

PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST

Nitrilové rukavice NITRIL IDEAL

ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné rukavice
Materiál:	100% syntetický nitril
Barva:	černá
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
100083	S	340	200×110×60	3.2 ± 0.2	8594177200407
100084	M	371	200×110×60	3.5 ± 0.2	8594177200414
100085	L	402	200×110×60	3.8 ± 0.2	8594177200421
100086	XL	491	200×110×60	4.1 ± 0.2	8594177200438

ČÁST V: NÁHLED PRODUKTU



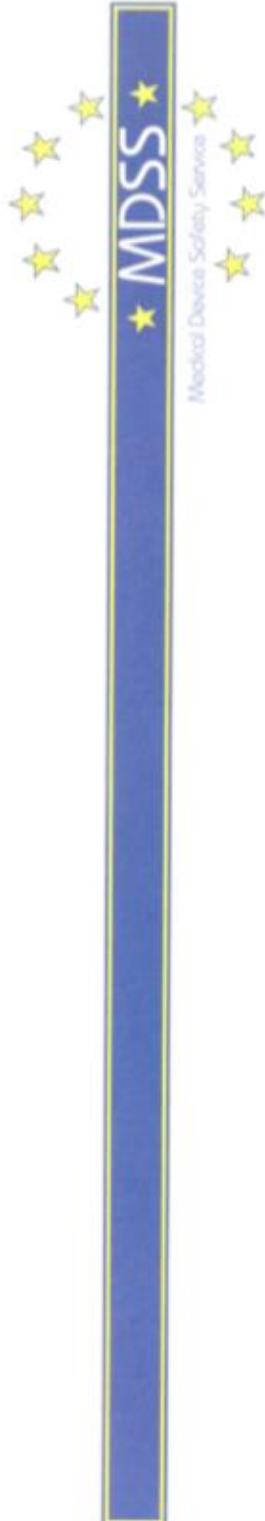
ČÁST VI: PŮVOD PRODUKTU

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						

Handwritten signature





PPE REGULATION (EU) 2016/425 MODULE D CERTIFICATE

This is to certify that:

Sri Trang Gloves (Thailand) Public Company Limited

110, 109/2, 352 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand
189 Moo 7, Phlai Wat Kanchanadit, Surat Thani 84160 Thailand
85 Moo 6, KhuanThani Kantang, Trang 92110 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 Manufacturing and distribution of Latex Powdered, Latex Powder Free and Nitrile Powder Free Non-Sterile Gloves as described in the listed EU type examination certificates.

2777/10466-04/E00-00	2777/10470-05/E00-00
2777/10467-04/E00-00	2777/10471-04/E00-00
2777/10468-04/E00-00	2777/10474-05/E00-00
2777/10469-04/E00-00	2777/14071-01/E00-00
2777/14362-01/E00-00	2777/14364-01/E00-00

Dated: 22nd June 2020

This certificate is valid until: May 2021



For and on behalf of SATRA Technology
Europe Limited



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
(Notified Body number 2777)

Tel: +353 (0) 1 437 2494 Web: www.satrapeurope.com



CERTIFICATE

The HACCP Management System
of

**SRI TRANG GLOVES (THAILAND)
PUBLIC COMPANY LIMITED**
85 Moo 6, Khuan Thani, Kantang
92110 Trang
Thailand

has been assessed and complies with the requirements of

TÜV MS Standard HACCP

Certification scheme for HACCP Management Systems which implements requirements of DIN EN 15593:2008 Packaging – management of hygiene in the production of packaging for foodstuffs and Codex Alimentarius: Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its implementation and General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4 - 2003).

This certificate is applicable for:

**Manufacture of natural rubber gloves
as food contact material.**

This certificate is provided on the base of the
TÜV MS Standard HACCP.

The certification system consists of a minimum annual audit of the HACCP management system and a minimum annual site inspection.

The certificate is valid from **2019-05-22** until **2020-10-16**.

Certificate Registration No.: **12 500 54708 TMS**.



Product Compliance Management
Munich, 2019-05-22



bsi.



Certificate of Registration

FOOD SAFETY MANAGEMENT SYSTEM - ISO 22000: 2005

This is to certify that:

SRI TRANG GLOVES (THAILAND)
PUBLIC COMPANY LIMITED
110 Kanjanavanit Road,
Pahtong, Hat Yai,
Songkhla
90230
Thailand

Holds Certificate Number:

FSMS 731225

and operates a Food Safety Management System which complies with the requirements of ISO 22000: 2005 for the following scope:

Category I
As detailed in the accompanying Scope of Certification;
Production of natural latex and nitrile gloves for food contact.

For and on behalf of BSI:


Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 2019-05-16

Latest Revision Date: 2020-06-08

Effective Date: 2020-06-08

Expiry Date: 2021-06-18

Page: 1 of 2



...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +66(2) 2944889-92.

Further clarifications regarding the scope of this certificate and the applicability of ISO 22000: 2005 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **FSMS 731225**

Location	Registered Activities
SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED 110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand	Production of natural latex and nitrile gloves for food contact.
SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED 109/2 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand	Production of natural latex and nitrile gloves for food contact.
SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED 352 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand	Production of natural latex and nitrile gloves for food contact.
SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED 189, Moo 7, Phlai Wat, Kanchanadit, Surat Thani 84160 Thailand	Production of natural latex and nitrile gloves for food contact.

Original Registration Date: 2019-05-16
Latest Revision Date: 2020-06-08

Effective Date: 2020-06-08
Expiry Date: 2021-06-18

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +66(2) 2944889-92.

Further clarifications regarding the scope of this certificate and the applicability of ISO 22000: 2005 requirements may be obtained by consulting the organization.

This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.



CERTIFICATE

No. QS5 099188 0010 Rev. 00

- | | |
|-------------------------|--|
| Facility(ies): | Sri Trang Gloves (Thailand) Public Company Limited
10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110, THAILAND |
| Facility Scopes: | Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves |
| Facility(ies): | Sri Trang Gloves (Thailand) Public Company Limited
110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla, 90230 THAILAND |
| Facility Scopes: | Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves |
| Facility(ies): | Sri Trang Gloves (Thailand) Public Company Limited
109/2 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla, 90230 THAILAND |
| Facility Scopes: | Production and Distribution of Sterile and Non-Sterile Examination Gloves |
| Facility(ies): | Sri Trang Gloves (Thailand) Public Company Limited
352 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla, 90230 THAILAND |
| Facility Scopes: | Production and Distribution of Sterile and Non-Sterile Examination Gloves |
| Facility(ies): | Sri Trang Gloves (Thailand) Public Company Limited
189, Moo 7, Phlai Wat, Kanchanadit, Surat Thani 84160, THAILAND |
| Facility Scopes: | Production and Distribution of Sterile and Non-Sterile Examination Gloves |
| Facility(ies): | Sri Trang Gloves (Thailand) Public Company Limited
85 Moo 6, Khuan Thani, Kantang, Trang 92110, THAILAND |
| Facility Scopes: | Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves |

Page 2 of 2
Date of issue: 2019-04-18

(Arie Henkin)
Manager, Certification Body MHS

 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,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 程建建

职位 Position Quality Manager

日期 Date 11-Sep-2020



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	<table border="0"> <tr> <td>1. The tested items complied with German Food & Feed Acts of September 1, 2005 (LFGB), Section 30 and 31.</td> <td></td> </tr> <tr> <td>- Overall migration test</td> <td style="text-align: right;">PASS</td> </tr> <tr> <td>- Color release</td> <td style="text-align: right;">PASS</td> </tr> <tr> <td>- Extractable formaldehyde</td> <td style="text-align: right;">PASS</td> </tr> <tr> <td>- Total lead and zinc content</td> <td style="text-align: right;">PASS</td> </tr> <tr> <td>- Sensory test</td> <td style="text-align: right;">PASS</td> </tr> <tr> <td>2. The tested items complied with AFPS GS 2019: 01 PAK</td> <td></td> </tr> <tr> <td>- Polycyclic Aromatic Hydrocarbons (PAHs) content(Category 1)</td> <td style="text-align: right;">PASS</td> </tr> <tr> <td>3. As per client's request</td> <td></td> </tr> <tr> <td>- Total Cadmium content</td> <td style="text-align: right;">PASS</td> </tr> </table>	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
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

TUV SUD 认证标志

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): 6dm³L

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 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-

