



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:

Date first issued: 25/06/2018

Date of issue: 14/03/2019

Hannah Coe

Geoff Graham

Expiry date: 25/06/2023

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

FACTORY 9 : Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia.
☎ +603 3392 1992 📠 +603 3392 1291 📠 +6012 2896 270 ✉ sales@topglove.com.my 🌐 www.topglove.com

BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES : 42 Factories (Malaysia, Thailand & China), 682 Production Lines, 63.9 Billion Gloves Per Annum, 18,000 Employees.

MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

DECLARATION OF CONFORMITY

Manufacturer's Name : TOP GLOVE SDN. BHD
Manufacturer's Address : Lot 4969, Jalan Teratai, Batu 6,
Off Jalan Meru, 41050 Klang,
Selangor Darul Ehsan
Malaysia

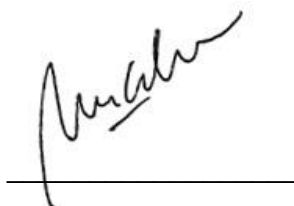
European Authorized Representative : Top Glove Europe GmbH
Bliersheimer Str. 80A, 47229 Duisburg
Germany
Tel.: +49-(0)2065-76421-0,
Fax: +49-(0)2065-76421-19

Name of Device : Nitrile Examination Gloves
Type : Powder Free
Classification : Class I
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,
Postfach 300865, 40408 Düsseldorf.

Registration Date : 31 March 2010
Registration No : DE/CA20/02-TOPGLOVEB-01/10
Date : 22nd May 2020



Name: Pn. Noor Akilah Saidin
Designation: Deputy General Manager, RA

ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ

Име на производителя:	TOP GLOVE SDN. BHD
Адрес на производителя:	Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan Malaysia
Оторизиран европейски представител:	Top Glove Europe GmbH Bliersheimer Str. 80A, 47229 Duisburg Germany
Наименование на изделието:	нитрилни ръкавици
Тип:	без талк
Класификация:	клас I
Процедура по съответствие на оценката:	Анекс VII
Вид на съответствие:	потвърждение на собствена отговорност

С настоящия документ декларираме на наша собствена отговорност, че горепосоченият продукт(и) с CE маркировка напълно отговаря на Основното изискване на Директива 93/42/ЕЕС от 14.06.1993 г. на Европейския съвет относно медицински изделия, изменена с Директива на Съвета 2007/47/ЕС.

Компетентен орган:	Bezirksregierung Düsseldorf, Postfach 300865, 40408 Düsseldorf.
Дата на регистрация:	31.03.2010 г.
Регистрационен номер:	DE/CA20/02-TOPGLOVEB-01/10
Дата:	22.05.2020 г.

Име: Pn. Noor Akilah Saidin
Позиция: Зам. главен мениджър

Управител „Номер Едно АДВ“ ЕООД
Николай Кондев

