



Issued to:

PPS Manufacturing JSC
Kaloyan, 8
Sofia
1000
Bulgaria

Notified Body: 2777

SATRA customer number: P20084

EU Type-Examination Certificate

Certificate number: 2777/24073-01/E14-01

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. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product reference:

PPSDTNG082023

Description:

Disposable Diamond Textured Nitrile Gloves, Powder Free orange gloves.
Weight (Size M): $\geq 6.5\text{g}$
Thickness: $\geq 0.16\text{mm}$

Sizes:

7/S – 11/XXL

Classification:

EN ISO 374-1:2016+A1:2018 /Type B	Level	EN ISO 374-4:2019 Degradation %
n-Heptane (J)	2	50.6
40% Sodium hydroxide (K)	6	-7.1
25% Ammonium hydroxide (O)	6	27.0
30% Hydrogen peroxide (P)	4	27.1
37% Formaldehyde (T)	5	17.7

EN ISO 374-5:2016

Protection against bacteria and fungi	Pass
Protection against viruses	Pass

Standards/Technical specifications applied:

EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:

SATRA: CHT0328812/2212/B/Issue 2, CHT0343267/2303, CHT0344467/2307, CHM0329706/2215/CC, CHM0344724 2308 1, CHM0330968/2219/JL, CHM0346761 2311 1

Signed on behalf of SATRA:

Geoff Graham

Date of issue: 08/04/2024
Expiry date: 19/04/2028

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. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified 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 manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU or UKCA declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11).
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification, or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. 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, or UK government.
9. 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.
10. SATRA 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 the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.

MODULE D CERTIFICATE

Issued To

PPS Manufacturing JSC
Tsar Kaloyan str., 8 1000 Sofia, Bulgaria

Has been found to conform to the requirements of Annex VIII (Module D) of the PPE Regulation (EU) 2016/425 – Conformity to type based on quality assurance of the production process, for the manufacture and distribution of disposable diamond textured nitrile gloves powder free.

Standards

EN ISO 374-1: 2016+A1: 2018
EN ISO 374-4: 2019
EN ISO 374-5: 2016
EN ISO 21420: 2020

Module B Certificates*

2777/24073-01/E14-XX

* Where 'XX' denotes the Module B certificate issue number

Date of first issue 10th September 2024
Date Issued 10th September 2024

Valid Until 24th June 2025
SATRA Reference STE2011800



Signed on behalf of SATRA Technology Europe Ltd – Notified Body Number: 2777

The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard which will be monitored by: SATRA Technology Europe Limited. Bracetown Business Park Clonee Dublin 15 D15 YN2P Ireland - Tel: +353 (0) 1 437 2484 Web: www.satra.com



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.

Please note:

1. Products covered by this certificate are classified by Regulation (EU) 2016/425 as category III Personal Protective Equipment and as such CE Marking is reliant on current compliance with Annex VIII Module D of this Regulation.
2. Full details of the scope of the certification and product(s) certified 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 on page 1 of this certificate.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on the relevant module B certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained are within the budget of uncertainty when compared to the pass requirement, classification, or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications, or performance levels.
8. 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 the authorities.
9. 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.
10. SATRA 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 (EU) 2016/425 on Personal Protective Equipment.