EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 093291 0001 Rev. 01

Manufacturer: Micomme Medical Technology Development Co., Ltd.
Room 101, North 1st Floor and Room 301
East 3rd Floor
Superstar Enterprise Center
No 8, Lujing Road, High-Tech Zone
410205 Changsha, Hunan
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Sleep Apnoea Therapy Devices , Heated Humidified High Flow Nasal Cannula Oxygen Therapy Device(HFNC)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: GZ1920901

Valid from: 2020-02-11
Valid until: 2021-02-18

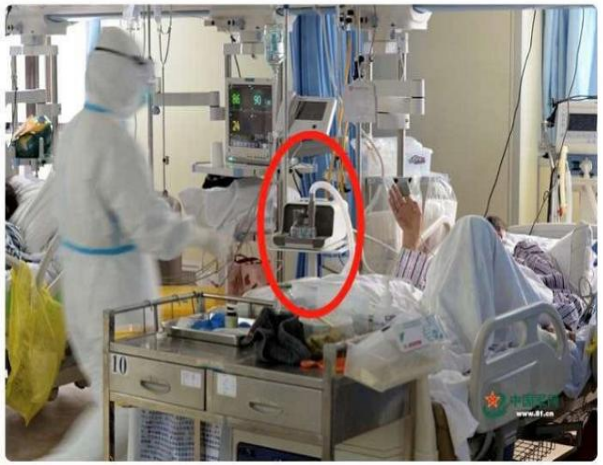
Date, 2020-02-11

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

1月27日上午，海军军医大学医疗队医护人员在武汉汉口医院重症监护室对新型冠状病毒感染的肺炎患者进行救治。这是医护人员迅速处置突发情况。中国军网记者 范显海摄

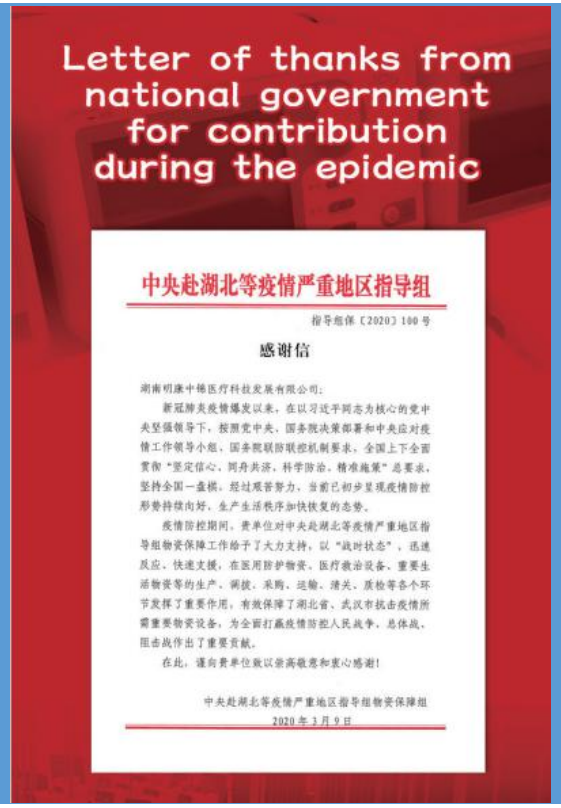


CZITC

yangyuan@czitc.cn

NO.H01-1

企业名称 Company		产品名称 Product		型号
湖南明康中锦医疗科技发展有限公司	**Micome Medical Technology Development Co.,Ltd**	高流量无创呼吸湿化治疗仪	Heated Humidified High Flow Nasal Cannula Oxyge Therapy Device(HFNC)	OH-70C
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√		



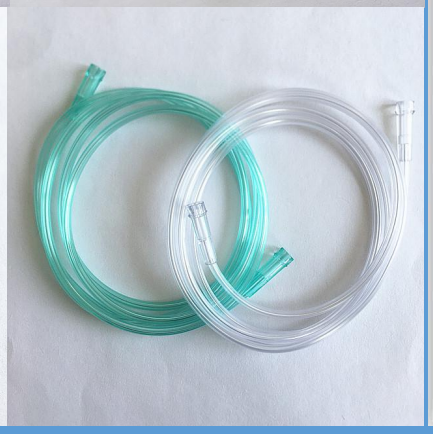
CZITC

yangyuan@czitc.cn

NO.H01-2

企业名称 Company		产品名称 Product		型号
湖南明康中锦医疗科技发展有限公司	**Micome Medical Technology Development Co.,Ltd**	无创呼吸机	Non-invasive ventilator	ST-30H
是否白名单企业	国内批准文号	CE	FDA	其他
是	湘械注准20192080049	——		呼吸机类白名单12#



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland

Registration No.: DD 60136362 0001

Report No.: 15054746 010

Manufacturer: Zhejiang Yuantong Medical Appliances Co., Ltd. East Side of Xinqiao, Shuangxin Highway Xinshi Town, Deqing County Huzhou 313201 Zhejiang China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60124099 0001

Expiry Date: 2022-10-17

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

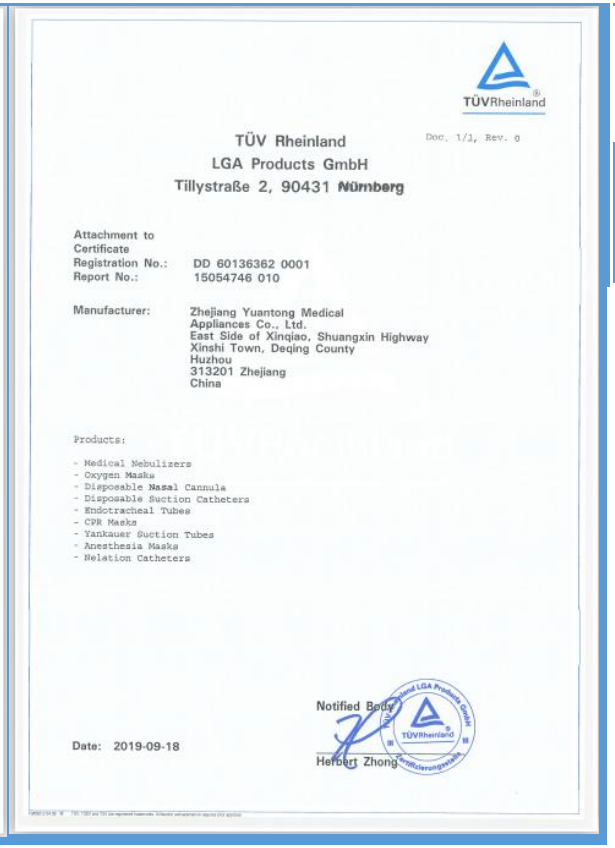
Effective Date: 2019-09-18

Date: 2019-09-18

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



TÜVRheinland

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate
Registration No.: DD 60136362 0001
Report No.: 15054746 010

Manufacturer: Zhejiang Yuantong Medical Appliances Co., Ltd. East Side of Xinqiao, Shuangxin Highway Xinshi Town, Deqing County Huzhou 313201 Zhejiang China

Products:

- Medical Nebulizers
- Oxygen Masks
- Disposable Nasal Cannula
- Disposable Suction Catheters
- Endotracheal Tubes
- CPR Masks
- Yankauer Suction Tubes
- Anesthesia Masks
- Nelaton Catheters

Notified Body

Herbert Zhong

Date: 2019-09-18

CZITC

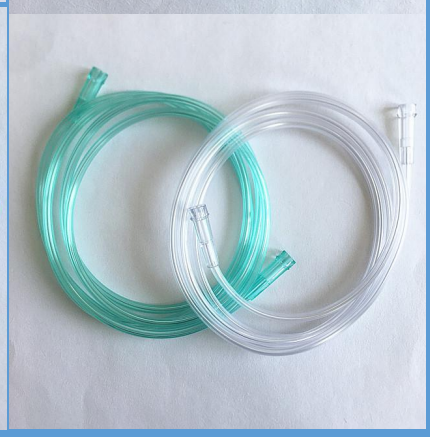
yangyuan@czitc.cn

NO.H02-1

企业名称 Company		产品名称 Product		型号
浙江源通医疗器械有限公司	Zhejiang Yuantong Medical Appliances Co., Ltd	氧气面罩	simple oxygen mask	A0106
是否白名单企业	国内批准文号	CE	FDA	其他
--	浙械注准20162560069	√	√	

Zhejiang Yuantong Medical Appliances Co., Ltd. is located in the famous ancient town- Xinshi Town, Deqing County, owning advanced equipment for management,production and monitor, and strictly carries out management in light of GB/T19001-2000,idtlSO9001-2000 and YY/T0287-2003.Company has got CE0197,FDA certificate, also the certificate approved by Chinese medical Bureau.The company specialized in manufacturing production for medical consumables with strong product development team and technology like oxygen mask,medical nebulizer, nasal oxygen cannula, suction catheter etc. Yuantong will serve broad customers with reliable quality, reasonable price and excellent service and credit.



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland

Registration No.: DD 60136362 0001

Report No.: 15054746 010

Manufacturer: Zhejiang Yuantong Medical Appliances Co., Ltd. East Side of Xinqiao, Shuangxin Highway Xinshi Town, Deqing County Huzhou 313201 Zhejiang China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60124099 0001

Expiry Date: 2022-10-17

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-09-18

Date: 2019-09-18

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate
Registration No.: DD 60136362 0001
Report No.: 15054746 010

Manufacturer: Zhejiang Yuantong Medical Appliances Co., Ltd. East Side of Xinqiao, Shuangxin Highway Xinshi Town, Deqing County Huzhou 313201 Zhejiang China

Products:

- Medical Nebulizers
- Oxygen Masks
- Disposable Nasal Cannula
- Disposable Suction Catheters
- Endotracheal Tubes
- CPR Masks
- Yankauer Suction Tubes
- Anesthesia Masks
- Nelaton Catheters

Notified Body

Herbert Zhong

Date: 2019-09-18

CZITC

yangyuan@czitc.cn

NO.H02-2

企业名称 Company		产品名称 Product		型号
浙江源通医疗器械有限公司	Zhejiang Yuantong Medical Appliances Co., Ltd	医用雾化器	Medical nebulizer	
是否白名单企业	国内批准文号	CE	FDA	其他
--	浙械注准20162540070	√	√	

Zhejiang Yuantong Medical Appliances Co., Ltd. is located in the famous ancient town- Xinshi Town, Deqing County, owning advanced equipment for management,production and monitor, and strictly carries out management in light of GB/T19001-2000,idtlSO9001-2000 and YY/T0287-2003.Company has got CE0197,FDA certificate, also the certificate approved by Chinese medical Bureau.The company specialized in manufacturing production for medical consumables with strong product development team and technology like oxygen mask,medical nebulizer, nasal oxygen cannula, suction catheter etc. Yuantong will serve broad customers with reliable quality, reasonable price and excellent service and credit.

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland

Registration No.: DD 60136362 0001

Report No.: 15054746 010

Manufacturer: Zhejiang Yuantong Medical Appliances Co., Ltd. East Side of Xinqiao, Shuangxin Highway Xinshi Town, Deqing County Huzhou 313201 Zhejiang China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60124099 0001

Expiry Date: 2022-10-17

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

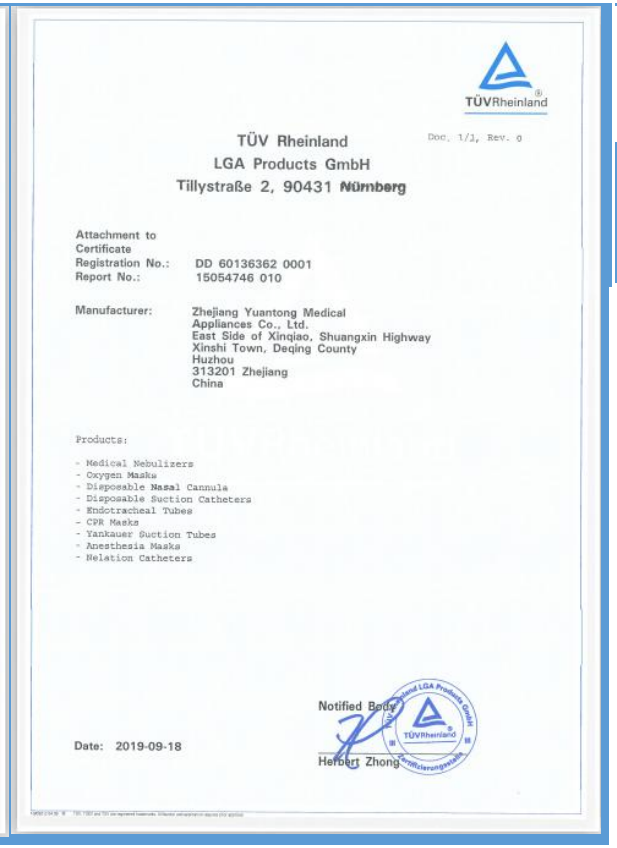
Effective Date: 2019-09-18

Date: 2019-09-18

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



TÜVRheinland

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate
Registration No.: DD 60136362 0001
Report No.: 15054746 010

Manufacturer: Zhejiang Yuantong Medical Appliances Co., Ltd. East Side of Xinqiao, Shuangxin Highway Xinshi Town, Deqing County Huzhou 313201 Zhejiang China

Products:

- Medical Nebulizers
- Oxygen Masks
- Disposable Nasal Cannula
- Disposable Suction Catheters
- Endotracheal Tubes
- CPR Masks
- Yankauer Suction Tubes
- Anesthesia Masks
- Nelaton Catheters

Notified Body

Herbert Zhong

Date: 2019-09-18

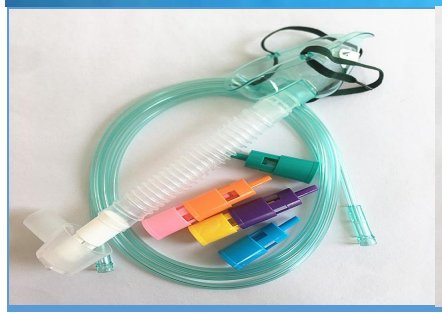
CZITC

yangyuan@czitc.cn

NO.H02-3

企业名称 Company		产品名称 Product		型号
浙江源通医疗器械有限公司	Zhejiang Yuantong Medical Appliances Co., Ltd	鼻氧管	nasal oxygen cannula	
是否白名单企业	国内批准文号	CE	FDA	其他
--	浙械注准20162560068	√	√	

Zhejiang Yuantong Medical Appliances Co., Ltd. is located in the famous ancient town- Xinshi Town, Deqing County, owning advanced equipment for management,production and monitor, and strictly carries out management in light of GB/T19001-2000,idtlSO9001-2000 and YY/T0287-2003.Company has got CE0197,FDA certificate, also the certificate approved by Chinese medical Bureau.The company specialized in manufacturing production for medical consumables with strong product development team and technology like oxygen mask,medical nebulizer, nasal oxygen cannula, suction catheter etc. Yuantong will serve broad customers with reliable quality, reasonable price and excellent service and credit.



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland

Registration No.: DD 60136362 0001

Report No.: 15054746 010

Manufacturer: Zhejiang Yuantong Medical Appliances Co., Ltd.
East Side of Xinqiao, Shuangxin Highway
Xinshi Town, Deqing County
Huzhou
313201 Zhejiang
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60124099 0001

Expiry Date: 2022-10-17

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

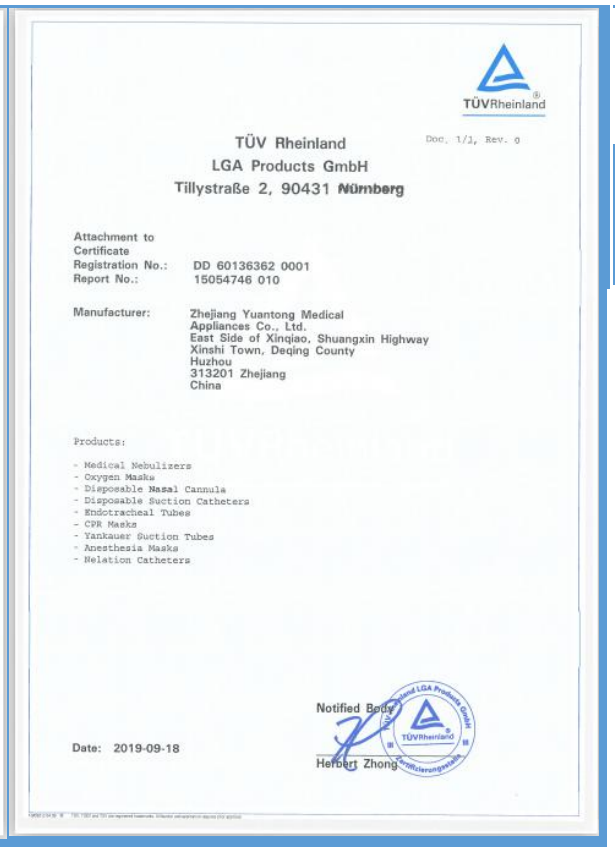
Effective Date: 2019-09-18

Date: 2019-09-18

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



TÜVRheinland

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate
Registration No.: DD 60136362 0001
Report No.: 15054746 010

Manufacturer: Zhejiang Yuantong Medical Appliances Co., Ltd.
East Side of Xinqiao, Shuangxin Highway
Xinshi Town, Deqing County
Huzhou
313201 Zhejiang
China

Products:

- Medical Nebulizers
- Oxygen Masks
- Disposable Nasal Cannula
- Disposable Suction Catheters
- Endotracheal Tubes
- CPR Masks
- Yankauer Suction Tubes
- Anesthesia Masks
- Nelaton Catheters

Notified Body

Herbert Zhong

Date: 2019-09-18

CZITC

yangyuan@czitc.cn

NO.H02-4

企业名称 Company		产品名称 Product		型号
浙江源通医疗器械有限公司	Zhejiang Yuantong Medical Appliances Co., Ltd	可调面罩	adjustable mask	
是否白名单企业	国内批准文号	CE	FDA	其他
--	浙械注准20162560069	√	√	

Zhejiang Yuantong Medical Appliances Co., Ltd. is located in the famous ancient town- Xinshi Town, Deqing County, owning advanced equipment for management,production and monitor, and strictly carries out management in light of GB/T19001-2000,idtlSO9001-2000 and YY/T0287-2003.Company has got CE0197,FDA certificate, also the certificate approved by Chinese medical Bureau.The company specialized in manufacturing production for medical consumables with strong product development team and technology like oxygen mask,medical nebulizer, nasal oxygen cannula, suction catheter etc. Yuantong will serve broad customers with reliable quality, reasonable price and excellent service and credit.

501#

502#

amtre veritas

AMTRE VERITAS STANDARD TECHNICAL TESTING LTD

Certificate of Compliance

With European Directives

Applicant Manufacture: Taizhou City Jixing Safety Protection Products Co.,Ltd.
Add.: Banyang Village , Duqiao Town , Linhai City , Zhejiang Province , China
Product Name: Safety Goggles
Model/type: KS315 , KS501 , KS502 , KS503 , KS504 , KS505 , KS506 , KS615 , KS3048 , KSET504

The submitted sample of the above product has been tested for CE marking according to the following European Directives:

(EU) 2016/425 PPE Directive

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

EN 166: 2002 Personal eye protection - Specifications
EN 167: 2002 Personal eye protection - Optical Test Methods
EN 168: 2002 Personal eye protection - Non - Optical Test Methods
EN 1938: 2010 Personal eye protection - Goggles for motorcycle and moped users

The referred report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The CE marking as shown below can be affixed on the product.

Certificate No.: AV-TZJX20200326030

Date: Mar 26 ,2020

for amtre veritas:

General Manager

amtre veritas:No.96 holcroft house ingrave street london
Tel:00442078010996 Fax:00442075014189
Http://www.amtre-veritas.com PC:SW1125Q
E-mail:amtreveritas@gmail.com

COMMON SEAL

Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: PP-GB-20190103-01-9B

Certificate holder:	Taizhou City Jixing Safety Protection Products Co.,Ltd. Banyang Village,Duqiao Town,Linhai City, Zhejiang Province, China P.C.317016
Product:	Protective eyewear Detailed product description listed in the Annex
Model(s):	See Annex
Standard(s):	EN166:2001 Personal Eye-Protection - specification EN170:2002 Personal Eye-Protection - UV filters
Issue date:	2019-03-08
Revision date:	2019-08-06
Expiry date:	2024-03-07

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the applicable Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425.
Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS UK Ltd.
CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.
This certificate is valid only if then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.
This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.

Approved by UK Government as a Notified Body for CE Marking No.1105

6038

Approved by:

Owen Bian – Office Manager

CCQS UK Ltd.
5 Harbour Exchange Square London, E14 9GE, United Kingdom
Tel: +44 (0) 20 7868 1509 Website: www.ccqs.co.uk E-mail: info@ccqs.co.uk
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Page 1 of 2

Module B EU Type-Examination Certificate

Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: PP-GB-20190103-01-9B

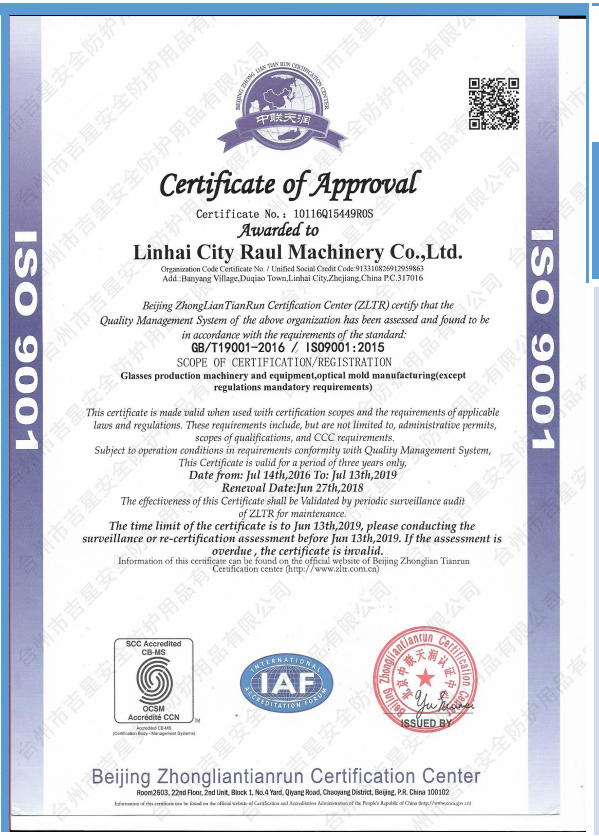
Applicable standards and specification:
EN166:2001 Personal Eye-Protection - specification
EN170:2002 Personal Eye-Protection - UV filters

Model reference	Product description
KS101	Spectacles with polycarbonate clear lens and frame with UV filtering lens, 2-1.2 or 2C-1.2, Low energy impact (F) , Optical Class 1
KS102	Spectacles with Clear lens and black nylon frame and temple, Low energy impact (F) , Optical Class 1
KS103	Spectacles with polycarbonate clear lens and frame with UV filtering lens, 2-1.2 or 2C-1.2, Low energy impact (F) , Optical Class 1
KS306	Spectacles with polycarbonate clear lens and frame with rubber temple tips and nose piece, Low energy impact (F) , Optical Class 1

Certificate Revision	Revision date	Revision details
A	08-03-2019	Initial issue
B	06-08-2019	Added reference to EN170

CCQS UK Ltd.
5 Harbour Exchange Square London, E14 9GE, United Kingdom
Tel: +44 (0) 20 7868 1509 Website: www.ccqs.co.uk E-mail: info@ccqs.co.uk
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

Page 2 of 2



ISO 9001

ISO 9001

Certificate of Approval

Certificate No.: 10116Q15449R0S

Awarded to

Linhai City Raul Machinery Co.,Ltd.

Organization Code Certificate No. / Unified Social Credit Code:91331082691295986J
Add.:Banyang Village,Duqiao Town,Linhai City,Zhejiang,China P.C.317016

Beijing ZhongLianTianRun Certification Center (ZLTR) certify that the Quality Management System of the above organization has been assessed and found to be in accordance with the requirements of the standard:

GB/T19001-2016 / ISO9001:2015

SCOPE OF CERTIFICATION/REGISTRATION

Glasses production machinery and equipment,optical mold manufacturing(except regulations mandatory requirements)

This certificate is made valid when used with certification scopes and the requirements of applicable laws and regulations. These requirements include, but are not limited to, administrative permits, scopes of qualifications, and CCC requirements.
Subject to operation conditions in requirements conformity with Quality Management System, This Certificate is valid for a period of three years only,
Date from: Jul 14th,2016 To: Jul 13th,2019
Renewal Date:Jun 27th,2018
The effectiveness of this Certificate shall be Validated by periodic surveillance audit of ZLTR for maintenance.
The time limit of the certificate is to Jun 13th,2019, please conducting the surveillance or re-certification assessment before Jun 13th,2019. If the assessment is overdue , the certificate is invalid.
Information of this certificate can be found on the official website of Beijing Zhonglian Tianrun Certification center (http://www.zltr.com.cn)

SCC Accredited CB-MS
OCSM Accrédité CCN

IAF

ISSUED BY

Beijing Zhongliantianrun Certification Center
Room2603, 22nd Floor, 2nd Unit, Block 1, No.4 Yard, Qiyang Road, Chaoyang District, Beijing, P.R. China 100102

CZITC

yangyuan@czitc.cn

NO.G-01

企业名称 Company		产品名称 Product		型号
台州市吉星安全防护用品有限公司	Taizhou Jixing Safety Protection Products Co., Ltd	医用隔离眼罩	Medical isolation goggles	501#，502#
是否白名单企业	国内批准文号	CE	FDA	其他
--	浙台械备20200005	√		

yangyuan@czitc.cn

NO.G-02

企业名称 Company		产品名称 Product		型号
安吉正邦医疗器械有限公司	ANJI ZHENGBANG MEDICAL INSTRUMENT CO.,LTD.	隔离面罩	Face Shield	
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	

“一次性医用防护服”产品生产厂家，白名单企业，浙械注准20202141035
白名单编号225#

Review Report – 审查报告 – 검토 보고서 – Rapport d'Evaluation

CE Documentation Review

No. 3J200312.HPU011

Holder: Hunan PLUCAN medical supplies Co., Ltd.
4th floor, building 6, Tianxin Venture Park, Xianfeng street, Tianxin District, Changsha City, Hunan Province, China

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Medical surgical mask **(no sterile)**

Model(s): Plane type ear hook type 17.5x9.5cm
Flat strap 17.5x9.5cm
Flat headband 17.5x9.5cm

Classification: Class I (no sterile)
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 12 March 2020
Service Manager
Luca Bedonni

Expiry date 11 March 2025
Deputy Manager
Amanda Bonfiglioli

Ente Certificazione Macchine
Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
+39.0516705141 +39.0516705156 info@entecerma.it www.entecerma.it

CERTIFICATION OF REGISTRATION

This certifies that:
Hunan PULCAN Medical Supplies Co., Ltd
4th floor, building 6, Tianxin Venture Park, Xianfeng street, Tianxin District, Changsha, Hunan, 410000, CHINA

is registered and has listed the following medical device with the U.S. Food and Drug Administration :

Owner/Operator Number : 10066161
Listing Number: D383334
Product Code : LYU
Product : Disposable medical mask
Model(s) : 17.5*9.5CM
Date Of Registration Status: 2020

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holderd's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.
Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."
The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration

Chief Engineer / Zaccheo Lee

Issued: Apr. 01, 2020
Validity Period:2020-12-31

FDA

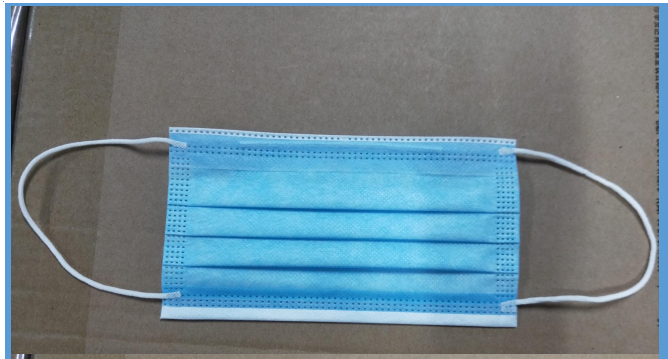
Web rep/www.fda.gov Tel 1-888-INF0-FDA(1-888-0332) E-mal vcrp@fda.gov

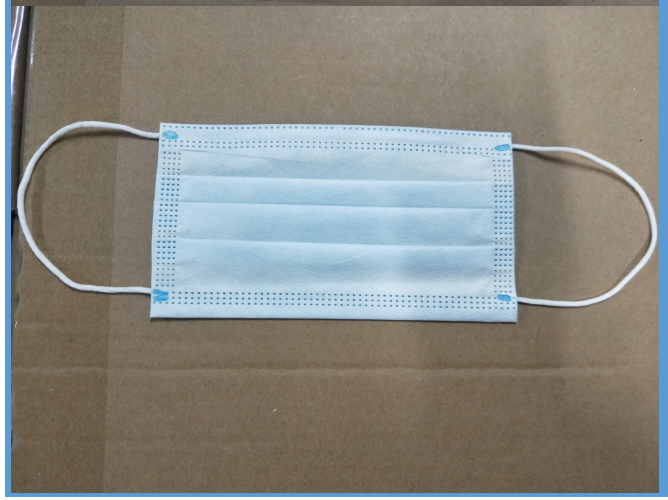
CZITC
yangyuan@czitc.cn

NO.K-01

企业名称 Company		产品名称 Product		型号
义乌市达康网络科技有限公司	Hunan PLUCAN medical supplies Co., Ltd.	医用外科口罩	Medical surgical mask (non sterile)	
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	

代理“医用外科口罩”产品生产厂家为白名单企业“湖南普瑞康医疗用品有限公司”
白名单编号370#





International Certification Registrar International Certification Registrar International Certification Registrar International Certification Registrar

Certificate

ICR Polska/CE/V/01RE482

Name and address of certificate owner:	Zhaoqing Jianxin Industrial Co.,Ltd Xinglong 1st street, Linjiang Industrial Park,National High_tech Zone,Zhaoqing City,Guangdong Province,P.R China
Name and address of manufacturer:	Zhaoqing Jianxin Industrial Co.,Ltd Xinglong 1st street, Linjiang Industrial Park,National High_tech Zone,Zhaoqing City,Guangdong Province,P.R China
Product name:	Disposable Medical Mask
Product types:	JA-301, JA-302, JA-303, JA-304, JA-305, JA-306, J-301, J-302, J-303, J-304, J-305, J-306
Product trademark:	JIANXIN 健新

- This certificate confirms that the product meets the requirements of the following standard
- The conformity was demonstrated based on following standard(s) listed by European Commission as harmonized with **Directive 93/42/EEC**

EN 14683:2019

The certification has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test report(s) No.:	MNK20200315015R
Test conducted by:	Shenzhen MONLKA Technology Co.,Ltd
Certificate issue date:	01.04.2020
Expiration date:	31.03.2025

NOTE:

- This certificate refers to the above mentioned product and its conformity in regards of above mentioned standard(s) was proven on test sample
- This certificate does not imply meeting all essential requirements, assessment of the series-production or any other restricted Notified Bodies conformity assessment procedure appropriate for the product
- This certificate holder shall use this certificate in connection to declaration of conformity and technical data relevant for the product the certificate was issued

Certificate modifications: n/a

ICR Polska Co. Ltd.
Plac Przymierza 6
02-944 Warsaw
www.icrpolska.com
e-mail: icrpolska@icrqa.com

Director: Rafał Kalinowski

Warsaw, 01. 04. 2020.

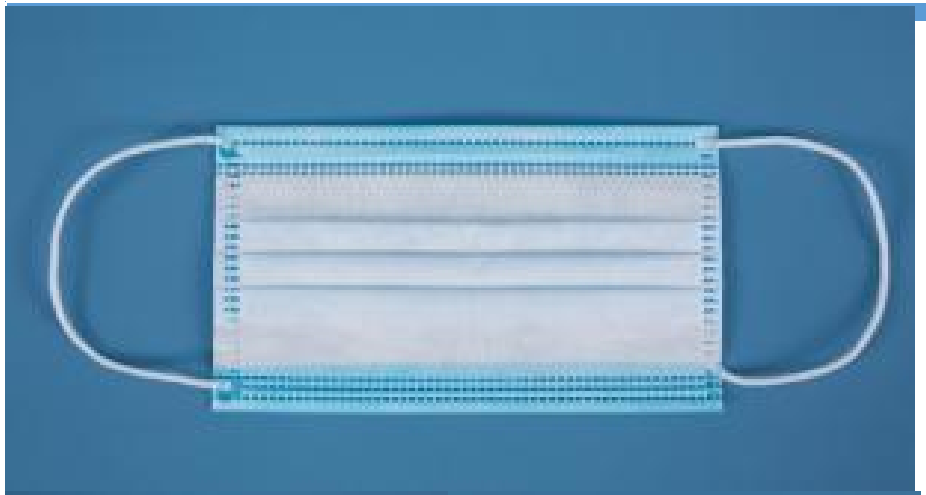
CZITC

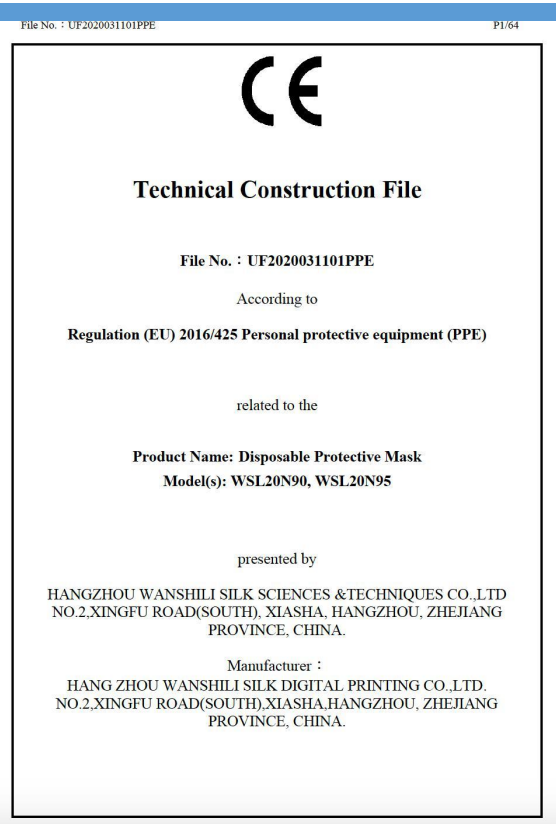
yangyuan@czitc.cn

NO.K-02

企业名称 Company		产品名称 Product		型号
杭州瑞迈杰贸易有限公司	HANGZHOU REMAGY TRADING CO.	一次性使用医用口罩	DISPOSABLE MASK	
是否白名单企业	国内批准文号	CE	FDA	其他
----	√	√		

代理“一次性医用口罩”产品生产厂家为“肇庆市健新实业有限公司”
粤肇械应急备20200027号





File No.：UF2020031101PPE P1/64

CE

Technical Construction File

File No.：UF2020031101PPE

According to

Regulation (EU) 2016/425 Personal protective equipment (PPE)

related to the

Product Name: Disposable Protective Mask
Model(s): WSL20N90, WSL20N95

presented by

HANGZHOU WANSHILI SILK SCIENCES &TECHNIQUES CO.,LTD
NO.2,XINGFU ROAD(SOUTH), XIASHA, HANGZHOU, ZHEJIANG PROVINCE, CHINA.

Manufacturer：
HANG ZHOU WANSHILI SILK DIGITAL PRINTING CO.,LTD.
NO.2,XINGFU ROAD(SOUTH),XIASHA,HANGZHOU, ZHEJIANG PROVINCE, CHINA.

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

ECM

No. 1N200313.HWSU072

Technical Construction File no. UF2020031101PPE

Certificate's Holder: Hangzhou Wanshili Silk Sciences &Techniques Co., Ltd. No.2, Xingfu Road (South), Xiasha, Hangzhou, Zhejiang Province, China.

Manufacturer: Hang Zhou Wanshili Silk Digital Printing Co., Ltd. No.2, Xingfu Road (South), Xiasha, Hangzhou, Zhejiang Province, China

Certification ECM Mark: Type Approved

Product: Disposable Protective Mask
Model(s): WSL20N90, WSL20N95

Verification to: Standard: EN 149:2001+A1:2009

related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it
This verification doesn't imply assessment of the production of the product(s).
Additional information, clarification about the CE Marking:

CE We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is responsible to start the CE Marking Certification Procedure through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

Date of Issue 13 March 2020 — Expiry date 12 March 2025

Service Manager Luca Bertocci — Deputy Manager Amanda Fayne

Ente Certificazione Macchine Srl
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

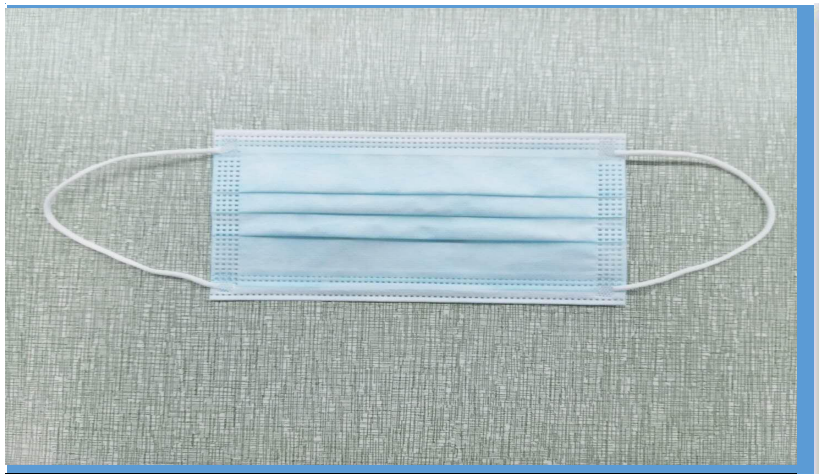
CZITC

yangyuan@czitc.cn

NO.K-03

企业名称 Company		产品名称 Product		型号
杭州鹏曜科技有限公司	Hangzhou Penya Technology Co.,ltd	平面一次性防护口罩	Flat disposable mask	WSL- 20N95
是否白名单企业	国内批准文号	CE	FDA	其他
---	√	√	√	

Hangzhou Penya technical Co.,Ltd was founded in 2009. mainly dealing with electronic products and dehumidifiers for worldwide market.
We have rich experiences in long-term working with European customers, like Legrand in France and Bticino in Italy. We clearly understand the European laws and business regulations, and familiar with the product certifications, like CE/TUV/ROHS etc. The professional team in our company can support you with prompt and excellent service on purchasing, quality control, logistic etc.
Our mask factory is a big factory, listed as the government designated medical devices registration provider. The factory has 10 automatic production lines, which can provide disposable medical masks and KN95 (FFP2) 3D masks. In addition to CE / FDA certificate, the product is also applying for DEKRA test report of EU and NIOSH test report of US.
We have enough professional testing machine inside the factory and can provide testing report with each shipment. At this critical moment, we firmly believe that quality first is the most important point, and we are willing to stand together with European to fight the virus.



Certificate

CE

Name and address of certificate owner: Hangzhou Runheng Medical Co., Ltd Room 701.7F, Building 1, NO.111 Hongxing road, Qiaonan block, Xiaoshan economic and technological development zone, Xiaoshan district, Hangzhou , Zhejiang Prv

Name and address of manufacturer:

Product name: Disposable medical mask

Product types: Type A (sterile) , type B (non sterile) , ear hook type 175 × 95

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC-P-07-07. Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co., LTD Laboratory.

Certificate issue date: 20.03.2020

Expiration date: 19.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-0118.

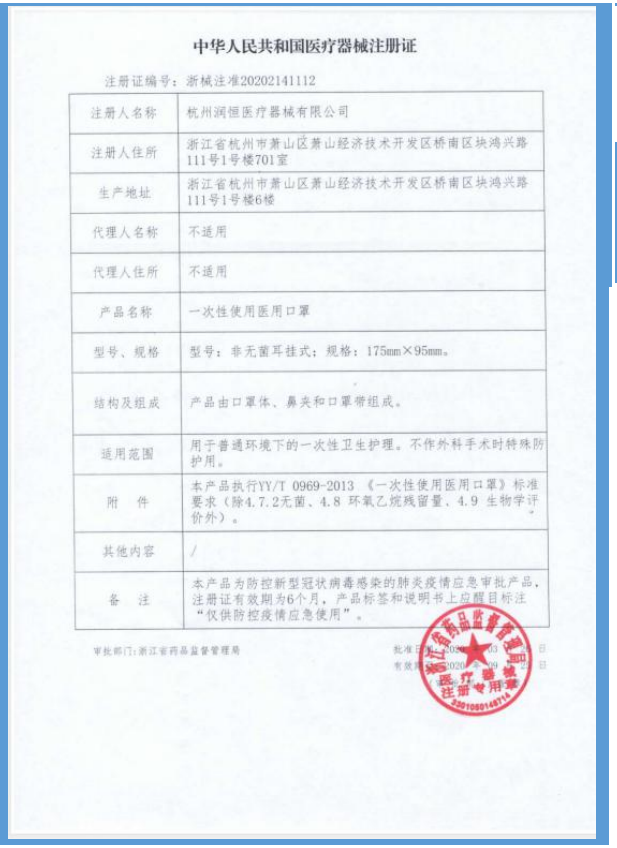
This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

Director: Rafał Kalinowski

Warsaw, 20.03.2020

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail icrpolska@icrqa.com

International Certification Registrar International Certification Registrar International Certification Registrar



中华人民共和国医疗器械注册证

注册证编号：浙械注准20202141112

注册人名称	杭州润恒医疗器械有限公司
注册人住所	浙江省杭州市萧山区萧山经济技术开发区桥南区块鸿兴路111号1号楼701室
生产地址	浙江省杭州市萧山区萧山经济技术开发区桥南区块鸿兴路111号1号楼6楼
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用医用口罩
型号、规格	型号：非无菌耳挂式；规格：175mm×95mm。
结构及组成	产品由口罩体、鼻夹和口罩带组成。
适用范围	用于普通环境下的一次性卫生护理。不作外科手术时特殊防护用。
附　件	本产品执行YY/T 0969-2013 《一次性使用医用口罩》标准要求（除4.7.2无菌、4.8 环氧乙烷残留量、4.9 生物学评价外）。
其他内容	/
备　注	本产品为防控新型冠状病毒感染的肺炎疫情应急审批产品，注册证有效期为6个月，产品标签和说明书上应醒目标注“仅供防控疫情应急使用”。

审批部门：浙江省药品监督管理局

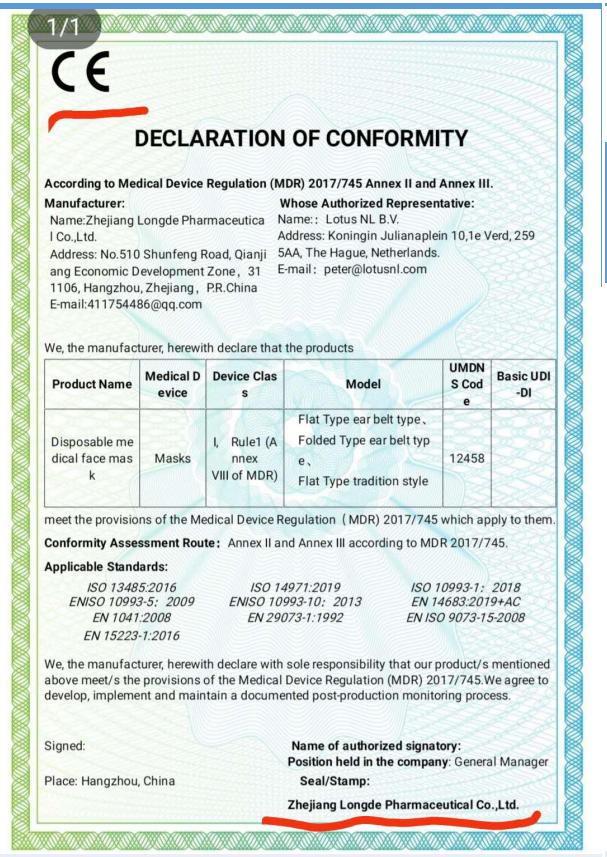
CZITC

yangyuan@czitc.cn

NO.K-04

企业名称　Company		产品名称　Product		型号
杭州润恒医疗器械有限公司	Hangzhou Runheng Medical Equipment Co., Ltd	一次性医用口罩（非灭菌型）	Disposable medical mask	
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	

“一次性医用口罩”产品生产厂家，白名单企业，浙械注准20202141112，
白名单编号705#


1/1

CE

DECLARATION OF CONFORMITY

According to Medical Device Regulation (MDR) 2017/745 Annex II and Annex III.

Manufacturer:
Name:Zhejiang Longde Pharmaceutical Co.,Ltd.
Address: No.510 Shunfeng Road, Qianjiang Economic Development Zone，31 1106, Hangzhou, Zhejiang，P.R.China
E-mail:411754486@qq.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	UMDNS Code	Basic UDI-DI
Disposable medical face mask	Masks	I, Rule1 (Annex VIII of MDR)	Flat Type ear belt type、Folded Type ear belt type、Flat Type tradition style	12458	

meet the provisions of the Medical Device Regulation（MDR) 2017/745 which apply to them.

Conformity Assessment Route: Annex II and Annex III according to MDR 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 Medical Device Regulation (MDR) 2017/745.We agree to develop, implement and maintain a documented post-production monitoring process.

Signed:

Place: Hangzhou, China

Name of authorized signatory:
Position held in the company: General Manager
Seal/Stamp:
Zhejiang Longde Pharmaceutical Co.,Ltd.

CZITC
yangyuan@czitc.cn

NO.K-05

企业名称　Company		产品名称　Product		型号
浙江龙德医药有限公司	Zhejiang Longde Pharmaceutical Co。，Ltd	一次性医用口罩	Disposable medical face mas	
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	--	

“一次性使用医用口罩”产品生产厂家，白名单企业，浙械注准20202141079，
白名单编号687#

EC-Registration Certificate

Directive 93/42/EEC on Medical Devices (MDD), Article 14
No. R A001 59 Rev. 01

MedPath

Manufacturer: Sunkiss Healthcare(Zhejiang) Co., Ltd

No.6 Panlongshan Road, Changkou New Zone,
Fuyang District, 311400 Hangzhou City,
Zhejiang Province, China

Product Category(ies): See Appendix A

CE

This is to certify that, in accordance of the Medical Device Directive 93/42/EEC (amended by 2007/47/EC), MedPath GmbH agrees to perform all duties and responsibilities as the Authorized Representative for the aforementioned manufacturer as stipulated and demanded by the aforementioned Directive. The German Competent Authority is notified of the manufacturer's medical device(s) and has allocated registration numbers shown in Appendix A. The manufacturer has provided MedPath GmbH with the appropriate Declaration(s) of Conformity confirming that the medical device(s) fulfills/fulfill the applicable requirements of the aforementioned Directive.

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

Date, 2020-03-18 MedPath GmbH

1 / 2

MedPath GmbH · Mies-van-der-Rohe-Strasse 8 · 80807 Munich · Germany

Appendix A: Product Category(ies)

MedPath

Name	Classification	UMDNS Code	Form No.	Registration No.
Medical Face Masks	I	12-447	00299020	to be issued

MedPath GmbH
Mies-van-der-Rohe-Strasse 8 · D-80807 München
Tel.089-189174474 · Fax 089-54858884

CE

2 / 2

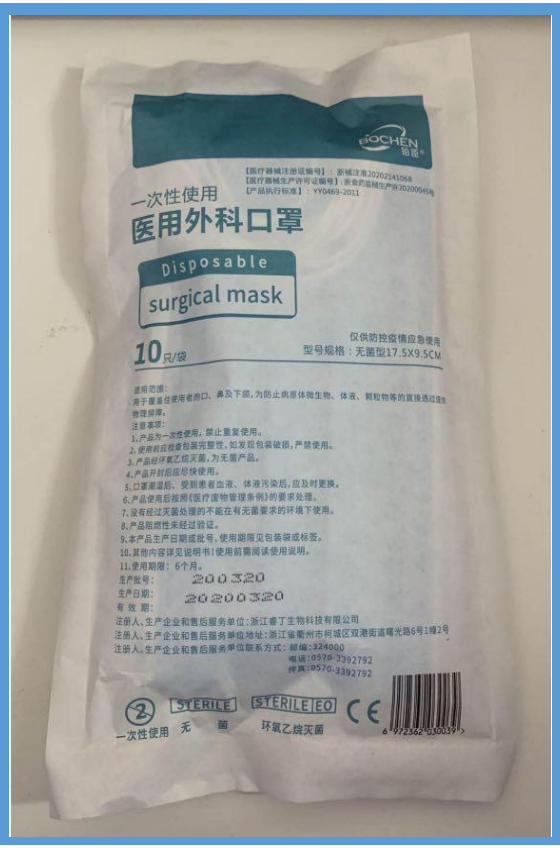
MedPath GmbH · Mies-van-der-Rohe-Strasse 8 · 80807 Munich · Germany

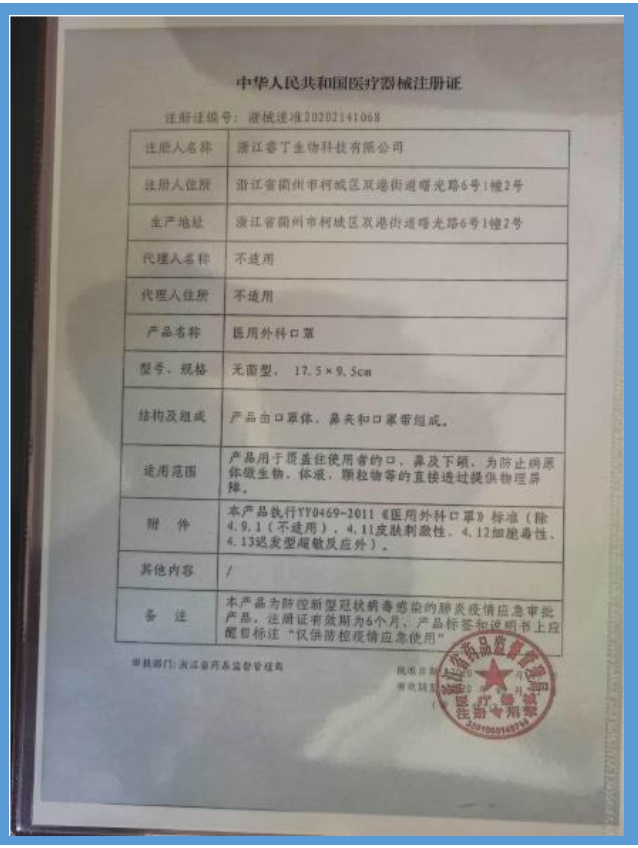
yangyuan@czitc.cn

NO.K-06

企业名称 Company		产品名称 Product		型号
浙江珍琦护理用品有限公司	Sunkiss Healthcare(zhejiang) Co., Ltd	一次性医用口罩	Disposable medical face mas	
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	

“一次性使用医用口罩”产品生产厂家，白名单企业，浙械注准20202141042，
白名单编号674#



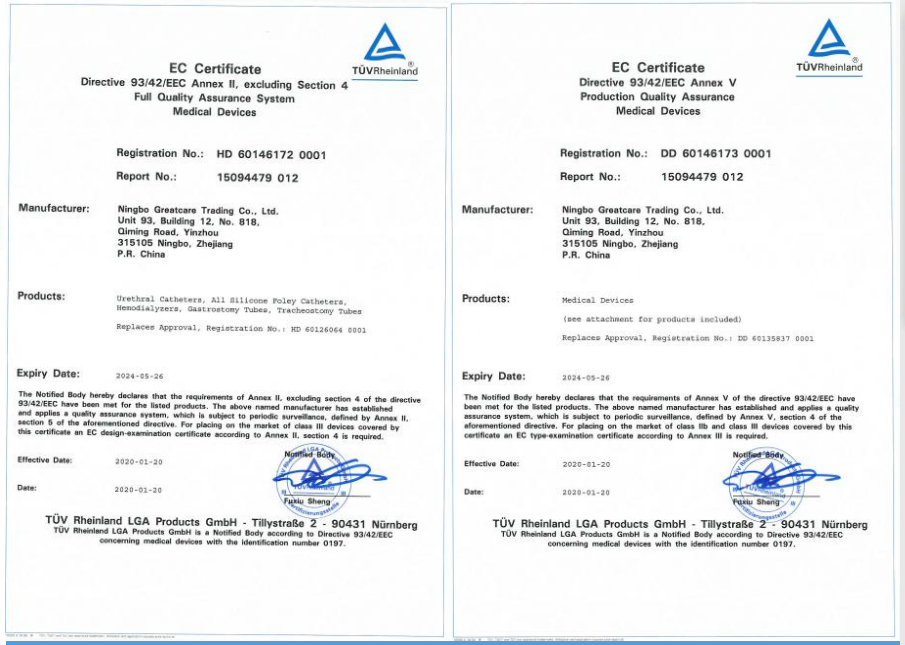


yangyuan@czitc.cn

NO.K-07

企业名称 Company		产品名称 Product		型号
浙江睿丁生物科技有限公司	Zhejiang Ruiding Biotechnology Co., Ltd.	医用外科口罩	Medical surgical mask	KN95
是否白名单企业	国内批准文号	CE	FDA	其他
是	√		--	

“医用外科口罩”生产厂家，白名单企业，浙械注准20202141068，
白名单编号357#



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland

Registration No.: HD 60146172 0001
Report No.: 15094479 012

Manufacturer: Ningbo Greatcare Trading Co., Ltd.
Unit 93, Building 12, No. 818,
Qiming Road, Yinzhou
315105 Ningbo, Zhejiang
P.R. China

Products: Urethral Catheters, All Silicone Foley Catheters, Hemodialyzers, Gastrostomy Tubes, Tracheostomy Tubes

Replaces Approval, Registration No.: HD 60126064 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-01-20
Date: 2020-01-20

Notified Body
Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland

Registration No.: DD 60146173 0001
Report No.: 15094479 012

Manufacturer: Ningbo Greatcare Trading Co., Ltd.
Unit 93, Building 12, No. 818,
Qiming Road, Yinzhou
315105 Ningbo, Zhejiang
P.R. China

Products: Medical Devices
(see attachment for products included)

Replaces Approval, Registration No.: DD 60135837 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-01-20
Date: 2020-01-20

Notified Body
Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

CERTIFICATE OF
FDA REGISTRATION

IRC

HEREBY CERTIFY THAT

FDA US AGENT
IRC USA

NINGBO GREATCARE TRADING CO., LTD.

HAS SUCESSFULLY COMPLETED/UPDATED
THE FDA REGISTRATION

FOR
OWNER/OPERATOR NUMBER: 9102181
ESTABLISHMENT REGISTRATION NUMBER: 3006652462
MEDICAL DEVICE LISTING NUMBER (MDL):

Refer to the Appendix at next page

PRINCIPAL ENGINEER

IRC
Your Partner in Achieving FDA Compliance

CERTIFICATE OF
FDA REGISTRATION

Appendix:

IRC

CZITC

yangyuan@czitc.cn

NO.K-08

企业名称 Company		产品名称 Product		型号
宁波冠克贸易有限公司	Ningbo GreatCare Trading Co., Ltd.	一次性医用口罩	face mask	3-ply non-woven material blue color earloop non-sterile
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	

代理“一次性医用口罩”产品生产厂家为白名单企业“仙桃市鼎成无纺布制品有限公司”
白名单编号52#（鄂械注准20152642206）

yangyuan@czitc.cn

NO.F-01

企业名称 Company		产品名称 Product		型号
安吉正邦医疗器械有限公司	ANJI ZHENGBANG MEDICAL INSTRUMENT CO.,LTD.	一次性医用防护服	disposable medical protective clothing	
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	

“一次性医用防护服”产品生产厂家，白名单企业，浙械注准20202141035
白名单编号225#

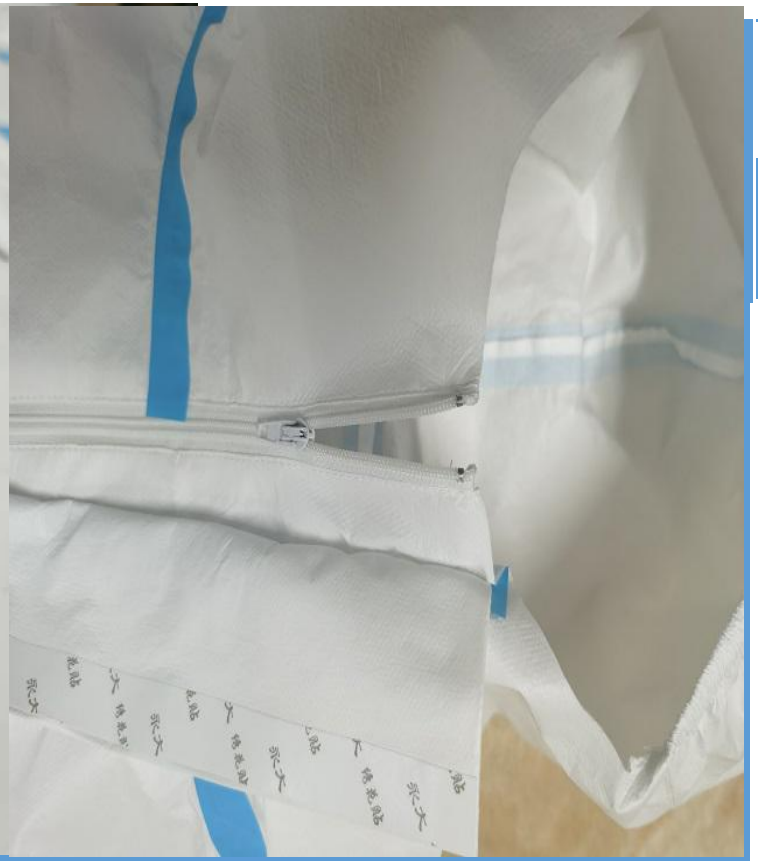
CZITC

yangyuan@czitc.cn

NO.F-02

企业名称 Company		产品名称 Product		型号
杭州瑞迈杰贸易有限公司	HANGZHOU REMAGY TRADING CO.	一次性医用防护服	DISPOSABLE PROTECTING CLOTH	
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√		

代理“一次性医用防护服”产品生产厂家为“宁波市小雨点制衣有限公司”
白名单编号232#



yangyuan@czitc.cn

NO.F-03

企业名称 Company		产品名称 Product		型号
杭州好德利智能科技有限公司	HANGZHOU GREAT TAKLEY INTELLIGENCE TECHNOLOGY COMPANY LIMITED	医用一次性防护服（非无菌）	disposable medical protective clothing	
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	

“一次性医用防护服”产品生产厂家，白名单企业，浙械注准20202141072， 海外认证证书照片以及产品符合的标准；EN14126：2003
白名单编号231#

康德芬

CEN TEX BEL

In application of the Regulation (EU) 2016/425 of 9 March 2016 concerning the harmonization of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorized by the FPS Economy (Federal Public Services) has issued the following:

EU TYPE EXAMINATION CERTIFICATE

Nr. 086/2018/0204

This EU Type examination certificate is valid until 21 Apr 2023

This certificate is valid from 21 Apr 2018.

to: **ChemDefend Co Ltd, Zhejiang**
for: **ChemDefend® 250**

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Regulation (EU) 2016/425.

For the argumentation, the following standards are used:

EN 1149-5:2008	Protective clothing - Electrostatic properties - Part 5: Material performance and design requirements
EN 13034:2005+A1:2009	Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB[6])
EN ISO 13982-1:2004+A1:2010	Protective clothing for use against solid particulates - Part 1:Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing)
EN 14126:2003	Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
EN ISO 13688:2013	Protective clothing - General requirements
EN 1073-2:2002	Protective clothing against radioactive contamination - Part 1 : Requirements and test methods for non-ventilated protective clothing against particulate radioactive contamination

If there is a former EC Type examination certificate according to the Directive 89/686/EEC this certificate remains valid until 21 April 2023 unless it expires before that date, for products that were manufactured before the issuance of this new EU Type examination certificate according to the Regulation (EU) 2016/425.

This is PPE of category III, subject to regular checks in accordance with article 19 of the European PPE Regulation. In agreement with the manufacturer's choice audits of the production process shall be carried out to assess the Conformity of type (Module D). The manufacturer must be able, on request, to present the audit report. A first audit shall be performed at the latest on 31 Dec 2019 and at least be repeated with intervals of one year.

This declaration applies to the equipment as submitted in the type testing and described in the manufacturer's technical documentation (As described in 2016/425 Annex III) that is registered with number 10158.

Issued by Centexbel, Notified Body 0493[1], in Ghent, on 29 Mar 2018

Inge De Wilde
Certification Manager

Attached: 1 Annex

[1]Recognized by FPS Economy (Federal Public Services)

BELAC 086-PROD

CENTEXBEL • TEXTILE COMPETENCE CENTRE

Technologiepark 7 • BE 9052 Gent • Belgium • phone +32 9 220 41 51 • fax +32 9 220 49 55 • gent@centexbel.be • www.centexbel.be

VAT • BE 0459.218.289 • IBAN • BE 44 2100 4729 6545 • BIC • GEBABEBB

Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

SHAOXING GOLD SUN TEXTILE CO.,LTD
Tongjitianfan, Yangqiao Village, Pingshui Town, Keqiao District, Shaoxing, Zhejiang, 312050, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10063046

FDA

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D375162	OEA	Non-surgical isolation gown	MEDICAL DISPOSABLE PROTECTIVE CLOTHING 100,250,255,310

CCT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CCT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CCT assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. CCT is not affiliated with the U.S. Food and Drug Administration.

Chief engineer
Issued: 03/15/2020
Expiration Date:12/31/2020

Shenzhen CCT Testing Technology Co.,Ltd.
W: www.fda-test.com E: fda@fda-test.com
T: 400-8788-298 T: 86-755-36916737

Website:www.fda.gov Tel:1-888-INFO-FDA (1-888-463-6332) e-mail:webmail@oc.fda.gov

CZITC

yangyuan@czitc.cn

NO.F-04-1

企业名称 Company		产品名称 Product		型号
绍兴金阳纺织有限公司	SHAOXING GOLD SUN TEXTILE CO.,LTD.	医用一次性防护服	Medical protective clothing (Non -Sterile、Sterile)	M、L、XL、XXL
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	European Standard EN14126

“一次性医用防护服”产品生产厂家，白名单企业，浙械注准浙械注准20202141022， 海外认证证书照片以及产品符合的标准CE，EN14126
白名单编号215#

CEN TEX BEL

In application of the Regulation (EU) 2016/425 of 9 March 2016 concerning the harmonization of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorized by the FPS Economy (Federal Public Services) has issued the following:

EU TYPE EXAMINATION CERTIFICATE

Nr. 086/2018/0204

This EU Type examination certificate is valid until 21 Apr 2023

This certificate is valid from 21 Apr 2018.

to: **ChemDefend Co Ltd, Zhejiang**
for: **ChemDefend® 250**

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Regulation (EU) 2016/425.

For the argumentation, the following standards are used:

EN 1149-5:2008	Protective clothing - Electrostatic properties - Part 5: Material performance and design requirements
EN 13034:2005+A1:2009	Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB[6])
EN ISO 13982-1:2004+A1:2010	Protective clothing for use against solid particulates - Part 1:Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing)
EN 14126:2003	Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
EN ISO 13688:2013	Protective clothing - General requirements
EN 1073-2:2002	Protective clothing against radioactive contamination - Part 1 : Requirements and test methods for non-ventilated protective clothing against particulate radioactive contamination

If there is a former EC Type examination certificate according to the Directive 89/686/EEC this certificate remains valid until 21 April 2023 unless it expires before that date, for products that were manufactured before the issuance of this new EU Type examination certificate according to the Regulation (EU) 2016/425.

This is PPE of category III, subject to regular checks in accordance with article 19 of the European PPE Regulation. In agreement with the manufacturer's choice audits of the production process shall be carried out to assess the Conformity of type (Module D). The manufacturer must be able, on request, to present the audit report. A first audit shall be performed at the latest on 31 Dec 2019 and at least be repeated with intervals of one year.

This declaration applies to the equipment as submitted in the type testing and described in the manufacturer's technical documentation (As described in 2016/425 Annex III) that is registered with number 10158.

Issued by Centexbel, Notified Body 0493[1], in Ghent, on 29 Mar 2018

Inge Dens
Certification Manager

Attached: 1 Annex

[1]Recognized by FPS Economy (Federal Public Services)

BELAC 086-PROD

CENTEXBEL • TEXTILE COMPETENCE CENTRE

Technologiepark 7 • BE 9052 Gent • Belgium • phone +32 9 220 41 51 • fax +32 9 220 49 55 • gent@centexbel.be • www.centexbel.be

VAT • BE 0458.218.289 • IBAN • BE 44 2100 4729 6545 • BIC • GEBABEBB

Fiscal Year 2020

CERTIFICATION OF FDA REGISTRATION

This certifies that:

SHAOXING GOLD SUN TEXTILE CO.,LTD
Tongjitianfan, Yangqiao Village, Pingshui Town, Keqiao District, Shaoxing, Zhejiang, 312050, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen CCT Testing Technology Co., Ltd.

Owner/Operator Number: 10063046

FDA

Device Listing#:

Listing No	Code	Device Name	Proprietary Name
D375162	OEA	Non-surgical isolation gown	MEDICAL DISPOSABLE PROTECTIVE CLOTHING 100,250,255,310

CCT will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CCT makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CCT assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. CCT is not affiliated with the U.S. Food and Drug Administration.

Chief engineer
Issued: 03/15/2020
Expiration Date:12/31/2020

CCT

Shenzhen CCT Testing Technology Co.,Ltd.
W: www.fda-test.com E: fda@fda-test.com
T: 400-6788-298 T: 86-755-86914737

Web:http://www.fda.gov Tel: 1-888-INFOFDA (1-888-463-6332) www: wsbmail@oc.fda.gov

CZITC

yangyuan@czitc.cn

NO.F-04-2

企业名称 Company		产品名称 Product		型号
绍兴金阳纺织有限公司	SHAOXING GOLD SUN TEXTILE CO.,LTD.	医用一次性隔离衣	Medical disposable isolation clothing	Model No: M、L、XL、XXL
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	European Standard EN14126

“一次性医用防护服”产品生产厂家，白名单企业，浙械注准浙械注准20202141022， 海外认证证书照片以及产品符合的标准CE，EN14126
白名单编号215#

Certificate

CE

Name and address of certificate owner: Hangzhou Runheng Medical Co., Ltd Room 701 7F, Building 1, NO.111 Hongxing road, Qiaonan block, Xiaoshan economic and technological development zone, Xiaoshan district, Hangzhou , Zhejiang Prv

Name and address of manufacturer:

Product name: Disposable Medical protective Coverall

Product types: Type A (sterile) , type B (non sterile) , conjoined 165 / 170 / 175 / 180 / 185

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PCP-07-07. Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co., LTD Laboratory.

Certificate issue date: 20.03.2020

Expiration date: 19.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-0118.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

Director: Rafał Kalinowski

Warsaw, 20.03.2020

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

International Certification Registrar

FDA

Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

HANGZHOU RUNHENG MEDICAL CO., LTD

Room 701 7F, Building 1, NO.111 Hongxing road, Qiaonan block, Xiaoshan economic and technological development zone, Xiaoshan district Hangzhou, Zhejiang, 311215, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.

Owner/Operator Number: 10063321

Listing No.	Product Code:	Device Name:
D376043	LYU	ACCESSORY, SURGICAL APPAREL - Disposable Medical Mask Type A (sterile) type B (non sterile) ear hook type 175*9 Non-surgical isolation gown
D376044	OEA	-Disposable Medical protective Coverall Type A (sterile) type B (non sterile) conjoined 165 / 170 / 175 / 180 / 18

UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. UCL-REG SERVICE INC. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S.Food and Drug Administration does not issue a certificate of registration, nor does the U.S Food and Drug Administration recognize a certificate of registration, UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.

UCL-REGSERVICE INC.
602 ROCKWOOD ROAD WILMINGTON,
NEW CASTLE DE 19802 USA

Cert. No.: M20620
Issued Date: 19 March 2020
Expiration Date: 31 December 2020

CZITC

yangyuan@czitc.cn

NO.F-05-1

企业名称 Company		产品名称 Product		型号
杭州润恒医疗器械有限公司	Hangzhou Runheng Medical Equipment Co., Ltd	医用一次性防护服(非灭菌型)	Disposable medical protective coverall	XS（160）、S（165）M（170）、L（175）XL（180）、XXL（185）
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	

“一次性医用防护服”产品生产厂家，白名单企业，浙械注准20202141097，
白名单编号241#

Certificate

CE

Name and address of certificate owner: Hangzhou Runheng Medical Co., Ltd Room 701 7F, Building 1, NO.111 Hongxing road, Qiaonan block, Xiaoshan economic and technological development zone, Xiaoshan district, Hangzhou , Zhejiang Prv

Name and address of manufacturer:

Product name: Disposable Medical protective Coverall

Product types: Type A (sterile) , type B (non sterile) , conjoined 165 / 170 / 175 / 180 / 185

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PCP-07-07.
Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co., LTD Laboratory.

Certificate issue date: 20.03.2020
Expiration date: 19.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-0118.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

Director: Rafał Kalinowski

Warsaw, 20.03.2020

ICR Polska Co. Ltd.
ul. Rac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

International Certification Registrar International Certification Registrar International Certification Registrar

FDA

Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

HANGZHOU RUNHENG MEDICAL CO., LTD

Room 701 7F, Building 1, NO.111 Hongxing road, Qiaonan block, Xiaoshan economic and technological development zone, Xiaoshan district Hangzhou, Zhejiang, 311215, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.

Owner/Operator Number: 10063321

Listing No.	Product Code:	Device Name:
D376043	LYU	ACCESSORY, SURGICAL APPAREL - Disposable Medical Mask Type A (sterile) type B (non sterile) ear hook type 175*9 Non-surgical isolation gown
D376044	OEA	-Disposable Medical protective Coverall Type A (sterile) type B (non sterile) conjoined 165 / 170 / 175 / 180 / 18

UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. UCL-REG SERVICE INC. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, " Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or it's products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S.Food and Drug Administration does not issue a certificate of registration, nor does the U.S Food and Drug Administration recognize a certificate of registration. UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.

UCL

UCL-REG SERVICE INC.

UCL-REGSERVICE INC.
602 ROCKWOOD ROAD,WILMINGTON,
NEW CASTLE DE 19802 USA

Cert. No.: M20620
Issued Date: 19 March 2020
Expiration Date: 31 December 2020

CZITC

yangyuan@czitc.cn

NO.F-05-2

企业名称 Company		产品名称 Product		型号
杭州润恒医疗器械有限公司	Hangzhou Runheng Medical Equipment Co., Ltd	医用一次性隔离衣	Medical disposable isolation clothing	XS（160）、S（165） M（170）、L（175） XL（180）、XXL（185）
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	

“一次性医用防护服”产品生产厂家，白名单企业，浙械注准20202141097，
白名单编号241#

Certificate

No. ICR Polska/P7700217

CE

Name and address of certificate owner: Chongqing Litai Clothing Group Co., Ltd. Textile City D7-1 #, Maliu Yanjiang Development Zone, Banan District, Chongqing, China

Product name: PROTECTIVE CLOTHING

Product types: LT- XXXXL, LT- M, LT- L, LT- XL, LT- XXL, LT- XXXL

Product trademark: N/A

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN14126:2003+AC:2004

The certification process has been carried out in accordance with the program PC-P-07-07.

Evaluation has been carried out in accordance with test reports made by UAC Quality Technology Service (UK) Ltd

No. of test reports: TCF-UAC-20200323697PPE

Certificate issue date: 25. 03. 2020

Expiration date: 24. 03. 2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3109.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.

Director: Rafał Kalinowski

Warsaw, 25. 03. 2020

ICR Polska Co. Ltd.

ul. Plac Przymierza 6, 03-944 Warszawa

International Certification Registrar

CERTIFICATE

CERTIFICATE OF COMPLIANCE

NO: BSI1449276-EC

Applicant: CHONGQING LITAI CLOTHING GROUP CO., LTD. TEXTILE CITY D7-1 #, MALIU YANJIANG DEVELOPMENT ZONE, BANAN DISTRICT, CHONGQING CHINA

Manufacturer: CHONGQING LITAI CLOTHING GROUP CO., LTD. TEXTILE CITY D7-1 #, MALIU YANJIANG DEVELOPMENT ZONE, BANAN DISTRICT, CHONGQING CHINA

Product: PROTECTIVE CLOTHING

Model: LT—XXXXL、LT-M、LT-L、LT-XL、LT-XXL、LT-XXXL

Reference to EC Directive: Regulation (EU) 2016/425 Personal protective equipment (PPE)

Tcf(s) orTest Report(s) No.: TR-003-049-2682EN

Relevant standard (s): EN 943-1-2015

REMARKS:

Assessment of the product(s) and the production process is not covered by this verification, which has been carried out on a voluntary basis. It is duty and fully responsibility of the manufacturer to carry out all necessary safety assessment of the product(s) according to all related EC Directive and Standard(s) before putting into market/service, affixing CE mark and issue EU Declaration of Conformity. The manufacturer shall affix CE mark on the product(s) according to 2006/42/EC Article 16 and Annex II , only if the product(s) fulfill the relevant essential health and safety requirements and the drawn-up EU Declaration of Conformity. Technical File should be drawn for each type/model of related product(s) by the manufacturer and/or his authorized representative in order to assure conformity with the essential health and safety requirements which demonstrate that the machinery complies with the requirements of the related directives/standards and must be compiled in one or more official Community languages. Before placing machinery into market/service, the manufacturer or his authorized representative shall ensure that the Technical File in accordance with related directives/standards is available. The manufacturer or his authorized representative shall keep Technical File and EU Declaration of Conformity available for a period of ten years from the last date of manufacture of the machinery. The certificate consists of 1(one) page.

The Certificate is valid Until: Mar 18,2025

Date of Issue:Mar 19,2020

CERTIFICATION MANAGER:

CE

BSI TEST LIMITED

Unit G25 Waterfront Studios, 1 Dock Road, London. E16 1AH

CZITC

yangyuan@czitc.cn

NO.F-06

企业名称 Company		产品名称 Product		型号
重庆立泰服饰集团有限公司	Chongqing Litai Clothing Group Co., Ltd.	医用防护服（无菌）	medical protective clothing (sterile)	L/XL/XXL
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	

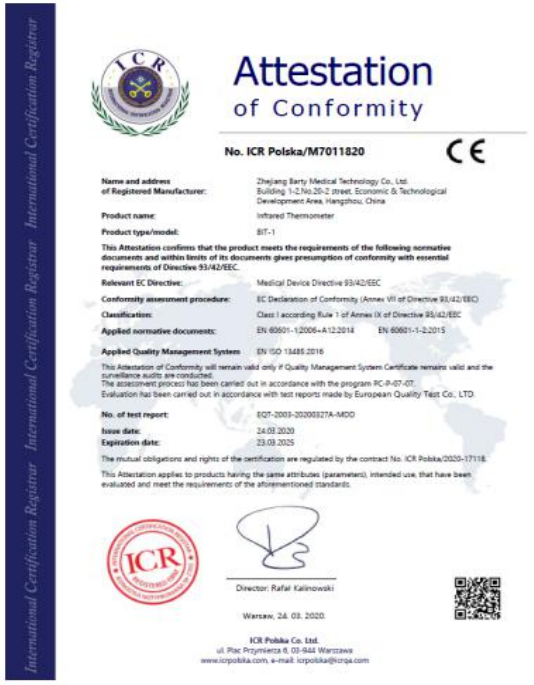
“一次性医用防护服”产品生产厂家，白名单企业，渝械注准20202140087，
白名单编号183#

Infrared Thermometer

40/CTN, 49.4*40.8*21.2cm

NW 3.3KG . Gw:4kg

CE Conformity



Attestation of Conformity

No. ICR Polska/M7011820 CE

Name and address of Registered Manufacturer: Zhejiang Barty Medical Technology Co., Ltd. Building 1-2,No.20-2 street, Economic & Technological Development Area, Hangzhou, China

Product name: Infrared Thermometer

Product type/model: BIT-1

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive: Medical Device Directive 93/42/EEC

Conformity assessment procedure: EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)

Classification: Class I according Rule 1 of Annex IX of Directive 93/42/EEC

Applied normative documents: EN 60601-1:2006+A12:2014 EN 60601-1-2:2015

Applied Quality Management System: EN ISO 13485:2016

This Attestation of Conformity will remain valid only if Quality Management System Certificate remains valid and the surveillance audits are conducted.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test reports made by European Quality Test Co., LTD.

No. of test report: EQT-2003-20200327A-MDD

Issue date: 24.03.2020

Expiration date: 23.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-17118.

This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

Director: Rafał Kalinowski

Warsaw, 24. 03. 2020

ICR Polska Co. Ltd.
ul. Plac Przymierza 8, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

International Certification Registrar International Certification Registrar International Certification Registrar

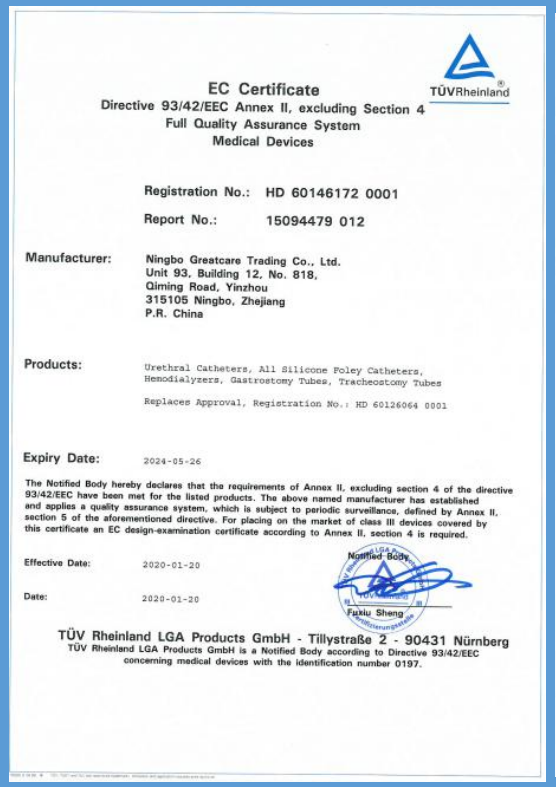
CZITC

yangyuan@czitc.cn

NO.T-01

企业名称 Company		产品名称 Product		型号
浙江巴泰医疗科技有限公司	Zhejiang Batai Medical Technology Co., Ltd.	红外额温计	infrared thermometer	BIT-1
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√		

红外额温计白名单生产企业，浙械注准20202071104
白名单编号220#



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland

Registration No.: HD 60146172 0001

Report No.: 15094479 012

Manufacturer: Ningbo Greatcare Trading Co., Ltd.
Unit 93, Building 12, No. 818,
Qiming Road, Yinzhou
315105 Ningbo, Zhejiang
P.R. China

Products: Urethral Catheters, All Silicone Foley Catheters, Hemodialyzers, Gastrostomy Tubes, Tracheostomy Tubes

Replaces Approval, Registration No.: HD 60126064 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

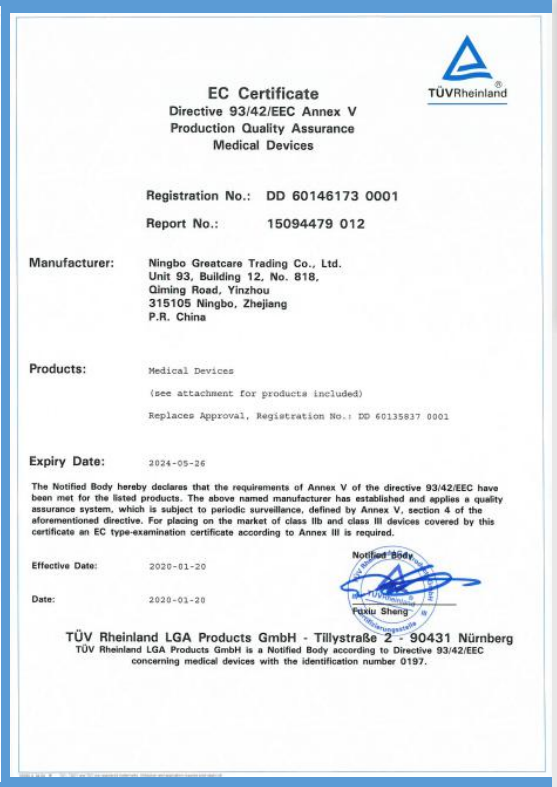
Effective Date: 2020-01-20

Date: 2020-01-20

Notified Body

Faxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland

Registration No.: DD 60146173 0001

Report No.: 15094479 012

Manufacturer: Ningbo Greatcare Trading Co., Ltd.
Unit 93, Building 12, No. 818,
Qiming Road, Yinzhou
315105 Ningbo, Zhejiang
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60135837 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-01-20

Date: 2020-01-20

Notified Body

Faxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

CERTIFICATE OF
FDA REGISTRATION

IRC

HEREBY CERTIFY THAT

NINGBO GREATCARE TRADING CO., LTD.

HAS SUCESSFULLY COMPLETED/UPDATED
THE FDA REGISTRATION

FOR

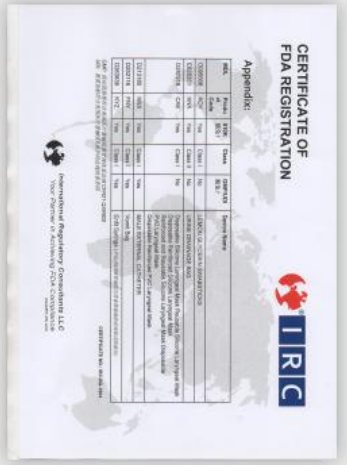
FDA US AGENT

IRC USA

PRINCIPAL ENGINEER

Refer to the Appendix at next page

Your Partner in Achieving FDA Compliance



CERTIFICATE OF
FDA REGISTRATION

Appendix:

IRC

CZITC

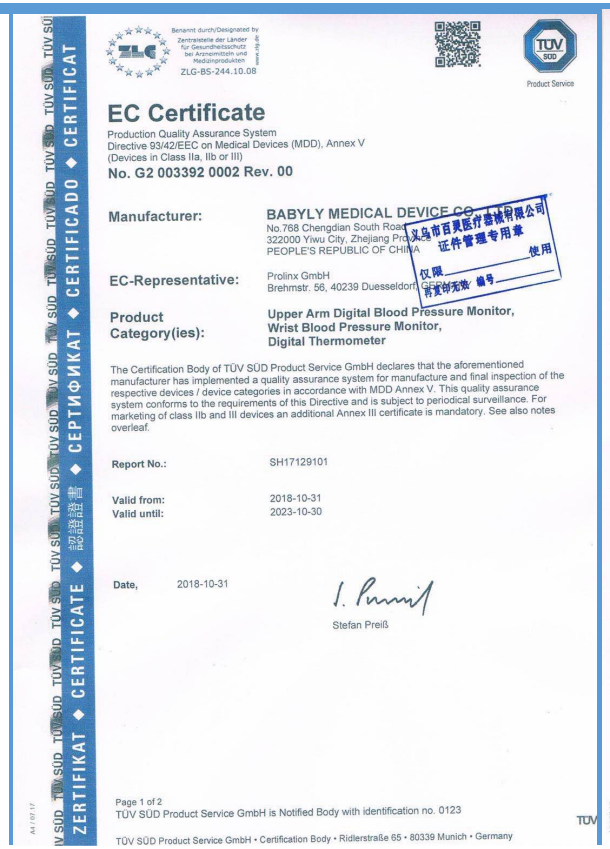
yangyuan@czitc.cn

NO.T-02

企业名称 Company		产品名称 Product		型号
宁波冠克贸易有限公司	Ningbo GreatCare Trading Co., Ltd.	红外额温计	forehead thermometer	BK8005
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√	√	

代理“红外额温计”产品生产厂家为白名单企业“温州博康医疗科技有限公司”
白名单编号154#

百贝丽®



EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)
No. G2 003392 0002 Rev. 00

Manufacturer: BABYLY MEDICAL DEVICE CO., LTD
No.768 Chengdian South Road, 322000 Yiwu City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Prolinx GmbH
Brehmstr. 56, 40239 Duesseldorf, GERMANY

Product Category(ies): Upper Arm Digital Blood Pressure Monitor, Wrist Blood Pressure Monitor, Digital Thermometer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH17129101
Valid from: 2018-10-31
Valid until: 2023-10-30

Date, 2018-10-31
Stefan Preiß

Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)
No. G2 003392 0002 Rev. 00

Facility(ies): BABYLY MEDICAL DEVICE CO., LTD
No.768 Chengdian South Road, 322000 Yiwu City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Page 2 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

CZITC
yangyuan@czitc.cn

NO.T-03

企业名称 Company		产品名称 Product		型号
义乌市百灵医疗器械有限公司	iwu Bailing Medical Devices Co., LTD	红外额温计	Non-contact Infrared Thermometer	BLIR-3
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√		

红外额温计白名单生产企业，浙械注准20162200312
白名单编号41#

International Certification Registrar

Attestation of Conformity

No. ICR Polska/M8508520 CE

Name and address of Registered Manufacturer:	Jiangxi AICARE Medical Technology Co., Ltd. South Side of South Ring Road, Le'an County, Fuzhou City, Jiangxi Province (Building No. 1, New Era Home Group, Le' an County).
Product name:	Infrared thermometer
Product type/model:	A66,A68,A69

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive:	Medical Device Directive 93/42/EEC
Conformity assessment procedure:	EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)
Classification:	Class I according Rule 1 of Annex IX of Directive 93/42/EEC
Applied normative documents:	EN 60601-1:2006+A12:2014 EN 60601-1-2:2015
Applied Quality Management System	EN ISO 13485:2016

This Attestation of Conformity will remain valid only if Quality Management System Certificate remains valid and the surveillance audits are conducted.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test reports made by European Quality Test Co., LTD.

No. of test report:	RBT20032021 1SR-1
Issue date:	24.03.2020
Expiration date:	23.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-8585.

This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

ICR REGISTERED NO. 1/2016

Director: Rafał Kalinowski

Warsaw, 24. 03. 2020.

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com

AICARE

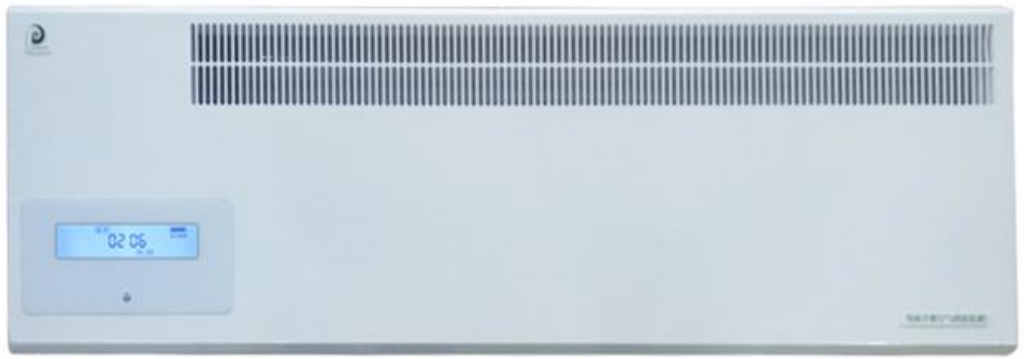
CZITC

yangyuan@czitc.cn

NO.T-04

企业名称 Company		产品名称 Product		型号
义乌市双孙进出口有限公司	Jiangxi AICARE Medical Technology Co., Ltd.	红外额温枪	Non Contact Infrared Thermometer	A66
是否白名单企业	国内批准文号	CE	FDA	其他
是	√	√		

代理“红外额温计”产品生产厂家为白名单企业“江西掌护医疗科技有限公司”,赣械注准20202070071
白名单编号167#



PM-B1000D2

PM-L1200D2

yangyuan@czitc.cn

NO.X-01

企业名称 Company		产品名称 Product		型号
浙江佩洁尔医疗科技有限公司	ZHEJIANG PEIJIEER MEDICAL TECHNOLOGY CO.,LTD	等离子体空气消毒器	Plasma Air Sterilizer	PM-B1000D2 PM-L1200D2
是否白名单企业	国内批准文号	CE	FDA	其他
		√		

Man Machine Symbiosis:
It can do sterilizing and purifying all the whole day under the dynamic state, which doesn′ t do any harm to human or medical device. Ii is not necessary for patients and medica l staff to leave when the plasma air sterilization purifier sterilizes the air in the room.
Spectrum Sterilization: it is highly effective to kill staphylococcus albus. In 706 cu ft closed simulation laboratory, the average killing rate of Staphylococcus albus was more than 99%.
The sterilization effect of the plasma air sterilization purifier will be improved with its working time being extended. Natural bacteria kill rate greater than 90% after a 60-minute working time according to the sterilization test.

FDA

Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

DONGYANG MEDICAL & HYGIENIC ARTICLES CO., LTD
Liushi Industrial Zone Dongyang, Zhejiang, 322104, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.
Owner/Operator Number: 10063527

Listing No.	Product Code:	Device Name:
D376662	LRJ	Disinfectant, medical devices Disinfectant spray 200ml

UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. UCL-REG SERVICE INC. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S.Food and Drug Administration does not issue a certificate of registration, nor does the U.S Food and Drug Administration recognize a certificate of registration, UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.

UCL

UCL-REGSERVICE INC.
602 ROCKWOOD ROAD WILMINGTON,
NEW CASTLE DE 19802 USA

UCL-REG SERVICE INC.

Cert. No.: M20625
Issued Date: 21 March 2020
Expiration Date: 31 December 2020

CZITC
yangyuan@czitc.cn

NO.X-02

企业名称 Company		产品名称 Product		型号
东阳市医药卫生用品有限公司	DONGYANG MEDICAL & HYGIENIC ARTICLES CO.,LTD.	消毒喷雾	Disinfectant spray	200ml
是否白名单企业	国内批准文号	CE	FDA	其他
	√		√	

Efficient to kill Staphylococcus aureus, Coliform bacteria, Pseudomonas aeruginosa and Candida albicans etc.

Review Report – 审查报告 – 검토 보고서 – Rapport d'Evaluation

Form QAT_10-M04, version 00, effective since March 6th, 2020

CE Documentation Review

No. 0B200319.SBUW17

Holder: Sanrace Biotechnology Co., Ltd.
268 Yanzhou Road, Lanxi Development Zone, Zhejiang Province, China

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Quick-dry wash-free Sanitizing Gel **(no sterile)**
Model(s): 250ml

Classification: Class I (no sterile)
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process.
The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 19 March 2020
Expiry date: 18 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

Ente Certificazione Macchine
Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
☎ +39.051.6705141 🖷 +39.051.6705156 ✉ info@entecerma.it 🌐 www.entecerma.it

CZITC

yangyuan@czitc.cn

NO.X-03

企业名称 Company		产品名称 Product		型号
圣蕾诗生物科技股份有限公司	Sanrace Biotechnology Co,ltd	速干免洗消毒凝胶	Qucik-dry wash-free Sanitizing gel	
是否白名单企业	国内批准文号	CE	FDA	其他
--	√	√		

SANRACE BIOTECHNOLOGY Co.,LTD was established in 2013 and is located in Lanxi, Zhejiang Province, which is a beautiful land of orchids. The registered capital is over 60 million yuan. The company integrates R & D, production and sales. Its main products include disinfection product ,perfume, cosmetics, skin care products and so on. It has three registered brands: EGOLAN, SURBBY and NUJET. Products are sold all over the world through stores in Dubai. In addition, the company also provides OEM order service. We have high-tech production equipment, high-standard quality system (successfully passed the international cosmetics industry ISO22716 and GMPC double certification), high-level management team, efficient logistics distribution. We pay attention to brand building and talent management, always adhere to the quality as a guarantee, market-oriented, technology as the strength of the policy, adhering to the service-oriented business philosophy, adhere to the indifferent, noble, grateful, virtuous orchid spirit. We look forward to working with global customers to create a better future.

仙 FAIRY SHIELD 盾

Hand Sanitizer (Washing Free)

Product Statement

Different from the ordinary 75% alcohol disinfectant, this product provides long time antiviral with triple protection, which compli es with the Chinese National Standard （Technical Standard for Disinfection version 2002) and EU CE Standard.

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Form QAT_10-M04, version 00, effective since March 25th, 2020

Certificate of Compliance

No. 0H200329.HSFDQ66

Test Report no. XMT0202001321LY/REACH

Certificate's Holder: Hangzhou Southern Fairy BioTech Co., Ltd. No.1 Xiyuan Road, Hangzhou, Zhejiang, China

Certification ECM Mark:

Product: Fairy Shield Disinfectant

Model(s): 500ml, 1000ml, 5000ml, 25L

Verification to: related to CE Directive(s): R 1907/2006 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 29 March 2020

Expiry date: 28 March 2025

Reviewer Technical expert Amanda Payne

Approver ECM Service Director Luca Bedogni

Ente Certificazione Macchine Srl

Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY

+39 051 6705141 +39 051 6705156 info@entecerma.it www.entecerma.it

CZITC

yangyuan@czitc.cn

NO.X-04-1

企业名称 Company		产品名称 Product		型号
杭州南仙生物技术有限公司	Hangzhou Southern Fairy Bio-Tech Co., Ltd	酒精免洗洗手液	hand sanitizer	
是否白名单企业	国内批准文号	CE	FDA	其他
--	√	√	--	

企业介绍


Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Form QAT_10-M04, version 00, effective since March 25th, 2020

Certificate of Compliance

No. 0H200329.HSFDQ66

Test Report no. XMT0202001321LY/REACH

Certificate's Holder: Hangzhou Southern Fairy BioTech Co., Ltd. No.1 Xiyuan Road, Hangzhou, Zhejiang, China

Certification ECM Mark: Type Approved

Product: Fairy Shield Disinfectant

Model(s): 500ml, 1000ml, 5000ml, 2.5L

Verification to: related to CE Directive(s): R 1907/2006 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 29 March 2020

Expiry date: 28 March 2025

Reviewer Technical expert Amanda Payne

Approver ECM Service Director Luca Bedogni

Ente Certificazione Macchine Srl

Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY

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CZITC

yangyuan@czitc.cn

NO.X-04-2

企业名称 Company		产品名称 Product		型号
杭州南仙生物技术有限公司	Hangzhou Southern Fairy Bio-Tech Co., Ltd	环保环境消毒液	Environmental Disinfectant	
是否白名单企业	国内批准文号	CE	FDA	其他
--	√	√	--	