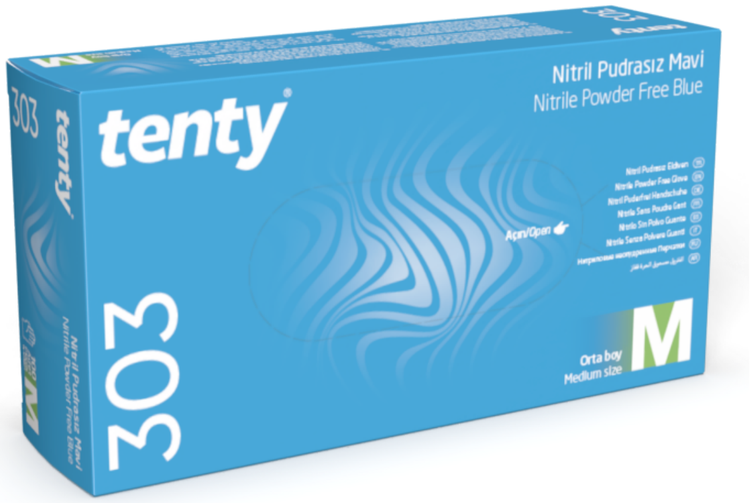
# PERSONAL PROTECTION GLOVES




## PERSONAL PROTECTION SUPPLIES

Product Documentation

# DISPOSABLE GLOVES

tenty®

Take care of your hands.

## MEDICAL GLOVES

### Purpose

- To protect the patient and the professional
- To prevent microbes from getting attached to hands and spreading infection via hands
- To protect the hands from
  - Occupational accidents
  - Cleansing agents
  - Chemicals
  - Stick injuries

### Use of gloves

- Medical gloves are always single-use
- They are used per procedure and per patient
- Depending on the situation either sterile or factory clean gloves are used
- Disposable gloves are neither washed nor disinfected

### Use the gloves correctly

- Medical gloves are donned onto clean, dry hands
- Hands are disinfected just prior to donning
- After disinfection hands must be allowed to dry before donning
- Hands may get contaminated when undonning the gloves, therefore hands must be disinfected also immediately after undonning
- In all cases involving contaminating materials attention must be paid to correct undonning
- The outer surface of the glove must not get into contact with skin
- When necessary double donning can be applied -> decreased risk of skin contamination while undonning (e.g. when handling cytostatics)

Product Documentation

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

TÜV SÜD Product Service

# EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

**No. G2 055729 0008 Rev. 01**

**Manufacturer:** **Top Glove Sdn. Bhd.**
Lot 4969, Jalan Teratai Batu 6
Off Jalan Meru
41050 Klang, Selangor D. E.
MALAYSIA

**Product Category(ies):** **Latex and Nitrile Surgical Powder free Glove, Sterile**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:** MYQMH0319070Rev2-721423225

**Valid from:** 2020-02-19
**Valid until:** 2024-05-26

**Date,** 2020-02-19

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

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

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Page 1 of 2
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# Product Documentation

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ZLG-BS-244.10.08

TÜV SÜD Product Service

## EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

**No. G2 055729 0008 Rev. 01**

**Facility(ies):** Top Glove Sdn. Bhd.
Lot 4969, Jalan Teratai Batu 6, Off Jalan Meru, 41050 Klang,
Selangor D. E., MALAYSIA

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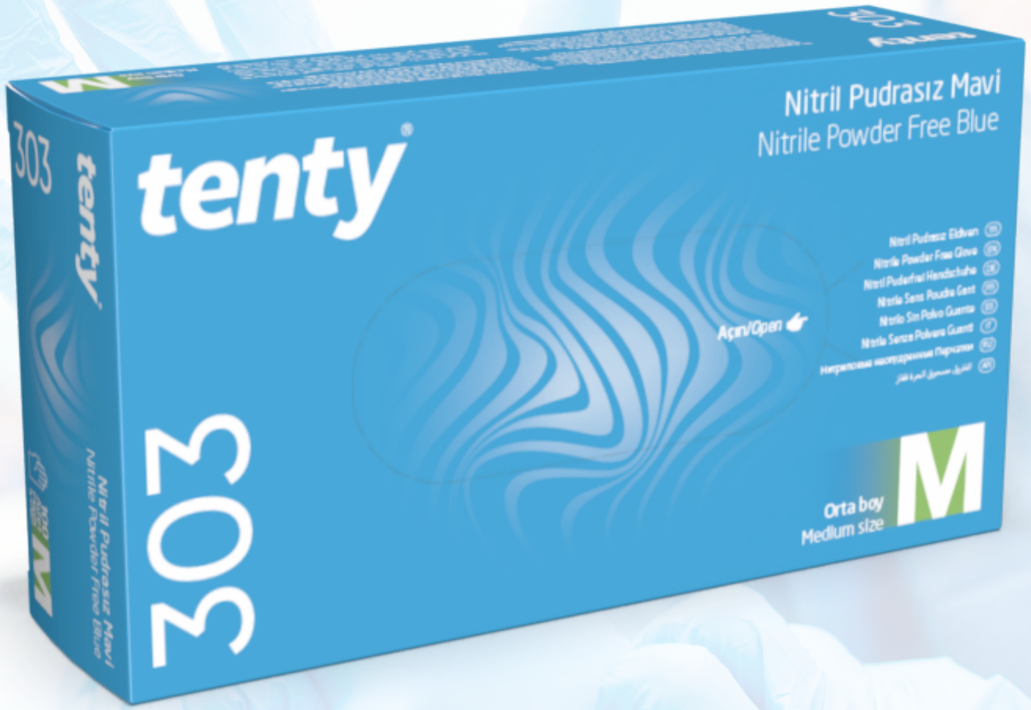

Product Documentation

SATRA TECHNOLOGY

Issued to:

Top Glove Sdn Bhd
Lot 4969 Jalan Teratai
Batu 6
Off Jalan Meru
41050 KLANG
Selangor D E
Malaysia

Notified Body: 2777

SATRA customer number: P0130

# EU Type-Examination Certificate

## Certificate number: 2777/10648-04/E00-00

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:**

EB201

**Description:**

Nitrile examination powder free gloves available in:
Black, White, Red, Pink, Blue, Light Purple, Green, Forest Green, Cool Blue, Cornflower Blue, Violet Blue, Marlin Blue, Sky Blue, Dodger Blue, Pearlescent Pink, Harmony Blue, Avocado.

**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 first issued: 25/06/2018**
**Date of issue: 14/03/2019**

**Expiry date: 25/06/2023**



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

# TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

Product Documentation

ZERTIFIKAT ■ CERTIFICATE ■ 認證證書 ■ СЕРТИФИКАТ ■ CERTIFICADO ■ CERTIFICAT

TÜV SÜD Management Service

# CERTIFICATE

**The Certification Body**
**of TÜV SÜD Management Service GmbH**

certifies that

**Top Glove Sdn. Bhd.**
**Lot 4969 Jalan Teratai, Batu 6, Off Jalan Meru,**
**41050 Klang, Selangor**
**Malaysia**

has established and applies
a Quality Management System for

**Production and Distribution of**
**Natural Latex, Nitrile And Synthetic Medical Examination Gloves**
**(Powdered And Powder Free),Unsterile**

An audit was performed, Report No. **70093569**.
Proof has been furnished that the requirements
according to

**ISO 9001:2015**

are fulfilled.

The certificate is valid from **2020-02-09** until **2021-06-14**
Certificate Registration No.: **12 100 25112 TMS**.

Product Compliance Management
Munich, 2020-02-09

IAF DAkkS

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www.tuev-sued.de/certificate-validity-check

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AWARDED ISO 9001

# TOP GLOVE SDN. BHD. (Company No. 220483-T)

**TOP QUALITY, TOP EFFICIENCY,**
**GOOD HEALTH, SAFETY FIRST & BE HONEST**

*A member of Top Glove Corporation Bhd, Public Listed Company on Bursa Malaysia.
Latex Examination, Nitrile, Surgical, Vinyl & Household Gloves Manufacturer and Exporter
The World's Largest Rubber Glove Manufacturer

Corporate Office & Factory 9 : Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D. E., Malaysia.
Tel: 603-3392 1992 / 1995 Fax: 603-3392 8413 / 1291
E-mail : sales@topglove.com.my Website : www.topglove.com.my

ENTREPRENEUR OF THE YEAR® MALAYSIA 2004 BY ERNST & YOUNG
Enterprise 1998 to 2017 Celebrating Malaysia's Enterprising Spirit

| | |
|---|---|
| BUSINESS DIRECTION | : To Produce Consistently High Quality Gloves At Efficient Low Cost. |
| FACILITIES | : 27 Factories (Malaysia, Thailand & China), 495 Production Lines, 44 Billion Gloves Per Annum, 11,000 Employees |
| MARKET | : Exports to more than 195 countries worldwide with Marketing offices in the USA and Germany. |

## EC DECLARATION OF CONFORMITY

| | |
|---|---|
| Manufacturer's Name | : TOP GLOVE SDN. BHD |
| Manufacturer's Address | : Lot 4969, Jalan Teratai, 6th Mile, Off Jalan Meru, 41050 Klang, Selangor D. E. Malaysia |
| European Authorized Representative | : Top Glove Europe GmbH<br>Bliersheimer Str. 80, D-47229 Duisburg<br>Deutschland/Germany<br>Tel.:+49-(0)2065-76421-0, Fax:+49-(0)2065-76421-19 |
| Name of Device | : NITRILE & LATEX EXAMINATION GLOVES |
| Type | : Powdered and Powder Free |
| Classification | : Class I, Non Sterile |
| Conformity Assessment Procedure | : Annex VII |
| Conformity Route | : Self Declaration |

We herewith declare with our own responsibility that above mentioned product(s) with CE mark is fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC.

| | |
|---|---|
| Competent Authority | : Bezirksregierung Düsseldorf,<br>Postfach 300865, 40408 Düsseldorf. |
| Registration Date | : 31 March 2010 |
| Registration No | : DE/CA20/02-TOPGLOVEB-01/10 |
| Date | : 1st December 2016 |

Name: Pn Noor Akilah Saidin
Designation: QA Deputy General Manager

RA/DOC/A

GERMANY · CE EUROPE · FDA REGISTERED U.S.A. · TGA AUSTRALIA · CUSB CANADA · SMG MALAYSIA

*"To Prevent & Against Corruption" and "Be Honest, No Cheating"*

# Product Documentation

DECLARATION-ДЕКЛАРАЦИЯ-宣言-DÉCLARATION-선언-إعلان

## FDA Certificate

| | |
|---|---|
| Certificate No.: | CTT201808221255FDAC |
| Applicant: | MBTW LLC |
| Address: | 54 Sonny Perdue Dr, Savannah, GA 31408 United States |
| Manufacturer: | MBTW LLC |
| Address: | 54 Sonny Perdue Dr, Savannah, GA 31408 United States |
| Product Name: | Disposable Nitrile Gloves |
| Model No.: | 40220-3/MS1440 |
| Trade Name: | MidPride |
| Test Report No.: | CTT201808221255FDA |

Remarks:
When tested as specified,the submitted sample(s),comply with the specifications for the amount of net chloroform-soluble extractives residue used as food-contact surface of articles in US.FDA 21 CFR 180.2

FDA

Tony Bi
Technical Director

SHENZHEN CTT TESTING CO.,LTD CTT CERTIFICATION

2019

## FDA REGISTRATION CERTIFICATE

Certificate No:JF-FDA-1101-0006

Certificate Holder

**Registration Number: 3009960170**
**Ower/Operator Number:10047539**
**Data of verification: Nov. 1st, 2019**

| Listing Number | Product codes | Device Name |
|---|---|---|
| D252570 | EID | FACE MASKS,INFARED THERMOMETERS,AND MEDICAL GLOVES |
| D224756 | IME | Pack,hot or cold,Reuseable |
| D278009 | IMA | PACK,HEAT,MOIST |

Registration Expiration Date: 2021/12/06

J&F TECHNOLOGY SERVICES LLC has verified and declares that the above stated facility is registered with the US Food & Drug Administration,Center for Drug Evaluation and Research,Office of Drug Registration and Listing pursuit to the Code of Federal Regulation 21 CFR 207,on the date stated above, and makes no other representations and warranties,nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder,for whose sole benefit it is issued.J&F TECHNOLOGY SERVICES LLC Assumes no Liability to any person or entity in connection with the foregoing.J&F TECHNOLOGY SERVICES LLC IS A PRIVATE REGISTRATION AGENT AND IS NOT AFFILIATED WITH THE FOOD AND DRUG ADMINISTRATION.

FDA

J&F TECHNOLOGY SERVICES LLC.
1961 MORRIS AVENUE UNION
NEW JERSEY 07083
UNITED STATE

J&F TECHNOLOGY SERVICES COMMON SEAL

Signature:

FANNY ZHAO G.M