
KINGHONOFENG TECHNOLOGY
Protect your health
Glove
Civil mixed nitrile gloves
No powder
Non-sterile
100 BRANCH
CE
2
Do Not Reuse
Do Not Use if Package Damaged
XL

CE

DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 -Article 19, Annex II and Annex III.

Manufacturer:

Name: Shenzhen xinghongfeng Technology Co., Ltd
Address: 9 Xinggong 1st Road, Hongxing community, Yutang street, Guangming New District, Shenzhen
Telephone: 0755-27174717
Email: hkhongfeng@163.com

Whose Authorized Representative:

Name:: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the products

Product Name	Medical Device	Device Class	Model
Disposable examination glove (non-Sterile)	Gloves	I, Rule1 (Annex VIII of MDR)	Durability L(SIZE)

meet the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745..

Applicable Standards:

ISO 13485:2016
ENISO 10993-5: 2009
EN 1041:2008
ISO 14971:2019
ENISO 10993-10: 2013
EN 15223-1:2016
ISO 10993-1: 2018
EN 388-2016

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745.We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Zongfeng Zhu

Signature: Zongfeng Zhu

Position held in the company: General Manager

Date: 13.06.2020

Place: Shenzhen, China

Seal/Stamp:

Shenzhen xinghongfeng Technology Co., Ltd

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
A.H. de Jong - van Dijk

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20202815

Bijlagen
-

Uw aanvraag
8 juni 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 12 juni 2020
Betreft: notificatie medisch hulpmiddel klasse I

Geachte heer Wei,

Hierbij bevestig ik de ontvangst op 8 juni 2020 van de notificatie van het medische hulpmiddel klasse I, dat bedrijf Shenzhen xinghongfeng Technology Co., Ltd, met Europees gemachtigde Lotus NL B.V. , als fabrikant overeenkomstig Verordening (EU) 2017/745 (MDR) op de markt wenst te gaan brengen.
Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie over dit product het bijbehorende kenmerk te vermelden en het bij telefoongesprekken bij de hand te houden.

Disposable examination gloves (non-sterile)
(geen merknaam) (NL-CA002-2020-51971)

Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelindicatie (UDI) moeten beschikken en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd. Bijlage VI van de MDR bevat de bij de registratie te verstrekken gegevens.
Op dit moment is Eudamed nog niet in gebruik, zodat het wat betreft het bovenstaande voldoende is dat u uw product overeenkomstig de huidige wet- en regelgeving hebt genotificeerd.

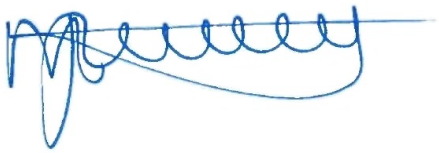
Zodra Eudamed volledig in gebruik is, wordt de fabrikant of diens gemachtigde geacht binnen achttien maanden bovenstaand hulpmiddel te registreren in Eudamed.

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

zer niet gedefinieerd.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

Fiscal Year 2020
FDA REGISTRATION

We:

Shenzhen Xinghongfeng Technology Co., Ltd.
Floor 1, No.9,Xinggong 1st Road, Hongxing Community, Gongming Office, Guangming New District, Shenzhen
has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration,

Owner/Operator Number: 10066275

Querylink:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Listing No.	Code	Device Name	Activities	Proprietary Name
D383541	KHA	MASK, SCAVENGING	Manufacturer	Disposable Mask X01,X02,X03,X04, X05,X06,X07
D398115	MSH	Respirator, surgical	Manufacturer	KN95 protective mask; N95 protective mask; N95 air valve mouthpiece; N95, KN95-X01, KN95-X02, KN95-X03, FFP1-01,FFP2-02, FFP3-03
D406829	IWP	Radiographic protective Glove	Manufacturer	Nitrile glove 001

Initial Registration Date: June 05, 2020
Expiration Date: December 31, 2020

中国认可
国际互认
检测
TESTING
CNAS L5772

Test Report

Report No.:PTC20081901701C-EN01 **Issue Date:** Aug. 25, 2020

Applicant: Shenzhen xinghongfeng Technology Co., Ltd

Address: No.9 Xinggong 1st Road, Hongxing community, Gongming office, Guangming New District, Shenzhen

The following merchandise was (were) submitted and identified by client as:

Sample Name: Mixed nitrile gloves

Style/Model No.: S/M/L/XL

Sample Received Date: Aug. 20, 2020

Completed Date: Aug. 25, 2020

Test Requested and Conclusion(s):

No.	Test Sample	Standard and Requirement	Conclusion(s)
1	Submitted sample	GB 4806.7-2016 National standard for food safety plastic products for food contact - Sensory Parameters, Physical and Chemical parameters(Overall migration, Consumption of Potassium permanganate, Heavy metal(express as lead), Decolorization test)	PASS

Test Result(s): Please refer to next page(s).

Signed for and on Behalf of PTC

Chaomei Dai

Chaomei Dai/ Laboratory Supervisor

Precise Testing & Certification (Guangdong) Co., Ltd.

Test Report

Test Result(s):

1) Sensory parameters

Method：GB 4806.7-2016

Test items	Requirements	Results	Conclusion
		1	
Appearance	Normal colour, no smell and impurity matter	Complied	PASS
Soak solution	The results of migration test showed no deterioration of sensory properties, such as turbidity, precipitation and different smell.	Complied	PASS

2) Physical and chemical parameters

Test items	Test condition	Test Method	Unit	limit	RL	Results
						1
Overall migration	10%ethanol, 40℃ for 1h	GB31604.8-2016	mg/kg	60	1	1.8
	20%ethanol , 40℃ for 1h	GB31604.8-2016	mg/kg	60	1	2.3
Consumption of Potassium permanganate	Distilled water，（60℃，2h）	GB31604.2-2016	mg/kg	10	1	1.7
Heavy metal (express as lead)	4%acetic acid（60℃，2h）	GB31604.9-2016	mg/kg	1	＜1	＜1
Decolorization test	65%ethanol	GB31604.7-2016	--	Negative	--	Negative
	vegetable oil					Negative
Conclusion						PASS

Note: 1. mg/kg = milligram per killogram by weight

2. N.D. = Not Detected (< RL).

3. RL = Reporting Limit.

Precise Testing & Certification (Guangdong) Co., Ltd. (PTC)
Building 1, No. 6, Tongxin Road, Dongcheng Street, Dongguan, Guangdong, China.
Tel: 86-769-38808222 Fax: 86-769-38826111 http:// www.ptc-testing.com

Test Report

No.: QDHL2008008688MD_EN Date: SEP.04,2020 Page: 1 of 5

Client name	:	SHENZHEN XINGHONGFENG TECHNOLOGY CO., LTD
Client address	:	NO.9 XINGGONG 1ST ROAD, HONGXING COMMUNITY, GONGMING OFFICE, GUANGMING NEW DISTRICT, SHENZHEN
Sample Description	:	MIXED NITRILE MEDICAL GLOVES
Lot No.	:	NOT PROVIDED
Lot Size	:	NOT PROVIDED
Sample Quantity	:	350PCS
Manufacturer	:	XING HONGFENG
Country of Origin	:	CHINA

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

Sample Receiving Date	:	AUG.20,2020
Test Performing Date	:	AUG.20,2020 TO SEP.04,2020

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Test Requested	Result
1. BS EN 455-1:2000 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes (Clause 5.1)	Pass
2. BS EN 455-2:2015 Medical Gloves for Single Use – Part 2: Requirements and Testing for Physical Properties (Clause 4.2, 4.3, 5.2, 5.3)	Pass
3. BS EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation (Clause 4.4)	Pass

Remark: - Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

scan to see the report
QDHL2008008688MD

Jessica Gao
Approved Signatory

Test Conducted:

1. **BS EN 455-1:2000 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes**

Number of test sample	:	231 PCS
Sample size	:	S
Number of non-conforming gloves	:	1 PC

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note	:	1	Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:1 pc The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.

2. **BS EN 455-2:2015 Medical gloves for single use – Part 2: Requirements and testing for physical properties**

Number of test sample	:	26 PCS
Type	:	Examination/procedure gloves: c)
Size	:	Examination/procedure gloves: S

Clause	Test Items	Result
4	Dimensions	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)

Result 1: Dimensions

Size	S	
No.	Length (mm)	Width (mm)
1	247	88
2	243	87
3	247	88
4	246	88
5	243	86
6	245	88
7	245	88
8	245	89
9	246	89
10	246	88
11	245	89
12	245	87
13	242	86
Standard requirement	≥240	80±10
Median value	245	88

Result 2: Strength

Size: S			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	3.6	1	3.6
2	3.5	2	3.3
3	4.0	3	3.4
4	3.5	4	3.5
5	4.3	5	3.6
6	3.8	6	3.4
7	3.8	7	3.6
8	4.2	8	3.7
9	3.7	9	3.7
10	3.7	10	3.7
11	4.4	11	4.0
12	3.6	12	3.7
13	3.9	13	3.7
Standard requirement	≥3.6	Standard requirement	≥3.6
Median value	3.8	Median value	3.6

3. BS EN 455-3:2015 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation

Number of test sample	:	5 PCS
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves
Size	:	S

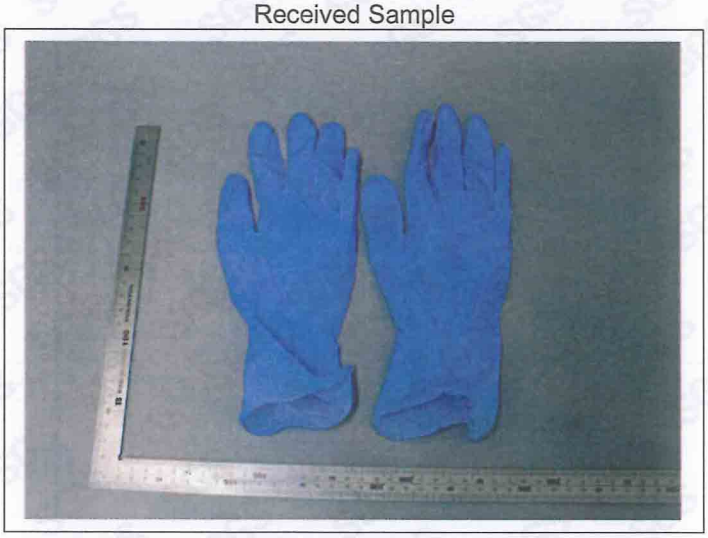
Clause	Test Items	Result
4.4	Powder-free gloves	Pass (See note 1)

Note	:	1	Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.06mg. (Requirement: ≤2mg per powder-free glove)

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Sample Photo:

Received Sample



SGS authenticate the photo on original report only

End of Report