PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST
Latexové rukavice LATEX STANDARD

ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné rukavice
Materiál:	přírodní latex s vysokým stupněm kvality
Barva:	přírodní bílá
Provedení:	pravolevé, zdrsněné konečky prstů, 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: 0.11 ± 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 -20)
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
100071	XS	480	200x120x70	4.0 ± 0.2	8594177200681
100072	S	520	200x120x70	4.5 ± 0.2	8594177200698
100073	M	565	200x120x70	5.0 ± 0.2	8594177200704
100074	L	619	200x120x70	5.4 ± 0.2	8594177200711
100075	XL	651	200x120x70	6.0 ± 0.2	8594177200728

ČÁST V: NÁHLED PRODUKTU

ČÁST VI: PŮVOD PRODUKTU

Výrobce:
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*						

Certificate of Verification

MDSS GmbH hereby declares

that an Authorized Representative's Mandate according to the

EU Regulation 2017/745 (MDR) is in place and that the following tasks have been carried out

in accordance with the requirements of the MDR on behalf of the Manufacturer:

Sri Trang Gloves (Thailand) Public Company Limited

10 Soi 10, Phetkasem Road

90110 Hat Yai Songkhla

THAILAND

MDSS verified that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS keeps available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

MDSS complied with the registration obligations laid down in Article 123.3(d) and until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and/or 93/42/EEC have been applied.

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2024-01-15
(YYYY-MM-DD)

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 740659

This certificate is subject to the following terms and conditions:
It is only valid for the device(s) listed hereafter;
It is not a proof for compliance to CE marking;
The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;
As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Art. 10.16 of the MDR are fulfilled.
This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or NB Certificate if applicable, whichever comes first.

Technical File	Generic Device Description/ Trade Name	GMDN or EMDN Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD	BfArM Registration Number*
TF-MD-LF-01-101 rev. 11	Latex Examination Gloves, Powder Free, Polymer Coated, Non-Sterile LC01	47172	I	EU Declaration of Conformity (LC01) Signed 5 January 2024	N.A.	N.A.	DE/CA09/00180939
TF-MD-LF-01-103 rev. 01	Latex Examination Gloves, Powder Free, Polymer Coated, Non-Sterile LC02	47172	I	EU Declaration of Conformity (LC02) Signed 03 January 2023	N.A.	N.A.	DE/CA09/00180939
TF-MD-LF-01-102 rev. 10	Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile LO01	47172	I	EU Declaration of Conformity (LO01) Signed 5 January 2024	N.A.	N.A.	DE/CA09/00180939
TF-MD-LP-01-101 rev. 09	Latex Examination Gloves, Powdered, Non-Sterile LX01	47173	I	EU Declaration of Conformity (LX01) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180943
TF-MD-NF-01-101 rev. 09	Nitrile Examination Gloves, Powder Free, Polymer Coated, Non-Sterile NC01	56286	I	EU Declaration of Conformity (NC01) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180945

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Downloaded by Espeon s.r.o., Martin Kames on date 30 May 2024

TF-MD-NF-01-102 rev. 09	Nitrile Examination Gloves, Powder Free, Polymer Coated, Accelerator Free, Non-Sterile NC02	56286	I	EU Declaration of Conformity (NC02) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180945
TF-MD-NF-01-103 rev. 10	Nitrile Examination Gloves, Powder Free, Chlorinated, Non-Sterile NO01	56286	I	EU Declaration of Conformity (NO01) Signed 5 January 2024	N.A.	N.A.	DE/CA09/00180945
TF-MD-NF-01-104 rev. 09	Nitrile Examination Gloves, Powder Free, Chlorinated, Non-Sterile NO02	56286	I	EU Declaration of Conformity (NO02) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180945
TF-MD-NF-01-105 rev. 09	Nitrile Examination Gloves, Powder Free, Chlorinated, Accelerator Free, Non-Sterile NO03	56286	I	EU Declaration of Conformity (NO03) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180945
TF-MD-NF-01-106 rev. 09	Nitrile Examination Gloves, Powder Free, Chlorinated, Non-Sterile NO04	56286	I	EU Declaration of Conformity (NO04) Signed 12 August 2022	N.A.	N.A.	DE/CA09/00180945

*The registration number has been issued by the German Competent Authority.

MODULE D CERTIFICATE

Issued To **Certificate 1 of 1**

Sri Trang Gloves (Thailand) Public Company Limited
110, 109/2, 352 and 110/3 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla, 90230, Thailand
207/1, Padang Besa Road, Sadao, Sadao, Songkhla, 90120, Thailand
88/8, Moo 3, Samnak Kham, Sadao, Songkhla, 90320, Thailand
85 Moo 6, KhuanThani, Kantang, Trang, 92110, Thailand
189 Moo 7, Phlai Wat, Kanchanadit, Surat Thani, 84160, Thailand
110/19 Ban Khao Mai Deang, Moo 7, Phlai Wat, Kanchanadit, Surat Thani, 84160, Thailand
88/8, Moo 11, Khao Chai Rat, Pathio, Chumphon, 86210, 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 manufacture and distribution of Latex and Nitrile Disposable Gloves.

Standards	Module B Certificates*		
EN ISO 374-1: 2016 +A1: 2018	2777/10466-XX/E00-00	2777/10474-XX/E00-00	2777/16141-XX/E00-00
EN ISO 374-2: 2019	2777/10467-XX/E00-00	2777/14071-XX/E00-00	2777/16142-XX/E00-00
EN ISO 374-4: 2019	2777/10468-XX/E00-00	2777/14362-XX/E00-00	2777/24437-XX/E00-00
EN ISO 374-5: 2016	2777/10469-XX/E00-00	2777/14364-XX/E00-00	
EN ISO 21420: 2020	2777/10470-XX/E00-00	2777/15155-XX/E00-00	

* Where 'XX' denotes the Module B certificate issue number

Date Issued 22/09/2023 **Valid Until** 29/09/2024
SATRA Reference STE0349789/R4

Signed on behalf of SATRA Technology Europe Ltd – Notified Body Number: 2777

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 Clonee Dublin 15 D15 YN2P Ireland - Tel: +353 (0) 1 437 2484 Web: www.satra.com

ESPEON

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 099188 0012 Rev. 01

Holder of Certificate: **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 and Sterile and Non-Sterile Surgical Gloves**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 099188 0012 Rev. 01

Report No.: 5675207Rev1-721430483

Valid from: 2023-11-01
Valid until: 2026-10-31

Date, 2023-10-06

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®