

# **SUMIRUBBER MALAYSIA**

## **SCHE TA TECNICA**

**Codice prodotto: R101-PF**

### **CONTENUTO**

1. Caratteristiche del prodotto
2. Applicazioni/Utilizzo
3. Descrizione del prodotto
4. Proprietà fisiche
5. Requisiti qualitativi AQL
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10. Marcatura del prodotto
11. Packaging

<b>Revision No.</b>	<b>Data di emissione</b>	<b>Motivo dell'emissione</b>
<b>0</b>	<b>Dicembre 29,2015</b>	<b>Prima Emissione</b>
<b>1</b>	<b>Maggio 04,2016</b>	<b>Aggiornamento informazione prodotto</b>
<b>2</b>	<b>Giugno 12,2016</b>	<b>Aggiornamento Certificato CE</b>
<b>3</b>	<b>Agosto 28,2019</b>	<b>Aggiornamento normativa DPI (EU) 2016/425</b>
<b>4</b>	<b>Settembre 17, 2019</b>	<b>Aggiornamento EU Test certificazione</b>
<b>5</b>	<b>Aprile 18, 2020</b>	<b>Aggiornamento informazione prodotto</b>

# TECHNICAL DATA SHEET

## SUMIRUBBER MALAYSIA

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<b>Revisione No</b> : 5	<b>Marchio</b> : Summitech Professional
<b>Data</b> : Aprile 18, 2020	
Prodotto da: Sumirubber Malaysia Sdn. Bhd. (172875-K) Lot 44, 45 & 86, Bakar Arang Industrial Estate 08000 Sungai Petani, Kedah, Malaysia. Telephone : (604) 421 3121 Facsimile : (604) 421 3123 E-mail : sumirubbermalaysia@srin.com.my Website : www.sumirubber.com	

### 1. Caratteristiche del prodotto

- 100% lattice naturale resiste agli acidi, alcoli e alcali
- Eccellente protezione della mano e del prodotto con una ottima sensibilità e grande destrezza
- Il guanto è privo di siliconi

### 2. Applicazione Utilizzo

- Uso in ospedali, cliniche, case di riposo, distribuzione pasti e altri casi dove non siano necessari guanti sterili
- Laboratori di analisi
- Industrie farmaceutiche
- Industrie di profumi e cosmetici

### 3. Descrizione del prodotto

#### Guanti monouso , ambidestri , in lattice naturale , senza polvere , zigrinati e con bordino arrotolato

Componente principale	: Gomma naturale
Materiale di copertura	: Gomma naturale, Senza Polvere
Tipo di polsino	: Arrotolato
Disegno sul palmo	: Non disponibile
Colore	: Naturale
Lungh (mm)	: Min 240
Spessore (mm)	: Min 0,12

Taglia del guanto	XS	S	M	L	XL
Larghezza del palmo ( ± 5 mm)	75	85	95	106	115

### 4. Proprietà fisiche (In conformità con ASTM D 3578)

Prima dell'invecchiamento	Tensione di rottura (MPa)	: min 18.0
	Allungamento alla rottura (%)	: min 650
Dopo l'invecchiamento	Tensione di rottura (MPa)	: min 14.0
	Allungamento alla rottura (%)	: min 500

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### 5. Requisiti qualitativi (for individual use) AQL

Characteristic	Inspection Level	AQL	Ref. Standard
Dimensioni	S-2	4.0	ASTM D 3578
Qualità della barriera protettiva ( test gonfiaggio con aria	G-1	2.5	ASTM D 3578
Ispezione visiva	S-4	2.5	ASTM D 3578
Proprietà fisiche & Dimensioni	S-2	4.0	ASTM D 3578
Contenuto polvere	S-2	< 2 mg/glove	ASTM 6124
Proteine estraibili in acqua	-	< 50 µg/dm2	EN 5712

### 6. Protezione Meccanica (in conformità con EN388:2016)

Resistenza all'abrasione (cicli)	: x di 4
Resistenza al taglio da lama- coupe test (Indice)	: x di 5
Resistenza allo strappo (N)	: x di 4
<resistenza alla puntura (N)	: x di 4
Resistenza al taglio - ISO 13997:1999 (N)	: x

x= il guanto non è stato testato

### 7. Protezione chimica (in conformità con EN374-1:2016)

#### Risultati test permeazione EN 16523-1:2015)

#### Risultati test degradazione ( EN 374-4:2013)

Idrossido di sodio 40% (K)	: 1 of 6	-14.7%
Formaldeide 37% (T)	: 6 of 6	-29.2%

\*Queste informazioni non rispecchiano la reale durata della protezione nel singolo posto di lavoro ne la differenza tra Miscele e elementi chimici puri

### 8. EU Certificazione di esame

Riferimento certificato n. : Nr. 060/2019/1403 (Cat III/Type C \_Protezione VIRUS)

### 9. Manuale d'uso per

Riferimento documentazione n.: Vedi allegato

### 10. Marcatura

Non applicabile

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### 11. Packaging

a) Packing

- 100 pezzi in un dispenser box.
- 10 dispenser box in un cartone
- 1000 pieces in un cartone

b) Layout Dispenser box

- Summitech Professional

c) Dimensione dispenser box

- Lungh: 235 mm x Largh: 122 mm x Alt: 75 mm

d) Marcatura cartone

- Summitech Professional

e) Dimensioni cartone

- Lungh: 390 mm x Largh: 249 mm x Alt: 245 mm

f) Capacità container

- 1 x 20ft : Circa 1090 cartoni ( 1090 000 pezzi)
- 1 x 40ft : Circa 2180 cartoni ( 2180 000 pezzi)

**Controllato da:**



Dipartimento Ass. Qualità  
Date: April 18, 2020

**Approvato da :**



Direttore assicurazione qualità  
Date: April 18, 2020

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In application of the Regulation (EU) 2016/425 of 9 March 2016 concerning the harmonization of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorized by the FPS Economy (Federal Public Services) has issued the following:

### EU TYPE EXAMINATION CERTIFICATE

**Nr. 060/2019/1403**

**This EU Type examination certificate is valid until 21 Apr 2023**

to: **Sumirubber Malaysia Sdn. Bhd., Sungai Petani, Kedah, West Malaysia**  
for: **SUMMITTECH™ Professional Powder Free Latex Gloves R101-PF**

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Regulation (EU) 2016/425.

For the argumentation, the following standards are used:

EN 420:2003+A1:2009	Protective gloves - General requirements and test methods
EN ISO 374-1:2016	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risk

If there is a former EC Type examination certificate according to the Directive 89/686/EEC this certificate remains valid until 21 April 2023 unless it expires before that date, for products that were manufactured before the issuance of this new EU Type examination certificate according to the Regulation (EU) 2016/425.

This is PPE of category III, subject to regular checks in accordance with article 19 of the European PPE Regulation. In agreement with the manufacturer's choice audits of the production process shall be carried out to assess the Conformity of type (Module D). The manufacturer must be able, on request, to present the audit report. A first audit shall be performed at the latest on 31 Dec 2020 and at least be repeated with intervals of one year.

This declaration applies to the equipment as submitted in the type testing and described in the manufacturer's technical documentation (As described in 2016/425 Annex III) that is registered with number 10330\_4.

Issued by Centexbel, Notified Body 0493, in Ghent, on 13 Sep 2019  
(Originally issued by Centexbel, Notified Body 0493<sup>(7)</sup>, in Ghent, on 12 Mar 2018)

  
Inge De Witte  
Certification Manager

Attached: 1 Annex



**CENTEXBEL • TEXTILE COMPETENCE CENTRE**

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INRICHTING ERKENND BIJ TOESPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECOGNU PAR APPLICATION DE L'ARRÊTÉ-LOI DU 30 JANVIER 1947

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## ANNEX

EU TYPE EXAMINATION CERTIFICATE Nr. 060/2019/1403

### 1. Applicant

Sumirubber Malaysia Sdn. Bhd.  
Lot 44, 45 & 86, Bakar Arang Industrial Estate  
08000 Sungai Petani, Kedah, West Malaysia  
Malaysia

### 2. Description

EN ISO 374-1 / Type C



EN ISO 374-5



VIRUS

### 3. Materials and accessories

#### Gloves

- SUMMITECH™ Professional R101-PF



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#### 4. Technical documentation

##### Summary test results

EN 420:2003+A1:2009 Gloves **SUMMITECH™ Professional R101-PF**

Method	Description	Result	Class
EN 1413	pH - textile	PASS	
EN 14362-1	AZO dyes for colored gloves	/	/
EN 420 length	Length	PASS	
EN 420 dexterity	Dexterity	/	/
1149-1 / 1149-2 / 1149-3	Electrostatic properties	/	/

EN ISO 374-1:2016 Gloves **SUMMITECH™ Professional R101-PF**

Method	Description	Result	Class
EN 374-2	Penetration	PASS	
EN 16523-1	Permeation T	PASS	Level 6
EN 16523-1	Permeation B	PASS	Level 0
EN 16523-1	Permeation K	PASS	Level 1
EN 374-4	Degradation T	PASS	
EN 374-4	Degradation B	PASS	
EN 374-4	Degradation K	PASS	
Type of glove		PASS	Type C

EN ISO 374-5:2016 Gloves **SUMMITECH™ Professional R101-PF**

Method	Description	Result	Class
EN 374-2	Penetration	PASS	
ISO 16604 Proc. B	Protection against viruses	PASS	

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## Description/Picture of article

Article **SUMMITECH™ Professional Powder Free Latex Gloves R101-PF**



The above picture is a general picture of the article. Possible variations of the above article can be present in the technical file.

### Note :

Any modification in material, design, or other technical features must be brought to the attention of the Notified Body.

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INDICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWIJZING VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE LOI DU 30 JANVIER 1947

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<b>Data</b>	<b>: Aprile 18, 2020</b>		



Document No : UI-110  
Revision : 01

### PROTECTIVE GLOVES : R101-PF (Disposable Natural Latex Powder Free Gloves )

**CE 0598**

#### Instruction for Use

##### Use

These gloves are designed to protect user's hands against certain chemical. Testing and marking on the gloves are in accordance with Regulation (EU) 2016/425 as well as applicable CE Standards (EN420:2003 + A1:2009 & EN 374-1:2016). Please ensure the gloves are used strictly for the intended applications.

Glove Size	Ex Small	Small	Medium	Large	X Large
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#### EN ISO 374-5:2016 (Protection against Micro-organisms)



##### VIRUS

Gloves are sampled and tested for leakage (penetration test) in accordance to annex A of EN 374-2:2014 and the results at performance level 2, inspection level G1 and AQL = 1.5

#### EN ISO 374-1:2016 (Protective gloves against dangerous chemicals)

##### EN ISO 374-1:2016 / Type C



##### Low risk chemical

Acetone (B) : 0 of 6  
Sodium Hydroxide 40 % (K) : 1 of 6  
Formaldehyde 37% (T) : 6 of 6

##### Permeation performance level

BTT (min)	>10	>30	>60	>120	>240	>480
Level	1	2	3	4	5	6

Type C : Gloves have achieved at least level 1 against minimum of one test chemicals

#### EN374-4:2013 -Resistance to Degradation by chemicals

Acetone (B) : 105.4%  
Sodium Hydroxide 40 % (K) : -14.7%  
Formaldehyde 37% (T) : -29.2%

#### Caution

This information does not reflect the actual duration of protection in the workplace and the differentiation mixtures and pure chemicals. The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. When used, protective glove may provide less resistance to the dangerous chemical due to changes in physical properties. Movement, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. Before usage, inspect the glove for any defect or imperfections. Discard immediately gloves which have become worn out or damaged when used. Never wear gloves which are wet or dirty inside to avoid dermatitis. Do not wear gloves with high tear resistant next to moving machine parts due to risk of entanglement. Quality of used gloves may deteriorate after long storage. The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen. The levels of performance mentioned are only valid for the palm of the glove.

Isolated cases of allergic reactions to latex rubber or powder have been reported. If you experience a reaction to this product, discontinue use immediately and consult your physician

This product contains Natural Rubber Latex which may cause allergic reactions in some individuals. Other components used in making gloves may also cause allergic reactions in some users

#### Storage

Do not store Latex Examination Gloves where temperature may rise above 104°F (40°C). Store in cool, dry and well ventilated area. Opened boxes of Latex Examination Gloves should be shielded from exposure to direct sunlight or fluorescent lighting to prevent discoloration. Improper storage of Latex Examination Gloves will result in decreased shelf life and produce efficacy

#### Cleaning

Not applicable as the glove is disposable in nature

#### Disposal

Uncontaminated gloves may be disposed off with household waste. Used gloves which have been contaminated with hazardous chemicals must be disposed off with care in accordance with requirements of local authorities.

In case of doubt or need for clarification, please contact Sumirubber Malaysia Sdn. Bhd.

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Conformity Assessment by:-

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