PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST
Nitrilové rukavice NITRIL IDEAL

ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné rukavice
Materiál:	100% syntetický nitril
Barva:	světle 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
100138	S	340	200×110×60	3.2 ± 0.3	8594177201350
100139	M	371	200×110×60	3.5 ± 0.3	8594177201367
100140	L	402	200×110×60	3.8 ± 0.3	8594177201374
100141	XL	491	200×110×60	4.1 ± 0.3	8594177201381

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

INTCO 英科医疗	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,Qiwang 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 _____

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

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:
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Phone : +86 (21) 6037 6375
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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

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

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

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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-

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