

KZB NITRIL EINWEG-HANDSCHUHE, PUDERFREI

Artikelnummer: kroe100KZBL, kroe100KZBM, kroe100KZBS (Größe: L, M, S)



Norm: EN374-1:2016 | Norm: EN455 | CE Kennzeichnung | Haltbarkeit: 3 Jahre

Merkmale der KZB NITRIL EINWEG-HANDSCHUHE?

- Schachtel mit 100 Handschuhen
- Deutlich gekennzeichnet mit Chargennummer, Ablaufdatum, Produktdatum und Größe
- Wasserdichtes und einstichfestes Nitril
- Strukturierte Fingerspitzen für bessere Fingerfertigkeit
- Hohe Zugfestigkeit
- Chloriert zum einfachen An- und Ausziehen

Im Anhang folgen weitere Informationen

- Declaration of Conformity – 1 Seite
- Certificate of Conformity – 1 Seite
- EU Type-Examination Certificate – 1 Seite
- SGS Certificate Regulation (EU) 2016/425 Module D – 2 Seiten
- SGS Test Reports – Auf Anfrage



Chlorinated PowderFree
Nitrile Examination Gloves
TF 005

Attachment 2

DECLARATION OF CONFORMITY

Plant of Manufacture : COMFORT RUBBER GLOVES INDUSTRIES SDN BHD

Lot 821 & 2209, Jalan Matang,
34750 Matang, Perak,
Malaysia.

Lot 1874, Jalan Kampung Dew,
Simpang Halt,
34700 Simpang,
Taiping, Perak,
Malaysia.

Contact Person : Mr. Ng Kok Howe
Telephone Number : 605-847 2777 / 2888
Facsimile No. : 605-847 9108 / 6250
Position : QA & QMS Manager
(Quality Management Representative)
E-mail : garyng@comfort-rubber.com.my

Competent Authority : SGS United Kingdom Ltd Systems & Services Certification
Certificate No. : MY09/77229

Product : Chlorinated PowderFree Nitrile Examination Gloves.

Classification : Class 1

Conformity Assessment Route : Rule 5

Intended Use : It is a disposable device intended for medical purpose that is worn on the
examiner's hands or fingers to prevent contamination between patient and
examiner.

Hereby declare that product described as Chlorinated PowderFree Nitrile Examination Gloves is in conformity with the
provision of Regulation (EU) 2017/745 of The European Parliament and of The Council (Invasive Devices – Rule 5).
Where such is the case, with the national standard transposing harmonized standard Nos. EN 455-1, EN 455-2, EN 455-3
and EN 455-4.

Signed :

Name : Ng Kok Howe
Position : QA Manager
Date : 09.02.2021



ComfortRubberGloves

Comfort Rubber Gloves Industries Sdn. Bhd.

(Company No.: 260990-U)

Lot 821, Jalan Matang,

34750 Matang, Perak, Malaysia..

P. : +605 847 2777 / 2888

F. : +605 847 9108 / 6250

E. : inquiry@comfort-rubber.com.my

W. : www.comfort-rubber.com.my


CERTIFICATE OF CONFORMITY

Date: 06th April 2020

To whom it may concern,

**Subject: CONTENT DECLARATION concerning to:
EC 1907/2006 Registration, Evaluation, Authorisation and Restriction of Chemicals.**

We hereby to confirm that Comfort Rubber Gloves Industries Sdn. Bhd. does not use the chemicals; which are listed as Substances of Very High Concern (SVHCs) Candidate List updated on 25th March 2020 to manufacture **Powder Free Nitrile and Natural Rubber Latex Examination Gloves.**

Signed : 
Name : Ng Kok Howe
Position : QA Manager
Date : 06th April 2020



Cert no: MY09/77228



Cert no: MY09/77229



Issued to: Comfort Rubber Gloves Industries Sdn.Bhd
Lot 821
34750 Matang
Jalang Matang
Perak
Malaysia

Notified Body: 2777

SATRA customer number: P1898

EU Type-Examination Certificate

Certificate number: 2777/12062-01/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: PFNBR244
Description: Powder free Nitrile examination gloves

Sizes: 7 – 10

| Classification: | | Level | EN 374-4:2013 Degradation % |
|---------------------------------------|--|--------------|------------------------------------|
| EN ISO 374-1:2016/Type C | | | |
| 25% Ammonium hydroxide | | 1 | 60.8 |
| 40% Sodium hydroxide | | 6 | -10.1 |
| 37% Formaldehyde | | 6 | 45.4 |
| EN ISO 374-5:2016 | | | |
| Protection against bacteria and fungi | | Pass | |
| Protection against viruses | | N/A | |

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: SPC0271175/1821/4, CHM0271163/1821/JS/B, CHM0271163/1821/JS/A

Signed on behalf of SATRA:

Mohammed Rahman

Austin Simmons

Date first issued: 26/02/2019
Date of issue: 26/02/2019

Expiry date: 26/02/2024

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Certificate MY19/1811029960

SGS

The management system of

Comfort Rubber Gloves Industries Sdn. Bhd.

Lot 821 & 2209, Jalan Matang
34750 Matang, Taiping, Perak Darul Ridzuan
MALAYSIA

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425 Module D

For the following activities

Manufacturer of Chemical Protective Gloves (Powdered & Powder free)
Regulation Note: All products marked CE0598 must have a valid EU
type-examination certificate issued under Module B or a valid EC type-
examination certificate issued under Article 10 of the PPE Directive
89/686/EEC (Dir 89/686/EEC)

This certificate is valid from 19 March 2019 until 07 April 2021 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 07 February 2021
Issue 1. Certified since 19 March 2019

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by

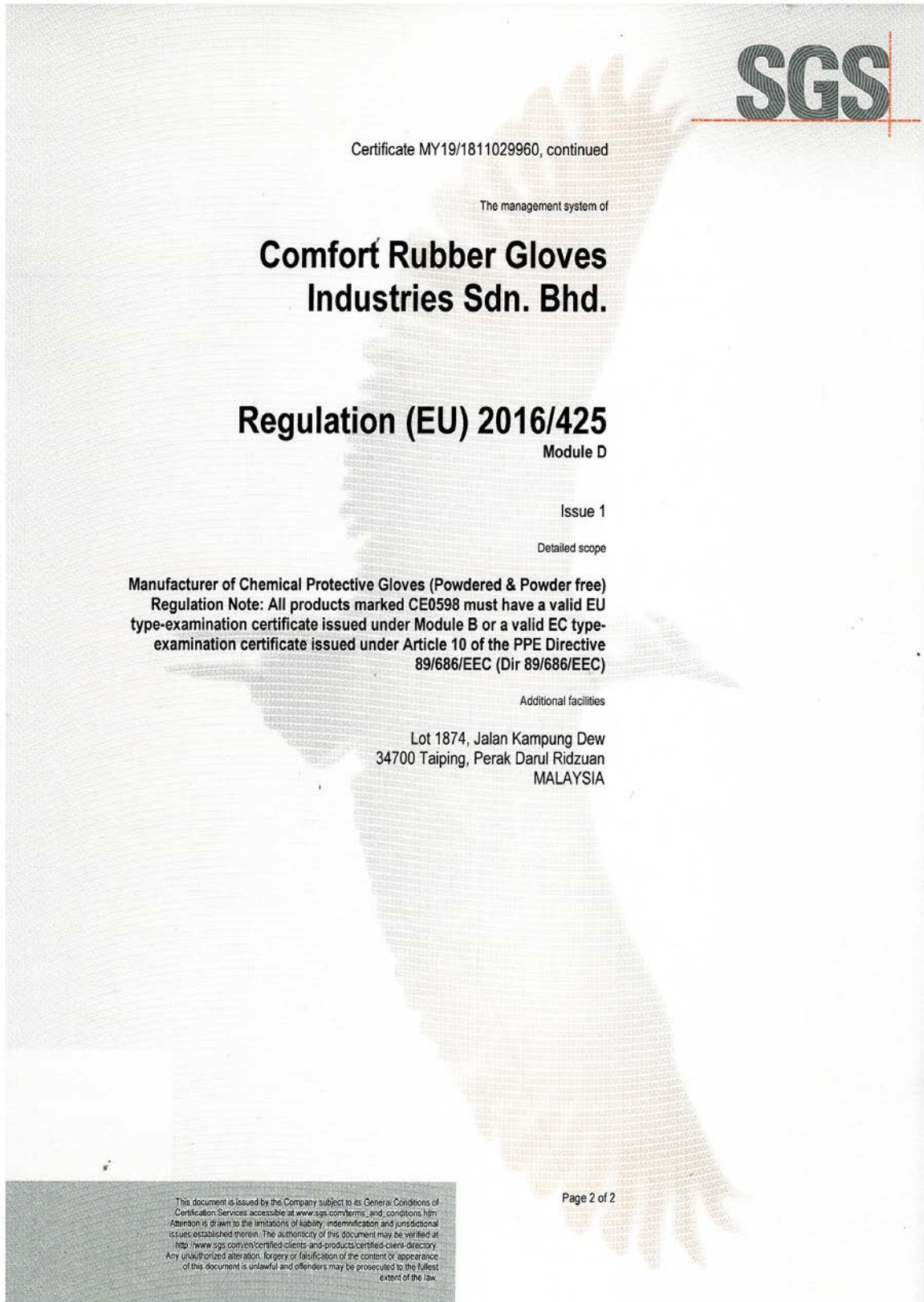
Tom Tom

SGS FIMKO OY, Notified Body 0598
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SGS

Certificate MY19/1811029960, continued

The management system of

**Comfort Rubber Gloves
Industries Sdn. Bhd.**

Regulation (EU) 2016/425

Module D

Issue 1

Detailed scope

Manufacturer of Chemical Protective Gloves (Powdered & Powder free)
Regulation Note: All products marked CE0598 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC (Dir 89/686/EEC)

Additional facilities

Lot 1874, Jalan Kampung Dew
34700 Taiping, Perak Darul Ridzuan
MALAYSIA

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