PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST
Nitrilové rukavice NITRIL IDEAL

ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné rukavice
Materiál:	100% syntetický nitril
Barva:	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. 220 (XS, S), min. 230 (M, L, XL)
Šířka (mm):	XS – 70 ± 10 S – 80 ± 10 M – 95 ± 10 L – 110 ± 10 XL – 120 ± 10
Tloušťka (mm):	prsty: 0.09 ± 0.02 (typická hodnota 0.08 – 0.09) dlaň: 0.07 ± 0.02 (typická hodnota 0.06 – 0.07)
Prodloužení do přetržení (%):	min. 500
Pevnost v tahu (MPa):	min. 14
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
100076	S	340	200×110×60	3.2 ± 0.2	8594177200094
100077	M	371	200×110×60	3.5 ± 0.2	8594177200100
100078	L	402	200×110×60	3.8 ± 0.2	8594177200117
100079	XL	491	200×110×60	4.1 ± 0.2	8594177200124

ČÁST V: NÁHLED PRODUKTU

ČÁST VI: PŮVOD PRODUKTU

Výrobce:

SRI TRANG GLOVES , 57 Wireless Road, Bangkok 10330, Thailand
INTCO Medical Technology Co., Ltd, No. 29 Zhangliu Road, Zibo, Shandong, China

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.

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.

This document and its contents are confidential of Sri Trang Gloves (Thailand) Public Company Limited only. Do not copy, discuss with or give to people not designated.

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®

Document Number ：INTCO-CE-DC-NBR-002 Version: A/0

EU DECLARATION OF CONFORMITY

Manufacturer	Authorized Representative
Name: **Shandong Intco Medical Products Co., Ltd.**	*Name:* **Lotus NL B.V.**
Address: Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China	*Address:* **Koningin Julianaplein 10, 1e Verd, 2595AA， The Hague，Netherlands**

Declares that the MDR described hereafter

Product name and model:

Disposable Nitrile Exam Gloves / SYNGUARD® Nitrile Exam Gloves

EMDN code：T01020204

Model: XS /S /M /L /XL/XXL

Product Code: NGV/B/H/PEM; SNV/B/H/PE (Please refer to the attachment for more details.).

Basic UDI-DI: 697024575Nitrile7G

SRN: CN-MF-000002100

This Declaration of Conformity is issued under the sole responsibility of the manufacturer: Shandong Intco Medical Products Co., Ltd.

Conformity Assessment Route： Annex II and Annex III according to EU 2017/745.

Applicable Standard:

EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016;

EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009;

ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-11:2017.

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them, The medical device has been assigned to Class I, based on rule 1 & rule 5 of Annex VIII Chapter III of the Regulation EU 2017/745 MDR. It bears the mark

CE

We agree to develop, implement and maintain a documented post-production monitoring process.

Shandong 2021-07-22

Place , date

Rick Cheng Quality Manager

Legally binding signature, function

Test Report No.: 721664284
Report Date: 9 June 2021

SUBJECT	**Chemical Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Shandong Intco Medical Products Co., Ltd**
CLIENT ADDRESS	No.9888 Qiwang Road, Naoshan Industry Park, Qingzhou, Shandong, China
TEST PERIOD	31-May-2021~07-Jun-2021

RESULT SUMMARY

1. The tested items **complied with** German Food & Feed Acts of September 1, 2005 (LFGB), Section 30 and 31.
   - Overall migration test **PASS**
   - Color release **PASS**
   - Extractable formaldehyde **PASS**
   - Total lead and zinc content **PASS**
   - Sensory test **PASS**
2. The tested items **complied with** AfPS GS 2019: 01 PAK
   - Polycyclic Aromatic Hydrocarbons (PAHs) content(Category 1) **PASS**
3. As per client's request
   - Total Cadmium content **PASS**

Prepared By

Nance Gao

(Nance Gao)
Report Drafter

Authorized By

Leo Liu

(Leo Liu)
Authorized Signatory

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai
201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Test Report No.: 721664284
Report Date: 9 June 2021

RECEIPT DATE / TEST DATE

31-May-2021/ 31-May-2021

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENTS AS

Sample Name: Disposable Nitrile Gloves
Sample Specification: /
Batch No./Date: /
Manufactory: Shandong Intco Medical Products Co., Ltd

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721664284	Blue glove	

TEST RESULT(S)

Note: The migration results in this report were tested and expressed based on single use articles.

1. Overall Migration Test
   - In accordance with BFR Recommendations XXI
   - Test method: With reference to EN 1186: Part 4(Test methods for overall migration into olive oil by cell), EN 1186: Part 5 (Test methods for overall migration into aqueous food stimulants by cell) and BFR Recommendations XXI
   - Migration ratio (S/V): 10dm²/L

Simulant(s) Used	Test Condition	Result(s) [mg/dm²]	Maximum Permissible Limit [mg/dm²]
3% Acetic acid	40°C for 0.5 hours	3.15	10
10% Ethanol	40°C for 2 hours	0.950	10
Olive oil	40°C for 2 hours	<0.500	10

2. Color release
   - Test method: With reference to Kunststoffe im Lebensmittelverkehr Book II, Teil B II, IX

Simulant(s) Used	Test Condition	Result(s)	Permissible Limit
10% Ethanol	50 ℃ for 5 hours	No bleeding	No bleeding
2% Acitic acid	50 ℃ for 5 hours	No bleeding	No bleeding
Peanut oil	50 ℃ for 5 hours	No bleeding	No bleeding
Water	50 ℃ for 5 hours	No bleeding	No bleeding

Note: 1. No bleeding denotes no difference was found between blank and sample
2. Bleeding denotes staining was found from sample

Chemical/Microbiology Laboratory:
TÜV SÜD Products Testing (Shanghai) Co., Ltd
B-3/4, No.1999 Du Hui Road, Minhang District
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201108
P.R. China

Phone : +86 (21) 6037 6375
Fax : +86 (21) 6037 6345
Email: food.chem@tuv-sud.cn
Webpage: www.tuv-sud.cn

Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

3. Extractable formaldehyde
   - Test method: For compliance with the Recommendation of the BfR "Kunststoffe im Lebensmittelverkehr" Part XXI. Commodities based on Natural and Synthetic Rubber
   - With reference to Section 2.7.1 of methods for the "Testing of commodities made of rubber"
   - Test condition: 3% Acetic acid, 40°C for 0.5 hours
   - Migration ratio (S/V): 6dm²/L

Test Item(s)	Result(s) [µg/ml]	Maximum Permissible Limit [µg/ml]
Extractable Formaldehyde	<0.5	3

4. Total lead and zinc content
   - Test method: Acid digestion, then followed by ICP-OES

Test Item(s)	Result(s) [%]	Maximum Permissible Limit [%]
Lead content	<0.001	0.003
Zinc content	0.250	3.0

5. Sensory test
   - Test method: With reference to DIN 10955.
   - The submitted sample was simulated in distilled water at 40°C for 2 hours. After this treatment treated water was examined by panels with regard to any divergence in smell and taste.

Sample(s)	Testing Parameter	Grading result(s)	Recommended level
721664284	Transfer of taste	0	<3
	Transfer of smell	0	<3

Note: 1. Available grading are listed as follow:

Grading 0: No perceptible taste/smell deviation
1: Just perceptible taste/smell deviation
2: Weak taste/smell deviation
3: Clear taste/smell deviation
4: Strong taste/smell deviation

6. Polycyclic Aromatic Hydrocarbons (PAHs) content
   - Test method: In accordance with AfPS GS 2019: 01 PAK

Compounds	Results [mg/kg]	Detection Limit [mg/kg]
Chrysene	ND	0.01
Benzo[a]anthracene	ND	0.01
Benzo[b]fluoranthene	ND	0.01
Benzo[j]fluoranthene	ND	0.01
Benzo[k]fluoranthene	ND	0.01
Benzo[e]pyrene	ND	0.01
Benzo[a]pyrene	ND	0.01
Indeno[1,2,3-cd]pyrene	ND	0.01
Dibenzo[ah]anthracene	ND	0.01
Benzo[ghi]perylene	ND	0.01
Naphthalene	0.0585	0.01
Phenanthrene	0.0619	0.01

Anthracene	ND	0.01
Fluoranthene	0.0109	0.01
Pyrene	0.0321	0.01
Sum of Phenanthrene, Pyrene, Anthracene and Fluoranthene	0.105	--
Group PAH	0.163	--
Category as in AfPS GS 2019: 01 PAK	**Category 1**	--

Note: 1. ND denotes not detected, less than Reporting Limit

Limits and Categories for PAH in product according to AfPS GS 2019: 01 PAK

Limits and Categories

Parameter [mg/kg]	**Category 1**	**Category 2**		**Category 3**	
	Materials indented to be put in the mouth, or materials of toys from 2009/48/EC for children aged < 3 years with intended skin contact (contact >30s)	Materials not covered by category 1, with foreseeable skin contact for longer than 30 s (long-term skin contact) or repeated short term skin contact*		Materials not covered by category 1 or 2 with foreseeable skin contact up to 30 s (short term skin contact)	
		Products for use by children aged < 14 years (active or passive direct contact)	All other products acc to ProdSG	Products for use by children aged < 14 years (active or passive direct contact)	All other products acc to ProdSG
Benzo[a]pyrene	<0.2	<0.2	<0.5	<0.5	<1
Benzo[e]pyrene	<0.2	<0.2	<0.5	<0.5	<1
Benzo[a]anthracene	<0.2	<0.2	<0.5	<0.5	<1
Benzo[b]fluoranthene	<0.2	<0.2	<0.5	<0.5	<1
Benzo[j]fluoranthene	<0.2	<0.2	<0.5	<0.5	<1
Benzo[k]fluoranthene	<0.2	<0.2	<0.5	<0.5	<1
Chrysene	<0.2	<0.2	<0.5	<0.5	<1
Dibenzo[a,h]anthracene	<0.2	<0.2	<0.5	<0.5	<1
Benzo[ghi]perylene	<0.2	<0.2	<0.5	<0.5	<1
Indeno[1,2,3-cd]pyrene	<0.2	<0.2	<0.5	<0.5	<1
Phenanthrene, Anthracene, Fluoranthene and Pyrene	**<1 sum**	**<5 sum**	**<10 sum**	**<20 sum**	**<50 Sum**
Naphthalene	**<1**	**<2**		**<10**	
Sum 15 PAH	**<1**	**<5**	**<10**	**<20**	**<50**

* Definition "short-term repetitive contact with the human skin" from REACH Annex XVII No. 50 amendment (COMMISSION REGULATION (EU) No 1272/2013)

7. Total Cadmium content

- Test method: Sample digested, analysed by ICP-MS

Test Item(s)	Result(s) [mg/kg]	Maximum Permissible Limit* [mg/kg]
Total Cadmium Content	<2	2

Note: 1. * denotes Maximum Permissible Limit was provided by client

Note: This report is for internal use only such as internal scientific research ,education, quality control, product R&D

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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