

DECLARATION OF CONFORMITY

MANUFACTURER : Smart Glove Corporation Sdn. Bhd.
Lot 6487, Batu 5 ¾, Sementa
Jalan Kapar, 42100 Klang
Selangor Darul Ehsan
Tel: 603-32916100
Fax: 603-32917526

EUROPEAN REPRESENTATIVE : Mdi Europa GmbH
Langenhanger Str. 71
30855 Langenhagen
Germany.

PRODUCT : Latex and Nitrile Examination Gloves

CLASSIFICATION : Class I

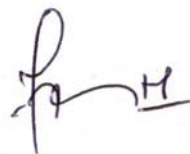
CONFORMITY ASSESSMENT ROUTE : Annex VII

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

APPLIED HARMONIZED STANDARD : EN 420:2003, EN 455-1:2000
EN 455- 2: 2009+A2:2013, EN455- 3:2006
EN 455 -4:2009

PLACE, DATE OF ISSUE : Smart Glove Corporation Sdn. Bhd.
Selangor, Malaysia
January 10, 2013

SIGNATURE :



Name : Poppy Farah Rosa
Position: QA/RA Manager
Date : December 06, 2018

EU Type-Examination Certificate

Certificate number: 2777/12322-02/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:

3mil powder free nitrile examination gloves

Description:

Five fingered blue powder free nitrile examination gloves.

4mil powder free nitrile examination gloves

Five fingered blue powder free nitrile examination gloves.

Sizes: 6 -11**Classification:****EN ISO 374-1: 2016 /Type C**

Acetone (B)
Diethylamine (G)
Ethyl acetate (I)
n-heptane (J)
40% Sodium hydroxide (K)
96% Sulphuric acid (L)

Level	EN ISO 374-4:2013	% Degradation
0		100
0		92.3
0		87.7
1		43
6		3.5
0		100

EN ISO 374-5: 2016

Protection against Bacteria and fungi
Protection against viruses

Level
Pass
Pass

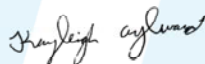
Standards/Technical specifications applied:

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

Technical reports/Approval documents:

SATRA: PRC0253480/1702/SPT, PRC0253480/1702/EN/A, PRC0253480/1702/EN/B, PRC0253480/1702/EN/D, PRC0253480/1702/EN/E, PRC0253480/1702/EN/G, PRC0253480/1702/EN/I, CHM0282156/1910/JG

Signed on behalf of SATRA:



Kayleigh Aylward



Quincey Brown

Date first issued: 12/03/2019

Date of issue: 14/06/2019

Expiry date: 12/03/2024

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.