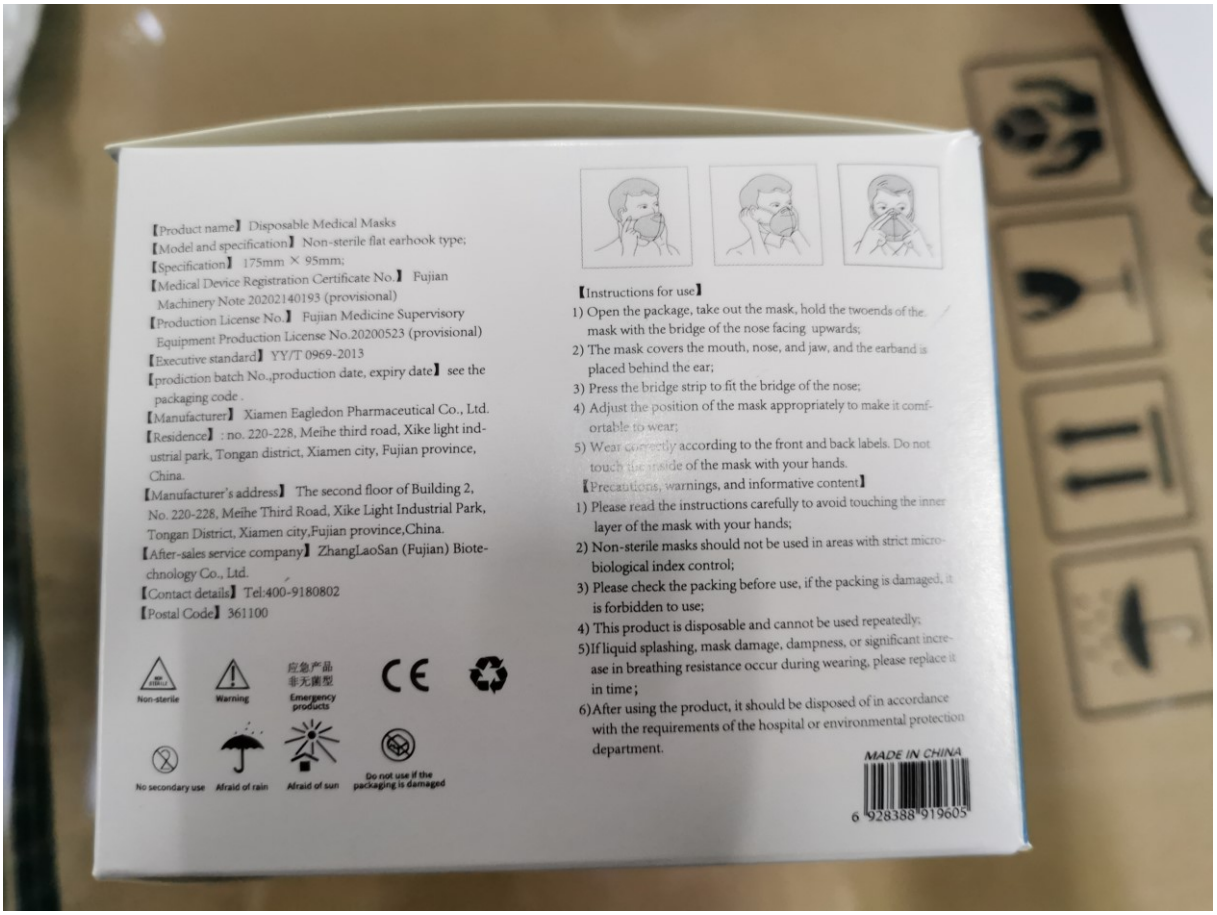

CE | 章老三
一次性使用
医用口罩
Disposable Medical Mask
细菌过滤率（BFE）
可以阻止超过95%的
含有细菌的飞沫
BATERIA FILTRATION RATE(BFE)
block more than 95% of bacteria
50 只/盒
pcs/box


【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
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
【Instructions for use】
1) Open the package, take out the mask, hold the twoends of the mask with the bridge of the nose facing upwards;
2) The mask covers the mouth, nose, and jaw, and the earband is placed behind the ear;
3) Press the bridge strip to fit the bridge of the nose;
4) Adjust the position of the mask appropriately to make it comfortable to wear;
5) Wear correctly according to the front and back labels. Do not touch the inside of the mask with your hands.
【Precautions, warnings, and informative content】
1) Please read the instructions carefully to avoid touching the inner layer of the mask with your hands;
2) Non-sterile masks should not be used in areas with strict microbiological index control;
3) Please check the packing before use, if the packing is damaged, it is forbidden to use;
4) This product is disposable and cannot be used repeatedly;
5)If liquid splashing, mask damage, dampness, or significant increase in breathing resistance occur during wearing, please replace it in time;
6)After using the product, it should be disposed of in accordance with the requirements of the hospital or environmental protection department.
MADE IN CHINA
6 928388 919605

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: +86-20-2331 4234

FAX: +86-20-8256 8534

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

Report reference No. ..... :	ENC2003192GZ01E1
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

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Testing

Date of receipt of test item ……:	Mar. 19, 2020
Date(s) of performance of test ……:	Mar. 19, 2020 - Mar. 26, 2020
Test Side……:	Either Side
BFE Area Tested……:	~40 cm^2
BFE Flow Rate……:	28.3 Liters per minute (L/min)
Delta P Flow Rate……:	8 L/min
Conditioning Parameters……:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours.
Positive Control Average……:	2.0x10^3 CFU
Negative Monitor Count……:	<1 CFU
MPS……:	3.0 μm

Summary of testing

The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of Staphylococcus aureus was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.7 - 2.7 x 10^3 colony forming units (cfu) with a mean particle size (MPS) at 3.0μm ± 0.3μm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with EN 14683:2019, Annex B.

The Differential pressure test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Differential pressure test was designed to comply with EN 14683:2019, Annex C.

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

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Test results:

Sample No.	Bacterial filtration efficiency (BFE), (%)	Differential pressure (Pa/cm^2)	Splash resistance Pressure (kPa)	Microbial cleanliness (cfu/g)	Verdict
1	98.7	26.5	Not required	18.1	PASS
2	98.5	24.5	Not required	17.7	PASS
3	98.8	25.5	Not required	17.9	PASS
4	98.7	23.5	Not required	18.2	PASS
5	98.7	23.5	Not required	18.2	PASS

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

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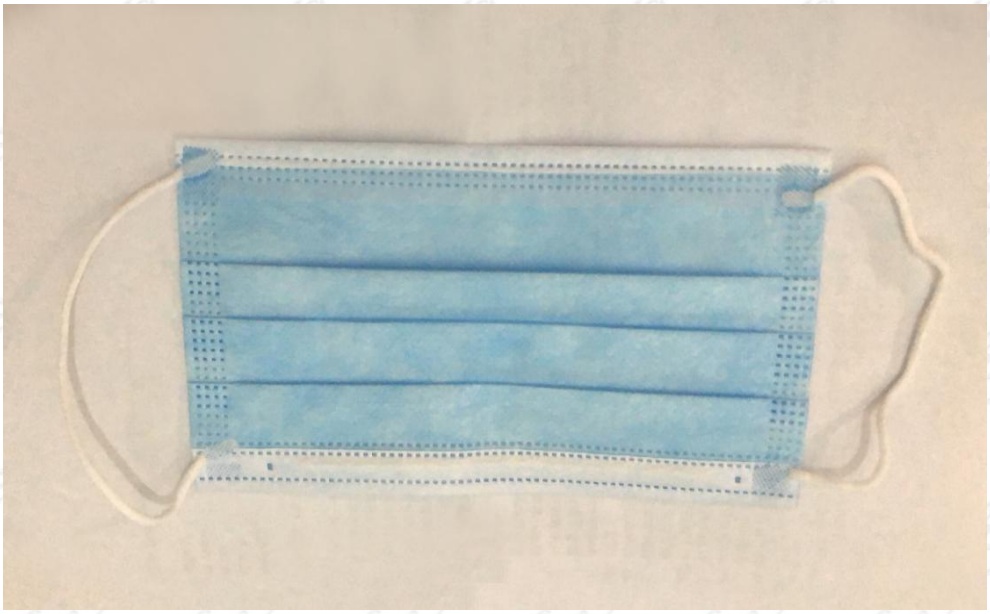
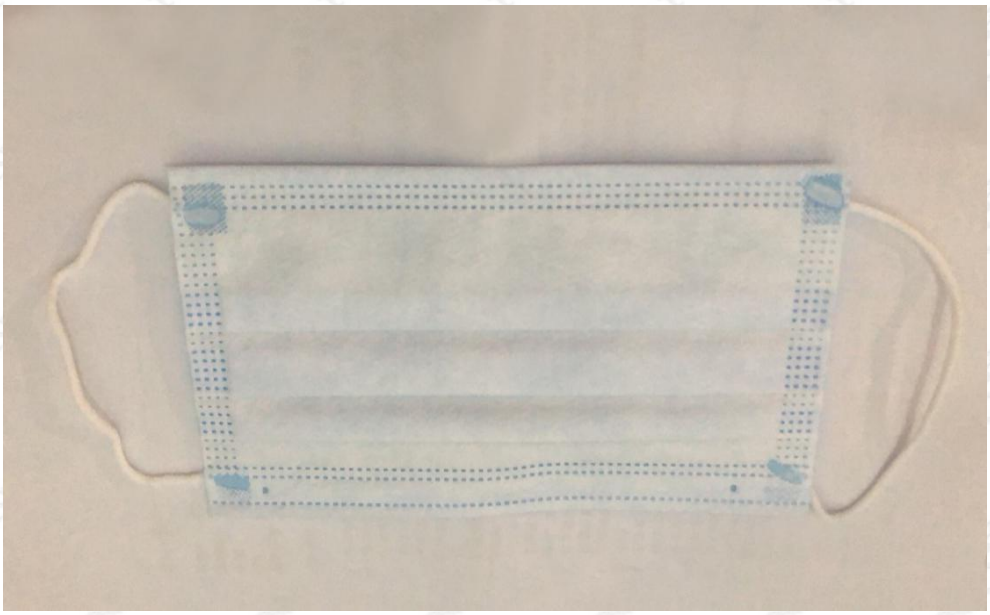
APPENDIX A
PHOTO(S) OF PRODUCT





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

The results shown in this test report refer only to the sample(s) tested unless otherwise stated and the sample(s) are retained for 30 days only. The document is issued by ENC, this document cannot be reproduced except in full with our prior written permission. The document is available on request and the brief information for its validation can be assessable and confirmed at http://www.enc-lab.com.

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.

XIAMEN EAGLE DON PHARMACEUTICAL CO., LTD. 厦门鹰君药业有限公司 3502123246045

Place and date of issue:

2020.04.16

Name position and signature of authorized person

Expiry date of document:

2020.12.30

中泰认证

质量管理体系认证证书

注册号：29020Q00329-04R0S

厦门鹰君药业有限公司

统一社会信用代码：9135021270548261X5

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）

ZHONGTAI UNION CERTIFICATION CO.,LTD 中泰联合认证有限公司

签发人：

ZHONGTAI UNION CERTIFICATION ZTC 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)。

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。

0011533

中泰认证

QUALITY MANAGEMENT SYSTEM CERTIFICATION

Registration NO: 29020Q00329-04R0S

Xiamen Eagledon Pharmaceutical Co., Ltd.

Unified social credit code:9135021270548261X5

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)

ZHONGTAI UNION CERTIFICATION CO.,LTD 中泰联合认证有限公司 证书专用章

Issuer:

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).

ZhongTai Union Certification Co., LTD.

Tel: +86 028-62521000 www.ztccc.org

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

0011584

中泰认证

质量管理体系认证证书

注册号：29020Q00328-04R0S

厦门鹰君药业有限公司

统一社会信用代码：9135021270548261X5

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 CO.,LTD 中泰联合认证有限公司

签发人：

ZHONGTAI UNION CERTIFICATION ZTC 中泰联合认证

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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：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。

00011582

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 using standards as indicated in the declaration of conformity Test report reference : BST200314379203CR	✔ 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

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Massimiliano Bertoldi
General Manager – CELAB
www.celab.com

www.celab.com

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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*
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Use of valid Harmonized standard in the declaration of conformity	✔ OK
Presence of product description in the technical construction file	✔ OK

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Massimiliano Bertoldi
General Manager – CELAB

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.

中泰认证

QUALITY MANAGEMENT SYSTEM CERTIFICATION

Registration NO: 29020Q00328-04R0S

Xiamen Eagledon Pharmaceutical Co., Ltd.

Unified social credit code:9135021270548261X5

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)

ZHONGTAI UNION CERTIFICATION CO.,LTD 中泰联合认证有限公司

Issuer:

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).

ZhongTai Union Certification Co., LTD.

Tel: +86 028-62521000 www.ztccc.org

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

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