

PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST

Nitrilové rukavice NITRIL IDEAL

ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné rukavice
Materiál:	100% syntetický nitril
Barva:	magenta
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 ISO 21420

Zdravotnictví: MDR(EU) 2017/745
Zdravotnictví: EN455

Potravinářství: EC 1935/2004
EC 2023/2006
EU 10/2011

ČÁST IV: POLOŽKY

Pol. č.	Velikost	Hmotnost (g)	Rozměry (mm)	Kvalita (g)	EAN
100195	XS	310	200×110×60	2.9 ± 0.2	6974844471897
100196	S	350	200×110×60	3.2 ± 0.2	6974844471903
100197	M	383	200×110×60	3.5 ± 0.2	6974844471910

ČÁST V: NÁHLED PRODUKTU



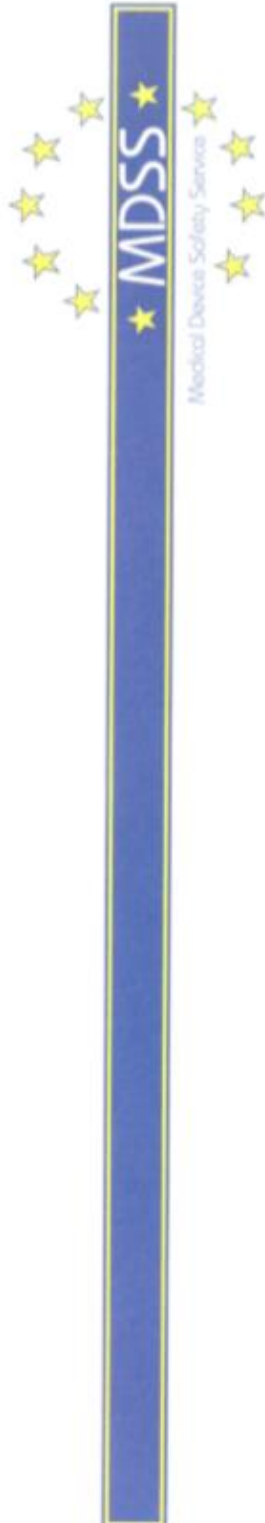
ČÁST VI: PŮVOD PRODUKTU

Výrobce:

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						
<i>Latex Powdered Gloves, Non Sterile: LX01, NP02</i>						
<i>Latex Powder Free Gloves, Non Sterile (Offline Chlorination): LC01</i>						
<i>Latex Powder Free Gloves, Non Sterile (Online Chlorination): LO01</i>						
<i>Nitrile Powder Free Gloves, Non Sterile (Offline Chlorination): NC01, NC02</i>						
<i>Nitrile Powder Free Gloves, Non Sterile (Online Chlorination): NO01, NO02, NO03, NO04</i>						
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						
<i>Latex Powder Free Offline Chlorination Gloves, Sterile</i>						
<i>Nitrile Powder Free Online Chlorination Gloves, Sterile</i>						
<i>Latex Powdered Gloves, Sterile</i>						

Hand



	山东英科医疗制品有限公司 Shandong Intco Medical Products Co., Ltd.	文件编号 Doc No. INTCO-PPE-NBR
		版 本 Ver. A3

EU Declaration of Conformity

We declare that the following product is carried out in accordance with Regulation (EU) 2016/425.

1. PPE: Disposable Nitrile Gloves

Glove sizes available: XS, S, M, L, XL, XXL (6, 7, 8, 9, 10, 11)

Product code :Blue:NGV/B/H/PEM(10013~10017), Violet:NGV/B/H/PEM(10033~10037),

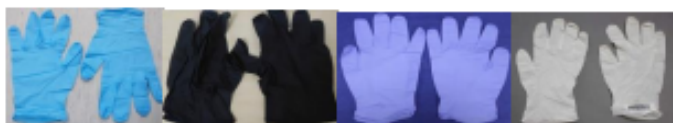
White: NGV/B/H/PEM(10023~10027),Black: NGV/B/H/PEM(10043~10047).

2. Manufacturer Name: Shandong Intco Medical Products Co., Ltd.

Address: No.9888,Qiawang Road, Naoshan Industrial Park. Qingzhou, Shandong, China

3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Shandong Intco Medical Products Co., Ltd.

4. Object of the declaration: Disposable Nitrile Gloves



5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: Regulation (EU)2016/425.

6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared: EN ISO 21420:2020, EN ISO 374-1:2016 +A1:2018, EN374-4:2019, EN ISO 374-5:2016.

7. The notified body SATRA Technology Europe Ltd (Number: 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate.

8. The PPE is subject to the conformity assessment procedure Module C2 under surveillance of the notified body : SATRA Technology (Number: 2777),

Adress: Bracetown Business Park Clonee, D15 YN2P, Ireland.

Signed for and on behalf of: Shandong Intco Medical Products Co., Ltd.

签名 Singnature 程建

职位 Position Quality Manager

日期 Date 11-Sep-2020



Document Number : INTCO-CE-DC-NBR-002

Version: A/0

EU DECLARATION OF CONFORMITY

Manufacturer

Name: Shandong Intco Medical Products Co., Ltd.
Address: Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China

Authorized Representative

Name: Lotus NL B.V.
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



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



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 Qiwan Road, Naoshan Industry Park, Qingzhou, Shandong, China
TEST PERIOD	31-May-2021-07-Jun-2021
RESULT SUMMARY	<p>1. The tested items complied with German Food & Feed Acts of September 1, 2005 (LFGB), Section 30 and 31.</p> <ul style="list-style-type: none"> - Overall migration test PASS - Color release PASS - Extractable formaldehyde PASS - Total lead and zinc content PASS - Sensory test PASS <p>2. The tested items complied with AFPS GS 2019: 01 PAK</p> <ul style="list-style-type: none"> - Polycyclic Aromatic Hydrocarbons (PAHs) content(Category 1) PASS <p>3. As per client's request</p> <ul style="list-style-type: none"> - Total Cadmium content PASS

Prepared By

Nance Gao

(Nance Gao)
Report Drafter

Authorized By

Leo Li

(Leo Li)
Authorized Signatory



Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested. (3) The test report shall not be reproduced except in full without the written approval of the laboratory. (4) Without the agreement of the laboratory, the client is not authorized to use the test results for unapproved propaganda.

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

TUV[®]

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: /
Manufacture: 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/dm ²]	Maximum Permissible Limit [mg/dm ²]
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 °C for 5 hours	No bleeding	No bleeding
2% Acetic acid	50 °C for 5 hours	No bleeding	No bleeding
Peanut oil	50 °C for 5 hours	No bleeding	No bleeding
Water	50 °C 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

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): 6dm ³L

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 intended 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	<0.2	<0.5	<0.5	<1
Benzo[e]pyrene	<0.2	<0.2	<0.2	<0.5	<0.5	<1
Benzo[a]anthracene	<0.2	<0.2	<0.2	<0.5	<0.5	<1
Benzo[b]fluoranthene	<0.2	<0.2	<0.2	<0.5	<0.5	<1
Benzo[k]fluoranthene	<0.2	<0.2	<0.2	<0.5	<0.5	<1
Chrysene	<0.2	<0.2	<0.2	<0.5	<0.5	<1
Dibenzo[a,h]anthracene	<0.2	<0.2	<0.2	<0.5	<0.5	<1
Benzo[ghi]perylene	<0.2	<0.2	<0.2	<0.5	<0.5	<1
Indeno[1,2,3-cd]pyrene	<0.2	<0.2	<0.2	<0.5	<0.5	<1
Phenanthrene, Anthracene, Fluoranthene and Pyrene	<1 sum	<5 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

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



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-



SMALL CO