



Compliance Report

Applicant: Shandong INTCO Medical Products Co., Ltd.
Address: QIWANG ROAD, NAO SHAN INDUSTRIAL PARK,
QINGZHOU, SHANDONG, 262500, CHINA

Product: Disposable Nitrile Examination Gloves (non-sterile)
Type: S, M, L, XL

Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **01982**

Initial Issue Date: **24 Oct 2012**

A handwritten signature in blue ink, appearing to read 'J. Smith', is written over a horizontal line.

General Manager (Signature)

CERTIFICATE

CERTIFICATE OF COMPLIANCE

NO: BS17449621-EC

Applicant:

FOSHAN BURNU CLOTHING CO.,LTD.
3RD FLOOR, XIYUEQUAN COMPLEX BUILDING,
LEIGANG COMMUNITY, GUICHENG SUBDISTRICT,
NANHAI DISTRICT FOSHAN, GUANGDONG, CHINA

Manufacturer:

FOSHAN BURNU CLOTHING CO.,LTD.
3RD FLOOR, XIYUEQUAN COMPLEX BUILDING,
LEIGANG COMMUNITY, GUICHENG SUBDISTRICT,
NANHAI DISTRICT FOSHAN, GUANGDONG, CHINA

Product:

PROTECTIVE CLOTHING

Model:

M, L, XL, XXL, XXXL
160, 165, 170, 175, 180, 185

Reference to EC Directive:

Regulation (EU) 2016/425
Personal protective equipment (PPE)

Tcf(s) or Test Report(s) No.:

TR-011-055-2685EN

Relevant standard (s):

EN 943-1-2015

REMARKS:

Assessment of the product(s) and the production process is not covered by this verification, which has been carried out on a voluntary basis. It is sole and full responsibility of the manufacturer to carry out all necessary safety assessment of the product(s) according to all related EC Directive and Standard(s) before putting into market/service, affixing CE mark and issue EU Declaration of Conformity. The manufacturer shall affix CE mark on the product(s) according to 2006/42/EC Article 10 and Annex II, only if the product(s) fulfil the relevant essential health and safety requirements and the draw-up EU Declaration of Conformity. Technical File should be drawn for each type/model of related product(s) by the manufacturer and/or his authorized representative in order to ensure conformity with the essential health and safety requirements which demonstrate that the machinery complies with the requirements of the related directives/standards and must be compiled in one or more official Community languages. Before placing machinery into market/service, the manufacturer or his authorized representative shall ensure that the Technical File in accordance with related directives/standards is available. The manufacturer or his authorized representative shall keep Technical File and EU Declaration of Conformity available for a period of ten years from the last date of manufacture of the machinery. The certificate consists of 1 signed page.

The Certificate is valid Until: Mar 18, 2025

Date of Issue: Mar 19, 2020

CERTIFICATION MANAGER:



BSI TEST LIMITED

Unit G25 Waterfront Studios, 1 Dock Road, London, E16 1AH

Nitrile gloves

Nitrile Examination Gloves

Comfortable, super soft flexible powder free nitrile gloves provide added safety in many applications. Designed with a special nitrile formulation they feel and fit like latex and allow full range of motion and excellent flexibility to minimize stress and fatigue. They do not contain natural rubber latex and are an excellent alternative for those suffering from Type I allergies.



Features

- 100% latex free – made from durable, puncture resistant, protein and powder-free nitrile, eliminates the Type I allergic reaction associated with natural rubber latex
- Highly elastic and super soft
- Rolled rim to facilitate easy donning
- Designed to give a natural rubber-like feel
- Textured in finger tips for enhanced grip in all situations
- Food safe, suitable for handling fatty foods incl. cooking, olive and cod liver oil (Special Product)
- Protects against a wide variety of chemicals
- AQL 1.5, 2.5, 4.0 Available

Quality standards

- Complies with EN 455 and EN 374
- Complies with ASTM D6319 (USA Related Product)

Technical information

Type	Powder-free, unsterile
Material	Nitrile butadiene rubber (NBR)
Colour	Blue, White, Purple, Pink, Black, Red
Model	Ambidextrous, with rolled rim
Storage	Protect from heat, humidity, strong light and ozone
Size/overall length as per EN 455-2	XS, S, M, L and XL 240 mm (≥230mm for USA)
Impermeability as per EN 455-1	AQL 1.5, 2.5, 4.0 Available
Durability, in original package if stored as per din 7716, ISO 2230	Min. 5 years



Powder-free

REF	Size	Dispenser	Transport carton
NG-141	XS	100	1000
NG-141	S	100	1000
NG-141	M	100	1000
NG-141	L	100	1000
NG-141	XL	100	1000

EU Type-Examination Certificate

Certificate number: 2777/11804-01/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: 697024575
Description: Five fingered disposable nitrile non-sterile gloves.

Blue 697024575 601-605

Violet 697024575 631-635

White 697024575 641-645

Black 697024575 651-655

Sizes:
 6/XS, 6.5/S, 7/M, 8/L, 9/XL

Classification:		Level	EN 374-4: 2013
EN ISO 374-1:2016+A1:2018 /Type B			
40% Sodium Hydroxide (K)		6	-11.5 %
30% Hydrogen peroxide (P)		2	-9.5%
37% Formaldehyde (T)		3	7.4 %
EN ISO 374-5: 2016			
Protection against Bacteria and fungi		Pass	
Protection against viruses		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: CHT0278438/1848
 SGS: QDHL1806013113OT, CH:TX:6420074520, CH:TX: 9420020333, CH:TX: 9420029243 CH:TX: 9420026599-1, CH:TX: 9420014953-1, CH:TX: 9420026316-1, CH:TX: 9420614959
 TUV: 721642857-2

Signed on behalf of SATRA:



Tara Saunders



Geoff Graham

Date first issued: 30/01/2019
Date of issue: 30/01/2019

Expiry date: 30/01/2024

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.