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:
M. Schmitz - Konte

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20203177

Bijlagen
-

Uw aanvraag
26 juni 2020

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

Datum: 3 juli 2020
Betreft: notificatie medisch hulpmiddel klasse I

Geachte heer Wei,

Hierbij bevestig ik de ontvangst op 26 juni 2020 van de notificatie van het medische hulpmiddel klasse I, dat bedrijf Xiantao Zhengxin Nonwoven Products 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.

Medical face mask(non-sterile)
(geen merknaam) (NL-CA002-2020-52304)

Ik wijs u erop dat medische hulpmiddelen die op de markt gebracht worden volgens de MDR over een systeem voor hulpmiddelindicatie (UDI) moeten beschikken[1] en dat fabrikanten, gemachtigden en importeurs in de Europese databank voor Europese hulpmiddelen (Eudamed) moeten worden geregistreerd[2]. 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.[3]

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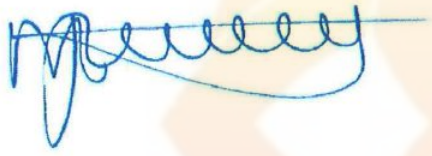
[1] O.g.v. art. 29 MDR.
[2] O.g.v. art. 31 MDR.
[3] www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf. Zie vraag en antwoord nummer 20.

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.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

正欣久久
ZHENG XIN JIU JIU

CE

DECLARATION OF CONFORMITY

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

Manufacturer:

Company name:Xiantao Zhengxin Nonwoven Products Co.,Ltd.
Address:PENGZHAO ROAD,PENGCHANG TOWN,XIANTAO CITY
Tel: +86-0728-2613968

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	Basic UDI-DI
Medical face mask（non-sterile）	Masks	I, Rule1 (Annex VIII of MDR)	ZX234	/

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
EN 15223-1:2016
ISO 14971:2019
ENISO 10993-10: 2013
EN 29073-1:1992
ISO 10993-1: 2018
EN 14683:2019+AC
EN ISO 9073-15-2008

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: 杨明 **Signature:**

Position held in the company: General Manager **Date: 2020/07/08**

Place: HuBei Province, China

Xiantao Zhengxin Nonwoven Products Co.,Ltd.

Seal/Stamp:

ZHENG XIN JIU JIU

Test Report

(Electronic version)

Verification Website: www.gttc.net.cn

Verification Code: LHSJ-8069-14

No:20R000316MO Issue Date: 2020-07-07

Applicant: XIANTAO ZHENGXIN NONWOVEN PRODUCTS CO.,LTD.
Address: PENGZHAO ROAD, PENGCHANG TOWN, XIANTAO CITY

Information confirmed by applicant:

Medical face mask(non-sterile)

Quantity: 60 pieces

Model: ZX234

Size: 17.5cm×9.5cm

Lot number: 200021537

Classification: Type ⅡR

Standard Adopted:

EN 14683:2019+AC:2019 <Medical face masks-Requirements and test methods>

Date Received/Date Test Started: 2020-05-20

Conclusion:

Bacterial filtration efficiency (BFE)	M
Microbial cleanliness	M
Differential pressure	M
Splash resistance pressure	M
Materials and construction	M
Design	M
General	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

Remark:
Modified content: modified client confirmed information.
This report replaces test report 20R000316 which has become invalid automatically.
All the tested items are tested under the standard condition (except for indication).
Copies of the report are valid only re-stamped.
The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By: WanLi Hu

WanLi Hu Engineer

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

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电话:020-37721161/66348638

Test Report

(Electronic version)

No: 20R000316MO

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Test Report

(Electronic version)

No: 20R000316MO

Bacterial filtration efficiency (BFE)
Test method: EN 14683: 2019+AC: 2019 Annex B

Test principle:
A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test equipment:
Incubator
Electronic balance
Autoclave
Experimental system for bacterial filtration efficiency (BFE) of mask

The environmental conditions of the laboratory and test condition:
Total bacteria: 0 CFU/plate
Total fungi: 0 CFU/plate
Blank experiment: Aseptic growth
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Culture medium: TSA agar medium
Culture temperature: 37℃， Culture time: 48h
Test bacteria : staphylococcus aureus ATCC 6538
Concentration of bacterium: 5.0×10^{5} CFU /ml
Positive control average (C): 1.9×10^{3} CFU
Negative monitor count: ＜1 CFU
Test area: 49 cm^{2}
Dimensions of the test specimens: 15cm×15cm
Flow rate: 28.3 l/min
Pretreatment: Condition each specimen for 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Mean particle size: 3.0 μm
The medical face mask in contact with the bacterial challenge: inside

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Test Report

(Electronic version)

No: 20R000316MO

Results:

Sample	T	BFE (%)	Requirement (%)	Classification	Conclusion
1	10	99.47	≥98 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	28	98.52			
3	24	98.73			
4	15	99.21			
5	18	99.05			

Remarks:

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$B = (C - T) / C \times 100$

where

B is bacterial filtration efficiency (BFE), %;

C is positive control average;

T is the total plate count for the test specimen.

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Test Report

(Electronic version)

No: 20R000316MO

Microbial cleanliness
Test method: EN ISO 11737-1:2018, Membrane filtration

Test principle:
Take the required samples from the original packaging. Weigh a certain amount of sample and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l Tween 20). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) for fungi enumeration. The plates are incubated for 3 days at 30℃ and 7 days at (20 to 25)℃ for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

Test equipment:
Constant temperature incubator
Electronic balance
Pressure steam sterilizer
Biosafety cabinet

The environmental conditions of the laboratory and test condition:
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth

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电话:020-37721161/66348638

Test Report

(Electronic version)

No: 20R000316MO

Results:

Sample	Bacteria (CFU/g)	Fungi (CFU/g)	Microbial cleanliness (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
1	3	3	6	≤30 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	5	4	9			
3	6	5	11			
4	2	1	3			
5	4	2	6			

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Test Report

(Electronic version)

No: 20R000316MO

Differential pressure

Test method: EN 14683:2019+AC:2019 Annex C

Test principle:

This procedure was performed to evaluate the differential pressure of the medical face mask material by measuring the air exchange pressure through a measured surface area at a constant air flow rate.

Test equipment:

GTTC-YLC-1 Apparatus for measuring differential pressure

The environmental conditions of the laboratory and test condition:

Air flow: 8 l/min

Test area: 4.9cm^2

Pretreatment: Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5) ℃ and a relative humidity of (85±5)%

General location of the areas of the mask the differential measurements: specimen center

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Test Report

(Electronic version)

No: 20R000316MO

Results:

Sample	Differential pressure (Pa/cm²)	Requirement (Pa/cm²)	Classification	Conclusion
1	42.9	＜60 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	35.9			
3	38.2			
4	41.0			
5	41.2			

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Test Report

(Electronic version)

No: 20R000316MO

Splash resistance pressure
Test method: ISO 22609:2004

Test principle:
A specimen medical face mask is supported on an apparatus. A volume of synthetic blood is sprayed horizontally at the specimen mask to simulate the scenario of a mask being splashed by a punctured blood vessel. The volume of fluid, distance to impact, orifice size and fluid velocity are defined in this method and intended to be consistent with this health care scenario. Any evidence of synthetic blood penetration on the side of the medical face mask contacting the wearer's face constitutes failure. Results are reported as "pass/fail". Specimen medical face masks are evaluated at a total of three different velocities corresponding to human blood pressures of 10.6 kPa, 16.0 kPa, and 21.3 kPa. Test results are reported at each velocity and the medical face mask is rated at the highest corresponding blood pressure for which medical face mask specimens demonstrate an acceptable quality limit of 4.0.

Test equipment:
Test apparatus for synthetic blood penetration LFY-227
Air compressor
Graduated cylinder
Electronic balance
Targeting plate

The environmental conditions of the laboratory and test condition:
Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5) ℃ and a relative humidity of (85±5)%
Surface tension of synthetic blood: 0.042 N/m
Pressure: 16.0 kPa
Velocity: 550 cm/s

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Test Report

(Electronic version)

No: 20R000316MO

Results:

Sample	Measured value	Requirement (kPa)	Classification	Conclusion
	Pressure			
	16.0 kPa			
1	pass	≥16.0 EN 14683:2019+AC:2019	Type ⅡR	Pass
2	pass			
3	pass			
4	pass			
5	pass			
6	pass			
7	pass			
8	pass			
9	pass			
10	pass			
11	pass			
12	pass			
13	pass			
14	pass			
15	pass			
16	pass			
17	pass			
18	pass			
19	pass			
20	pass			
21	pass			
22	pass			
23	pass			
24	pass			
25	pass			
26	pass			
27	pass			
28	pass			
29	pass			
30	pass			
31	pass			
32	pass			
Final result	pass			

Remarks:

An acceptable quality limit of 4.0 % is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.

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Test Report

(Electronic version)

No: 20R000316MO

Materials and construction

Test Method: EN 14683:2019+AC:2019 5.1.1

Results:

Requirement	Conclusion
The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	**Pass**
The medical face mask shall not disintegrate, split or tear during intended use.	**Pass**
In the selection of the filter and layer materials, attention shall be paid to cleanliness.	**Pass**

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Test Report

(Electronic version)

No: 20R000316MO

Design

Test Method: EN 14683:2019+AC:2019 5.1.2

Results:

Requirement	Conclusion
The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.	**Pass**
Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	**Pass**

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Test Report

(Electronic version)

No: 20R000316MO

General

Test Method: EN 14683:2019+AC:2019 5.2.1

Results:

Requirement	Conclusion
All tests shall be carried out on finished products or samples cut from finished products.	**Pass**

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———End of Report———

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电话:020-61994598/61994599
电话:020-37721161/66348638

European Authorized Representation Agreement

No. 4898 #

Party A:

Company Name: **XIANTAO ZHENGXIN NONWOVEN PRODUCTS CO.,LTD.**
Company Address: PENGZHAO ROAD, PENGCHANG TOWN, XIANTAO CITY, CHINA.
Tel: +0086-728-2613968 Fax: +0086-728-2613968

Party B:

Company Name : **Lotus NL B.V.**
Company Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel: +31644168999 Email: peter@lotusnl.com

Party A hereby appoints party B as the Authorized Representative within the European Union,Turkey and Switzerland, and party B accepts the appointment to be the Authorized Representative within the forsaid area for party A. Both parties enter this agreement as follow:

Party A

1. Party A assures to provide the updated technical files of each category products bearing the CE marking to party B.

2. If there are any changes of products, party A shall notify party B at once.

3. Party A shall keep records of serial numbers or production lot numbers for all Products delivered to Party B. Records shall include the following information :
   a)name and address of the customer,
   b)product name and specification,
   c)quantity dispatched,
   d)date transferred to the customer,
   e)serial or production lot numbers.
   It is agreed that these records shall be available for inspection upon request by party B or by the relevant authorities.
4. If any serious accident of products occurs within the member states of the European Union, party A shall help party B to investigate the reason in time, and complete the initial report together with party B. Party A shall present the investigation result and final report to party B within the time limit stipulated by EU laws and/or regulations. If the accident of the product occurs outside

the member states of the European Union, party A shall notify party B as soon as possible, and make decision whether to report to competent authority or not.

5. Party A shall be responsible for any business dispute such as claim for compensation caused by medical accident after sale, party B may handle the dispute in accordance with the authorization of party A. All the expenses which should be confirmed by party A occurred during the party B's handling of the accident shall be borne by party A.

6. Party A shall be responsible for the content of instruction(user's) manuals, and shall ensure that English language instruction manuals are available to Party B. Party A shall ensure that the required local language instruction manuals are provided to the customers.

Party B:

1. Party B shall be responsible to record all customer and market claims related to the products of Party A and transfer the information to Party A upon receiving of such claims.

2. Party B shall notify Part A about any claims of customers, and change of laws and regulations related to Part A's products bearing CE marking.

3. If any serious accident of products happen within boundary of EU, party B shall notify party A as soon as possible and assist party A to execute vigilance system of medical device products, and also make initial report, investigation result and final report to competent authority of country in which the accidents occur.

4.Party B shall keep technical files of party A's products bearing the CE marking, and take up the responsibility of confidentiality. The technical files shall be kept at least 10 years（implantable devices 15 years） after manufacturing the product of last batch. Party B should present the technical files timely to any competent authority that, for vigilance purpose, needs to inspect or audit the technical files.

5. Party B shall keep records of the Products delivered to end-users or distributors so that the traceability of sold products can be performed at any time upon request.

Appendix A

1. This agreement will be terminated automatically if the CE certification of party A be withdrawn by the notified body during the implementation of the agreement.

2.If party A plans to ship the devices to British and EU countries, party B can support party A to get the devices registered at British according to MHRA and related applicable regulation （Including CIBG）. This service is not included in this European Authorized Representative Agreement, and party A should inform party B at least 2 months ealier before the shipment and pay the involved registration fee(MDD Class I,and all IVDD Products).

3.Validity term of agreement is for **5 years** after it is signed by European Authorized Representative.
（有效期 5 年：22/JUN/2020-21/JUN/2025）

4. The following countries represent party B's Business Area :
European Union（E.U.）,EEA and Switzerland,Turkey.

5. For the following Product Categories :
Medical face mask(non-sterile).

Party A	**Party B**
XIANTAO ZHENGXIN NONWOVEN PRODUCTS CO.,LTD.	**Lotus NL B.V.**
Signature:	Signature:
Date:	Date: **22/JUN/2020**
Place:	Place: **Hague**

正欣久久 ZHENG XIN JIU JIU