

## PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST

### Nitrilové rukavice NITRIL<sup>SOFT</sup>

#### ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné rukavice
Materiál:	100% syntetický nitril
Barva:	tmavě modrá
Provedení:	pravolevé, hladké, korálková manžeta
Pudr:	není přidán
Skladování:	rukavice neztrácejí své vlastnosti při skladování v suchu při teplotě od 10 do 30 °C
Životnost:	5 let od data výroby při dodržení podmínek skladování
Balení:	100 ks v krabičce, 10 krabiček v kartonu

#### ČÁST II: SPECIFIKACE PRODUKTU

Délka (mm):	min. 240
Šířka (mm):	XS – 76 ± 3 S – 84 ± 3 M – 94 ± 3 L – 105 ± 3 XL – 113 ± 3
Tloušťka (mm):	prsty: 0.09 ± 0.02 (typická hodnota 0.08 – 0.09) dlaň: 0.07 ± 0.02 (typická hodnota 0.05 – 0.06)
Prodloužení do přetržení (%):	min. 500
Pevnost v tahu (MPa):	min. 6
AQL:	1.5



### ČÁST III: NORMY A NAŘÍZENÍ

Tímto potvrzujeme, že výše uvedený výrobek je v souladu s:

Obecné: PPER (EU) 2016/425 Cat. I  
EN 420

Potravinářství: EC 1935/2004  
EC 2023/2006

### ČÁST IV: POLOŽKY

Pol. č.	Velikost	Hmotnost (g)	Rozměry (mm)	Kvalita (g)	EAN
100060	S	340	200×110×60	2.7 ± 0.2	8594177200575
100061	M	360	200×110×60	3.0 ± 0.2	8594177200582
100062	L	388	200×110×60	3.3 ± 0.2	8594177200599

### ČÁST V: NÁHLED PRODUKTU



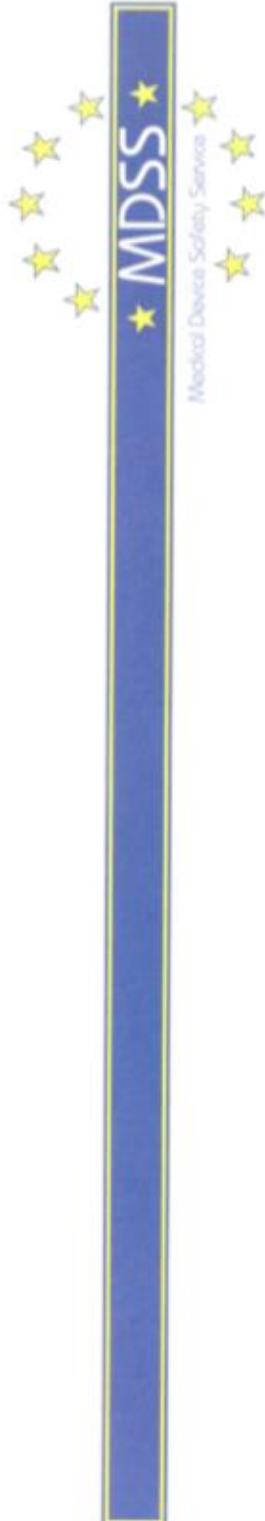
### ČÁST VI: PŮVOD PRODUKTU

Výrobce:

Top Glove Sdn Bhd, No 16, Persiaran Setia Dagang, Setia Alam, Seksyen U13, 40170 Shah Alam, Selangor, Malaysia

Distributor:

Espeon s.r.o., U větrolamu 1212/53, 184 00 Praha 8, [info@espeon.cz](mailto:info@espeon.cz), [www.espeon.cz](http://www.espeon.cz)



## Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

**Sri Trang Gloves (Thailand) Public Company Limited**  
10 Soi 10, Phetkasem Road, Hat Yai  
Songkhla 90110  
Thailand

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

**Annex A dated June 22, 2020**

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2020-06-22



Dr. Philipp Hohenbrink  
Senior Consultant  
MDSS GmbH



**Annex A dated June 22, 2020**  
**Manufacturer: Sri Trang Gloves (Thailand) Public Company Limited**

UMDNS Code Description Notified Medical Device Product Name & Catalogue Number	UMDNS Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD
Gloves, Examination/Treatment	11-882	I	10	DE/CA09/0170/S40/001-02	N.A	N.A
Latex Powdered Gloves, Non Sterile; Latex Powder Free Gloves, Non Sterile; Nitrile Powder Free Gloves, Non Sterile						
Latex Powdered Gloves, Non Sterile: LX01, NP02						
Latex Powder Free Gloves, Non Sterile (Offline Chlorination): LC01						
Latex Powder Free Gloves, Non Sterile (Online Chlorination): LO01						
Nitrile Powder Free Gloves, Non Sterile (Offline Chlorination): NC01, NCO2						
Nitrile Powder Free Gloves, Non Sterile (Online Chlorination): NO01, NO02, NO03, NO04						
Gloves, Examination/Treatment	11-882	Is	10	DE/CA09/0170/S40/002-02	0123/G2S0991880008	2022-12-12
Latex Powder Free Offline Chlorination Gloves, Sterile; Nitrile Powder Free Online Chlorination Gloves, Sterile; Latex Powdered Gloves, Sterile						
Latex Powder Free Offline Chlorination Gloves, Sterile						
Nitrile Powder Free Online Chlorination Gloves, Sterile						
Latex Powdered Gloves, Sterile						

*Handwritten signature*





## PPE REGULATION (EU) 2016/425 MODULE D CERTIFICATE

This is to certify that:

*Sri Trang Gloves (Thailand) Public Company Limited*

110, 109/2, 352 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand  
189 Moo 7, Phlai Wat Kanchanadit, Surat Thani 84160 Thailand  
85 Moo 6, KhuanThani Kantang, Trang 92110 Thailand

Has been found to conform to the requirements of Annex VIII (Module D) of the PPE Regulation (EU) 2016/425 – Conformity to type based on quality assurance of the production process, for the Manufacturing and distribution of Latex Powdered, Latex Powder Free and Nitrile Powder Free Non-Sterile Gloves as described in the listed EU type examination certificates.

2777/10466-04/E00-00	2777/10470-05/E00-00
2777/10467-04/E00-00	2777/10471-04/E00-00
2777/10468-04/E00-00	2777/10474-05/E00-00
2777/10469-04/E00-00	2777/14071-01/E00-00
2777/14362-01/E00-00	2777/14364-01/E00-00

Dated: 22<sup>nd</sup> June 2020

This certificate is valid until: May 2021



For and on behalf of SATRA Technology  
Europe Limited



*The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard which will be monitored by:*

SATRA Technology Europe Limited, Bracetown Business Park Clonree Dublin 15 D15 YN2P Ireland  
(Notified Body number 2777)

Tel: +353 (0) 1 437 2494 Web: [www.satrapeurope.com](http://www.satrapeurope.com)



# CERTIFICATE

The HACCP Management System  
of

**SRI TRANG GLOVES (THAILAND)  
PUBLIC COMPANY LIMITED**  
85 Moo 6, Khuan Thani, Kantang  
92110 Trang  
Thailand

has been assessed and complies with the requirements of

## TÜV MS Standard HACCP

Certification scheme for HACCP Management Systems which implements requirements of DIN EN 15593:2008 Packaging – management of hygiene in the production of packaging for foodstuffs and Codex Alimentarius: Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its implementation and General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4 - 2003).

This certificate is applicable for:

**Manufacture of natural rubber gloves  
as food contact material.**

This certificate is provided on the base of the  
TÜV MS Standard HACCP.

The certification system consists of a minimum annual audit of the HACCP management system and a minimum annual site inspection.

The certificate is valid from **2019-05-22** until **2020-10-16**.

Certificate Registration No.: **12 500 54708 TMS**.



Product Compliance Management  
Munich, 2019-05-22



**bsi.**



# Certificate of Registration

FOOD SAFETY MANAGEMENT SYSTEM - ISO 22000: 2005

This is to certify that:

SRI TRANG GLOVES (THAILAND)  
PUBLIC COMPANY LIMITED  
110 Kanjanavanit Road,  
Pahtong, Hat Yai,  
Songkhla  
90230  
Thailand

Holds Certificate Number:

**FSMS 731225**

and operates a Food Safety Management System which complies with the requirements of ISO 22000: 2005 for the following scope:

Category I  
As detailed in the accompanying Scope of Certification;  
Production of natural latex and nitrile gloves for food contact.

For and on behalf of BSI:

  
Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 2019-05-16

Latest Revision Date: 2020-06-08

Effective Date: 2020-06-08

Expiry Date: 2021-06-18

Page: 1 of 2



...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +66(2) 2944889-92.

Further clarifications regarding the scope of this certificate and the applicability of ISO 22000: 2005 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate No: **FSMS 731225**

Location	Registered Activities
SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED 110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand	Production of natural latex and nitrile gloves for food contact.
SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED 109/2 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand	Production of natural latex and nitrile gloves for food contact.
SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED 352 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand	Production of natural latex and nitrile gloves for food contact.
SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED 189, Moo 7, Phlai Wat, Kanchanadit, Surat Thani 84160 Thailand	Production of natural latex and nitrile gloves for food contact.

Original Registration Date: 2019-05-16  
Latest Revision Date: 2020-06-08

Effective Date: 2020-06-08  
Expiry Date: 2021-06-18

Page: 2 of 2

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE



# CERTIFICATE

No. QS5 099188 0010 Rev. 00

**Certificate Holder:**  
Sri Trang Gloves (Thailand)  
Public Company Limited  
10 Soi 10, Phetkasem Road  
Hat Yai, Songkhla 90110  
THAILAND

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves

**Standard(s):** ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

**Report No.:** MYQMH0119069Rev1-721421976

**Effective Date:** 2019-04-10

**Expiry Date:** 2022-04-09

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**Date of Issue:** 2019-04-18

( Arie Henkin )  
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com



# CERTIFICATE

No. QS5 099188 0010 Rev. 00

- |                         |  |
|-------------------------|--|
| <b>Facility(ies):</b>   | <b>Sri Trang Gloves (Thailand) Public Company Limited</b><br>10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110, THAILAND        |
| <b>Facility Scopes:</b> | Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves                                |
| <b>Facility(ies):</b>   | <b>Sri Trang Gloves (Thailand) Public Company Limited</b><br>110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla, 90230 THAILAND   |
| <b>Facility Scopes:</b> | Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves                                |
| <b>Facility(ies):</b>   | <b>Sri Trang Gloves (Thailand) Public Company Limited</b><br>109/2 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla, 90230 THAILAND |
| <b>Facility Scopes:</b> | Production and Distribution of Sterile and Non-Sterile Examination Gloves  |
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| <b>Facility Scopes:</b> | Production and Distribution of Sterile and Non-Sterile Examination Gloves  |
| <b>Facility(ies):</b>   | <b>Sri Trang Gloves (Thailand) Public Company Limited</b><br>85 Moo 6, Khuan Thani, Kantang, Trang 92110, THAILAND               |
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Date of issue: 2019-04-18

( Arie Henkin )  
Manager, Certification Body MHS

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