

Issued to:

Shandong IntcoMedical Products Co. Ltd Qiwang Road, Naoshan Industrial Park Qingzhou Shandong 262506 China

Disposable vinyl Powdered and Powder-Free, non-sterile gloves

Notified Body: 2777

SATRA customer number: P1720

# **EU Type-Examination Certificate**

### Certificate number: 2777/11030-03/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:**

#### **Description:**

Clear - 697024575 XXX Yellow - 697024575 XXX Blue - 697024575 XXX White - 697024575 XXX

Size	Blue	White	Clear	Yellow	Classification:		
6 XS	221	231	201	211	EN ISO 374-1:2016/Type B	Level	<b>Degradation %</b>
7 S	222	232	202	212	Sodium Hydroxide 40% (K)	6	-19.9
8 M	223	233	203	213	Hydrogen peroxide 30%(P)	2	22.1
9 L	224	234	204	214	Formaldehyde 37% (T)	3	19.2
10 XL	225	235	205	215	EN ISO 374-5:2016	Dees	
					Protection against bacteria and fungi	Pass	
					Protection against viruses	Pass	

Standards/Technical specifications applied: EN 420: 2003+A1: 2009; EN 388:2016; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents: SGS: CH:TX:7420016049, CH:TX:7420016055,QDHL1703003987OT, QDHL1703003988OT, CH:TX: 9420028491-1, CH:TX:9420028490, CH:TX:1042061966, CH:TX:1042059408 SATRA: CHT0272448/1814. CHT0285339/1921, CHT0280247/1903 TUV: 721642857-1, 719223458-EEC19-WBH\_CR1, 7191221099-CHM19-TSL

Signed on behalf c	of SATF	RA:	Anita Be	ennan	Anita Brennan	delasspood	٤.	Jacque Glassp	lood
Date first issued: Date of issue:	06/08/ 09/01/				Expiry date:	06/08/2023			
								Page 1 of 2	

## **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:

- 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 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 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. 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 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 Regulation 2016/425.