Príloha č. 2 výzvy č. 3 - „Ochranné jednorazové rúška" v rámci zriadeného DNS „Ochranné, zdravotnícke pomôcky a hygienické potreby"

NÁVRH NA PLNENIE KRITÉRIA NA VYHODNOTENIE PONÚK A IDENTIFIKÁČNÉ ÚDAJE UCHÁDZAČA

Obchodné meno uchádzača:	STATUS S, s.r.o.
Sídlo uchádzača:	Lipová 10924/21, 036 08 Martin
IČO:	44015828
Meno a priezvisko štatutárneho zástupcu	IGOR PRAMUK
IČ DPH:	SK 202 2560284
Názov banky:	TATRA BANKA, a.s.
Číslo účtu (IBAN):	[redacted]
Telefónne číslo:	+421 [redacted]
E-mailová adresa:	pramukova.status@gmail.com

Predmet zákazky: „Ochranné jednorazové rúška"

Kritérium na vyhodnotenie ponúk:

najnižšia cena za celý predmet zákazky v EUR s DPH

Celková cena za predmet zákazky v EUR bez DPH	Výška DPH	Celková cena za predmet zákazky v EUR s DPH
Jednorazové rúška v množstve 50 000 ks s tvarujúcim pásikom, ploché, 3-vrstvové v súlade s opisom predmetu tejto výzvy	20 %	7140,00

Cena uvedená uchádzačom obsahuje všetky náklady, ktoré uchádzačovi vzniknú v súvislosti s plnením predmetnej zákazky.

Som – ~~Nie som~~ platiteľom DPH (nehodiace sa preškrtnite)

Ak uchádzač nie je platiteľom DPH, na túto skutočnosť upozorní verejného obstarávateľa. Ak uchádzač nie je platcom DPH, ním uvedená cena bude považovaná za konečnú aj v prípade, ak by sa počas plnenia predmetu zákazky stal platiteľom DPH. V prípade, ak uchádzač je platiteľom DPH, avšak jeho sídlo je v inom členskom štáte EÚ alebo sídli mimo EÚ, uvedie v ponuke cenu, ktorá bude rozdelená na ním navrhovanú cenu bez DPH, výšku DPH a aj cenu s DPH podľa slovenských právnych predpisov (20%), aj keď samotnú DPH nebude v súlade s komunitárnym právom fakturovať.

V Martine, dňa 10.9.2020

[redacted]

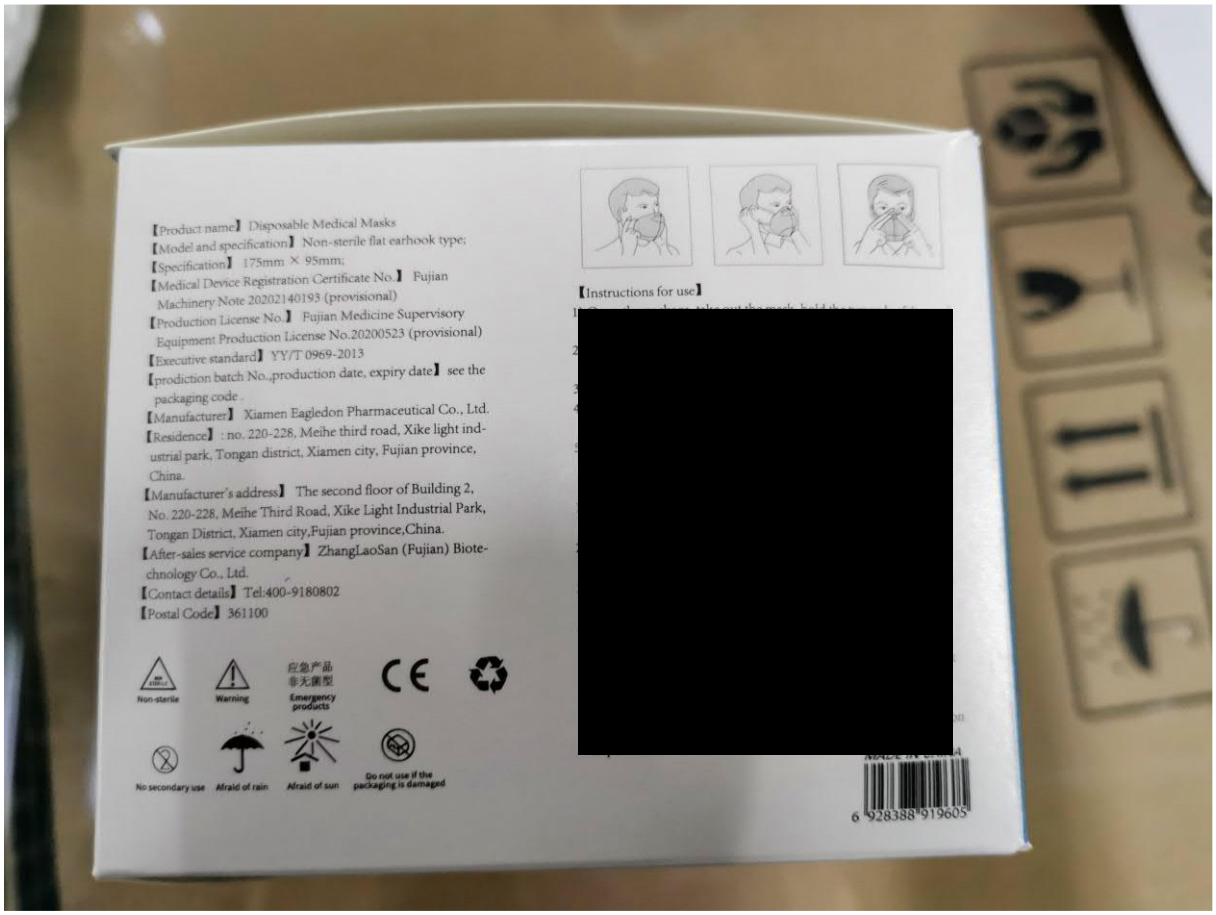
meno

podpis štatutárneho zástupcu,

pečiatka IGOR PRAMUK

KONATEĽ


CE | 章老三
一次性使用
医用口罩
Disposable Medical Mask
细菌过滤率（BFE）
可以阻止超过95%的
含有细菌的飞沫
BATERIA FILTRATION RATE(BFE)
block more than 95% of bacteria
50 只/盒
pcs/box


【Product name】Disposable Medical Masks
【Model and specification】Non-sterile flat earhook type;
【Specification】175mm × 95mm;
【Medical Device Registration Certificate No.】Fujian Machinery Note 20202140193 (provisional)
【Production License No.】Fujian Medicine Supervisory Equipment Production License No.20200523 (provisional)
【Executive standard】YY/T 0969-2013
【prodiction batch No.,production date, expiry date】see the packaging code .
【Manufacturer】Xiamen Eagledon Pharmaceutical Co., Ltd.
【Residence】: no. 220-228, Meihe third road, Xike light industrial park, Tongan district, Xiamen city, Fujian province, China.
【Manufacturer's address】The second floor of Building 2, No. 220-228, Meihe Third Road, Xike Light Industrial Park, Tongan District, Xiamen city,Fujian province,China.
【After-sales service company】ZhangLaoSan (Fujian) Biotechnology Co., Ltd.
【Contact details】Tel:400-9180802
【Postal Code】361100
【Instructions for use】
Non-sterile
Warning
应急产品
非无菌型
Emergency products
No secondary use
Afraid of rain
Afraid of sun
Do not use if the packaging is damaged
6 928388 919605

EC DECLARATION OF CONFORMITY

Manufacturer: Xiamen Eagledon Pharmaceutical Co., Ltd
No. 220-228, Meihe 3rd Road, Xike Light Industrial Park
Tongan, Xiamen City, China

European Representative: Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product name: Disposable Medical Mask
Model: 17,5 x 9,5 cm

Type: Type I (according to EN 14683:2019)

Classification MDD: I class, rule 1

Conformity Assessment Procedure: Annex VII of Directive 93/42/EEC

We, Xiamen Eagledon Pharmaceutical Co., Ltd, manufacturer of the above products, hereby declare under sole responsibility for this declaration of Conformity that the referenced products comply with all relevant provisions of Directive 93/42/EEC, and its transposition into national laws. The products comply with the essential requirements of Annex I, further applicable standards and/or normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

Place and date of iss

Xiamen, 05.05.202

Name position and signature of authorized person

CE

DECLARATION OF CONFORMITY

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

Manufacturer:

Company name: Xiamen Eagledon Pharmaceutical Co., Ltd.
Address: No. 220-228, Meihe 3rd Road, Xike Light Industrial Park Tongan, Xiamen, Fujian Province, China
Tel: +[redacted]
E-mail: zhangyu@eaglehealthltd.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	Basic UDI-DI
Disposable medical mask(non-sterile)	Masks	I, Rule1 (Annex VIII of MDR)	Non-sterile flat earloop type	

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 14683:2019+AC

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 a[redacted]: Zhang Mingwang

Position [redacted]: General Manager

Place: Fuji[redacted]

Seal/Stam[redacted]

Signature: [redacted]

Date： 2020. 05. 05

Xiamen Eagledon Pharmaceutical Co., Ltd.

CELAB®
Via Maira snc
04100 Latina
Italy
celab@celab.com

CERTIFICATE

Certificate Number **UCN** : **802776235221**
Job : J29826
Date of Issue : *2020-03-24*
Certificate valid up to : *2024-03-23*

Brand Name : *yingjun*
Type : *Disposable Medical Masks*
Model N : *175mm*95mm*

Manufacturer : Xiamen Eagledon Pharmaceutical Co., Ltd
Address : No.220-228, Meihe 3rd Road, Xike Light Industrial Park, Tongan, Xiamen City, China

Standard Used : EN 14683:2005, EN ISO 10993-1:2009+AC:2010

Conclusion :
After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:
93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .
The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✔ OK
Presence of test report u[redacted]icated in the declaration of conformity Test report reference : B[redacted]	✔ OK
Presence of CE symbol in the product label.	✔ OK
Presence of instruction manual	✔ OK
Use of valid Harmonized standard in the declaration of conformity	✔ OK
Presence of product description in the technical construction file	✔ OK

Check the authenticity of this certificate and related information before use in the web site www.celab.com introducing the UCN number in the 'Check document authenticity' area. You will see copy of this certificate and regulation on certificate use. This document is released only for scope allowed by laws- Do not use this document without full understanding of regulation.

Massimiliano Bertoldi
General Manager – CELAB
www.celab.com

CE
TEST REPORT

For

Disposable Medical Masks

Model: 175mm*95mm

Brand: Eagledon

Report No.: ENC2003192GZ01E1

Date of Issue: Mar. 26, 2020

Prepared For

Xiamen Eagledon Pharmaceutical Co., Ltd

No.220-228, Meihe 3rd Road, Xike Light Industrial Park, Tongan, Xiamen City, China

Prepared By

East Notice Certification Service Co., Ltd.

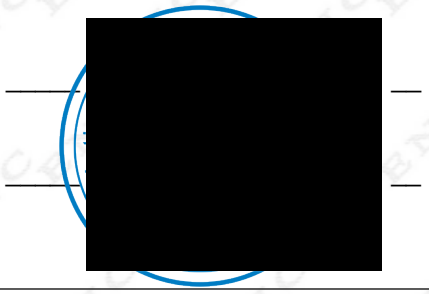
1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City, China

TEL: +[redacted]

FAX: [redacted]

TEST REPORT
EN 14683:2019
Medical face masks — Requirements and test methods

Report reference No. ..... :	[redacted]
Tested by ..... :	Samliu
Review by (+ Signature). ..... :	Yemig
Approved by (+ signature) ..... :	Ray zhou
Date of issue ..... :	Mar. 26, 2020
Contents ..... :	Total 4 pages



Testing laboratory

Name ..... :	East Notice Certification Service Co., Ltd.
Address ..... :	1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City, China
Testing location ..... :	Same as above

Application

Name..... :	Xiamen Eagledon Pharmaceutical Co., Ltd
Address ..... :	No.220-228, Meihe 3rd Road, Xike Light Industrial Park, Tongan, Xiamen City, China

Manufacturer

Name..... :	Xiamen Eagledon Pharmaceutical Co., Ltd
Address..... :	No.220-228, Meihe 3rd Road, Xike Light Industrial Park, Tongan, Xiamen City, China

Test specification

Standard ..... :	EN 14683:2019
Test procedure ..... :	Medical Devices Directive 93/43/EEC
Procedure deviation ..... :	N/A
Non-standard test method ..... :	N/A

Test Report Form/blank test report

Test Report Form No. ..... :	ENC14683-A2
TRF originator. ..... :	ENC

Test item

Description ..... :	Disposable Medical Masks
Brand name ..... :	Eagledon
Model..... :	175mm*95mm
Classification..... :	Type I

Testing

[redacted]

Summary of testing

[redacted]

All tests were found satisfactory in accordance with Classification Type I in EN 14683:2019.

Eas[redacted]n
1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City
Tel:+[redacted] Fax:+[redacted]
E-mail: enc@ enc-lab.com Http:// www.enc-lab.com

Test results:

Sample No.	Bacterial filtration efficiency (BFE), (%)	Differential pressure (Pa/cm^2)	Splash resistance Pressure (kPa)	Microbial cleanliness (cfu/g)	Verdict
[redacted]					

The filtration efficiency percentages were calculated using the following equation:

$$\%BEF = \frac{C - T}{C} \times 100$$

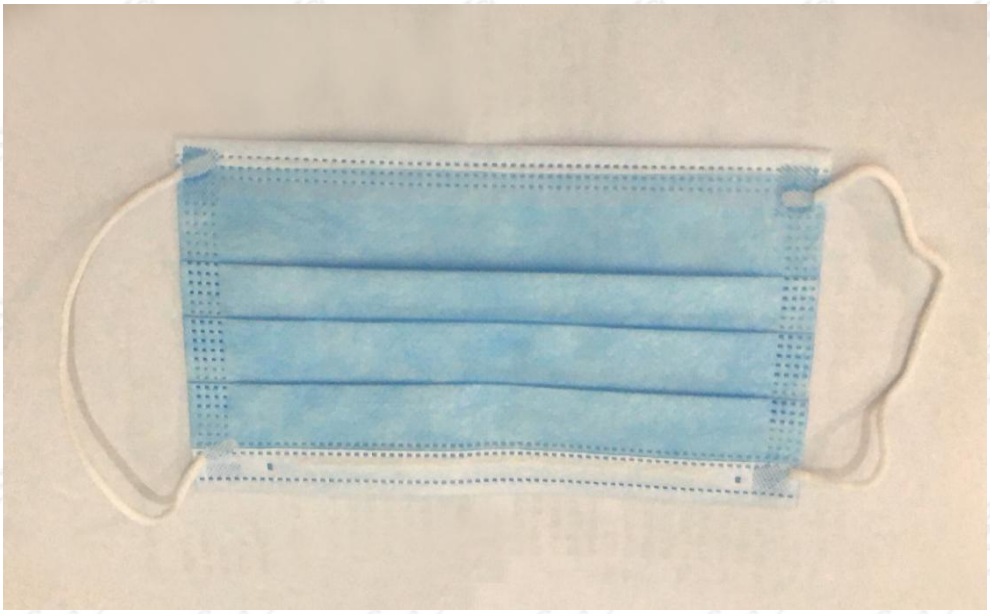
C = Positive control average

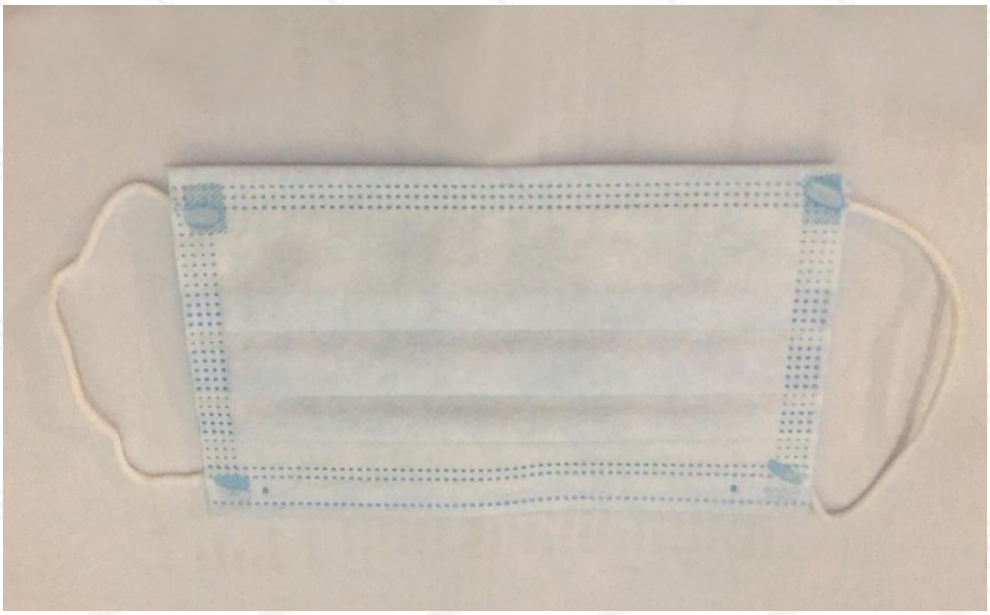
T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request

Eas[redacted]
1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City
Tel:+[redacted] Fax:+8[redacted]
E-mail: enc@ enc-lab.com Http:// www.enc-lab.com

APPENDIX A
PHOTO(S) OF PRODUCT





------END OF REPORT------

E[redacted]
1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City
Tel:+[redacted] Fax:+[redacted]
E-mail: enc@ enc-lab.com Http:// www.enc-lab.com

CELAB®
Via Maira snc
04100 Latina
Italy
celab@celab.com

CERTIFICATE

Certificate Number **UCN** : **802776235221**
Job : J29826
Date of Issue : *2020-03-24*
Certificate valid up to : *2024-03-23*

Brand Name : *yingjun*
Type : *Disposable Medical Masks*
Model N : *175mm*95mm*

Manufacturer : Xiamen Eagledon Pharmaceutical Co., Ltd
Address : No.220-228, Meihe 3rd Road, Xike Light Industrial Park, Tongan, Xiamen City, China

Standard Used : EN 14683:2005, EN ISO 10993-1:2009+AC:2010

Conclusion :
After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:
93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .
The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✔ OK
Presence of test report usi[redacted]cated in the declaration of conformity Test report reference : BS[redacted]	✔ OK
Presence of CE symbol in the product label.	✔ OK
Presence of instruction manual	✔ OK
Use of valid Harmonized standard in the declaration of conformity	✔ OK
Presence of product description in the technical construction file	✔ OK

Check the authenticity of this certificate and related information before use in the web site www.celab.com introducing the UCN number in the 'Check document authenticity' area. You will see copy of this certificate and regulation on certificate use. This document is released only for scope allowed by laws- Do not use this document without full understanding of regulation.

Massimiliano Bertoldi
General Manager – CELAB [redacted]
www.celab.com

Annex : Regulation for Voluntary Certification Activities

1. Release of certificate

These certificates are issued on a voluntary basis on request of manufacturer.
The certificate is released for product after inspection of the documentation relative to the technical construction file.
This Certificate is released only after that, is opinion of a CELAB approved technician, that the technical construction file (test reports, documentations, instruction manuals) demonstrate that the essential requirements indicated in the directives himself was covered.
Note: the technical requirement are related to the physical propriety of a product and his production process and not the legal requirements of directives.
When the opinion is positive, the certificate is released.
The inspection provided by CELAB is not relative to: The product; The production; The law requirements; The work performed or that will be performed by Notified Bodies.
The Inspection cover ONLY the following aspects (where applicable):

- Presence of declaration of conformity;
- Presence of test report as indicated in the certificate ;
- Presence of CE symbol in the product label template;
- Presence of Instruction manual;
- Use of actual harmonized standards as for EU official Journal;
- Presence of production description in the technical construction file.

2. Validity of certificate

All certificate have 4 years of validity. After such time the certificate will not be any more valid.

3. Withdraw of certificate

The certificate are withdraw if there is a reasonable justification that the product do not comply with the requirement of a directive, or when this agreement was not addressed.

4. Responsibility of manufacturer

As many directives require use of a Notified Body, in such case is responsibility of producer or his representative in Europe to follow all applicable directives requirement and contact.
This regulation will always be consigned together with the certificate and is a part of them, use of the certificate without text of this regulation is not allowed or accepted.
Is responsibility to the manufacturer to comply with CE marking law prescriptions.

5. Responsibility of CELAB

CELAB take no responsibility on product tested except that, in case of advice from market, CELAB will investigate on such compliant and, if found acceptable, the certificate will be withdraw.
CELAB is not responsible for the product, the production, the importing, the distribution, the sales, the advertisement, the technical assistance, the consulting or as EU mandatories.
Certificate is the result of technical opinion, given as a private owned company. There is no any warranty that the product will comply with all requirements of directives or a law.
CELAB is not responsible for CE marking of the product indicated in the certificate.

6. Responsibility of user of certificate

Is responsibility of the user of the certificate to comply with all laws requirements. Only as a general reference, the user of certificate will need to get copy of test-report from his supplier and be responsible for technical construction file. User of the certificate take full legal responsibility on such use.
Such certificate are not legal requirements except when used between private company as a specific contract agreement between them.
User of certificate need to full comply with applicable requirements indicated in such directives. User of certificate are not allowed to induce the market on a different destination of use of the certificate different from what stated in this agreement. Use of certificate of conformity is restricted to expert in CE Marking field that can fully understand scope of this certificate and is not for general public.
This certificate cannot be publicized in a misuses or in a way that It can confuse general public. The user of the certificate will Always do not use the certificate for customs control or public authority requirement control.

7. Scope of the certificate.

The ONLY Scope of this kind of certificate is :

- Allow the manufacturer to demonstrate to a customer that a product was tested without need to give him test reports (if both accepted by manufacturer and by the customer);
- Allow a private customer to have an evidence that an independent 3th part have inspected the documentation on voluntary basis.

The certificate provide an added value for manufacturer in situation where the manufacturer don't want to provide to his customer the test reports (if not required by law).
Such certificate will need to be used only as demonstration that a sample of a product was really tested between companies that recognize this agreement. Such certificate are not required by law (as they are voluntary certificate), and are intended to be used between private company for commercial issue. These certificate where not to be used to demonstrate conformity of the product to authority or for government control. The certificate are not an authorization by CELAB to put the CE marking on the product.
The Certificate is not a legal requirement for CE marking activities. Is the opinion of CELAB that manufacture can provide the CE marking in the product IF he comply with all prescription of the directives. The Certificate is not a declaration of conformity or an attestation of conformity. Note that some directive require use of Notified Body, the certificate of conformity and the certificate of compliance are NOT related to Notified Body work and are not related to law requirements.
The certificate is a Technical Opinion issued by CELAB to the manufacturer of the product where, after review of document issued by manufacturer, CELAB certify his opinion regarding the conformity between the product and the prescription of the standard and/or the technical requirement of the directive.
The certificate where not issued in the role or the task of Notified Body or accredited testing laboratory or accredited certification body. Warning : do not confuse this certificate with certificates issued by notified bodies. In case of doubt on using this certificate, do not use it and consult a consultant or expert or contact CELAB for request of information at celab@celab.com

8. Technical construction File storage

The technical construction file is normally not stored in CELAB archives, after review of CELAB the documents were not archived in the CELAB databases. Is responsibility of the manufacturer that the documents is available for law requirements. CELAB is not responsible for the storage of the technical construction file.
Note : that the technical construction files for activities related to CE marking will need to be available in Europe.

9. CE Marking General information's

All person/company/body involved on a CE marking product are responsible to perform all task indicate in the directive. Full text of directive can be found in European Union Web Site : http://ec.europa.eu/growth/index_en
We recommend to search in such web site full information about CE marking related directives.

ZTC

中泰认证

质量管理体系认证证书

注册号：[redacted]

厦门鹰君药业有限公司

统一社会信用代码：[redacted]

注册地址：福建省厦门市同安区西柯轻工业园美禾三路 220-228 号

办公地址：福建省厦门市同安区西柯轻工业园美禾三路 220-228 号

生产地址：福建省厦门市同安区西柯轻工业园美禾三路 220-228 号

建立的质量管理体系符合

GB/T 19001-2016 idt ISO9001:2015 标准

通过认证范围如下

一次性使用日常防护口罩和一次性使用医用口罩的生产

首次发证日期：2020 年 04 月 30 日

本次发证日期：2020 年 04 月 30 日

有 效 期 至：2021 年 04 月 29 日

第一次监督合格	第二次监督合格	第三次监督合格
（贴 花）	（贴 花）	（贴 花）

（本证书有效期内每年度须接受至少一次监督审核，并张贴监督合格标签方为有效）

签发人：[redacted]

ZHONGTAI UNION CERTIFICATION 中泰联合认证

证书时效及适用性可登陆中泰联合认证官方网站 www.ztccc.org 或致电中泰联合认证综合部进行查询，本证书信息亦可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询。

中国四川省成都市成华区东三环路二段宝耳路 2 号第 1 号办公楼(610052)。

[redacted]

中泰联合认证有限公司

电话：028-62521000 www.ztccc.org

本证书在新冠状病毒感染肺炎疫情解除 90 后需与确认审核通过证明合并使用，方为有效。

0011523

中泰认证

QUALITY MANAGEMENT SYSTEM CERTIFICATION

Registration NO: [redacted]

Xiamen Eagledon Pharmaceutical Co., Ltd.

Unified social credit code:[redacted]

Registered Address:NO.220-228 ,Meihe third road ,Xike Light Industrial park ,Tongan District, Xiamen city ,Fujan province, China

Office Address:NO.220-228 ,Meihe third road ,Xike Light Industrial park ,Tongan District, Xiamen city ,Fujan province, China

Production Address:NO.220-228 ,Meihe third road ,Xike Light Industrial park ,Tongan District, Xiamen city ,Fujan province, China

Established Quality Management System Accord With

GB/T 19001-2016 idt ISO9001:2015 standard

Through the certification scope is as follows

Production of disposable daily protective masks and disposable medical masks

The release date for the first time: 30-04-2020

The issuance date: 30-04-2020

Will be valid until: 29-04-2021

Approval of the first surveillance audit	Approval of the second surveillance audit	Approval of the third surveillance audit

(This certificate within the period of validity at least once annually must accept supervision and audit,in order to be valid and post supervision qualified label)

Issuer [redacted]

ZHONGTAI UNION CERTIFICATION ZTC 中泰联合认证

Certificate of limitation and applicability to the zhongtai Union Certification official website or call zhongtai Union Certification comprehensive query, this certificate information can also be in the national Certification and accreditation supervision and administration commission official website (www.cnca.gov.cn).No.1 Office Build,no.2,baoer road, the The second paragraph,east third ring road,chenghua district,chengdu,sichuan((610052).

[redacted]

ZhongTai Union Certification Co., LTD.

Tel: [redacted] www.ztccc.org

This certificate is valid only 90 days after the epidemic situation of new coronavirus infection and pneumonia has been resolved.

0011584

ZTC

中泰认证

质量管理体系认证证书

注册号：[redacted]S

厦门鹰君药业有限公司

统一社会信用代码：[redacted]

注册地址：福建省厦门市同安区西柯轻工业园美禾三路 220-228 号

办公地址：福建省厦门市同安区西柯轻工业园美禾三路 220-228 号

生产地址：福建省厦门市同安区西柯轻工业园美禾三路 220-228 号

建立的医疗器械质量管理体系用于法规的要求体系符合

YY/T0287-2017/ISO13485:2016 标准

通过认证范围如下

一次性使用医用口罩的生产

首次发证日期：2020 年 04 月 30 日

本次发证日期：2020 年 04 月 30 日

有 效 期 至：2021 年 04 月 29 日

第一次监督合格	第二次监督合格	第三次监督合格
（贴 花）	（贴 花）	（贴 花）

（本证书有效期内每年度须接受至少一次监督审核，并张贴监督合格标签方为有效）

ZHONGTAI UNION CERTIFICATION 中泰联合认证

签发人：[redacted]

证书时效及适用性可登陆中泰联合认证官方网站 www.ztccc.org 或致电中泰联合认证综合部进行查询，本证书信息亦可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询。

中国四川省成都市成华区东三环路二段宝耳路 2 号第 1 号办公楼(610052)。

中泰联合认证有限公司

电话：[redacted] www.ztccc.org

本证书在新冠状病毒感染肺炎疫情解除 90 后需与确认审核通过证明合并使用，方为有效。

00[redacted]582

中泰认证

QUALITY MANAGEMENT SYSTEM CERTIFICATION

Registration NO: [redacted]S

Xiamen Eagledon Pharmaceutical Co., Ltd.

Unified social credit code:9[redacted]

Registered Address:NO.220-228 ,Meihe third road ,Xike Light Industrial park ,Tongan District, Xiamen city ,Fujan province, China

Office Address:NO.220-228 ,Meihe third road ,Xike Light Industrial park ,Tongan District, Xiamen city ,Fujan province, China

Production Address:NO.220-228 ,Meihe third road ,Xike Light Industrial park ,Tongan District, Xiamen city ,Fujan province, China

The establishment of the medical device quality management system for compliance with the requirements of the system

YY/T0287-2017/ISO13485:2016 standard

Through the certification scope is as follows

Production of disposable medical masks

The release date for the first time: 30-04-2020

The issuance date: 30-04-2020

Will be valid until: 29-04-2021

Approval of the first surveillance audit	Approval of the second surveillance audit	Approval of the third surveillance audit

(This certificate within the period of validity at least once annually must accept supervision and audit,in order to be valid and post supervision qualified label)

Issuer: [redacted]

ZHONGTAI UNION CERTIFICATION ZTC 中泰联合认证

Certificate of limitation and applicability to the zhongtai Union Certification official website or call zhongtai Union Certification comprehensive query, this certificate information can also be in the national Certification and accreditation supervision and administration commission official website (www.cnca.gov.cn).No.1 Office Build,no.2,baoer road, the The second paragraph,east third ring road,chenghua district,chengdu,sichuan((610052).

[redacted]

ZhongTai Union Certification Co., LTD.

Tel: [redacted] www.ztccc.org

This certificate is valid only 90 days after the epidemic situation of new coronavirus infection and pneumonia has been resolved.

[redacted]

Technický list výrobku

Výrobok	Medicínske rúško, 3 vrstvové, nesterilné	
Kvalita	Norma EN 14683, Typ I	
	BFE %	≥ 95%
	Diferenčný tlak (Pa/cm²)	≤ 29,4
	Odolnosť voči striekajúcej vode pod tlakom (mm Hg)	Nevyžaduje sa
	Mikrobiálna čistota CfU/g	< 18
Lab test	Laboratórny test preukazuje súlad výrobku s európskou normou EN 14683:2019 TYP I, laboratórny test preukazuje BFE ≥ 98,5%,	
Materiál	3 vrstvová ochranná maska bez latexu, 1. vrstva - vonkajšia strana 25 gsm netkaná textília, 2. vrstva - 25 gsm meltblown filter, 3. vrstva - vnútorná, strana 25 gsm netkaná textília	
Rozmer/príslušenstvo	Tvárová maska s rozmermi 17,5 x 9,5 cm, z vonkajšej strany ultrazvukom pripevnené gumičky na uchytenie, bez latexu	
Balenie	Primárne: 50 kusov v balení s označením šarže v krabičke Alternatívne: 50 kusov v balení v polyetylénovom obale s priloženým informačným štítkom	
Účel použitia	Spôsob použitia medicínskych tvárových masiek napomáha prevencii rozširovania veľkých častíc vydychovaných používateľom (kýchaním, kašlaním) k iným osobám alebo do prostredia. Tekutiny ktoré sa dostanú do kontaktu s vonkajším povrchom tvárových masiek sa nevstrebú do vnútornej časti masky, t.j. nedochádza ku prieniku k perám alebo koži nositeľa.	
Použitie	Medicínske tvárové masky sú využívané na špeciálne úkony/procedúry. Kvôli infekčným opatreniam sú masky jednorazové a vyhadzujú sa po každom použití.	
Životnosť	Odporúčaná skladovacia doba: 3 roky od dátumu výroby.	

NÁVOD NA POUŽITIE

Popis

[redacted]

Skladovanie

[redacted]

Likvidácia

[redacted]

Návod na nasadenie rúška

1. [redacted]

6. [redacted]

Návod na odstránenie rúška

1. [redacted]

ODPORÚČANIA A VAROVANIA

1. [redacted]

8. [redacted]

Prekladateľka: Ing. Dana Bednárová, Jozefa Kronera 3951/20, Martin, +421 [redacted], preklady@finefox.sk

Zadávateľ: STATUS S, s. r. o., Lipová 10927/21, Martin

Preklad č. 101 /2020

z jazyka anglického do jazyka slovenského

Predmet prekladu: Vyhlásenie o zhode

Počet strán prekladanej listiny: 7

Počet strán preloženej listiny: 7

Počet odovzdaných vyhotovení: 1

Martin, 25. 08. 2020

EC DECLARATION OF CONFORMITY

Manufacturer: Xiamen Eagledon Pharmaceutical Co., Ltd
No. 220-228, Meihe 3rd Road, Xike Light Industrial Park
Tongan, Xiamen City, China

European Representative: Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product name: Disposable Medical Mask
Model: 17,5 x 9,5 cm

Type: Type I (according to EN 14683:2019)

Classification MDD: I class, rule 1

Conformity Assessment Procedure: Annex VII of Directive 93/42/EEC

We, Xiamen Eagledon Pharmaceutical Co., Ltd, manufacturer of the above products, hereby declare under sole responsibility for this declaration of Conformity that the referenced products comply with all relevant provisions of Directive 93/42/EEC, and its transposition into national laws. The products comply with the essential requirements of Annex I, further applicable standards and/or normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

[redacted]

Place and date of issu

Xiamen, 05.05.2020

Name position and signature of authorized person

[redacted]

CE

DECLARATION OF CONFORMITY

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

Manufacturer:

Company name: Xiamen Eagledon Pharmaceutical Co., Ltd.
Address: No. 220-228, Meihe 3rd Road, Xike Light Industrial Park Tongan, Xiamen, Fujian Province, China
Tel: +[redacted]
E-mail: zhangyu@eaglehealthltd.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	Basic UDI-DI
Disposable medical mask(non-sterile)	Masks	I, Rule1 (Annex VIII of MDR)	Non-sterile flat earloop type	

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 14683:2019+AC

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 a[redacted] Zhang Mingwang **Signature:** [redacted]

Position h[redacted] General Manager **Date:** 2020. 05. 05

Place: Fuji[redacted]

Seal/Stam[redacted] Xiamen Eagledon Pharmaceutical Co., Ltd.

LAB®
Maira snc
00 Latina
y
ab@celab.com

celab

CERTIFICATE

rtificate Number **UCN**	: **802776235221**
b	: J29826
ate of Issue	: *2020-03-24*
ertificate valid up to	: *2024-03-23*
rand Name	: *yingjun*
ype	: *Disposable Medical Masks*
Model N	: *175mm*95mm*
Manufacturer	: Xiamen Eagledon Pharmaceutical Co., Ltd
Address	: No.220-228, Meihe 3rd Road, Xike Light Industrial Park, Tongan, Xiamen City, China

Standard Used : EN 14683:2005, EN ISO 10993-1:2009+AC:2010

Conclusion :
After inspection of the technical documentation issued by the customer, and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards:
93/42/EEC Medical devices (MDD)

This opinion is only valid for the directive, the equipment and configuration described, in conjunction with the test data detailed above and with compliance with all applicable legal requirement for the product .
The following manufacturer documents was inspected:

Presence of Declaration of conformity template	✔ OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference : [redacted]	✔ OK
Presence of CE symbol in the product label.	✔ OK
Presence of instruction manual	✔ OK
Use of valid Harmonized standard in the declaration of conformity	✔ OK
Presence of product description in the technical construction file	✔ OK

Check the authenticity of this certificate and related information before use in the web site www.celab.com introducing the UCN number in the 'Check document authenticity' area. You will see copy of this certificate and regulation on certificate use. This document is released only for scope allowed by laws- Do not use this document without full understanding of regulation.

Massimiliano Bertoldi
General Manager – CELAB
www.celab.com

www.celab.com

CE
TEST REPORT

For

Disposable Medical Masks

Model: 175mm*95mm

Brand: Eagledon

Report No.: ENC2003192GZ01E1

Date of Issue: Mar. 26, 2020

Prepared For

Xiamen Eagledon Pharmaceutical Co., Ltd

No.220-228, Meihe 3rd Road, Xike Light Industrial Park, Tongan, Xiamen City, China

Prepared By

East Notice Certification Service Co., Ltd.

1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City, China

TEL: +[redacted]

FAX: +[redacted]

TEST REPORT
EN 14683:2019
Medical face masks — Requirements and test methods

Report reference No.	:	[redacted]
Tested by	:	Samliu
Review by (+ Signature).	:	Yemig
Approved by (+ signature)	:	Ray zhou
Date of issue	:	Mar. 26, 2020
Contents	:	Total 4 pages

Testing laboratory

Name	:	East Notice Certification Service Co., Ltd.
Address	:	1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City, China
Testing location	:	Same as above

Application

Name	:	Xiamen Eagledon Pharmaceutical Co., Ltd
Address	:	No.220-228, Meihe 3rd Road, Xike Light Industrial Park, Tongan, Xiamen City, China

Manufacturer

Name	:	Xiamen Eagledon Pharmaceutical Co., Ltd
Address	:	No.220-228, Meihe 3rd Road, Xike Light Industrial Park, Tongan, Xiamen City, China

Test specification

Standard	:	EN 14683:2019
Test procedure	:	Medical Devices Directive 93/43/EEC
Procedure deviation	:	N/A
Non-standard test method	:	N/A

Test Report Form/blank test report

Test Report Form No.	:	ENC14683-A2
TRF originator.	:	ENC

Test item

Description	:	Disposable Medical Masks
Brand name	:	Eagledon
Model	:	175mm*95mm
Classification	:	Type I

Testing

[redacted]

Summary of testing

[redacted]

All tests were found satisfactory in accordance with Classification Type I in EN 14683:2019.

1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City
Tel:+[redacted] Fax:+[redacted]
E-mail: enc@ enc-lab.com Http:// www.enc-lab.com

Test results:

Sample No.	Bacterial filtration efficiency (BFE), (%)	Differential pressure (Pa/cm²)	Splash resistance Pressure (kPa)	Microbial cleanliness (cfu/g)	Verdict
1	98.7	[redacted]			

The filtration efficiency percentages were calculated using the following equation:

$$\%BEF = \frac{C - T}{C} \times 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request

1/F, Hachui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City
Tel:+[redacted]
E-mail: enc@ enc-lab.com
Fax:+[redacted]
Http:// www.enc-lab.com

ES VYHLÁSENIE O ZHODE

Výrobca: Xiamen Eagledon Pharmaceutical Co.,Ltd
Č. 220-228, Meihe 3. Road, Xike Light Industrial Park,
Tongan, Xiamen City, Čína

Zástupca pre Európu: Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, Haag,
Holandsko

Názov výrobku: Jednorazová medicínska maska

Model: 17,5 x 9,5 cm

Typ: Typ I (podľa nariadenia EN 14683:2019)

Klasifikácia SZP Trieda I, pravidlo 1

Postup posudzovania zhody: Príloha VII Smernice 93/42/EHS

My, Xiamen Eagledon Pharmaceutical Co., Ltd., výrobca vyššie uvedených výrobkov, týmto čestne vyhlasujeme na našu vlastnú zodpovednosť, že vyššie uvedené výrobky spĺňajú ustanovenia Smernice 93/42/EHS a jej transpozície do vnútroštátnych právnych poriadkov. Produkty spĺňajú podstatné požiadavky Prílohy I, ďalšie uplatniteľné štandardy a/alebo normatívne dokumenty ako je uvedené v príslušnej technickej dokumentácii. Všetka podporná dokumentácia je uchovávaná v priestoroch výrobcu.

Miesto a dátum podpisu:

Xiamen, 05.05.2020

Meno, pozícia a podpis oprávnenej osoby
(nečitateľný podpis)

CE

VYHLÁSENIE O ZHODE

Podľa NARIADENIA (EÚ) 2017/745 - článok 19, príloha II a príloha III.

Výrobca:
Názov spoločnosti: Xiamen Eagledon Pharmaceutical Co., Ltd.
Adresa: Č. 220-228, Meihe 3. Road, Xike Light Industrial Park Tongan, Xiamen, Fujian Province, Čína
Tel: +[redacted]
E-mail: zhangyu@eaglehealthltd.com

Splnomocneného zástupcu:
Meno: Lotus NL B. V.
Adresa: Koningin Julianaplein 10, 1e Verd, 2595AA, Haag, Holandsko
E-mail: peter@lotusnl.com

My, výrobca, týmto vyhlasujeme, že výrobky

Názov výrobku	Zdravotnícka pomôcka	Trieda pomôcky	Model	Základný UDI-DI
Jednorazová medicínska maska (nesterilná)	Maska	I, pravidlo 1 (príloha VIII. Nariadenia)	Nesterilná ploché prevedenie na gumičky	

spĺňajú ustanovenia NARIADENIA (EÚ) 2017/745, ktoré sa na ne vzťahujú.

Spôsob posudzovania zhody: Článok 19, Príloha II. A Príloha III. NARIADENIA (EÚ) 2017/745.

Príslušné normy:

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 14683:2019+AC

My, výrobca, týmto prehlasujeme, že sme výhradne zodpovední za to, že náš/naše vyššie uvedený/é výrobok/výrobky spĺňa/jú ustanovenia NARIADENIA (EÚ) 2017/745. Súhlasíme s tým, že budeme vyvíjať, implementovať a udržiavať zdokumentovaný proces monitorovania po výrobe.

Meno oprávneného podpisujúceho: Zhang Mingwang **Podpis:** *nečitateľný*

Pozícia v spoločnosti: generálny riaditeľ **Dátum:** 05. 05. 2020

Miesto: Fujian, Čína Xiamen Eagledon Pharmaceutical Co., Ltd.

Pečiatka: *okrúhla pečiatka*

CELAB
Via Maira snc
04100 Latina
Taliansko
celab@c elab.com

OSVEDČENIE

Číslo osvedčenia UCN	: [redacted]
Vec	: J298 26
Dátum vydania	: 24. 03. 2020
Osvedčenie platné do	: 24. 03. 2024
Obchodná značka	: yingjun
Typ	: jednorazová medicinska maska
Model N	: 175 mm* 95 mm
Výrobca	: Xiamen Eagledon Pharmaceutical Co., Ltd.
Adresa	: Č. 220-228, Meihe 3. Road, Xike Light Industrial Park, Tongan, Xiamen City, Čína
Použitý štandard	: EN 14683:2005, EN ISO 10993-1:2009+AC:2010

Záver:
Po preskúmaní technickej dokumentácie vydanej zákazníkom a na jeho žiadosť potvrdzujeme, že produkt spĺňa technické požiadavky nasledujúcich smerníc a noriem:
93/42/EHS Zdravotnícke pomôcky (Smernica o medicínskych pomôckach)

Toto stanovisko platí iba pre uvedenú smernicu, opísané vybavenie a konfiguráciu v spojení s vyššie uvedenými údajmi o skúškach a v súlade so všetkými uplatniteľnými zákonnými požiadavkami na výrobok.
Skontrolovali sa nasledujúce dokumenty výrobcu:

Predložené Vyhlásenie o zhode	√ OK
Predložený protokol o skúške s použitím noriem uvedených vo vyhlásení o zhode Protokol o skúške: [redacted]	√ OK
Na etikete výrobku je uvedený symbol CE	√ OK
Predložený návod na použitie	√ OK
Použitie platnej harmonizovanej normy vo vyhlásení o zhode	√ OK
Predložený opis výrobku v technickej dokumentácii	√ OK

Skontrolujte pravosť tohto certifikátu a súvisiace informácie pred použitím na web stránke www.celab.com zadaním UCN čísla do políčka „Overte pravosť dokumentu". Uvidíte kópiu tohto certifikátu a usmernenie o používaní certifikátu. Tento dokument sa vydáva iba pre rozsah povolený zákonmi. Nepoužívajte tento dokument bez úplného porozumenia usmernenia.

Massimiliano Bertoldi
Generálny riaditeľ – CELAB
www.celab.com

vlastnoručný podpis

CE

PROTOKOL O SKÚŠKE

Pre

Jednorazové medicinske masky

Model: 175mm*95mm

Značka: Eagledon

Číslo protokolu: [redacted]

Dátum vydania: 26. marec 2020

Pripravené pre

Xiamen Eagledon Pharmaceutical Co., Ltd.

Č. 220-228, Meihe 3. Road, Xike Light Industrial Park, Tongan, Xiamen City, Čína

Vykonal

East Notice Certification Service Co., Ltd.

1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City, Čína

TEL: +[redacted]

FAX: +[redacted]

PROTOKOL O SKÚŠKE
EN 14683:2019
Medicínske tvárové masky – požiadavky a skúšobné metódy

Referenčné číslo protokolu o skúške	[redacted]
Testoval	Samliu
Preskúmal (+ podpis)	Yemig
Schválil (+ podpis)	Ray Zhou
Dátum vydania	26. marec 2020
Obsah	celkom 4 strany

okrúhla pečiatka a podpis ENS

Skúšobné laboratórium

Názov	East Notice Certification Service Co., Ltd.
Adresa	1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City, Čína
Testovacie miesto	rovnaké ako vyššie

Použitie

Názov	Xiamen Eagledon Pharmaceutical Co., Ltd.
Adresa	Č. 220-228, Meihe 3. Road, Xike Light Industrial Park, Tongan, Xiamen City, Čína

Špecifikácia skúšky

Štandard	EN 14683:2019
Skúšobný postup	Smernica o medicínskych pomôckach
Odchýlka postupu	nevzťahuje sa
Neštandardná skúšobná metóda	nevzťahuje sa

Skúšobný protokol / prázdny skúšobný protokol

Skúšobný protokol č.	ENC14683-A2
Pôvodca TRF	ENC

Položka testu

Opis	Jednorazové medicínske masky
Obchodná značka	Eagledon
Model	175mm*95mm
Klasifikácia	Typ 1

Okrúhla pečiatka ENC
East Notice Certification 1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City Tel: +[redacted] F[redacted] E-mail: enc@enc-lab.com http://www.enc-lab.com

Testovanie

[redacted]

Súhrn testov

[redacted]

považovali za uspokojivé v súlade s klasifikáciou typu I v EN 14683: 2019.

Okrúhla pečiatka ENC
East Notice Certification 1/F, Hachui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City Tel: +[redacted] Fax: +[redacted] E-mail: enc@enc-lab.com http://www.enc-lab.com

...ledky testovania

Číslo vzorky	Účinnosť bakteriálnej filtrácie (BFE) (%)	Diferenčný tlak	Odolnosť voči postriekaniu (kPA)	Mikrobiálne čistenie (cfu/g)	Záver
[redacted]					

Percentá účinnosti filtrácie sa vypočítali pomocou nasledujúcej rovnice

$$\%BEF = \frac{C - T}{C} \times 100$$

C = Priemer pozitívnej kontroly

T = Celkový počet dotličiek získaných v smere toku testovaného výrobku

Poznámka: Celkový počet dotličiek je k dispozícii na požiadanie

Okrúhla pečiatka ENC
East Notice Certification
1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town, Tianhe District, Guangzhou City
Tel: [redacted] Fax: [redacted]
E-mail: enc@enc-lab.com http://www.enc-lab.com

PREKLADATEĽSKÁ DOLOŽKA

Preklad som vypracovala ako prekladateľka zapísaná v zozname znalcov, tlmočníkov a prekladateľov, ktorý vedie Ministerstvo spravodlivosti Slovenskej republiky v odbore jazyk slovenský – anglický pod evidenčným číslom 970215.

Preklad je zapísaný v denníku pod číslom 101/2020.

Prekladané listiny súhlasia s preloženými listinami.

Zároveň vyhlasujem, že som si vedomá následkov vedome nepravdivého prekladu.

[redacted]

[redacted]