

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

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

**Manufacture and Distribution of Non-sterile
Patient Examination 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: 2019-11-27
Certificate Registration No.: SX 60143698 0001
An audit was performed. Report No.: 16806409 004
This Certificate is valid until: 2022-10-26

Certification Body



Date 2019-11-27



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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Business Stream Products
Certification Department



TÜVRheinland®

LGAP

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date November 27, 2019

Application for : QMS
Certificate No. : SX 60143698 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the
new certificate No. SX 60143698 0001
replacing the previous certificate.

Kind regards

Certification body

Wenxiang Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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Board of Management

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**EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ**

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: /
the medical device: /
le dispositif médical: /
il dispositivo medico:

Examination Synthetic Vinyl Gloves
Model: XS, S, M, L, XL

der Klasse: /
of class: /
de la classe: /
di classe:

Class I

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Directive 93/42/EEC Annex VII

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

Jin Zhou, China, 5 November 2018

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione



SGS

VERIFICATION OF EN 455 CONDITIONAL COMPLIANCE

No.: SHHG1511044686MD-01C
Product Name: EXAMINATION VINYL GLOVES
Style No. XS,S,M,L,XL,XXL

Sufficient samples of the product have been tested and found to be in conformity with

Test Standard: EN455-1:2000 MEDICAL GLOVES FOR SINGLE USE-
PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES
EN455-2:2015 MEDICAL GLOVES FOR SINGLE USE-
PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPRIETIE
EN455-3:2015 MEDICAL GLOVES FOR SINGLE USE-
PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION (EXCEPT CLAUSE 4.2 CHEMICALS)

as shown in the
Test Report Number(s): SHHG1511044686MD-01

This verification is only valid for the equipment and configuration described, and in conjunction with the test data detailed. It contains the result of the single examination of the subject being in hand and does not represent any universally valid decision concerning the quality of any subject of the current production.


Donna Gu
CRS/Hardline SBU Section Head
SGS-CSTC Standards Technical Services Co., Ltd.

June 1, 2016

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SGSPAPER
16943528



EU Type-Examination Certificate

Certificate number: 2777/11158-01/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: | Description: |
|--------------------|--|
| WLPFXXX | Disposable Vinyl gloves PF = Powder free PP = Pre Powdered |
| WLPPXXX | Disposable Vinyl gloves PF = Powder free PP = Pre Powdered |

Available in the following colour:
Clear 101

| Sizes: | Classification: | Level | EN ISO 374-4:2013 | Degradation % |
|--------|--|-------|-------------------|---------------|
| XS 6 | EN ISO 374-1 2016 Type C 40% Sodium Hydroxide (K) 96% Sulphuric Acid (L) | 6 | | -28.6 |
| S 7 | | 1 | | -62.5 |
| M 8 | EN ISO 374-5: 2016 Protection against bacteria and fungi Protection against viruses | Level | | |
| L 9 | | Pass | | |
| XL 10 | | Pass | | |

Standards/Technical specifications applied:
EN ISO 374-1:2016; EN 374-4: 2013; EN ISO 374-5:2016; EN 420: 2003+A1: 2009

Technical reports/Approval documents:
SATRA: CHT0272948/1828, CHT0269921/1816/EN/A, CHT0269921/1816/EN/B, CHT0269921/1816/JS/C, CHT0269921/1816/SPT/issue 2, CHT0270613/1819/ issue 3.

Signed on behalf of SATRA:  Daniel Cotter  Austin Simmons

Date first issued: 28/08/2018
Date of issue: 28/08/2018 **Expiry date: 28/08/2023**