALL
CTS38SS	SMALL
CTS38MM	MEDIUM
CTS38LL	LARGE
CTS38XL	X-LARGE

FEATURES

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

PACKAGING

200 gloves per box for XS to L
180 gloves per box for XL
10 boxes per carton

REGULATORY COMPLIANCE

FDA 510(k), MDD 93/42/EEC,
REACH, EC 10/2011,
REGULATION (EC) No. 1935/2004,
PPE 89/686/EEC

STANDARDS

ASTM D6319, EN 455 part 1, 2, 3 & 4,
EN 1186, EN 13130, CEN/TS 14234,
EN 420, EN 374 part 1, 2 & 3

PATENTS

Patent 6,953,582; Patent 6,630,152;
Patent 6,423,328; Patent 6,274,154;
Patent 7,691,436; Patent 7,718,240;
Patent 7,740,622; Patent 8,075,965;
Patent 8,458,818

MANUFACTURING ACCREDITATIONS

ISO 9001:2008
ISO 13485:2003
EN ISO 13485:2012

Chemotherapy Drugs and Concentration
(Tested for Resistance to Permeation by Chemotherapy
Drugs as per ASTM D6978-05 Test Report PN 104145B)

Minimum Breakthrough
Detection Time (minutes)

Carmustine (BCNU), 3.3mg/ml (3,300 ppm)	0.7 minutes
Cisplatin, 1.0mg/ml (1,000 ppm)	>240 minutes
Cyclophosphamide (Cytoxan), 20.0mg/ml (20,000 ppm)	>240 minutes
Dacarbazine (DTIC), 10.0mg/ml (10,000 ppm)	>240 minutes
Doxorubicin Hydrochloride, 2.0mg/ml (2,000 ppm)	>240 minutes
Etoposide (Toposar), 20.00mg/ml (20,000 ppm)	>240 minutes
Fluorouracil, 50.0mg/ml (50,000 ppm)	>240 minutes
Methotrexate, 25.0mg/ml (25,000 ppm)	>240 minutes
Mitomycin C, 0.5mg/ml (500 ppm)	>240 minutes
Paclitaxel (Taxol), 6.0mg/ml (6,000 ppm)	>240 minutes
Thiotepa, 10.0mg/ml (10,000 ppm)	1.2 minutes
Vincristine Sulfate, 1.0mg/ml (1,000 ppm)	>240 minutes

WARNING: Carmustine and Thiotepa, at the tested concentration, degraded COATS nitrile glove at 0.7 minutes and 1.2 minutes, respectively. The safe use of gloves in chemotherapy treatment is solely the decision of clinicians authorised to make such decision.

A brand by

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www.munglobal.com

Mun Australia
Toll free: 1800 456 837 (GLOVES)
info.au@munglobal.com

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Products

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Products

Overview

Market Segment

Nitrile Gloves

Latex Gloves

OEM

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

Print

Enquire now



COATS® Colloidal Oatmeal Coated Nitrile Powder Free 2.5 Mil

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EN 455

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Colour

Dawn blue, white



SGS OFFICES & LABS

SEARCH THE DIRECTORY

Certification ID

—or—

Company name

Location

—and—

SEARCH

COMPANY NAME	ADDRESS	LOCATION	STANDARD	CERTIFICATE ID	CERTIFICATE STATUS
Hartalega NGC Sdn. Bhd.	No. 1, Persiaran Tanjung Kawasan Perindustrian Tanjung, Sepang Selangor Darul Ehsan 43900	Malaysia	BRCPCH Issue 4 (BRCPCH Higher)	MY19/1811030122 Compounding, dipping and packing of disposable food handling nitrile gloves(Nitrile Powder Free Examination Gloves)	Valid
				View translation	



TREASURE AND INFINITY CO.,LTD.

1767/8 SOI LADPRAO 94, PHAPPHLA WANG THONGLANG BANGKOK 10310

THAILAND



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 C)
HSB-TF-009
Nitrile Powder Free Gloves with Colloidal Gummeal 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 - 5: 2016
EN ISO 374 - 6: 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 2777/13771-01/E00-00.

The PPE is subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the Notified body SATRA Technology Centre with Notified Body Number of 2777.

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

Kuan Eu Jin
Quality Management Representative



TREASURE AND INFINITY CO.,LTD.

1767/8 SOI LADPRAO 94, PHAPPHLA WANG THONGLANG BANGKOK 10310



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



Medical Device Safety Service

MDSS - Schiffgraben 41 - 30175 Hannover, Germany

[Redacted address information]

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 [Redacted Name],

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



TR2020-Hartalega-Gloved-Pro...



TREASURE AND INFINITY CO.,LTD.
 1767/8 SOI LADPRAO 94, PHAPPHLA WANG THONGLANG BANGKOK 10310
 THAILAND

Product Specification Sheet

1. Product Number and Description : Update Date : 03rd October 2018

Product No.	Brand	Product Description	Product Weight
NBF	Star Safe	Powder Free Nitrile Disposable Glove	5.0g

2. Physical Dimension :

2.1 Widths, Length and Weight :

Size	Total Length (mm)	Width (mm)	Weight
X-Small	Min 240	75 +/- 5	4.2 - 4.4g
Small	Min 240	85 +/- 1.5	4.4 - 4.6g
Medium	Min 240	95 +/- 1.5	4.6 - 4.8g
Large	Min 240	105 +/- 1.5	4.8 - 5.0g
X-Large	Min 240	115 +/- 1.5	5.0 - 5.2g

2.2 Thickness (Single Wall) :

Location Of Thickness Measurement	Single Wall Thickness (mm)
Palm (at centre of palm)	Min 0.10
Fingertip (at 13mm from the existing hole)	Min 0.12

3. Physical Properties :

Characteristic	Before Ageing	After Ageing 7 days @ 70°C +/- 2 hours
	Force at Break (N)	Min 7.5
Tensile Strength (MPa)	Min 14	Min 14
Elongation at Break (%)	Min 500	Min 400

4. Quality Assurance :

Characteristics	Inspection Level & Sampling Plan	AQL & Acceptance Limit
Pinhole (Reference D5151)	G - 1	AQL 1.5
Major Defects	G - 1	AQL 2.5
Physical Properties Related Non Conformities	S - 2	AQL 4.0
Physical Dimension	S - 2	AQL 4.0

5. Shelf Life :

Under normal Storage condition, gloves shall have a shelf life of minimum 3 years from date of manufacture.

6. Suggested Storage Condition :

Storage Condition	
Temperature range	Recommended storage temperature shall not exceed 40 degrees Celsius. Recommended temperature is between 20 to 25 degrees Celsius.
Humidity range	Prolong storage humidity shall not exceed 50%.
Sunlight effect	Keep away from Sunlight. Sunlight could cause discoloration and long exposure could severely reduce physical properties of gloves.



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TR2020-Hartalega-Gloved-Pro...



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THAILAND

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Ms. Nurul Aiyah Kong
Hartalega SDN. BHD

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RESULTS:

Table 5. Permeation Test Results on Nitrile Powder Free Examination Gloves (Blue) Code: ABLU.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm ² /minute)	OTHER OBSERVATIONS
Carbustine (BCNU), 3.3 mg/ml (3,300 ppm)	35.80 (45.31, 30.46, 31.63)	(1.32, 1.32, 1.20)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytosan), 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	85.48 (105.33, 75.52, 75.60)	1.32 (1.33, 1.32, 1.32)	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

Tiffany L. Heller
Tiffany L. Heller
Chemical Technician, Chemical Services
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Ana C. Barbur
Ana C. Barbur, M.S.
Chemical and Pharmaceutical Services



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TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6975-05
Deviation From Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm ²
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area
Comments/Other Conditions:	Magnetic stir bar was used in the sampling chamber

DETECTION METHOD OF CHEMICAL PERMEATION: UV/VIS ABSORPTION SPECTROMETRY

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 milliliter of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	200
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	268
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens: Nitrile Powder Free Examination Gloves (Blue) Code: ABLU.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m ²)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.080	0.084	0.082	0.082	79.2
Cisplatin	0.086	0.082	0.088	0.085	79.2
Cyclophosphamide (Cytoxan)	0.087	0.083	0.081	0.084	79.2
Dacarbazine (DTIC)	0.086	0.080	0.084	0.083	79.2
Doxorubicin Hydrochloride	0.087	0.084	0.082	0.084	79.2
Etoposide (Toposar)	0.085	0.088	0.090	0.088	79.2
Fluorouracil	0.082	0.082	0.084	0.086	79.2
Methotrexate	0.081	0.084	0.087	0.084	79.2
Mitomycin C	0.082	0.082	0.084	0.083	79.2
Paclitaxel (Taxol)	0.086	0.081	0.082	0.083	79.2
Thiotepa	0.084	0.083	0.087	0.085	79.2
Vincristine Sulfate	0.088	0.084	0.082	0.085	79.2