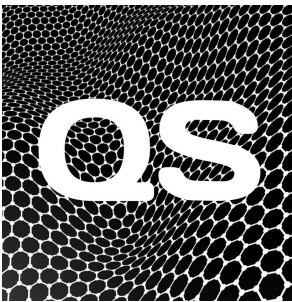


PPE GLOVES & GOWNS



Medical Grade Gloves

BTC Gloves - 01



Certifications

CE Certified	EN ISO 374-1:2016/TypeB
ISO 13485:2016	EN ISO 374-5:2016
GB 15979-2002	EN ISO 374-1:2016+A1:2018 TypeB

Specifications

Color	Light Blue
Material	Nitrile Powder and Latex Free
Medical Grade	Yes
Disposable	Yes

Details

Protects user against bacteria, viruses, fungii, bodily fluids

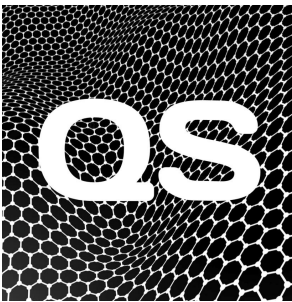
Non-sterile

Fits either hand

Packing: 100 gloves/box, 10 box/carton or 1,000 gloves/carton

www.Quettil.Com

PPE GLOVES & GOWNS



SATRA TECHNOLOGY

Issued to: [Redacted]
China

Notified Body: 2777 SATRA customer number: P1720

EU Type-Examination Certificate

Certificate number: [Redacted]

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: [Redacted] **Description:** Disposable vinyl Powdered and Powder-Free, non-sterile gloves

Size	Blue	White	Clear	Yellow	Classification:	Level	Degradation %
6 XS	221	231	201	211	EN ISO 374-1:2016/Type B	6	-19.9
7 S	222	232	202	212	Sodium Hydroxide 40% (K)	2	22.1
8 M	223	233	203	213	Hydrogen peroxide 30%(P)	3	19.2
9 L	224	234	204	214	Formaldehyde 37% (T)		
10 XL	225	235	205	215	EN ISO 374-5:2016	Pass	
					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, QDHL 1703003987OT, QDHL1703003988OT, CH:TX: 9420028491-1, CH:TX:9420028490, CH:TX:1042061966, CH:TX:1042059408
SATRA: CHT0272449/1814, CHT0285339/1921, CHT0280247/1903
TUV: 721642867-1, 718223458-EEC19-WBH_CR1, 7191221099-CHM19-TSL

Signed on behalf of SATRA: *Anita Brennan* Anita Brennan *Jacque Glasspool* Jacque Glasspool

Date first issued: 06/06/2018 Expiry date: 06/08/2023
Date of issue: 09/01/2020

SATRA Technology Europe Limited, Bracktown Business Park, Clonsilla, D15YN2P, Republic of Ireland.

SATRA TECHNOLOGY

PPE REGULATION (EU) 2016/425 MODULE C2 CERTIFICATE

Issued to: [Redacted]

This is to certify that the following products tested under SATRA reports referenced: STE0293607 & CHM0295494/2009/JH have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/11804-01/E00-00	[Redacted]	Disposable nitrile Non-sterile glove	EN ISO 374-1:2016+A1:2018 Type B

Dated: 5th March 2020 This certificate is valid until: March 2021

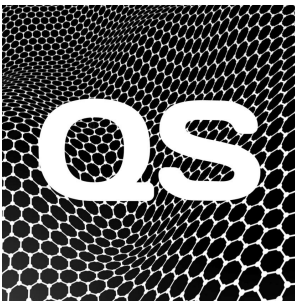
Alan Weston
Signed By (Alan Weston)

For and on behalf of SATRA Technology Europe Limited

CE

The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.
SATRA Technology Europe Limited, Bracktown Business Park Clonsilla Dublin 15 D15 YN2P, Republic of Ireland.
(Notified Body number 2777)
Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com

PPE GLOVES & GOWNS



Intertek
Total Quality Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

[Redacted]

Products Co., Ltd.

[Redacted]

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

Manufacture of non-sterile NBR (Nitrile Butadiene Rubber) and PVC (Poly Vinyl Chloride) patient examination gloves.

Certificate Number:
008 [Redacted]

Initial Certification Date:
28 April 2014

Certificate Issue Date:
17 January 2019

Certificate Expiry Date:
31 December 2021

CCSM Accredited CCN

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.

CT-ISO 13485_2016-SCC-EN-A4-01_jul17

SGS **MA** **ILAC-MRA** **CNAS** 中国认可 国际互认 检测 TESTING CNAS L2774

报告编号: TJAFN17110264 [Redacted] 报告日期: 2017-12-18

客户名称: [Redacted] 有限公司
客户地址: [Redacted] 齐东路9888号
样品名称: 一次性丁腈手套
样品批号: /
生产日期: /
生产商: /

以上样品及信息由客户提供及确认, SGS 不承担证实客户提供信息的准确性、适当性和(或)完整性责任。

SGS 样品编号: TJAFN17 [Redacted]
SGS 相关号: QDF17-003776.001/QDHL171102 [Redacted]
样品接收日期: 2017-11-20
样品测试日期: 2017-11-21 ~ 2017-11-29

测试要求:
根据客户要求进行测试。

测试项目	单位	测试方法	测试结果	参考标准: GB 15979-2002	单项说明
细菌菌落总数	CFU/g	GB 15979-2002	< 4	≤ 200	符合
大肠菌群	/0.25g		未检出	不得检出	符合
金黄色葡萄球菌	/0.25g		未检出	不得检出	符合
真菌	CFU/g		< 4	≤ 100	符合
溶血链球菌	/0.25g		未检出	不得检出	符合
绿脓杆菌	/0.25g		未检出	不得检出	符合

本报告替代报告编号 TJAFN17110 [Redacted] 日期 2017-11-29, 原报告作废。

除非另有说明, 本检验结果仅对测试样负责。未经检验机构书面同意, 委托人不得擅自使用检验结果进行不当宣传。

SGS 授权签字人

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第 1 页 共 2 页

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