ITALSALUS

GUANTI PROTETTIVI INTCO IN VINILE

Senza polveri

Codice articolo GV-06

Guanti protettivi in vinile extra strong senza polveri. Codice Prodotto GV-06.
offrono protezione in svariati campi di applicazione, sono sintetici al 100%, sono morbidi, flessibili ed offrono una buona vestibilità garantendo piena sensibilità.I guanti protettivi in vinile sono DOP, DEHP-free e privi di lattice, e sono quindi un'ottima alternativa per chi soffre di allergie di tipo I.

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CERTIFICAZIONI

- Guanto protettivo in Vinile
- Conforme alle disposizioni del regolamento (UE) 2016/425
- Conforme alle disposizioni del regolamento (UE) 2016/425 e alle norme europee armonizzate EN 420:2003 + A1:2009, EN 421:2010, EN ISO 374-1:2016, EN ISO 374-5:2016,
- Categoria III, EN 374:2003, EN 420:2003 + A1:2009, EN 421:2010, EN 455 1-4, EN ISO 374-1:2016, EN ISO 374-5:2016, ISO 13485, ISO 10993-10:2002
- Soggetto all'esame UE del tipo (modulo B, allegato V al regolamento);
- Certificato numero 032/2018/1898 rilasciato dall'organismo notificato: Mandatario Lotus NLBV Koningin Julianaplein 10 Leverd 2595 Netherland

CARATTERISTICHE

- Guanto in vinile, ipoallergenico e senza polvere
- Modello: Vinile extra strong
- Conforme alla normativa standard EN 455, EN 374 – ASTM D5250 – FDA510 (K)
- AQL 1.5 medical grade
- Box da 100 pezzi, ambidestro con bordo arrotolato
- Brand name: Intco
- Fabbicante: Shandong Intco Medical Products Co. Ltd. Qiwang Road Naoshan, Industrial Park, Qingzhou, Shandong, China.
- Misure: XS – S – M – L – XLne

PACKAGING

- Cartoni da 10 scatole da 100 (1.000 guanti)
- Dimensioni cartone cm 31,5X25,8X25
- Peso cartone Kg. 5

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公司名称	英科医疗	尺寸	230x125x60mm	制图人	江硕印刷包装
物料名称	内盒	材质	400g白卡哑光	制图日期	2021-03-19
产品号	VGBEM10005HB	色号	K/C/M/Y/300C	确认人	
型号	M	版本		确认日期	

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SATRA TECHNOLOGY

Issued to:

Anhui Intco Medical Products Co, Ltd
No 1 Haitang Road
Suixi District economic development area
Huaibei City
Anhui Province
235100
China

Notified Body: 2777

SATRA customer number: P20118

EU Type-Examination Certificate

Certificate number: 2777/14715-02/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:

Clear – VGPFXXXX
Yellow – SMPFXXXX
Blue – BMPFXXXX
White – WMPFXXXX

Description:

Disposable vinyl gloves(Powdered and Powder free)

Sizes:

XS-6	S-7	M-8	L-9	XL-10
3000	3001	3002	3003	3004

Classification:

EN ISO 374-1:2016+A1:2018 TYPE C	**Level**	**EN 374-4:2013 Degradation%**
40% Sodium hydroxide	6	13.0
EN ISO 374-5:2016		
Protection against bacteria and fungi	Pass	
Protection against virus	Pass	

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0296245/2012
SGS: CH:TX:1142011146-1, CH:TX:1142011144, CH:TX:1142011143
TUV: 721652919

Signed on behalf of SATRA: Ting Huang — Ting Huang — Jacque Glasspool

Date first issued: 23/06/2020
Date of issue: 29/06/2020

Expiry date: 23/06/2025

Page 1 of 2

SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland.

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GUANTI PROTETTIVI INTCO IN VINILE

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Codice articolo GV-06

Issued to:

Anhui Intco Medical Products Co Ltd
Haitang Road West And Yinhua Road North
Suixi Wuhu Modern Industrial Park
Suixi Town Huaibei
Anhui
China

Notified Body: 2777

SATRA customer number: P20118

EU Type-Examination Certificate

Certificate number: 2777/15661-01/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:

SGB/HE100XX

Description:

Disposable Synmax Vinyl Gloves, Powdered and Powder-Free, Non-Sterile.

Colours:

Blue: SGB/HE10014(S) - 10017(XL)
Violet: SGB/HE10034(S) - 10037(XL)
Black: SGB/HE10044(S) - 10047(XL)

Sizes:

7/S, 8/M, 9/L, 10/XL

Classification:

EN ISO 374-1:2016+A1:2018 /Type B	Level	EN ISO 374-4:2019 Degradation %
40% Sodium Hydroxide (K)	6	-51.4
30% Hydrogen Peroxide (P)	2	19.6
37% Formaldehyde (T)	6	-47.7

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: CHT0305116/2047, CHM0304422/2045/LH/A, CHM0304422/2045/LH/B, CHM0304350/2045/EN/A, CHT0304350/2045/EN/B, CHT0303912/2043
CTC: S201010806_2, S201011264_1, S201011263_1
TUV: 721659016

Signed on behalf of SATRA: Quincey Brown

Date first issued: 29/01/2021
Date of issue: 29/01/2021
Expiry date: 29/01/2026

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INTCO
英科医疗

Document Number ：INTCO-CE-DC-PVC-001 Version: A/1

EU DECLARATION OF CONFORMITY

Manufacturer

Name: **Shandong Intco Medical Products Co., Ltd.**
Address: **Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China**

Authorized Representative

Name: **Lotus NL B.V.**

Address: **Koningin Julianaplein 10, le Verd, 2595AA, The Netherlands**

Declares that the MDR described hereafter

Product name and model:

Disposable Vinyl（PVC）Gloves

UMDNS code：11882

UDI-DI: 6970245751019 / 6970245751026 / 6970245751033 / 6970245751040 / 6970245751057

Meet the provisions of the Council Regulation EU 2017/745 which apply to them.

The medical device has been assigned to class **I** according to Annex *VIII* of the Regulation EU 2017/745. It bears the mark

CE

CONFORMITY ASSESSMENT ROUTE: *EU 2017/745, Annex I & VII*

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shandong Intco Medical Products Co., Ltd.
Address: Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China

Shandong 2019-05-06

Place , date

Chi Yongtao Plant manager

Legally binding signature, Function

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INTCO 英科医疗	山东英科医疗制品有限公司 Shandong Intco Medical Products Co., Ltd.	文件编号 Doc No.	INTCO-TF-PVC-PPE
		版　本 Ver.	A1
一次性 PVC 手套–PPE 技术文档 Vinyl Gloves-Technical File for PPE		页　次 Page	1/1
		日　期 Date	2018-04-17

INTCO-TF-PVC-PPE-14

EU Declaration of Conformity

Declaration that application for the products listed has not been made to any other notified body.

1. PPE： Vinyl Gloves （Code：697024575）

   Glove sizes available: XS, S, M, L, XL

2. Manufacturer Name: Shandong Intco Medical Products Co., Ltd.

   Address: Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China

3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Shandong Intco Medical Products Co., Ltd.

4. Object of the declaration: Vinyl Gloves （Code：697024575）

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: EN420:2003+A1:2009, EN374-1:2016, EN374-2:2013, EN 374-5:2016;

6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

7. The notified body SATRA Technology Europe Ltd (Number: 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate.

8. The PPE is subject to the conformity assessment procedure Module C2 under surveillance of the notified body : SATRA Technology (Number: 2777),

Adress: Bracetown Business Park Clonee, D15 YN2P, Ireland.

Signed for and on behalf of: Shandong Intco Medical Products Co., Ltd.

Signature 崔忠强

Position Quality Manager

Date 12-Apr-2018

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SGS

Certificate No. TC6176

TEST REPORT

Report No. : CH:TX:1142013558 **DATE : 09/06/2020**

CASE NO:QDHL2003001764MD

ANHUI INTO MEDICAL PRODUCTS CO, LTD
NO:1, HAITANG ROAD,SUIXI DISTRICT ECONOM HUAIBEI CITY
ANHUI PROVINCE
A/C F619701 SGS-CSTC STANDARD TECHNICAL SERVICES (QINGDAO) CO., LTD.
CONTACT PERSON :

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION GLOVES
DISPOSABLE VINYL GLOVE(PVC)

QD REF NO QDHL2003001764MD

PHOTO APPENDIX.

SAMPLE RECD ON 18/03/2020 **TESTING PERIOD :** 18/03/2020 - 09/06/2020

Summary of Test Results/Conclusion		
Test Method / Standard	**Clause/Test Name**	**Status / Performance Level**
EN 16523-1:2015	**Permeation by Liquid chemical under conditions of continuous contact.**	
	Formaldehyde 37%	Level -2

Per pro SGS India Private Ltd.

K. Pachaiyappan

K. PACHAIYAPPAN
ASST. MANAGER
Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

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SGS India Pvt. Ltd. **Consumer and Retail,Testing Laboratory, 28 B/1(SP), 28 B/2(SP), Second Main Road, Ambattur Industrial Estate, Ambattur,Chennai - 600 058.India**
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