
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

TITAN

# Nitrile



## 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**<br>Not necessary under conditions of intended use. | **SKIN PROTECTION**<br>Not necessary under conditions of intended use. |
| **RESPIRATORY PROTECTION**<br>Not necessary under conditions of intended use. | **VENTILATION**<br>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)<br>Palm (mm) | 0.09 ± 0.02<br>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**<br>N/A | **VAPOR PRESSURE** (mm Hg)<br>N/A | **VAPOR DENSITY** (air=1)<br>N/A |
| **SPECIFIC GRAVITY** (water=1)<br>N/A | **SOLUBILITY IN WATER**<br>Insoluble | **% VOLATILE BY VOLUME**<br>N/A |
| **EVAPORATION RATE**<br>N/A | **VISCOSITY**<br>N/A | |

## SECTION 11: TOXICOLOGICAL INFORMATION

| | |
|---|---|
| **STABILITY**<br>Stable. | **CONDITIONS TO AVOID**<br>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

# Certificate of CE-Registration

MDSS
Medical Device Safety Service

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

Lödger Möller
President
MDSS GmbH

MDSS · Medical Device Safety Service · Schiffgraben 41 · 30175 Hannover, Germany

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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/A/Final
TUV: 7191143339-CHM16-01-RC

Signed on behalf of SATRA: Hannah Coe Geoff Graham

**Date of issue:** 17/04/2019 **Expiry date:** 25/06/2023

Page 1 of 2

SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland.

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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 GmbH
Handelsregister Hannover HRB 57318 · USt-IdNr: DE 177546163 · Geschäftsführer: Ludger Möller
Bankverbindungen
Sparkasse Hannover
S.W.I.F.T.: SPKHDE2H
IBAN: DE24 2505 0180 0910 0798 77
Commerzbank AG, Hannover
S.W.I.F.T.: COBADEFF250
IBAN: DE67 2504 0066 0358 8816 00

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SGS

**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



SGS (Malaysia) Sdn. Bhd. (Company No. 10871-T)
Lot 4, Persiaran Jubli Perak, Seksyen 22, 40300 Shah Alam, Selangor, Malaysia
t +6 (03) 5481 8282 f +6 (03) 5481 8215 www.sgs.com



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TITAN

U.S. FOOD & DRUG ADMINISTRATION

Hartalega Sdn. Bhd.
Nurul Kong
Quality Assurance Senior Manager
No. 7, Kawasan Perusahaan Suria
Bestari Jaya, 45600 My

Re: K180505
Trade/Device Name: Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP with Low-Dermatitis Potential Claim and Tested For Use with Chemotherapy Drugs (White)

Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: May 15, 2018
Received: May 17, 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. 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); good

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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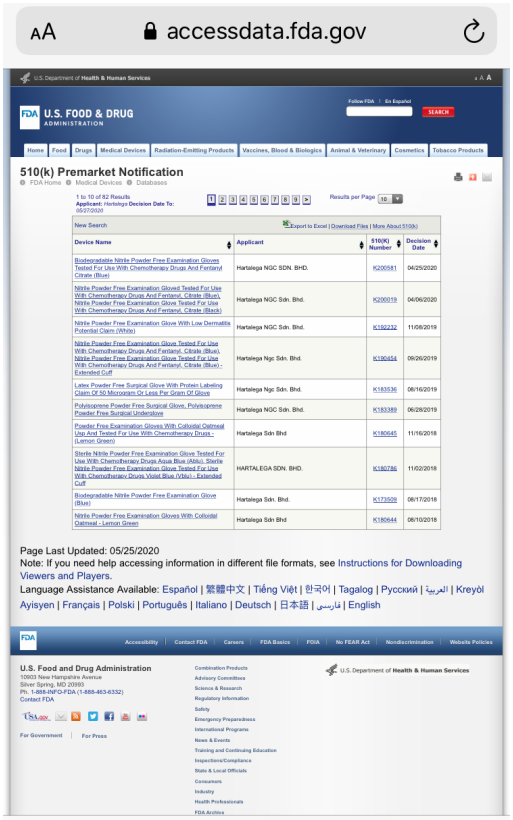
manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 (http://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
-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

**Indications for Use**

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

510(k) Number (if known)
K180505

Device Name
Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs (White)

Indications for Use (Describe)
Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs (White) 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. Its also tested to be used against Chemotherapy Drugs.

The list of Chemotherapy Drugs tested (with breakthrough times) is as below;

| | |
|---|---|
| Carmustine(3.3 mg/ml) | 17.2 minutes |
| Cisplatin (1.0mg/ml) | >240 minutes |
| Cyclophosphamide (20 mg/ml) | >240 minutes |
| Ducarbazine (B.0 mg/ml) | > 240 minutes |
| Doxorubicin Hydrochloride (2.0 mg/ml) | > 240 minutes |
| Etoposide (20 mg/ml) | > 240 minutes |
| Fluorouracil (50 mg/ml) | > 240 minutes |
| Methotrexate (25 mg/ml) | > 240 minutes |
| Mitomycin C (0.5 mg/ml) | > 240 minutes |
| Paclitaxel (6.0 mg/ml) | > 240 minutes |
| Thiotepa (10.0 mg/ml) | 36.1 minutes |
| Vinorelbine Sulfate (1.0 mg/ml) | >240 minutes |

Do not use with Carmustine. Do not use with Thiotepa.

Type of Use (Select one or both, as applicable)
Prescription Use (Part 21 CFR 801 Subpart D) X 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.
"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."
The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:
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FORM FDA 3881 (7/17) Page 1 of 1

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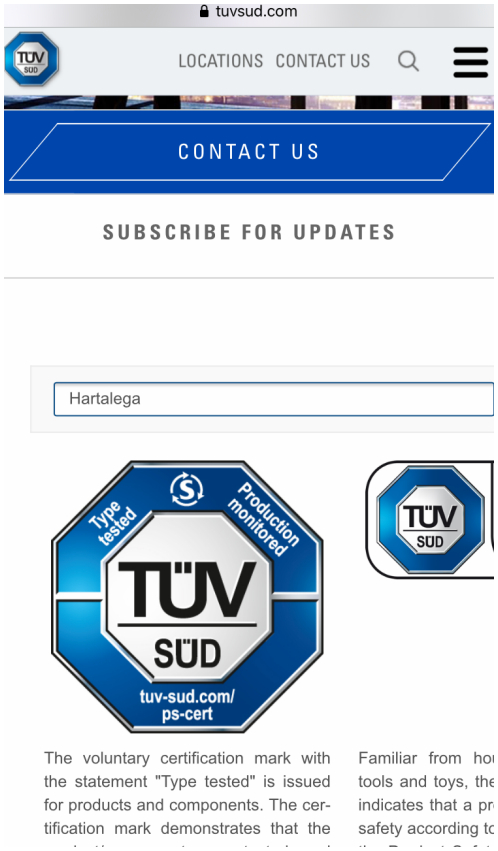
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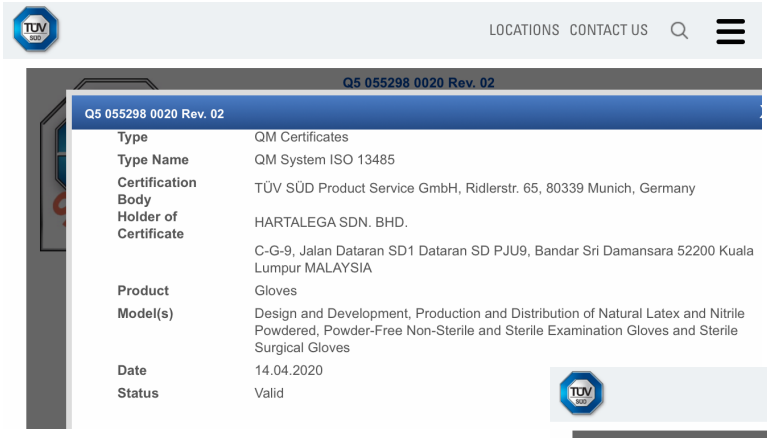
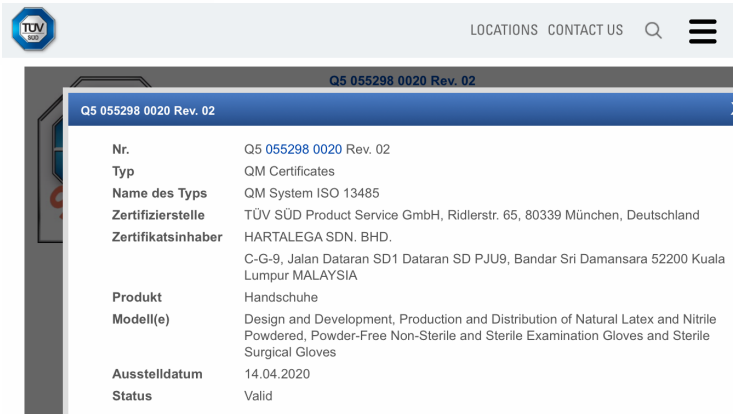
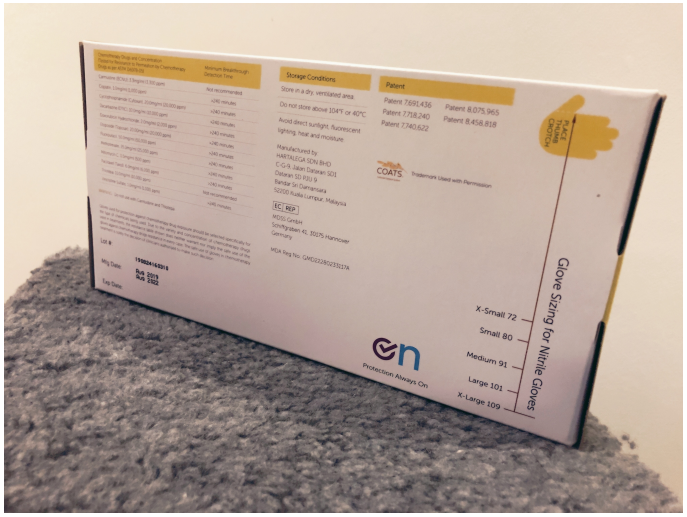
LOCATIONS CONTACT US
CONTACT US
SUBSCRIBE FOR UPDATES
Hartalega
Type tested
Production monitored
TÜV SÜD
tuv-sud.com/ps-cert
The voluntary certification mark with the statement "Type tested" is issued for products and components. The certification mark demonstrates that the
Familiar from ho
tools and toys, the
indicates that a pr
safety according to


LOCATIONS CONTACT US
Q5 055298 0020 Rev. 02
Q5 055298 0020 Rev. 02
Type QM Certificates
Type Name QM System ISO 13485
Certification Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany
Holder of Certificate HARTALEGA SDN. BHD.
C-G-9, Jalan Dataran SD1 Dataran SD PJU9, Bandar Sri Damansara 52200 Kuala Lumpur MALAYSIA
Product Gloves
Model(s) Design and Development, Production and Distribution of Natural Latex and Nitrile Powdered, Powder-Free Non-Sterile and Sterile Examination Gloves and Sterile Surgical Gloves
Date 14.04.2020
Status Valid


LOCATIONS CONTACT US
Q5 055298 0020 Rev. 02
Q5 055298 0020 Rev. 02
Nr. Q5 055298 0020 Rev. 02
Typ QM Certificates
Name des Typs QM System ISO 13485
Zertifizierstelle TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Deutschland
Zertifikatsinhaber HARTALEGA SDN. BHD.
C-G-9, Jalan Dataran SD1 Dataran SD PJU9, Bandar Sri Damansara 52200 Kuala Lumpur MALAYSIA
Produkt Handschuhe
Modell(e) Design and Development, Production and Distribution of Natural Latex and Nitrile Powdered, Powder-Free Non-Sterile and Sterile Examination Gloves and Sterile Surgical Gloves
Ausstelldatum 14.04.2020
Status Valid

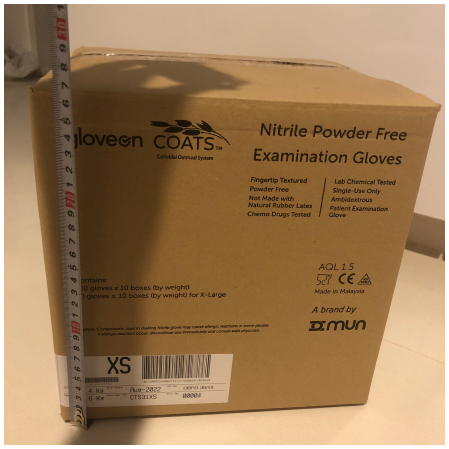
TITAN


gloveon COATS
Nitrile Powder Free
Examination Gloves
Protection Always On
XS S M L XL


Glove Sizing for Nitrile Gloves
X-Small 72
Small 80
Medium 91
Large 101
X-Large 109
Protection Always On


Nitrile Powder Free
Examination Gloves
EXTRA SMALL
XS
100 Gloves by Weight
MEDIUM
LARGE
EXTRA LARGE
100 gloves by weight (XS-L)
90 gloves by weight (XL)
A brand by mun


Nitrile Powder Free
Examination Gloves
gloveon COATS
Nitrile Powder Free
Examination Gloves
XS
100 gloves by weight (XS-L)
90 gloves by weight (XL)
A brand by mun


gloveon COATS
Nitrile Powder Free
Examination Gloves
Fingertip Textured
Powder Free
Non Made with
Natural Rubber Latex
Chemo Drugs Tested
Lab Chemical Tested
Single-Use Only
Ambidextrous
Patient Examination
Glove
AQL 1.5
Made in Malaysia
A brand by mun
XS


EXTRA SMALL
SMALL
MEDIUM
LARGE
EXTRA LARGE
XS


XS

TITAN