



Issued to:

Suqian Green Glove Co. Ltd.
No.1 Xiangshan Road
Suyu High-Tech Zone
Suqian City
Jiangsu Province
223800
China

Notified Body: 2777

SATRA customer number: P1724

EU Type-Examination Certificate

Certificate number: 2777/11628-01/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: All Fine GL-TF-PVC
Description: Five Finger Disposable Vinyl Glove

Sizes:
S/7- GL-TF-PVC
M/8- GL-TF-PVC
L/9- GL-TF-PVC
XL/10- GL-TF-PVC

Classification:		
EN ISO 374-1:2016 Type C	Level	EN 374-4:2013 % degradation
Methanol	0	18.4
40% Sodium hydroxide (K)	6	-16.2
EN ISO 374-5:2016		
Protection against bacteria and fungi – Pass		
Protection against viruses – N/A		
EN388:2016	Level	
Abrasion Resistance	0	
Blade Cut Resistance	0	
Tear Resistance	0	
Puncture Resistance	0	
TDM Cut Resistance	0	

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

Technical reports/Approval documents:
SATRA: CHM0257794/1721/SMcD/A, CHM0257794/1721/SMcD/B, SPC0259252/1726, SPC0258121/1722/2

Signed on behalf of SATRA:

Tara Saunders

Geoff Graham

Date first issued: 05/12/2018
Date of issue: 05/12/2018

Expiry date: 05/12/2023



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Suqian Green Glove Co., Ltd.
South Side of Development Avenue
East District of
Economic Development Area
Suqian City
223814 Jiangsu
China

has established and applies a quality management system for medical devices
for the following scope:

Manufacture and Distribution of Medical Gloves

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-04-01
Certificate Registration No.: SX 60135581 0001
An audit was performed. Report No.: 15096086 003
This Certificate is valid until: 2022-03-20

Certification Body



Date 2019-04-01



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety