



LOT 6070
Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia
Tel: 603-33929888 (8 lines) Fax: 603-33923328
E-MAIL: info@maxter.com.my

27th April 2020

To Whom It May Concern:

DECLARATION OF CONFORMITY

We, MAXTER GLOVE MANUFACTURING SDN. BHD., located at Lot 6070, Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru, 41050 Klang, Selangor, Malaysia, declare that the medical devices described hereafter,

**“MAXTER” label, Non Sterile Powdered Latex Examination Gloves
“MAXTER” label, Non Sterile Powder Free Latex Examination Gloves
“MAXTER” label, Non Sterile Powder Free Nitrile Examination Gloves**

- **Are in conformity with the general safety and performance requirements of Annex I Medical Device Regulation (EU) 2017/745 for Class I medical devices**
- **Classification: Class I based on Rule 5 transient use, Annex VIII of Medical Device Regulation (EU) 2017/745**
- **Are in conformity with the national standard transposing harmonized standard EN 455-1, EN 455-2, EN 455-3 and EN455-4**
- **The gloves are manufactured according to ISO 9001:2015 and ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS, 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**



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- **The provisions of Personal Protective Equipment (PPE) – Regulation (EU) 2016/425 and, the requirement of the European harmonized standard EN420 and EN374**
- **EEC regulations concerning the conformity of materials and products that has to get in touch with food:
Reg. EEC 1935/2004, Regulation EC 10/2011 & Regulation (EC) No 2023/2006**
- **The gloves are for contact of dry, fatty, alcoholic and aqueous food for short term contact based on the outcome of the overall migration test on the food simulants.**
- **Our UK Representative is Supermax Healthcare Limited., 12-16 Titan Drive, Fengate, Peterborough, PE1 5XN, United Kingdom.**
- **Our European Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords, Co. Dublin, Ireland**



**Klang, Selangor
Malaysia**

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



M A X T E R
GLOVE MANUFACTURING SDN BHD
(229862-H)

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6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia
Tel: 603-33929888 (8 lines) Fax: 603-33923328
E-MAIL: maxter@tm.net.my
www.maxter.com.my

Declaración UE de Conformidad con arreglo al Reglamento (UE) 2016/425 relativo a los EPI
EU Declaration of Conformity in accordance with PPE Regulation (EU) 2016/425

El fabricante:

The manufacturer:

MAXTER GLOVE MANUFACTURING SDN. BHD.
Lot 6070, Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia

Declara por la presente que el EPI que se describe a continuación

Hereby declares that PPE described hereafter

Guante de examen de nitrilo sin polvo 2.2 mil PFSN-FTCB

Powder free nitrile examination gloves 2.2 mil PFSN-FTCB

Talla / Size	Referencia / Reference Maxter Glove Manufacturing SDN. BHD.	Referencia / Reference Barna Import Medica, S.A.
XS	93775	160578
S	93776	160577
M	93777	160576
L	93778	160575
XL	93779	160574

Presenta conformidad con lo dispuesto en el Reglamento (UE) 2016/425 y las normas armonizadas EN ISO 374-1:2016, EN ISO 374-5:2016 y EN 420:2003+A1:2009.

Este producto se incluye entre los EPI de la Categoría III del Anexo I de dicho reglamento, siendo idéntico al EPI objeto del Examen UE de tipo (**Módulo B**) nº 2777/12706-01/E00-00 emitido por SATRA TECHNOLOGY, número de identificación **2777**, y conforme al aseguramiento de calidad del proceso de producción del Anexo VIII (**Módulo D**) nº MY19/1811030073 emitido por SGS FIMKO OY, número de identificación **0598**.

Complies with the requirements of Regulation (EU) 2016/425 and the harmonized standards of EN ISO 374-1:2016, EN ISO 374-5:2016 y EN 420:2003+A1:2009.

*This product is a PPE Category III in accordance with Annex I of the regulation and is identical with that PPE which was subject to the EU Type-examination (**Module B**) no. 2777/12706-01/E00-00 issued by SATRA TECHNOLOGY identification number **2777** and in accordance with the quality assurance of the production process in Annex VIII (**Module D**) no. MY19/1811030073 issued by SGS FIMKO OY identification number **0598**.*

Nombre, cargo, fecha:

Name, position, date:

Yap Peak Geeh, QA & Regulatory
Affairs Manager

30.11.2020



The management system of

Maxter Glove Manufacturing Sdn. Bhd.

Lot 6070, Jalan Haji Abdul Manan
6th Miles Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module D

For the following activities

Natural Latex, Nitrile Rubber Gloves, Chemical Protective Gloves

Note: All products marked CE0598 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.

This certificate is valid from 08 November 2019 until 04 May 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 04 March 2021

Issue 2. Certified since 01 July 2019

Authorised by

SGS FIMKO OY, Notified Body 0598

P.O. Box 30 (Särkiniementie 3), 00211 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

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