

EU Type-Examination Certificate

Certificate number: 2777/12707-01/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:

PFTN-FTPI
PFTN-FTT

Description:

Non sterile powder free nitrile examination glove, 2.5 mil
Available in colours: Pink and Teal

Sizes:

Extra Small – 6
Small – 7
Medium – 8
Large – 9
Extra Large – 10

Classification:**EN ISO 374-1:2016 Type C**

n-Heptane (J)
Sodium hydroxide 40% (K)
Hydrogen peroxide 30% (P)

Level

1
6
1

EN 374-4: 2013

44.6%
7.5%
45.0%

EN ISO 374-5: 2016

Protection against bacteria & fungi
Protection against viruses

Level

Pass
Pass


Standards/Technical specifications applied:

EN ISO 374-1:2016; EN ISO 374-5:2016; EN 420: 2003+A1: 2009

Technical reports/Approval documents:

SATRA: CHM0277509/1844/JH/L, CHM0277509/1844/JH/K, CHM0277509/1844/SPT/2, CHM0277509/1844/JH/AA/Final, CHM0277509/1844/JH/J

Signed on behalf of SATRA:



Tara Holly



Quincey Brown

Date first issued: 16/05/2019

Date of issue: 16/05/2019

Expiry date: 16/05/2024

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.



MAXTER
GLOVE MANUFACTURING SDN BHD
(229862-H)

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6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia
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E-MAIL: maxter@tm.net.my
www.maxter.com.my

09th May 2017

To Whom It May Concern:

MANUFACTURER DECLARATION

We, MAXTER GLOVE MANUFACTURING SDN. BHD., located at Lot 6070, Jalan Haji Abdul Manan, 6th Miles off Jalan Meru, ~~41050 Klang~~ declare that the devices manufactured by us,

- *"MAXSAFE" Label, Non Sterile Pink Powder Free Nitrile Examination Gloves*
- *"MAXSAFE" Label, Non Sterile Regular Blue Powder Free Nitrile Examination Gloves*

are in conformity with:-

- Regulations concerning the conformity of materials and products that intended to come into contact with food:
 1. Regulation (EC) No 10/2011
 2. Regulation (EC) No 1935/2004
- The gloves have passed the TUV SUD overall migration test as per EN1186-9:2002 and EN1186-8:2002 test methods for the following simulants:
 - 10% ethanol
 - 20% ethanol
 - 50% ethanol
 - Olive oil

Klang, Selangor
Malaysia



Yap Peak Geeh
QA & Regulatory Affairs Manager



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LOT 6070

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41050 Klang, Selangor, Malaysia
Tel: 603-33929888 (8 lines) Fax: 603-33923328
E-MAIL: info@maxter.com.my

24th June 2020

To Whom It May Concern:

EC DECLARATION OF CONFORMITY

We, **MAXTER GLOVE MANUFACTURING SDN. BHD., located at Lot 6070, Jalan Haji Abdul Manan, 6th Miles off Jalan Meru, 41050 Klang**, declare that the medical devices manufactured by us,

- Non Sterile Powder Free Nitrile Examination Gloves, Pink

are PPE Category III and are in conformity with:

- The provisions of Regulation (EU) 2016/425 and, the requirements of the European harmonized standard EN420:2003+A1:2009 and EN374-1:2016, and it is identical to the PPE which is subject to the EC Type Examination Certificate (Module B) issued by the Notified Body:
SATRA (2777)
Bracetown Business Park,
Clonee D15YN2P, Republic of Ireland.
- Is subject to the procedure set out in Module D of regulation (EU) 2016/425 under the supervision of the Notified Body:
SGS FIMKO OY (0598)
P.O. Box 30 (Särkinenentie 3), 00211 Helsinki, Finland.
- The gloves are manufactured according to ISO 9001:2015 and ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS UK Ltd System & Services Certification, Rossmore Business Park Ellesmere Port Cheshire CH653EN, United Kingdom.
- Our European Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.



**Klang, Selangor
Malaysia**

**Yap Peak Geeh
QA & Regulatory Affairs Manager**

TEST REPORT: 7191154424-CHM16-01-TSL_AD1_CR1

Date: 17 JAN 2017

Tel: +65 68851312 Fax: +65 67784301

Client's Ref: 221411220

Email: zhou.xiao@tuv-sud-psb.sg

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.



PSB Singapore

Choose certainty.
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SUBJECT

Overall Migration for "Powder Free Nitrile Examination Gloves" Sample

CLIENT

Maxwell Glove Manufacturing Berhad
Plot 116 & 117, Jalan Logam 7
Kws Perindustrian Kamunting Raya 3
34600 Kamunting
Perak, Malaysia

Attn : Ms Yap Peak Geeh

SAMPLE SUBMISSION DATE

22 Nov 2016 & 04 Jan 2017

DESCRIPTION OF SAMPLE

A packet of glove sample labelled as follows was received.

No	Description of Gloves	Size	Sample size (Pieces)
1	Powder Free Nitrile Examination Gloves	M	25

DATE OF ANALYSIS

25 Nov 2016 – 12 Dec 2016 (for 10% Ethanol, 20% Ethanol and Vegetable Oil (Olive Oil))

06 Jan 2017 – 16 Jan 2017 (for 3% Acetic Acid and 50% Ethanol)



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TUV®

METHOD OF TEST**1. Preparation of Test Specimen**

Only the exterior of the glove sample was performed for the test.

2. Overall Migration Content with Aqueous Food Simulant (10% Ethanol, 3% Acetic Acid, 20% Ethanol & 50% Ethanol)

According to BS EN 1186-9:2002 – Test Methods for overall migration into aqueous food simulants by article filling.

3. Overall Migration Content with Fatty Food Simulant (Olive Oil)

According to BS EN 1186-8:2002 – Test Methods for overall migration into olive oil by article filling.

RESULTS

Table 1 : Overall Migration Content with Food Simulant for the “Powder Free Nitrile Examination Gloves” Sample

Type of Simulant	Testing Condition	Surface Area (dm ²)	Volume of Extractant (ml)	Overall Migration (mg/dm ²)	Commission Regulation (EU) No 10/2011 Requirement for Overall Migration Content (mg/dm ²)
1. 10% Ethanol	40 °C, 2 hours	5.30	265	<1.0	<10
2. 3% Acetic Acid	40 °C, 2 hours	4.96	265	9.1	<10
3. 20% Ethanol	40 °C, 2 hours	5.31	265	2.2	<10
4. 50% Ethanol	40 °C, 2 hours	4.97	265	2.5	<10
5. Vegetable Oil (Olive Oil)	40 °C, 2 hours	5.21	265	<1.0	<10

Based on the above result, the “Powder Free Nitrile Examination Gloves” sample met the overall migration requirement under Commission Regulation (EU) No 10/2011 – “Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 10 milligrams of total constituents released per dm² of food contact surface (mg/dm²) (overall migration limit)” for 3% Acetic Acid and 50% Ethanol.



MS TAN SER LING
TECHNICAL EXECUTIVE



DR XIAO ZHOU
PRODUCT MANAGER
MICROCONTAMINATION DIAGNOSIS
CHEMICAL & MATERIALS



Please note that this Report is issued under the following terms :

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5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No. 1 Science Park Drive Singapore 118221.

July 2011

