

PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST

Latexové rukavice LATEX^{FIT}

ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné rukavice
Materiál:	přírodní latex s vysokým stupněm kvality
Barva:	přírodní bílá
Provedení:	pravolevé, hladké, korálková manžeta
Pudr:	uvnitř rukavice vstřebatelný kukuřičný škrob USPXX1
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 – 80 ± 10 M – 95 ± 10 L – 110 ± 10 XL – 115 ± 10
Tloušťka (mm):	prsty: 0.11 ± 0.02 (typická hodnota 0.09 – 0.11) dlaň: 0.10 ± 0.02 (typická hodnota 0.08 – 0.10)
Prodloužení do přetržení (%):	min. 650 (typická hodnota 650 – 750)
Pevnost v tahu (MPa):	min. 18 (typická hodnota 18 -22)
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
EU 10/2011 * Vyhovuje pro všechny simulanty kromě 3% kyseliny octové. Tento produkt je vhodný pro manipulaci s potravinami, kromě kyselých potravin (testováno 2 hodiny při 40 ° C)

ČÁST IV: POLOŽKY

Pol. č.	Velikost	Hmotnost (g)	Rozměry (mm)	Kvalita (g)	EAN
100003	S	520	200x120x70	4.5 ± 0.2	8594177200056
100004	M	565	200x120x70	5.0 ± 0.2	8594177200063
100005	L	619	200x120x70	5.5 ± 0.2	8594177200070
100010	XL	651	200x120x70	6.0 ± 0.2	8594177200087

ČÁST V: NÁHLED PRODUKTU



ČÁST VI: PŮVOD PRODUKTU

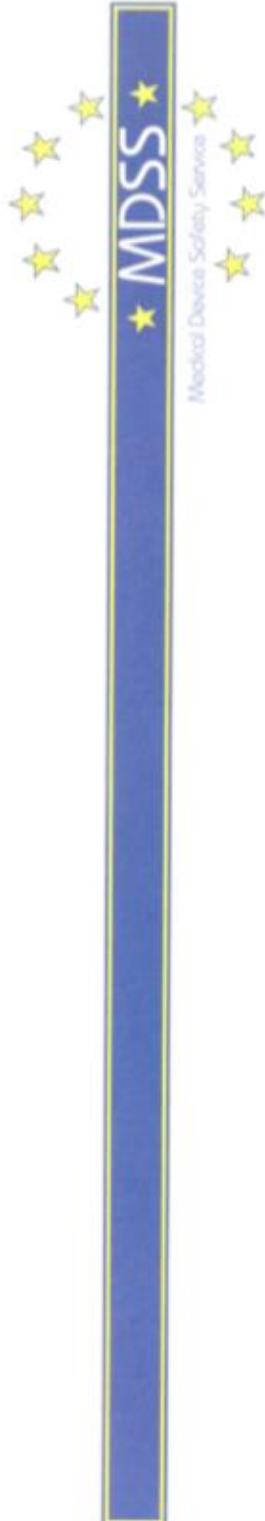
Výrobce:

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

SRI TRANG GLOVES , 57 Wireless Road, Bangkok 10330, Thailand

Distributor:

Espeon s.r.o., U větrolamu 1212/53, 184 00 Praha 8, info@espeon.cz , 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: 22nd 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



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 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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A Member of the BSI Group of Companies.



CERTIFICATE

No. QS5 099188 0010 Rev. 00

- | | |
|-------------------------|--|
| Facility(ies): | Sri Trang Gloves (Thailand) Public Company Limited
10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110, THAILAND |
| Facility Scopes: | Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves |
| Facility(ies): | Sri Trang Gloves (Thailand) Public Company Limited
110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla, 90230 THAILAND |
| Facility Scopes: | Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves |
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85 Moo 6, Khuan Thani, Kantang, Trang 92110, THAILAND |
| Facility Scopes: | Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves |

Page 2 of 2
Date of issue: 2019-04-18

(Arie Henkin)
Manager, Certification Body MHS