

PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST

Nitrilové rukavice NITRIL ^{SOFT/DEAL}

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: 0.07 ± 0.02 (typická hodnota 0.07 – 0.08) dlaň: 0.06 ± 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 | 311 | 200×110×60 | 2.7 ± 0.3 | 8594177201350 |
| 100139 | M | 341 | 200×110×60 | 3.0 ± 0.3 | 8594177201367 |
| 100140 | L | 372 | 200×110×60 | 3.3 ± 0.3 | 8594177201374 |
| 100141 | XL | 403 | 200×110×60 | 3.6 ± 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

| | | |
|---|--|----------------------------|
|  | 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),

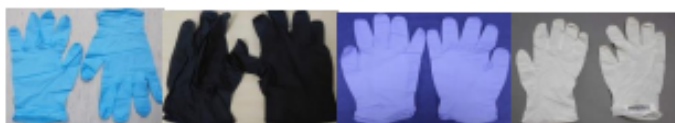
White: NGV/B/H/PEM(10023~10027),Black: NGV/B/H/PEM(10043~10047).

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

| | |
|--|-------------|
| 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



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

| | | |
|--|-------------------|------|
| 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 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) | Category 2 | | Category 3 | |
|---|---|---|----------------------------------|---|----------------------------------|
| | | 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[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 |

(S.P.) 01/06/2021

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-



AMM CO