

MASK 口罩



产品Product		区间价格Price (Eur) / pc	起订量MOQ
KN95	KN95	€ 1.09~2.80	Online negotiation
一次性外科口罩	Disposable medical mask (sterile)	€ 0.27~0.46	Online negotiation
一次性医用口罩	Disposable medical face mask	€ 0.23~0.41	Online negotiation
一次性民用口罩	Disposable Mask	€ 0.23~0.30	Online negotiation



yangyuan@czitc.cn

NO.K-01

企业名称 Company		产品名称 Product		型号
振德医疗用品股份有限公司	Zhende Medical Co., Ltd.	医用口罩	Medical Mask	
是否白名单企业	国内批准文号	CE	其他	
√	√	√	乙	

医用防护口罩白名单生产企业，浙械注准20172640093
 白名单序号：87#
 认证：EN 14683-2019

kidsyard®



INDIVIDUAL PACKAGE	CARTON PACKAGE
50PCS/BOX (205*105*90mm)	10BOXES/CARTON (550*215*200mm)
WEIGHT: 0.181KG	GROSS WEIGHT: 2.84KG NET WEIGHT: 1.44KG

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

Form QAT_104/04, version 00, effective since March 6th, 2020

CE Documentation Review 

No. 4J200323.HQSDD10

Holder: HANGZHOU QIANZHIYA SANITARY PRODUCTS CO., LTD.
No.88 Fengwang Road, Economic Development Zone Tonglu, Tonglu County, Hangzhou,311500 Zhejiang, P.R.China

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable Medical Mask (Not Sterile)
Model(s): plane ear-loop type, plane elastic non-woven ear-loop type, 3D type

Classification: Class I (Not Sterile) (accordingly to the Manufacturer's declaration)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. Technical documentation identified with the no. GGC-200319-MDD-316. 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. RGO1_ECM rev.3 available at www.entecerma.it

Date of issue 23 March 2020 Expiry date 22 March 2025

Approver: ECM Service Director Lucia Belloni  Technical Expert Amanda Pini 

Ente Certificazione Macchine
Via Cà Beffa, 243 - 40053 Valsamoggia loc. Castello di Serovalle (Bo) Italy
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NO.K-02

企业名称 Company	产品名称 Product	型号
杭州千芝雅卫生用品有限公司 HANGZHOU QIAN ZHI YA SANITARY PRODUCTS CO.,LTD	一次性使用医用口罩 Disposable Protective Mask	
是否白名单企业	CE	其他
是	√	丙

白名单企业，浙械注准20202141013
白名单序号：667#



NO.K-03

企业名称 Company	产品名称 Product	型号
宁波海田控股集团有限公司 Ningbo Haitian Holding Group Co.,Ltd.	医用外科口罩 Medical Surgical Mask	
是否白名单企业	CE	其他
√	√	丙

代理产品医用外科口罩生产厂家为白名单企业：浙江银达生物技术有限公司；浙械注准20202141064
白名单序号：356#

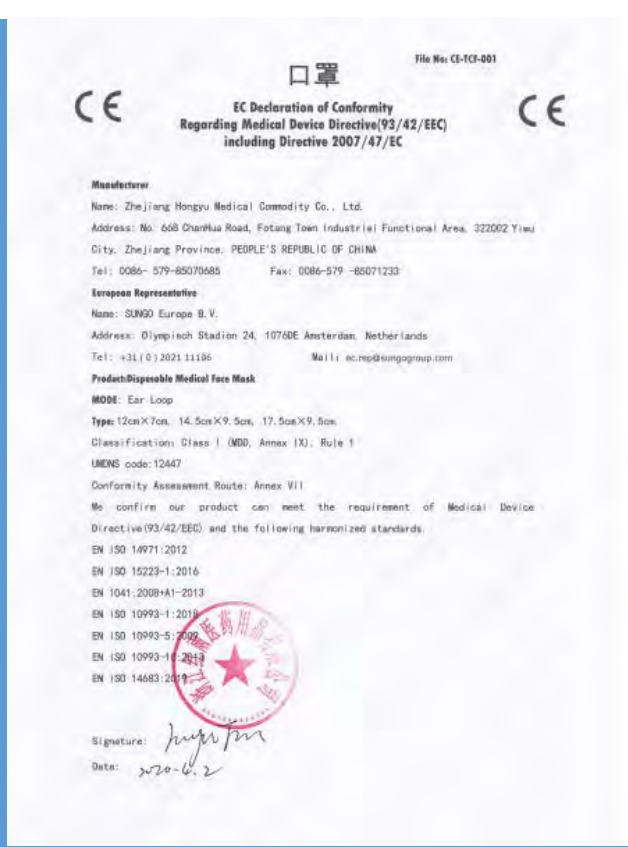


yangyuan@czitc.cn

NO.K-04-1

企业名称 Company		产品名称 Product		型号
浙江红雨医药用品有限公司	Zhejiang Hongyu Medical Commodity Co. Ltd.	一次性医用口罩	Disposable Face masks	
是否白名单企业	国内批准文号	CE	其他	
是	√	√	甲	

一次性使用医用口罩 白名单企业, 浙械注准20202141020
白名单序号: 670#

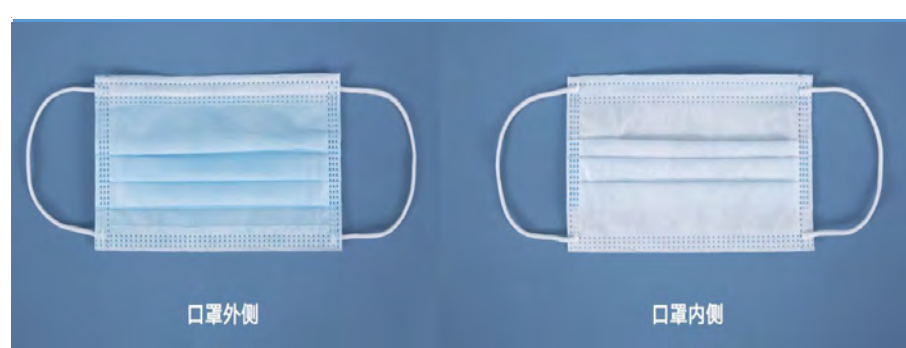


yangyuan@czitc.cn

NO.K-04-2

企业名称 Company		产品名称 Product		型号
浙江红雨医药用品有限公司	Zhejiang Hongyu Medical Commodity Co. Ltd.	医用外科口罩	Surgical face masks	
是否白名单企业	国内批准文号	CE	其他	
是	√	√	甲	

一次性使用医用口罩，白名单企业，浙械注准20202141020
白名单序号：670#



口罩外侧

口罩内侧



شهادة - 證明書 - Certificat - 證書 - Certificate

Certificate of Compliance

No. 1N20031 3JHWSU072
Technical Construction File no. UF.202031 101PPE

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

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

Certification ECM Mark:

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

Verification to: Standard: ENT49:2001+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 applicable Standard(s), the above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its national and its use. The regulation can be found at www.ecm.eu. The Certificate of Compliance can be checked for validity at www.ecm.eu. The verification (above) imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:
We attest that 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
Service Manager: Lucia Redondel

Expiry date: 12 March 2025
Deputy Manager: Amanda Payne

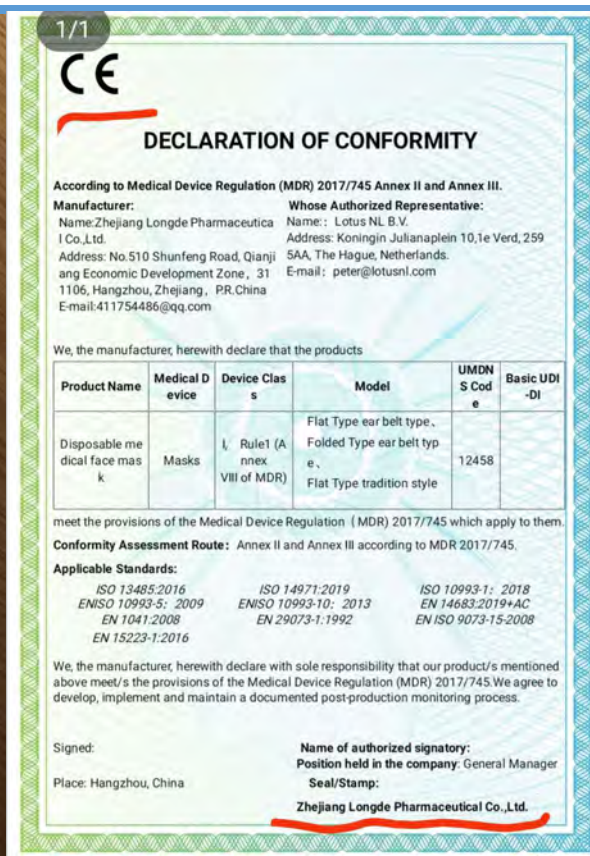
Ente Certificazione Macchine S.r.l.
Via Ca' Basso, 243 - Loc. Castello di Serravalle - 40055 Valsamoggia (BO) - ITALY
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NO.K-05

企业名称 Company	产品名称 Product	型号
杭州万事利丝绸数码印花有限公司 Hangzhou Wensli Silk Sciences & Techniques Co., Ltd.	一次性使用医用口罩 Disposable Protective Mask	
是否白名单企业	CE	其他
是	√	丙
白名单企业，浙械注准20202141082 白名单序号：689#		



NO.K-06

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 mask	
是否白名单企业	CE	其他
√	√	甲

“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#



Form QAT_10 (4/04) - Version 02, effective since March 6th, 2020

CE Documentation Review

No. 08200318.HCHUS38

Holder: Hangzhou Coco Healthcare Products Co., Ltd.
No.2 Huaqiao Rd., West Industrial Zone, Jincheng Street, Lin'An District, Hangzhou City, Zhejiang Province 311300, China.

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

Product: Disposable Face Mask (no sterile)

Model(s): Disposable Face Mask
COM-0120 Medical Face Mask
COM-0220 Surgical Face Mask
COM-0320 Non-Sterile Medical Disposable Face Mask
COM-0420 Sterile Medical Disposable Face Mask
COM-0520 Disposable Children's Face Mask

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 conformity activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM.rv.3 available at: www.entecema.it

Issuance date: 18 March 2020
Expiry date: 17 March 2025

Reviewer: Technical expert
Amanda Payne

Approver: ECM Service Director
Luca Bedonni

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yangyuan@czitc.cn

NO.K-07-1

企业名称 Company		产品名称 Product		型号
杭州可靠护理用品股份有限公司	HANGZHOU COCO HEALTHCARE PRODUCTS CO.,LTD	一次性医用口罩	Disposable Medical Face Mask	COM-0120
是否白名单企业	国内批准文号	CE	其他	
是	√	√	丙	

白名单企业，浙械注准20202141074
白名单序号：684#



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NO.K-07-2

企业名称 Company	产品名称 Product	型号
杭州可靠护理用品股份有限公司 HANGZHOU COCO HEALTHCARE PRODUCTS CO.,LTD	一次性医用口罩 (弹性无纺布耳挂) Disposable Medical Face Mask (Elastic Non-woven Ear Loop)	COM-0320
是否白名单企业	CE	其他
是	√	丙

白名单企业, 浙械注准20202141074
白名单序号: 684#



Certificate – Сертификат – 證明書 – 증명서 – 證書

Form QAT

Certificate of Conformity

No. 0P2003225F.ZHC0016

Technical Construction File no. TPMJ20031036101

Certificate's Holder: Zhejiang Huaguang Capsule Co., Ltd.
No. 2 of 1st High-Tech Industrial Zone (Nanyan District), Xinchang County, Shaoxing City, Zhejiang Province, P.R. China

Certification ECM Mark:

Product Model(s): Protective Medical Mask
95mm

Verification to: Standard: EN 149: 2001
related to CE Marking R 2016/425 (F)

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 meets the requirements of the ECM Certification Mark. The certificate is issued on the basis of the information provided by the manufacturer. Additional information and clarification about the 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

CE

Issuance date: 22 March 2020
Expiry date: 21 March 2025

Reviewer
Technical expert
Amanda Payne

Ente Certificazione
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Review Report – 審査報告 – 검토 보고서 – Rapport d'Evaluation

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

CE Documentation Review

No. 0P2003225F.ZHC0017

Holder: Zhejiang Huaguang Capsule Co., Ltd.
No. 2 of 1st Huaguang Road, High-Tech Industrial Zone (Nanyan District), Xinchang County, Shaoxing City, Zhejiang Province, P.R. China

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product Model(s): Disposable Medical Mask (Not Sterile)
Disposable Medical Mask

Classification: Class I (Not Sterile)
(accordingly to the Manufacturer's declaration)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. Technical documentation identified with the no. TPMJ20030736102 dated 22 march. 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

Date of issue 22 March 2020
Approver
ECM Service Director
Luca Baladani

Expiry date 21 March 2025
Technic of Expert
Amanda Payne

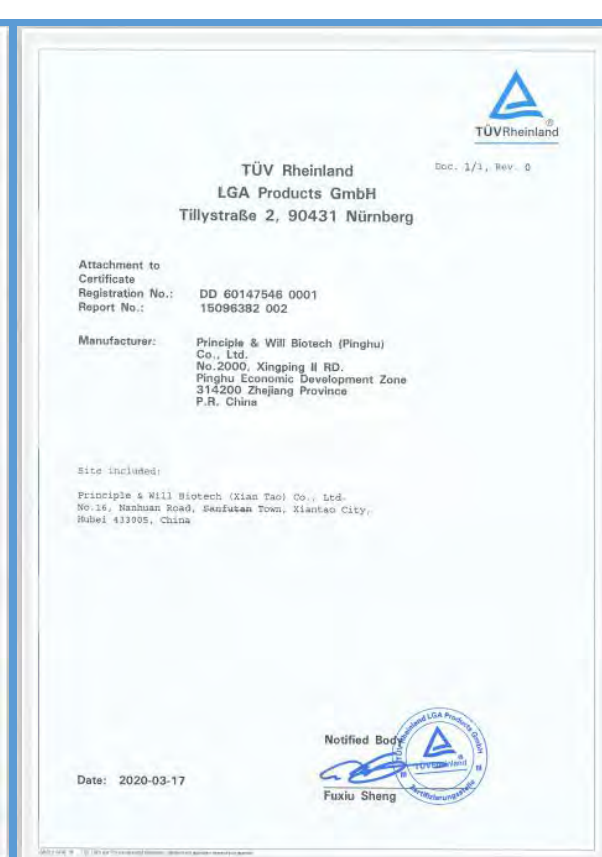
Ente Certificazione Macchine
Via Cù Bella, 243 – 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
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NO.K-08

企业名称 Company	产品名称 Product	型号
浙江华光胶囊股份有限公司 Zhejiang Huaguang capsule Co., Ltd.	一次性使用医用口罩 Disposable medical mask	Type B (non sterile)
是否白名单企业	CE	其他
是	√	丙

医用外科口罩，白名单企业，浙械注准20202141120
白名单序号：488#



NO.K-09

企业名称 Company	产品名称 Product	型号
宏昌生物医疗科技有限公司 Principle & Will Biotech (PingHu) Co., Ltd.	医用外科口罩 surgical masks	非无菌型耳挂式 Non sterilize 3-layer pleated with ear loop
是否白名单企业 是	国内批准文号 √	CE √
		其他 甲

白名单企业;浙械注准20202141060
白名单序号: 355#



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NO.K-10-1

企业名称 Company		产品名称 Product		型号
杭州天翔供应链管理有 限公司	SINOSKY LTD	外科口罩	Medical Mask	
是否白名单企业	国内批准文号	CE	其他	
√	√	√	丙	

代理产品生产厂家为白名单企业：杭州山友医疗器械有限公司；浙械注准20202141054
白名单序号：345#



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NO.K-10-2

企业名称 Company	产品名称 Product	型号
杭州天翔供应链管理有 限公司	民用口罩	Mask
是否白名单企业	CE	其他
√	√	丁

代理产品生产厂家为白名单企业：杭州山友医疗器械有限公司；浙械注准20202141054
白名单序号：345#



International Certification Registrar - International Certification Registrar



Certificate



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 P.R.

Name and address of manufacturer:

Product name: Disposable medical mask
Product types: Type A (sterile), type B (non sterile), ear hook type 1.75 x 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/A25
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: Rafal Kalinowski

Warsaw, 20.03.2020

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



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。
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

批准日期: 2020年03月20日

有效期至: 2020年09月19日

发证机关: 浙江省药品监督管理局



yangyuan@czitc.cn

NO.K-11

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

其他

√

√

√

丙

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



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	其他	
√	√		丙	

“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#



NO.K-13

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	Medical 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	其他	
√	√	√	甲	

代理“一次性医用口罩”产品生产厂家为白名单企业白名单编号52# (鄂械注准20152642206)



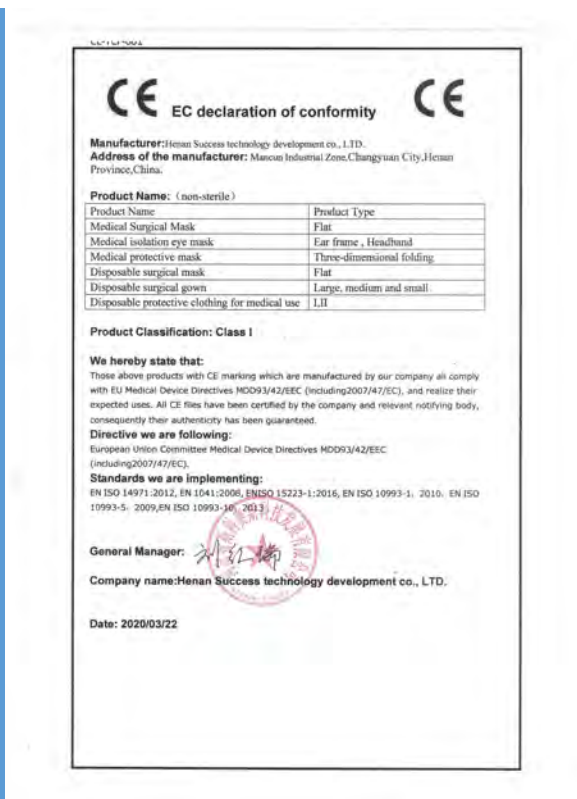
- ✓ 可调式鼻梁压条
Adjustable nose wire
- ✓ 舒适里层材质
Soft and non-irritating texture
- ✓ 舒适耳挂绳材质
Non-irritating earloops



NO.K-14

企业名称 Company		产品名称 Product		型号
杭州立山皮件有限公司	Hilltop (Hangzhou) Co., Ltd.	一次性医用口罩	Single-use medical mask	175*75mm
是否白名单企业	国内批准文号	CE	其他	
√	√	√	甲	

一次性使用医用口罩白名单企业，浙械注准20202141080
白名单序号688#



yangyuan@czitc.cn

NO.K-15-1

企业名称 Company	产品名称 Product	型号
杭州启硕进出口有限公司 Hangzhou Qishuo IMP&EXP Co., Ltd.	医用防护口罩N95 Medical Protective Mask (STERILE) N95	
是否白名单企业	CE	FDA
√	√	其他 (甲)

代理“一次性使用医用口罩”产品生产厂家为白名单企业，豫械注准20162640609
白名单编号563#

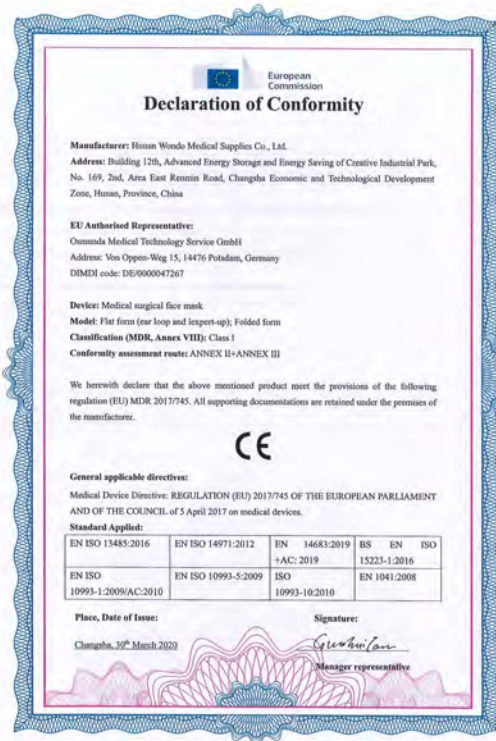


中华人民共和国医疗器械注册证

注册证编号：湘械注准20202140333

注册人名称	湖南豌豆医疗用品有限公司
注册人住所	长沙经济技术开发区人民东路二段169号先进储能节能创意示范产业园12栋502
生产地址	长沙经济技术开发区人民东路二段169号先进储能节能创意示范产业园4楼
代理人名称	不适用
代理人住所	不适用
产品名称	医用外科口罩（非无菌型）
型号、规格	型号：平面形（耳挂式，带带式），尺寸规格为17cm×9cm。
结构及组成	本产品由口罩体、鼻夹、耳带等组成。口罩体分为内、中、外三层组成，内层、外层为无纺布，中层为熔喷无纺布。口罩带由松紧带制成。鼻夹由可弯折的聚丙烯材料制成。产品为非无菌供应。
适用范围	适用于医务人员或相关人员的基本防护，以及在有创操作过程中防止体液和喷溅物传播的防护。
附件	产品技术要求
其他内容	
备注	1. 该产品为应急审批注册，有效期为八个月；2. 该产品在延续/变更注册时应按医疗器械注册管理要求完善相关资料。

审批部门：湖南省药品监督管理局



yangyuan@czitc.cn

NO.K-15-2

企业名称

Company

产品名称 Product

型号

杭州启硕进出口有限公司

Hangzhou Qishuo IMP&EXP Co., Ltd.

一次性使用医用口罩
(无菌型)

Disposable medical
mask (sterile)

是否白名单企业

国内批准文号

CE

其他

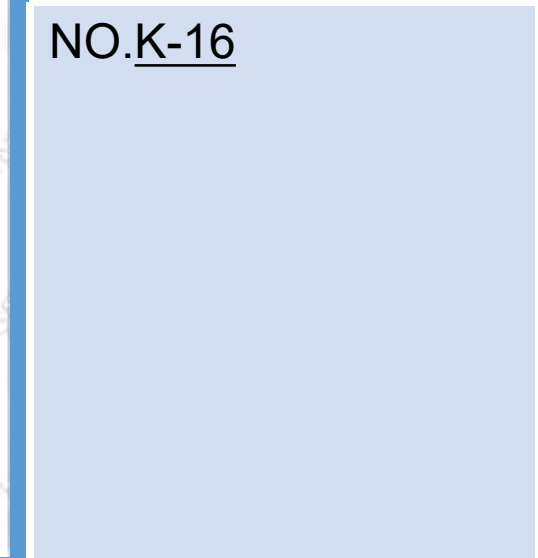
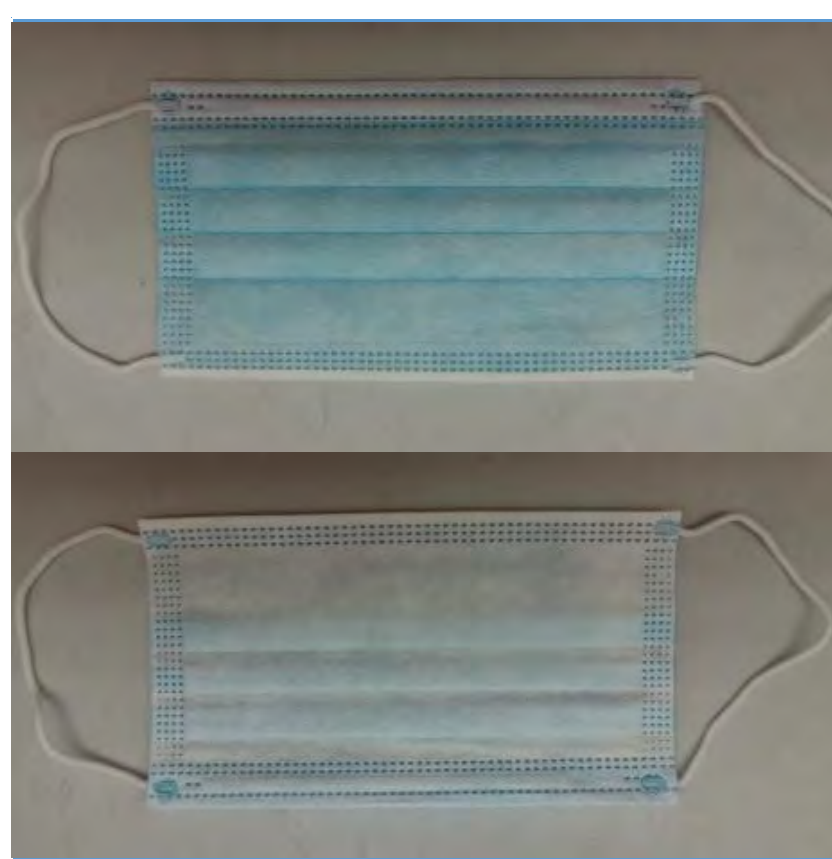
√

√

√

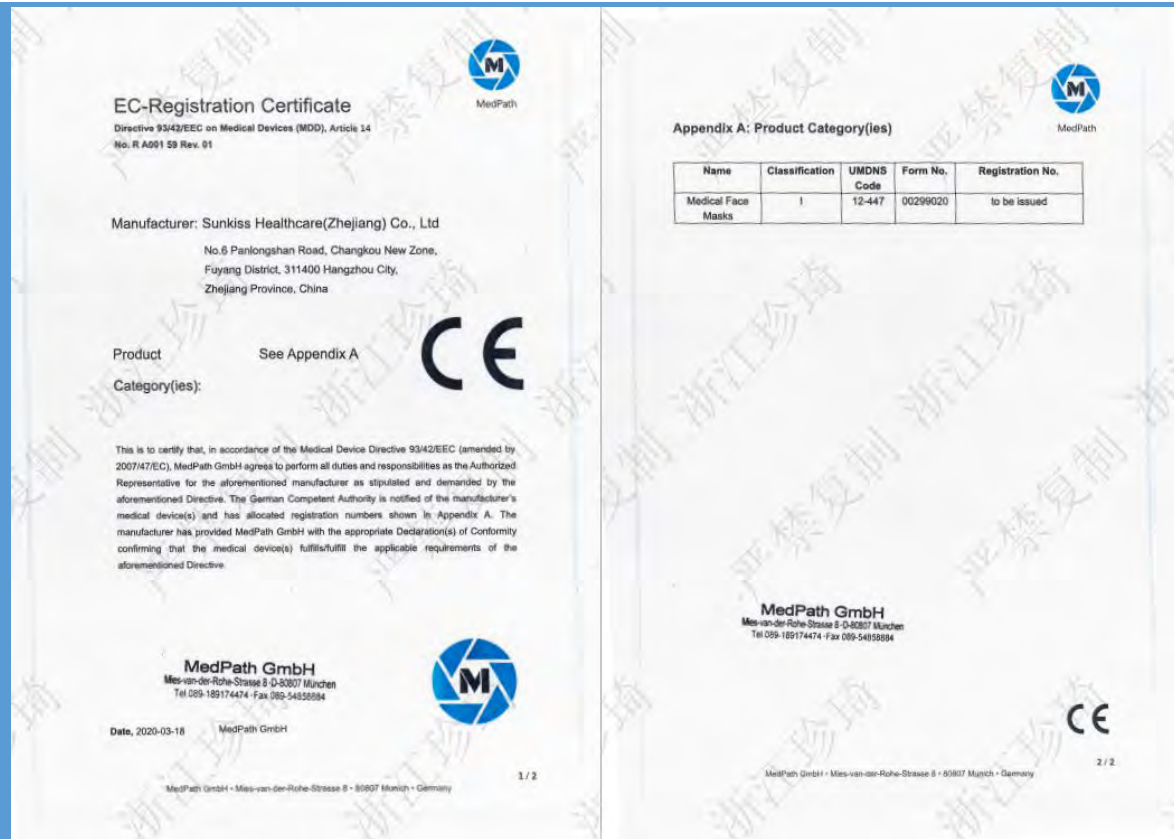
甲

代理“一次性医用口罩”产品生产厂家为白名单企业、湘械注准20202140282
白名单编号460#、461#



企业名称 Company		产品名称 Product		型号
东阳市富郎进出口有限公司	Dongyang Fulang Imp & Exp Co., Ltd.	一次性医用口罩	Disposable medical face mask	
是否白名单企业	国内批准文号	CE	其他	
√	√	√	丁	

代理产品生产厂家为白名单企业：“金华市景迪医疗用品有限公司”浙械注准20202141033
 医用外科口罩白名单序号275#



yangyuan@czitc.cn

NO.K-17

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
mask

是否白名单企业

国内批准文号

CE

其他

√

√

√

甲

“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#



NO.K-18

企业名称 Company	产品名称 Product	型号
绍兴上虞澳璞特国际贸易有限公司 Shaoxing Shangyu Allbranded International Trading Co.,Ltd.	医用外科口罩/一次性医用口罩 Medical Surgical Mask/ Disposable Medical Mask	
是否白名单企业	CE	其他
√	√	丙

代理“一次性使用医用口罩”生产厂家为白名单企业，“豫械注准20162640076；白名单序号547#
代理“医用外科口罩”生产厂家为为白名单企业，“豫械注准20162640729；白名单序号42#



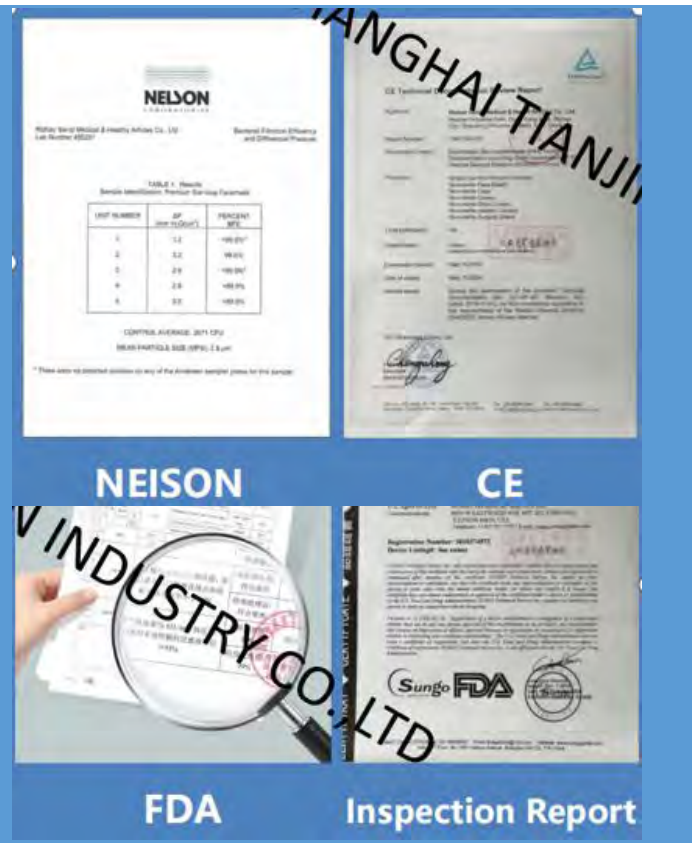
yangyuan@czitc.cn

NO.K-19

企业名称 Company		产品名称 Product		型号
国药器械浙江医疗器材有限公司	Sionpharm Zhejiang Medical Device Co.,Ltd.	一次性外科口罩	Disposable surgical mask	
是否白名单企业	国内批准文号	CE	其他	
√	√	√	乙	

代理产品生产工厂为医用外科口罩白名单企业：豫械注准20182140714

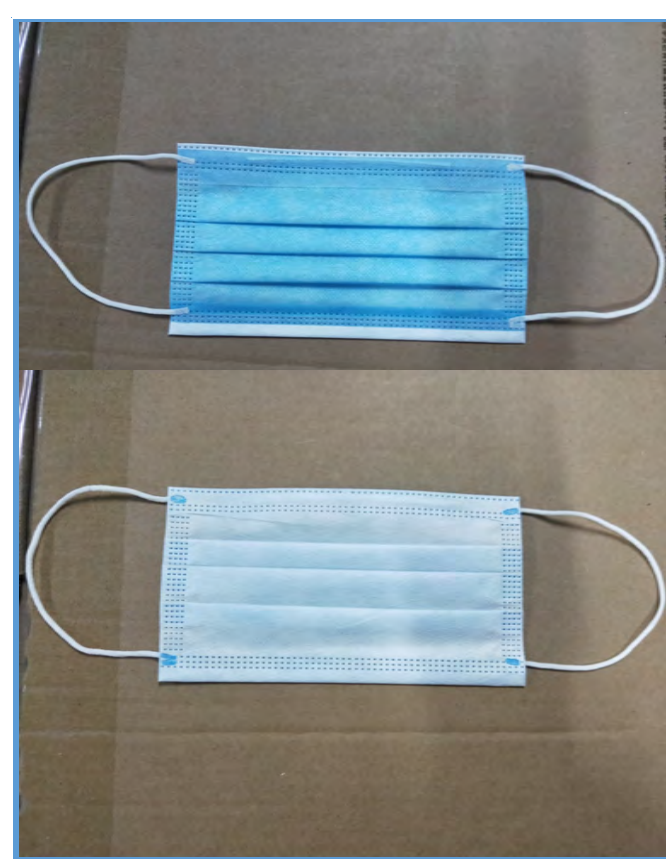
白名单序号：115#



NO.K-20

企业名称 Company	产品名称 Product	型号
日照三奇医疗卫生用品有限公司 Rizhao Sanqi Medical and Health Articles Co., Ltd.	N95口罩 N95mask	
是否白名单企业	CE	其他
√	√	甲

医用防护口罩，白名单企业，鲁械注准20202140114，白名单序号45#



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 Prymitywa 6
03-944 Warsaw
www.icrpolska.com
e-mail: icrpolska@icrp.com



Director: Rafal Kalinowski

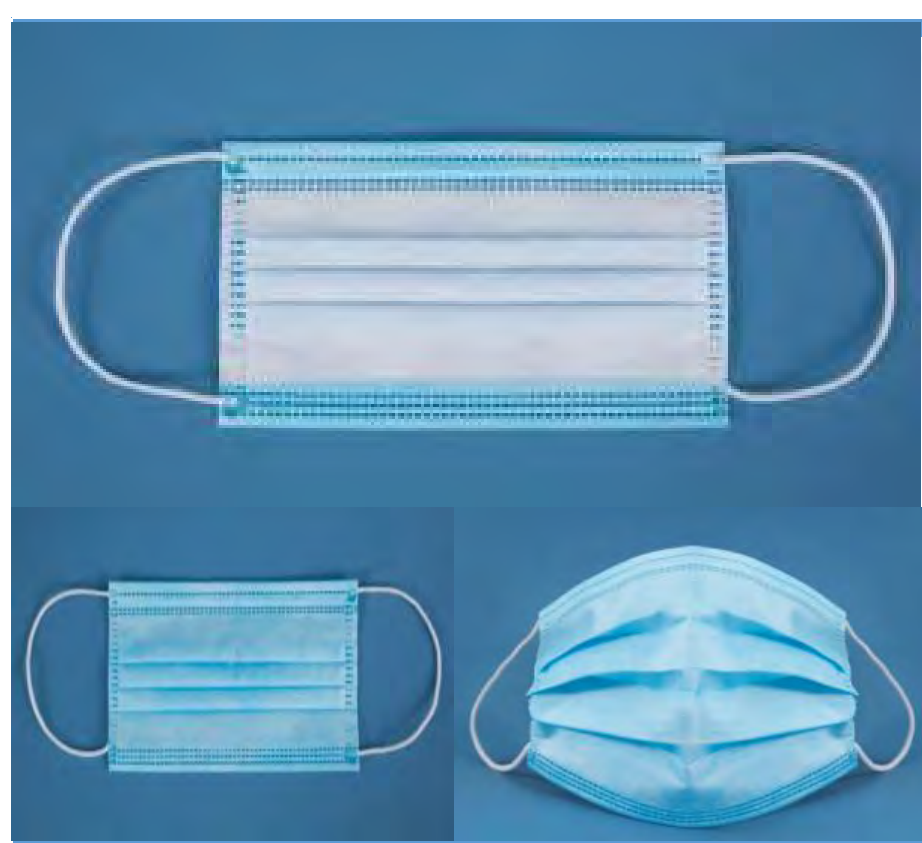
Warsaw, 01. 04. 2020.



yangyuan@czitc.cn

NO.K-21

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..LTD.	一次性使用医用口罩 DISPOSABLE MEDICAL MASK	
是否白名单企业	CE	其他
国内批准文号	√	丁
----	√	



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.

شهادة - Certificate - 증명서 - Сертификат - 證明書 - Certificat

Certificate of Compliance

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: 

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 standards. 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.enteccerma.it. This Certificate of Compliance can be checked for validity at www.enteccerma.it. The verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:
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 to 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).

CE

Date of issue 12 March 2020 Expiry date 12 March 2025

Service Manager:  Lucca Biondani Deputy Manager:  Amanda Pozzani

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

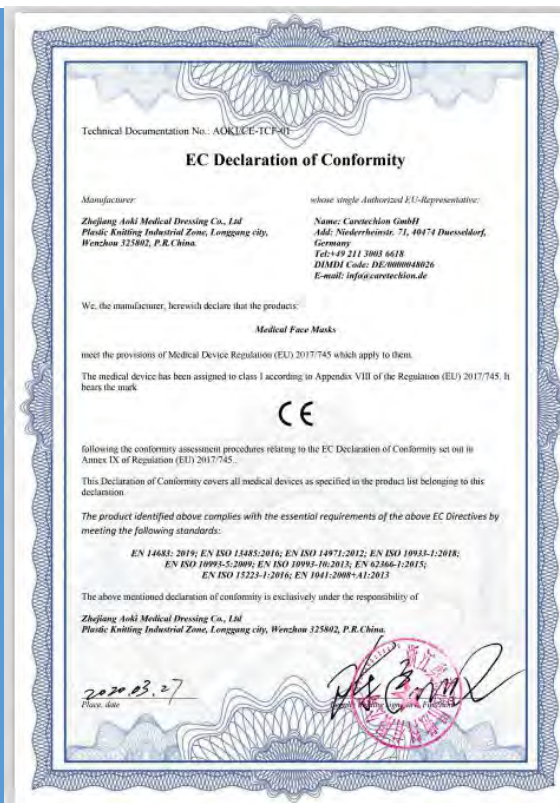


yangyuan@czitc.cn

NO.K-22

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.	平面一次防护口罩 Flat disposable mask	WSL- 20N95
是否白名单企业	CE	其他
---	√	乙

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.



yangyuan@czitc.cn

NO.K-23

企业名称	Company	产品名称	Product	型号
浙江奥奇医用敷料有限公司	Zhejiang Aoki Medical Dressing Co.,Ltd.	外科口罩, 一次性口罩,	Surgical Face Mask, Disposable Face Mask, Medical Dressing	
是否白名单企业	国内批准文号	CE	其他	
	√	√	甲	



NO.K-24

企业名称 Company	产品名称 Product	型号
杭州绿宇进出口有限公司 Qingdao utesmart Co.,Ltd.	一次性三层民用口罩 DISPOSABLE MASK	
是否白名单企业	CE	其他
国内批准文号	√	丁

代理“一次性民用口罩”产品生产厂家为“青岛酷特智能股份有限公司”



NO.K-25

企业名称 Company	产品名称 Product	型号
绍兴上虞湘舜进出口有限公司	一次性医用外科口罩	Surgical Face Mask (3-layers)
是否白名单企业	CE	其他
----	国内批准文号	丁
	√	

代理“一次性医用外科口罩”产品生产厂家为“海宁爱康医疗科技有限公司”
国内批准文号“浙械注准20172641165号”



1#



2#

شهادة - Certificate - Сертификат - 證明書 - Certificat - 口口口 - 口口口

Form GAI_10A/04, version 00, effective since March 6th, 2020

Certificate of Compliance



No. 0P200318T.CU0009
 Technical Construction File no. TPMJ2003043578

Certificate's Holder: Chilong Industrial (JIAXING) Co., Ltd.
 No.258, Xuyuan Road, Shimen Gaoyangji Town, Jiaxing City, Zhejiang Province, China

Certification ECM Mark:
 

Product: Protection Mask
 Model(s): KN95 MASK-001, KN95 MASK-002, 3PLY MASK-001, 3PLY MASK-002

Verification to: Standard: EN 149:2001+A1:2009
 related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

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:

CE The manufacturer is responsible for the CE Marking process. 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.entecma.it

Issuance date: 18 March 2020
 Expiry date: 17 March 2025

Reviewer: Amanda Payne
 Approver: Luca Bedogni

Ente Certificazione Macchine Srl
 Via Ciri' Beilo, 243 - Loc. Castello di Santavalle - 40053 Valsamoggia (BO) - ITALY
 ☎ +39 051 6703141 ☎ +39 051 6703156 ✉ info@entecma.it 🌐 www.entecma.it

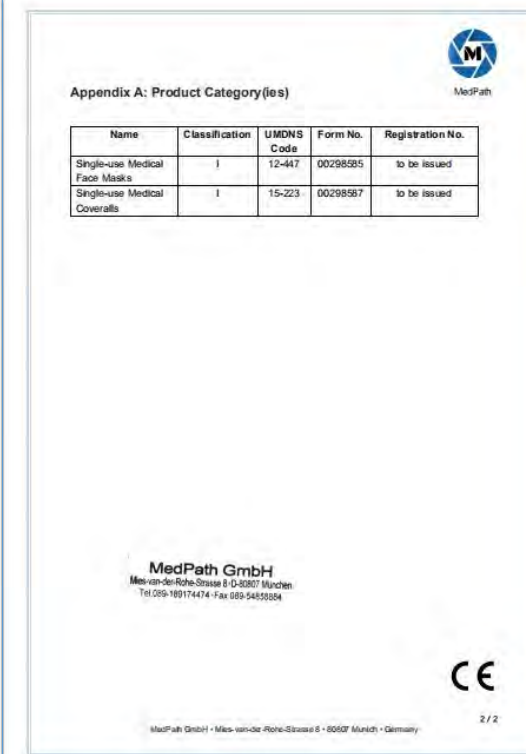


yangyuan@czitc.cn

NO.K-26

企业名称 Company	产品名称 Product	型号
杭州群沃贸易有限公司 HANGZHOU CHINEWORLD TEXTILE CO.,LTD.	口罩 Mask	1#、2#
是否白名单企业	CE	其他
----	√	丁

代理产品生产企业为“全隆实业（嘉兴）有限责任公司”浙嘉食药监械生产备20180017号



yangyuan@czitc.cn

NO.K-27

企业名称

Company

产品名称 Product

型号

杭州康寿医疗器械有限公司
责任公司

CONOD MEDICAL CO.,
LTD.

一次性外科口罩

SINGLE USE
SURGICAL MASK

是否白名单企业

国内批准文号

CE

其他

√

√

甲



中华人民共和国医疗器械注册证

注册证编号：浙械注准20202141154

注册人名称	浙江丽莱内衣有限公司
注册人住所	浙江省金华市婺城区秋滨街道文溪街358号
生产地址	浙江省金华市婺城区秋滨街道文溪街358号
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：非无菌型；规格：175mm×95mm。
结构及组成	产品由口罩体、鼻夹、口罩带组成，为耳带式结构。
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（除4.7.2无菌（不适用）、4.8环氧乙烷残留量（不适用）、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



International Certification Registrar - International Certification Registrar



Certificate

No. ICR Polska/M8308520



Name and address of certificate owner: ZHEJIANG LILY UNDERWEAR CO., LTD. No 358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, China

Name and address of manufacturer: ZHEJIANG LILY UNDERWEAR CO., LTD. No 358 Wenxi Street, Wucheng District, Jinhua City, Zhejiang, China

Product name: Disposable Mask

Product types: PT17.5*9.5*3

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.

No. of test reports: EQT-20/01-0312010-PPE

Certificate issue date: 18.03.2020

Expiration date: 17.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-8385.

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: Rafal Kalinowski

Warsaw, 18. 03. 2020

ICR Polska Co. Ltd.
ul. Plac Polimierza 5, 03-544 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqac.com



yangyuan@czitc.cn

NO.K-28

企业名称 Company	产品名称 Product	型号
杭州川至医疗器械有限公司 Hangzhou Cuanz Medical Devices Co., Ltd.	一次性医用口罩 Disposable Medical Face Mask	Non sterile
是否白名单企业	CE	其他
国内批准文号	√	乙



● HUAWEI Mate 20 Pro
● LEICA TRIPLE CAMERA | AI



● HUAWEI Mate 20 Pro
● LEICA TRIPLE CAMERA | AI



● HUAWEI Mate 20 Pro
● LEICA TRIPLE CAMERA | AI

Form QA1_J04M04, version 00, effective since March 4th, 2020

Certificate of Compliance



No. 08.200.401.E.H5H00047
Technical Construction file no.

Certificate's Holder: Hangzhou SJ Health Technology Co., Ltd.
No.428 Qianzhangzhang Village, Huangzhangang, Shushan Street, Xiaoshan District, Hangzhou, Zhejiang, China

Certification ECM Mark:  Type Approved

Product: Mask (Not Sterile)
Model(s): SJY101, SJY102, SJY103, SJY104, SJY105, SJM206, SJM207, SJM208, SJM209, SJM210
Trademark: N/A

Verification to: Standard: EN 149:2001+A1:2009
related to CE Directive (s): R 2016/425 (Personal Protective Equipment)

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. (K00)_ECM rev.3 available at: www.entecerma.it

issuance date: 01 April 2020
Expiry date: 31 March 2025

Reviewer: Technical expert Amanda Payne
Approver: ECM Service Director Luca Santoro

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

شهادة - 증명서 - Certificate - Сертификат - 證明書



yangyuan@czitc.cn

NO.K-29-1

企业名称 Company	产品名称 Product	型号
杭州施洁健康科技有限责任公司 Hangzhou SJ health technology co.,ltd.	民用KN95 KN95	
是否白名单企业 国内批准文号	CE	其他
---- GB2626-2006	√	乙



●○ HUAWEI Mate 20 Pro
○● LEICA TRIPLE CAMERA | AI



●○ HUAWEI Mate 20 Pro
○● LEICA TRIPLE CAMERA | AI

Form GAT_104/04, version 00, effective since March 6th, 2020

Certificate of Compliance



No. 08200401 EHS00047
Technical Construction file no.

Certificate's Holder: Hangzhou SJ Health Technology Co., Ltd.
No.428 Qianzhangzhang Village, Huangjiatang, Shushan Street, Xiaoshan District, Hangzhou, Zhejiang, China

Certification ECM Mark:  Type Approved

Product: Mask (Not Sterile)
Model(s): SJY101, SJY102, SJY103, SJY104, SJY105, SJM206, SJM207, SJM208, SJM209, SJM210
Trademark: N/A

Verification to: Standard: EN 149:2001+A1:2009
related to CE Directive (s): R 2016/425 (Personal Protective Equipment)

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 as a first release on-site 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_ECMA rev.3 available at: www.enlacerma.it

CE

Issuance date: 01 April 2020
Expiry date: 31 March 2025

Reviewer: Technical expert Amanda Payne
Approver: ECM Service Director Luca Bergamini




Enle Certificazione Macchine Srl
Via Ca' Sella, 243 - Loc. Castello di Senovalle - 40053 Valcamoglia (BO) - ITALY
☎ +39 051 4705141 ☎ +39 051 4705156 ✉ info@enlecerma.it 🌐 www.enlecerma.it

شهادة - Certificate - Сертификат - 證明書 - Certificat - 증명서

CZITC

yangyuan@czitc.cn

NO.K-29-2

企业名称 Company	产品名称 Product	型号
杭州施洁健康科技有限责任公司 Hangzhou SJ health technology co.,ltd.	一次性医用口罩 Disposable Medical Mask	折叠式
是否白名单企业	CE	其他
----	√	乙



شهادة - 증명서 - Certificate - Сертификат - 證明書 - Certificat



yangyuan@czitc.cn

NO.K-30

企业名称 Company	产品名称 Product	型号
开化米欧医疗科技有限公司 KAIHUA MIOU MEDICAL TECHNOLOGY CO.,LTD.	一次性使用防护口罩 Disposable Mask	
是否白名单企业	CE	其他
-----	√	乙

We are one manufacturer of face masks, focusing on the customized production , integrated sales, 24-hour shift production, long-term preparation, products through the various testing and certification, real-time customer tracking sales, home delivery throughout the country.
国内批准文号：国纺委字第YJ202004088号



● Packing details: 50pcs / box,2000pcs/CTN

● Carton size: 52*40*34cm

● Gross weight:8.4kgs

● Net weight:6.2kgs



Packing details

1.Simple polybag packing , 4000pcs Into one carton

2.Carton size: 54*45*50cm

3.Gross Weight: 14 KGS

4.Net Weight: 13 KGS

International Certification Registrar



Certificate

No. ICR Polska/P4003550 CE

Name and address of certificate owner: ZHEJIANG YONGDA GARMENTS CO.,LTD
MOJIALOU VILLAGE,TAOYAN TOWN,YUECHENG DISTRICT, SHAOXING CITY, ZHEJIANG PROVINCE

Name and address of manufacturer: ZHEJIANG YONGDA GARMENTS CO.,LTD
MOJIALOU VILLAGE,TAOYAN TOWN,YUECHENG DISTRICT, SHAOXING CITY, ZHEJIANG PROVINCE

Product name: Disposable protective masks

Product types: YDFZ-M2002,YDFZ-M2003,YDFZ-M2004,YDFZ-M2005,YDFZM2006, YDFZ-M2007

Product trademark: Veykong

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 Shenzhen Zhongheng Testing Technology Co., Ltd.

No. of test reports: NCTC:0200901253

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/20-0-31-09.

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



Director: Ratal Kalinowski

Warsaw, 25. 03. 2020




ICR Polska Co. Ltd.
ul. Piłsudskiego 4, 00-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrpocz.com



yangyuan@czitc.cn

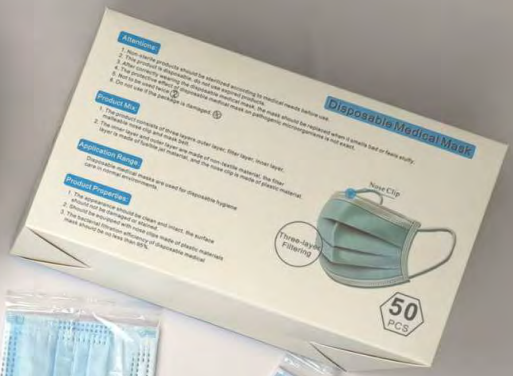
NO.K-31

企业名称	Company	产品名称	Product	型号
浙江勇大服装有限公司	ZHEJIANG YONGDA GARMENTS CO.,LTD.	一次性防护口罩	Face mask	
是否白名单企业	国内批准文号	CE	其他	
----	----	√	丙	



NO.K-32

企业名称 Company	产品名称 Product	型号
金华市鸥硕家居用品有限公司 Jinhua Oushuo HomeProduct co.,ltd.	FFP2标准民用防护口罩 FFP2 Standard Face Mask	
是否白名单企业	CE	其他
---	√	丙



NO.K-33

企业名称 Company	产品名称 Product	型号
绍兴统竞服饰有限公司 SHAOXING TONGJING GARMENTS CO.,LTD.	一次性口罩 Disposable Mask	ONBOX Disposable Mask
是否白名单企业	CE	其他
国内批准文号	√	丙



yangyuan@czitc.cn

NO.K-34

企业名称 Company	产品名称 Product	型号
义乌市飘神服饰有限公司 YIWU FLOATING GOD CLOTHING CO.,LTD.	一次性使用民用口罩 DISPOSABLE 3-LAYER FACIAL MASK	
是否白名单企业	CE	其他
国内批准文号	√	丙

YIWU FLOATING GOD CLOTHING CO.LTD IS LOCATED IN YIWU CITY IN 2007YEARS, IT IS SPECIALIZED IN CLOTHING R & D PRODUCTION AND SALES,THERE ARE TWO COMPLETE SETS OF JAPANESE HEAVY PRODUCTION LINES. AND MORE THAN 160 EMPLOYEES PLEANT EREA IS MORE THAN 15000 SQUARE MTERES. OUR COMPANY HAVE ISO9000 AND ISO14000 GREEN ENVIROMENTAL CERTIFICATION. ZHEJIANG INDUSTRIAL AND ADMINISTRATION AWARDED "KEEPING PROMISE KEEPING CONTRACT "AAA ENTERPRISES THE ANNUAL OUTPUT VALU IS MORE THAN 100MILION AND PRODUCTION IS MORE 1.5MILION CLOTHING, WE HAVE STABLE SUPPLIER STRONG TEAM AND NETWORK AND AFTER-SALES SERVICE. OUR COMPANY IS WILLING TO WORK WITH ALL SECTORS OF SOCIETY TO CREAT THE BRILLIANT FUTURE.

PROFESSIONAL RESPIRATORS

“SUPERNAL” PRODUCT TRUSTWORTHY





Certificate of Registration

This is to certify that:

JINHUA ENJOY & WONDERFUL INC.
FUHOU ROAD XIAOSHUN TOWN
JINHUA, ZHEJIANG 321000 CHINA

is registered and has listed the following medical device with the U.S. Food & Drug Administration pursuant to Part 807 of the United States Code of Federal Regulations Title 21, such registration and listing having been verified as currently effective by Wonderka.

Registration Number: To Be Assigned
Device Classification Name: See the table below
Product Code: See the table below
Official Correspondent: Wonderka Group
and U.S. Agent: 10535 Stewart Avenue, Garden City NY 11530

This certificate is valid until 2020-12-31 unless said registration is terminated after issuance of this certificate.

Listing Number	Product Code(s)	Device Name
D386366	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance
D386369	HOY	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydratic eyewear)
D386370	DEA	Non-surgical isolation gown
D386372	IWP	Radiographic protective Glove

Remark: D386366 is only valid during the COVID-19 pandemic according to FDA related guidelines. It is the manufacturer's responsibility to comply with the FDA requirements.

Derek L. Dai
Derek L. Dai
Chief Executive Officer
Dated: 2020-6-6

Wonderka Group
10535 Stewart Avenue, Garden City
NY 11530

According 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."
This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food & Drug Administration. Wonderka assumes no liability for any persons or entities related to the above.
The U.S. Food & Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Wonderka is not affiliated with the U.S. Food & Drug Administration.

Form QAL_10A104, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 4Q200331G.JNW0D44

Certificate's Holder: Jinhua Enjoy & Wonderful Inc.
Fuhou Road Xiaoshun Town Jinhua City Zhejiang China

Certification ECM Mark: 

Product: Disposable Mask FFP2
Model(s): 105*155mm
Verification to: EN 149:2001+A1:2009
related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

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 registration on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecema.it

Issuance date: 31 March 2020
Expiry date: 30 March 2025

Reviewer: Amanda Paganò
Approver: Luca Bergami

Ente Certificazione Macchine Srl
Via Co' Sella, 243 - Loc. Castello di Senovalle - 40053 Valsamoggia (BO) - ITALY
☎ +39 051 4705141 📠 +39 051 4705156 📧 info@entecema.it 🌐 www.entecema.it

شهادة - 證明書 - Certificat - 證書 - Certificate



yangyuan@czitc.cn

NO.K-35

企业名称 Company	产品名称 Product	型号
金华万得福日用品股份有限公司 Jinhua Enjoy & Wonderful Inc.	民用KN95口罩 KN95 mask	
是否白名单企业	CE	其他
国内批准文号	√	乙



yangyuan@czitc.cn

NO.K-36

企业名称 Company		产品名称 Product		型号
湖州祥涛医疗科技有限公司	Huzhou Xiangtao Medical Technology Co., Ltd.	一次性民用防护口罩	Disposable Protective Facial Mask	
是否白名单企业	国内批准文号	CE	其他	
----	----	√	丙	



NO.K-37

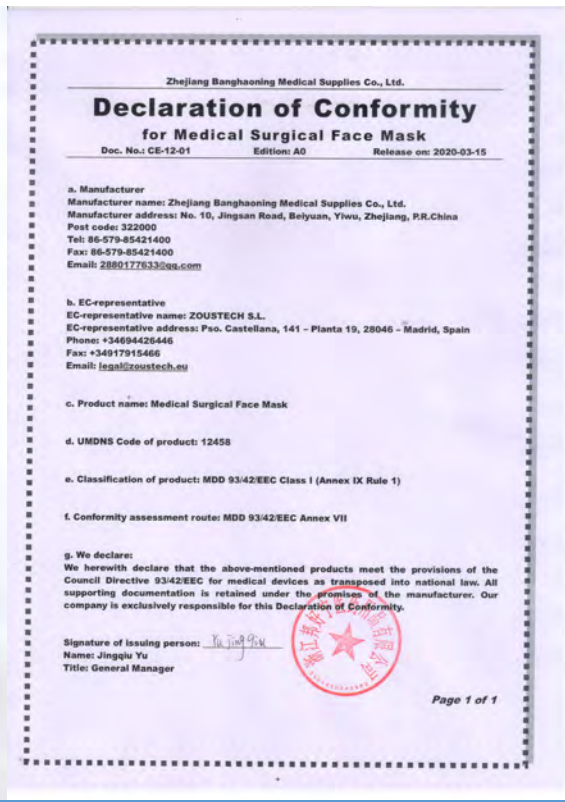
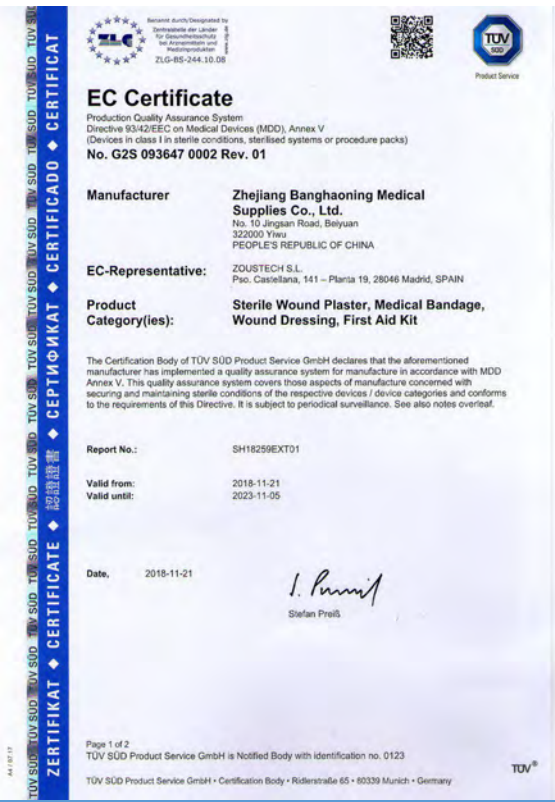
企业名称 Company		产品名称 Product		型号
常山顺发箱包有限公司	Changshan Shunfa Bags Co.,Ltd.	一次性民用口罩	Disposable mask	
是否白名单企业	国内批准文号	CE	其他	
-----	----	√	丙	

Changshan Shunfa Bags Co., Ltd is established in 2007. Located in Quzhou city, Zhejiang province, China. It covers land area of 18,000 sqm,standardized workshop of 13,000 sqm, and potentially holds 200 people to work, which is one of the large scale gift packing enterprises in Zhejiang.

Our product line covers dust bag, shopping bag, garment bag, and all kinds of gift packing bag according to customer's requirements.With great achievement in past one decade, Shunfa has become the nominated supplier of several famous brands in America and Europe region .The company are very experienced in OEM, familiar with customer's quality requirements. We have advanced manufacturing equipment and excellent management team, our monthly output are more than 1000000pcs

We carry out a strict quality management system in accordance with ISO9001 requirements.The company also passed SGS:SA8000 Social Responsibility Certificate .We are not only strict with excellent quality but also human rights.

We insist on the principle of development of ' High quality, Efficiency, Sincerity and Down-to-earth working approach' to provide you with excellent service. We sincerely welcome you to visit our company and contact us for cooperation.



NO.K-38

企业名称 Company	产品名称 Product	型号
浙江邦好宁医药用品有限公司 Zhejiang Banghaoning Medical Supplies Co.,Ltd.	一次性民用口罩 Disposable civilian mask	
是否白名单企业	CE	其他
国内批准文号	√	乙
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Review Report - 审查报告 - 검토 보고서 - Rapport d'Evaluation

CE Documentation Review

No. 3/200312.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)
(according 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 Expiry date 11 March 2025

Service Manager: Luca Becconi Deputy Manager: Amanda...

Ente Certificazione Macchine
Via Cò Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
☎ +39.051.6705141 📠 +39.051.6705136 📧 info@entecerma.it 🌐 www.entecerma.it



yangyuan@czitc.cn

NO.K-39

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	其他	
√	√	√	丙	

代理“医用外科口罩”产品生产厂家为白名单企业
白名单编号370#



yangyuan@czitc.cn

NO.K-40-1

企业名称 Company		产品名称 Product		型号
海宁众凯服饰有限公司	Haining Zhongkai Garment Co.,LTD.	一次性民用口罩	DISPOSABLE FACE MASK	
是否白名单企业	国内批准文号	CE	其他	
----	----	√	丙	

图片



yangyuan@czitc.cn

NO.K-40-2

企业名称 Company

产品名称 Product

型号

海宁众凯服饰有限公司

Haining Zhongkai
Garment Co.,Ltd.

KN95 民用口罩

DISPOSABLE FACE
MASK

是否白名单企业

国内批准文号

CE

其他

√

丙



Certificate

No. ICR Polska/P4910035



Name and address of certificate owner: Hangzhou Yuchan Technology Co., Ltd
16 Zhuantang science and technology economic block, Xihu District,
Hangzhou City, Zhejiang Province

Name and address of manufacturer: Hangzhou Yuchan Technology Co., Ltd
16 Zhuantang science and technology economic block, Xihu District,
Hangzhou City, Zhejiang Province

Product name: MASK

Product types: KN95, N95, Adult mask, Children Mask

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

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 EUTEST International Testing Limited

No. of test reports: 2020001C

Certificate 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/2020-3109

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: Rafal Kalnowski

Warsaw, 24.03.2020



ICR Polska Co. Ltd.
ul. Plac Przymierza 5, 03-344 Warszawa
www.icrpolska.com, e-mail: icrpolska@wp.pl



yangyuan@czitc.cn

NO.K-41

企业名称 Company

产品名称 Product

型号

杭州钰蝉科技有限公司

HANGZHOU YUCHAN
TECHNOLOGY CO.,LTD.

KN95民用口罩

Disposable Protective Mask
KN95

是否白名单企业

国内批准文号

CE

其他

√

丙



Medical disposable protective clothing

防护服

产品Product		区间价格Price (Eur) / pc	起订量MOQ
防护服	Medical disposable protective clothing	€ 4.80~17.94	Online negotiation
隔离衣	Medical disposable isolation clothing	€ 4.20~13.62	Online negotiation
一次性医用手套	Medical gloves	€ 0.09 more each	Online negotiation



yangyuan@czitc.cn

NO.F-01

企业名称 Company	产品名称 Product	型号
振德医疗用品股份有限公司 Zhende Medical Co., Ltd.	一次性使用手术衣 Sterile Surgical Gown	
是否白名单企业	CE	其他
√	√	甲

医用一次性防护服,白名单生产企业, 浙械注准20192140166
 白名单序号: 212#

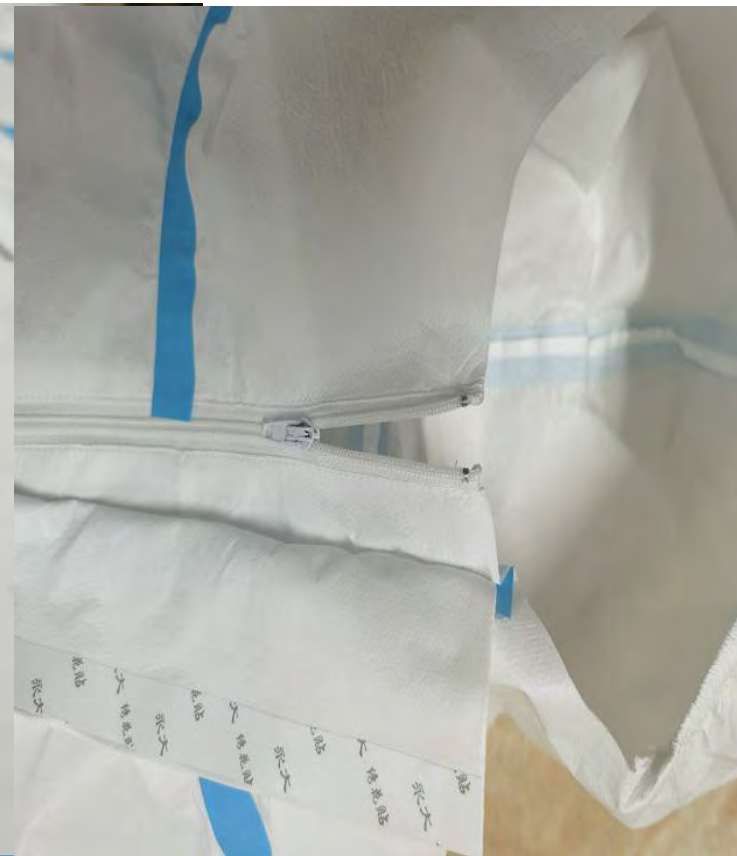


yangyuan@czitc.cn

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., LTD.	一次性防护服	Disposable protective clothing	
是否白名单企业	国内批准文号	CE	其他	
√	√	√	乙	

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
LTD.

医用一次性防护服
(非无菌)

Medical disposable
protective clothing
(Non-Sterile)

是否白名单企业

国内批准文号

CE

其他

√

√

√

甲

“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#



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, CENBEL Notified Body (4925) 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 1345-1:2008 Protective clothing - Electrostatic protection - Part 5: Static performance and design considerations
- EN 13042:2005+A1:2008 Protective clothing against liquid chemical - Performance requirements for chemical protective clothing offering limited protection against liquid chemicals (Type B and Type P601)
- EN ISO 13962:1:2004+A1:2010 Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing offering protection to the full body against airborne solid particulates (Type S: clothing)
- EN 14126:2003 Protective clothing - Performance requirements and test methods for protective clothing against infectious agents
- EN ISO 13958:2014 Protective clothing - General requirements
- EN 1273-2:2002 Respiratory 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 2021 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 II 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 Article III) that is registered with number 19139.

Issued by CENBEL Notified Body (4925) in Ghent, on 29 Mar 2018


 Inge De Witte
 Certification Manager
 Attached: 1 Annex

*Recognized by FPS Economy (Federal Public Services)



CENBEL - TEXTILE COMPETENCE CENTRE

Technologiepark 7 • BE-8050 Gent • Belgium • phone +32 9 220 41 52 • fax +32 9 220 41 53 • general@cenbel.be • info@cenbel.be
 VAT • BE 0408 318 280 • IBAN • BE 44 2300 4729 0345 • BIC • CEBABEBB



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

其他

√

√

√

甲

“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#



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 FRS 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.

for: **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 attestation, the following standards are used:

- EN 1345:2008 Protective clothing - Assessment - aspects - Part 5: Static performance and weight requirements
- EN 13442:2016 Protective clothing against liquid chemical - Performance requirements for chemical protective clothing offering limited protection against liquid chemicals (Type B and Type PB2C)
- EN ISO 13982-1:2014+A1:2015 Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing offering protection for the full body against airborne solid particulates (Type 3 clothing)
- EN 14126:2013 Protective clothing - Performance requirements and test methods for protective clothing against infectious agents
- EN ISO 15090:2012 Protective clothing - General requirements
- EN 1273:2012 Protective clothing against airborne 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 this Directive 89/686/EEC, this certificate remains valid until 21 April 2021 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 2018 and at least be repeated with intervals of one year.

This decision applies to the equipment as submitted in the type setting and described in the manufacturer's technical documentation (As described in 2016/425 Annex III) that is registered with number 10156.

Issued by Centexbel (Notified Body 0493) on 29 Mar 2018

Notified Body
Certification Manager
Attached: 1 Annex

Recognized by FRS Economy (Federal Public Services)



CENTEXBEL - TEXTILE COMPETENCE CENTRE

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VAT • BE 0408 218 209 • IRAN • BE 44 2100 4729 8045 • BIC • GZBABEL33

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

其他

√

√

√

甲

“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#



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	其他	
√	√	√	乙	

“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#

产品展示



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 (非灭菌类)

Disposable Isolation Gown

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

其他

√

√

√

乙

“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#

医用二类防护服（无菌）



International Certification Registrar - International Certification Registrar



Certificate

No. ICR Polska/P7700217 CE

Name and address of certificate owner: Chongqing Litai Clothing Group Co., Ltd
Textile City D7-1 #, Malu 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
EN1426:2003+A2:2004

The certification process has been carried out in accordance with the program PG-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-202003236979PE

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 Rafal Kalinowski
Warsaw, 25. 03. 2020
ICR Polska Co. Ltd.
ul. Pao Przymierza 6, 03-044 Warszawa



CERTIFICATE

CERTIFICATE OF COMPLIANCE

NO: BS11449276-EC

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

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

Product: PROTECTIVE CLOTHING

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

Relevant standard (s): EN 143-1-2015

Model: LT-XXXXL, LT-M, LT-L, LT-XL, LT-XXL, LT-XXXL

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

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 Standards 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 2004/43/EC Article 18 and Annex A, only if the product(s) fulfil 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 representatives 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 is 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

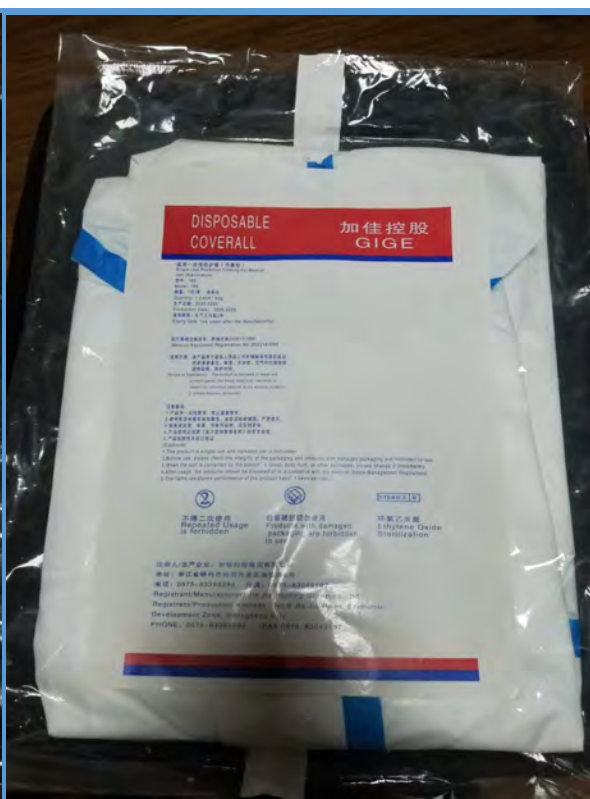


yangyuan@czitc.cn

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	CE	其他
√	√	乙

“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#



NO.F-08

企业名称 Company	产品名称 Product	型号
杭州郑成功实业有限公司 Jiajia Holding Group Co.,Ltd.	医用一次性防护服 Medical disposable protective suit (Sterilized)	
是否白名单企业	CE	其他
国内批准文号	√	丙

代理产品胜场厂家为“加佳控股集团有限公司”，浙食药监械生产许20200317号



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

CE Documentation Review 

No. 3J200312.SOC0N92

Holder: Shaoming Omega Clothing Co., Ltd.
No.49, Cai Road, Lushan Street, Shengzhou City, 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: Isolation Clothing, Disposable Medical Protective Clothing (no sterile)

Model(s): 160, 165, 170, 175, 180, 185

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 Expiry date 11 March 2025

Service Manager: Luca Bedonni Deputy Manager: Amanca...

Ente Certificazione Macchine
Via Ca' Bella, 243 - 40053 Volcamoglia Loc. Castello di Senovalle (Bo) Italy
+39 051 6705141 | +39 051 6705156 | info@entecerma.it | www.entecerma.it



yangyuan@czitc.cn

NO.F-09

企业名称 Company	产品名称 Product	型号
嵊州市金亿家居用品有限公司 SHENGZHOU JINYIHOUSEHOLD ARTICLES CO.,LTD.	医用一次性防护服 Medical disposable protective clothing	
是否白名单企业	CE	其他
√	√	乙

代理产品生产企业为白名单企业“绍兴欧米茄服装有限公司”浙械注准20202141062
白名单序号235#

Medpro SMS Isolation Gown



Material: SMS, Medical Use

Color: Blue

Size: M/L/XL/XXL

Quality Standard: AAMI-2 / AAMI-3

Advantage: Excellent Bacteria Barrier, Waterproof, Breathable
Antistatic,

Packing: 50pcs/ctn

Sterile or Non-sterile

3-ply Fabric Structure



yangyuan@czitc.cn

NO.F-10

企业名称

Company

产品名称

Product

型号

国药器械浙江医疗器材
有限公司

Sionpharm Zhejiang
Medical Device Co.,Ltd.

医用一次性防护服

Disponsible Medical
Protective Apparel

是否白名单企业

国内批准文号

CE

其他

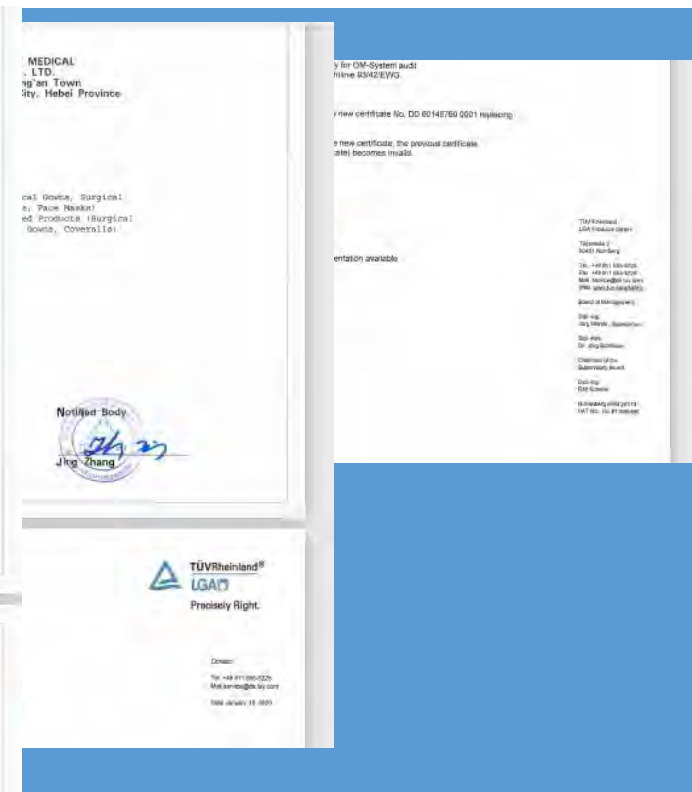
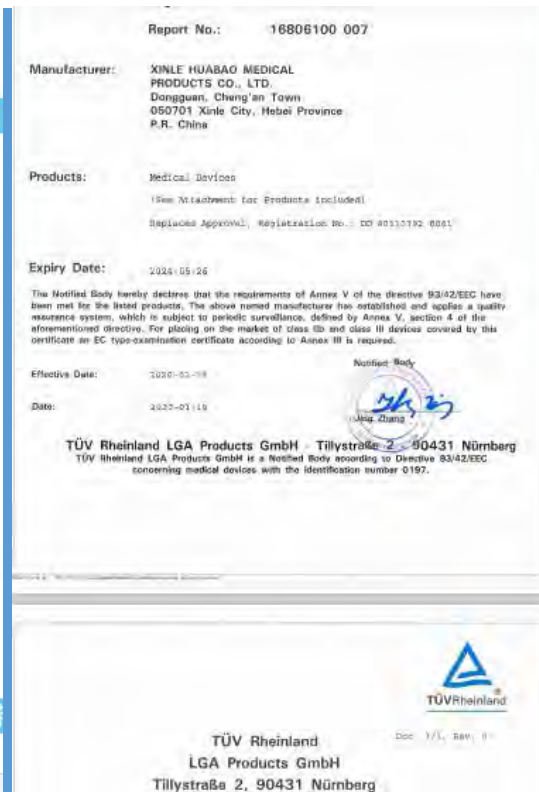
√

√

√

乙

代理产品生产企业为白名单企业，皖械注准20182640035
白名单序号115#



yangyuan@czitc.cn

NO.F-11-1

企业名称 Company	产品名称 Product	型号
杭州经成进出口贸易有限公司 Hangzhou Golden City Import and Export Trade Co., Ltd.	一次性医用隔离服 Disposable isolation clothing	连身式
是否白名单企业	CE	其他
国内批准文号	√	丙



Product Name	Medical Device	Device Class	Model	UMDNS Code	Basic UDI-DI
Single-use medical protective clothing (non-sterile)	Gowns	I, Rule I (Annex VIII of MDR)	Conjoined, 160, 165, 170, 175, 180, 185	11897	

Extent of conformity assessment					
specification	Body length	chest circumference	outside sleeve	cuff	leg opening
160	165	120	84	18	24
165	169	125	86	18	24
170	173	130	90	18	24
175	176	136	93	18	24
180	181	140	96	18	24
185	188	145	99	18	24
deviation	±2	±2	±2	±2	±2

杭州经成进出口贸易有限公司



yangyuan@czitc.cn

NO.F-11-2

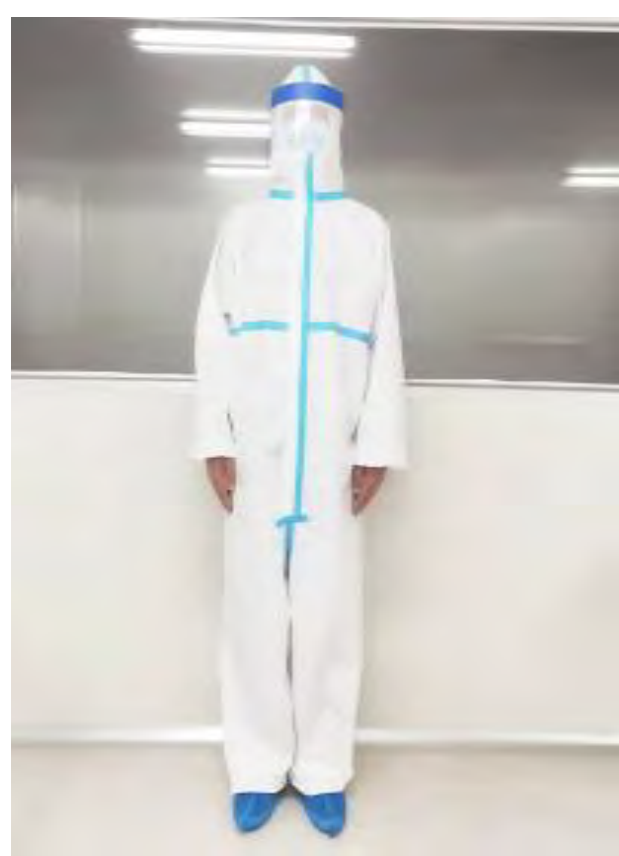
企业名称 Company	产品名称 Product	型号
杭州经成进出口贸易有限公司 Hangzhou Golden City Import and Export Trade Co., Ltd.	隔离鞋套 Isolated shoe cover	
是否白名单企业	CE	其他
国内批准文号	甲	
----	√	



yangyuan@czitc.cn

NO.F-11-3

企业名称	Company	产品名称	Product	型号
杭州经成进出口贸易有限公司	Hangzhou Golden City Import and Export Trade Co., Ltd.	医用手套	Medical gloves	
是否白名单企业	国内批准文号	CE	其他	
----	√	√	甲	



yangyuan@czitc.cn

NO.F-12

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.	医用一次性防护服	Disposable Medical Protective Clothing	
是否白名单企业	国内批准文号	CE	其他	
√	√	√	乙	

“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#

图片



yangyuan@czitc.cn

NO.F-13

企业名称 Company

产品名称 Product

型号

宁波海田控股集团有限公司

Ningbo Haitian Holding Group Co.,Ltd.

医用一次性防护服

Medical disposable protective clothing

是否白名单企业

国内批准文号

CE

其他

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√

丙

代理产品医用一次性防护服生产厂家为白名单企业：辽械注准20202140031

白名单序号：279#



شهادة - 증명서 - Certificate - Сертификат - 證明書

Form QAT_10-M4, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 0P200316.ZMIUQ66
Technical Construction File no. TPZJ20031122220

Certificate's Holder: Zhejiang Mingfeng Industrial Co., Ltd.
No.7 Badu Road Tiantai County 317200 Zhejiang China

Certification ECM Mark:

Product: Medical disposable protective clothing
Model: MF-160-D, MF-165-D, MF-170-D, MF-175-D, MF-180-D, MF-185-D, MF-160-P, MF-165-P, MF-170-P, MF-175-P, MF-180-P, MF-185-P.

Verification to: Standard: EN 14605:2005+A1:2009
related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

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:

CE The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on EC's Voluntary Mark for the certification of products. R001_ECM rev.3 available at: www.entecema.it

Issuance date: 16 March 2020
Expiry date: 15 March 2025

Reviewer: Technical expert Amanda Payne
Approver: ECM Service Director Luca Badonni

Ente Certificazione Macchine Srl
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☎ +39 051 6705141 ☎ +39 051 6705156 ✉ info@entecema.it 🌐 www.entecema.it

Certificate - Сертификат - 證明書 - 증명서

Form QAT_10-M4, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 0P2003195.LMI0027
Technical Construction File no. TPZJ20031722769

Certificate's Holder: Zhejiang Mingfeng Industrial Co., Ltd.
No.7 Badu Road Tiantai County Zhejiang China

Certification ECM Mark:

Product: Medical disposable protective clothing
Model(s): MF-160-D, MF-165-D, MF-170-D, MF-175-D, MF-180-D, MF-185-D, MF-160-P, MF-165-P, MF-170-P, MF-175-P, MF-180-P, MF-185-P.

Verification to: Standard: EN 14126:2003
related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

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:

CE The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on EC's Voluntary Mark for the certification of products. R001_ECM rev.3 available at: www.entecema.it

Issuance date: 20 March 2020
Expiry date: 18 March 2025

Reviewer: Technical expert Amanda Payne
Approver: ECM Service Director Luca Badonni

Ente Certificazione Macchine Srl
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yangyuan@czitc.cn

NO.F-14

企业名称 Company

产品名称 Product

型号

海宁众凯服饰有限公司

Haining Zhongkai
Garment Co.,LTD.

防护服

Disposable coveralls
(Non-sterile)

是否白名单企业

国内批准文号

CE

其他

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yangyuan@czitc.cn

NO.F-15-1


企业名称 Company		产品名称 Product		型号
杭州天翔供应链管理有 限公司	SINOSKY LTD	医用防护服	Disposable Protective Coverall Non-sterile	
是否白名单企业	国内批准文号	CE	其他	
----	√	√	甲	



第一类医疗器械备案信息表

备案号: 鲁潍械备 20160022 号

备案人名称	山东英科医疗制品有限公司
备案人组织机构代码	56143965-4
备案人注册地址	青州市铝山工业园齐王路
生产地址	青州市铝山工业园齐王路
代理人	/
代理人注册地址	/
产品名称	一次性丁腈检查手套
型号/规格	型号: XS/S/M/L/XL, 规格: 100 支/盒。
产品描述	医疗检查过程中穿戴于检查者手部的用品, 该产品原材料为丁腈胶乳, 交联剂, 遮蔽剂, 防老剂, 凝固剂, 表面处理剂, 色膏。成品颜色有蓝色, 黑色, 紫色, 白色四种。
预期用途	用于防止医生与患者之间的交叉感染。
备注	/
备案单位和日期	潍坊市食品药品监督管理局 备案日期: 2016 年 07 月 29 日
变更情况	/


 INTCO
 英科医疗

Declaration Number: INTCO-CE-DC-NBR-001 Version: A/1
EU DECLARATION OF CONFORMITY

Manufacturer: Shandong Inteco Medical Products Co., Ltd.
 Address: Qiwang Road, Naoshan Industrial Park, Qingzhou, Shandong, China
 Declares that the MDR described hereafter


Authorized Representative: Lotus NL B.V.
 Address: Konings Julianaplein 10, le Verd, 2595AA, The Netherlands

Product name and model:
 Disposable Nitrile (NBR) Gloves
 UMDNS code: 11882

UDI-DE: (XS, S, M, L, XL, XXL)
 Blue Gloves: 6970245756014 / 6970245756021 / 6970245756038 / 6970245756045 / 6970245756052 / 6970245756069
 White Gloves: 6970245756410 / 6970245756427 / 6970245756434 / 6970245756441 / 6970245756458 / 6970245756465
 Black Gloves: 6970245756519 / 6970245756526 / 6970245756533 / 6970245756540 / 6970245756557 / 6970245756564
 Violet Gloves: 6970245756311 / 6970245756328 / 6970245756335 / 6970245756342 / 6970245756359 / 6970245756366

Meet the provisions of the Council Regulation EU 2017/745 which apply to them.

The medical device has been assigned to class I according to Annex VIII of the Regulation EU 2017/745. It bears the mark:



CONFORMITY ASSESSMENT ROUTE: EU 2017/745, Annex I & VII

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shandong Inteco Medical Products Co., Ltd.
 Address: Qiwang Road, Naoshan Industrial Park, Qingzhou, Shandong, China

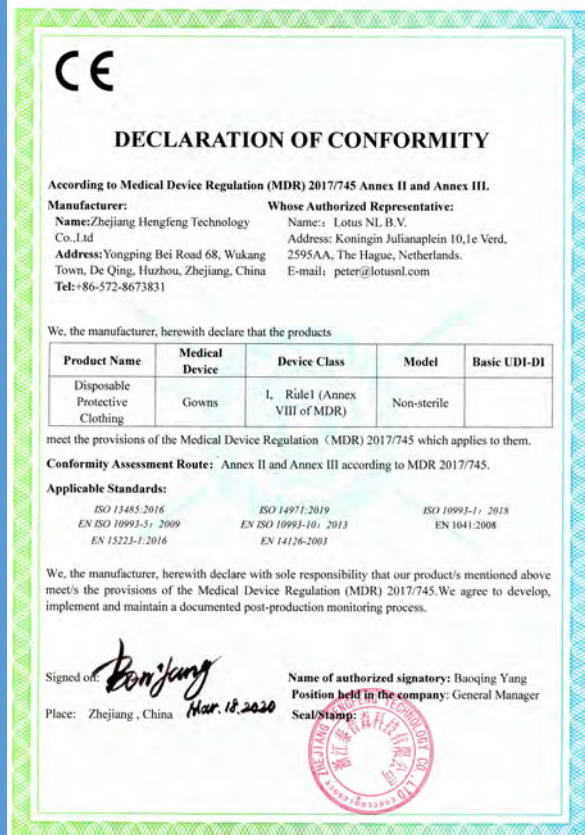
Shandong, 2019-05-06 Chi Yongtao Plant manager
Place, date Legally binding signature, Function



yangyuan@czitc.cn

NO.F-15-2

企业名称 Company	产品名称 Product	型号
杭州天翔供应链管理有 限公司	医用手套	Nitrile Medical Gloves
是否白名单企业	CE	其他
----	√	甲



yangyuan@czitc.cn

NO.F-16

企业名称 Company

浙江泰普森科技有限公
司

Zhejiang Hengfeng
Technology Co.,Ltd.

产品名称 Product

一次性医用防护服

Disposable Protective
Coverall

型号

HF170,
HF180, HF185, HF190

是否白名单企业

√

国内批准文号

√

CE

√

其他

甲

医用一次性防护服, 白名单企业;浙械注准 20202141018
白名单序号: 222#



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

Form QAT_10-MD6, version 00, effective since March 25th, 2020

CE Documentation Review

No. 0H2003295.ZLTOW46

Holder: Zhejiang Lovely Technology Textile Co., Ltd
No.28 Shanxing Road, Shengzhou

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable medical protective clothing (Not Sterile)

Model(s): 160,165,170,175,180,185

Classification: Class I (Not Sterile)
(accordingly to the Manufacturer's declaration)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. Technical documentation identified with the no. XM10202001120LY/MDD dated 29 March 2020. 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 - RCG1_ECM rev.3 available at: www.entecema.it

Date of issue: 29 March 2020
Approver: ECM Service Director
Luca Bedonchi

Expiry date: 28 March 2025
Technical Expert
Anindita Prasad

Ente Certificazione Macchine
Via Cò Bella, 243 - 40053 Valmaggia Loc. Castello di Serravalle (Bo) Italy
☎ +39.051.6705141 📠 +39.0514.705156 📧 info@entecema.it 🌐 www.entecema.it



yangyuan@czitc.cn

NO.F-17

企业名称 Company

浙江乐芙技术纺织品有限公司

Zhejiang Lovely Technology Textile Co.,Ltd.

产品名称 Product

医用防护服 (非无菌)

Disposable medical protective clothing (Not Sterile)

型号

160, 165, 170, 175, 180, 185

是否白名单企业

国内批准文号

CE

其他

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乙

一次性医用防护服,白名单企业;浙械注准 20202141081
白名单序号: 236#



Infrared Thermometer

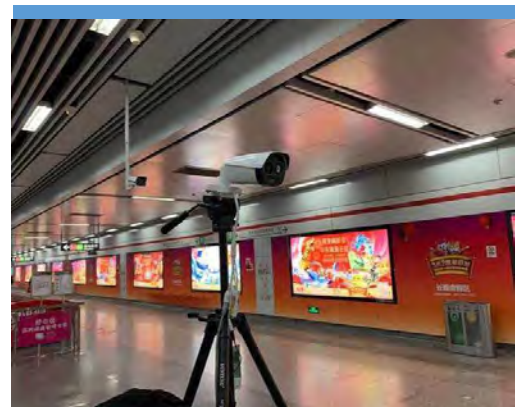
体温检测产品

产品Product		区间价格 Price (Eur) / pc	起订量MOQ
额温计	Infrared Thermometer	€ 23.30~36.40	Online negotiation
热成像人体测温仪	Body Temp. Measurement System	€ 12000.00 more each	Online negotiation
红外人体表面温度快速筛查仪 (红外热像仪)	Thermal imaging camera for rapid body temperature screening	----	Online negotiation



yangyuan@czitc.cn

NO.T-01



企业名称 Company		产品名称 Product		型号
浙江大华技术股份有限公司	Zhejiang Dahua Technology Co.,Ltd.	热成像人体测温仪	Body Temp. Measurement System	DH-TPC-BF5421P-T/ DH-TPC-HBB-AHW/ DHI-NVR5216-16P-I
是否白名单企业	国内批准文号	CE	其他	
----	----	√	甲	

高精度非接触热成像人体测温，可实现远距离快速人体温度检测，自动预警。

High precision non-contact thermal imaging of the human body temperature measurement, can achieve a long distance rapid temperature detection, automatic early warning.

Infrared Thermometer



40/CTN, 49.4*40.8*21.2cm
NW 3.3KG . Gw:4kg

CE Conformity



Attestation
of Conformity

No. ICR Polska/M7011820



Name and address of Registered Manufacturer: Zhejiang Batai 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 IV) 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+A 12:2014 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: EQP-2023-0000327A-MDQ

Issue date: 24.02.2023

Expiration date: 23.02.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/0203-17118.
This Attestation 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, 24. 02. 2023

ICR Polska Co. Ltd.
ul. Plac Prymitywa 9, 01-644 Warszawa
www.icrpolska.com e-mail: support@icrpolska.com



yangyuan@czitc.cn

NO.T-02

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

其他

√

√

√

乙

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

Infrared Thermometer
Model no.: IT01



Form QAT_104405, version 00, effective since March 6th, 2020

Certificate of Compliance

No. OP200327.SYEDD94
Technical Construction File no. TEMCM/200323359-5-AG05

Certificate's Holder: **SHAOXING YIQIANG ELECTRIC APPLIANCE TECHNOLOGY CO., LTD.**
Yuebei Village, Xiaoyue Street, Shangyu District, Shaoxing City, Zhejiang, China

Certification ECM Mark: 

Product: Infrared Thermometer
Model(s): IT01, IT02, IT03, IT04, IT05, IT06

Verification to: Standard:
EN 55011:2009/A1:2010,
EN 60601-1:2006/A1:2013, EN 60601-1-2:2015
related to CE Directive(s):
2014/30/EU (Electromagnetic Compatibility)

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. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. R001_ECM rev3 available at: www.entecema.it

Issuance date: 27 March 2020
Expiry date: 26 March 2025

Reviewer: **Technical expert**
Amanda Rognoni

Approver: **ECM Service Director**
Luca Benigni

Ente Certificazione Macchine Srl
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☎ +39 051 6705141 ☎ +39 051 6705156 ✉ info@entecema.it 🌐 www.entecema.it



yangyuan@czitc.cn

NO.T-03

شهادة - Certificate - 證明書 - Сертификат



企业名称 Company		产品名称 Product		型号
绍兴市益强电器科技有限公司	SHAOXING YIQIANG ELECTRIC APPLIANCE TECHNOLOGY CO., LTD.	红外额温计	Infrared Thermometer	IT01
是否白名单企业	国内批准文号	CE	其他	
是	√	√	乙	

医用红外额温计白名单生产企业；浙械注准20202071131
白名单序号：236#

百贝丽®



ZERTIFIKAT • CERTIFICATE • 認證證書 • CERTIFICADO • CERTIFICAT


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. 788 Chengdian South Road,
322000 Yiwu City, Zhejiang Province,
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Prolix GmbH
Brehmstr. 56, 40239 Düsseldorf, 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 Preis

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

ZERTIFIKAT • CERTIFICATE • 認證證書 • CERTIFICADO • CERTIFICAT

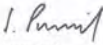
EC Certificate

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. 788 Chengdian South Road,
322000 Yiwu City, Zhejiang Province,
PEOPLE'S REPUBLIC OF CHINA

义乌市百贝丽医疗器械有限公司
 证件管理专用章
 仅限
 使用
 打印无效 编号

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

Date: 2018-10-31

 Stefan Preis

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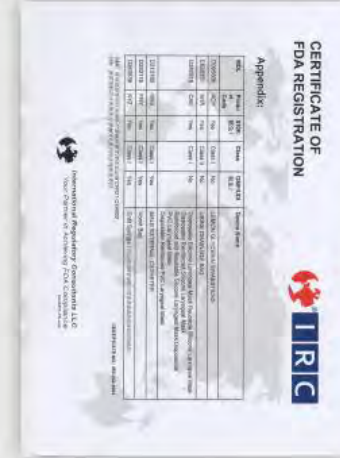
CZITC

yangyuan@czitc.cn

NO.T-04

企业名称 Company	Company	产品名称 Product	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	其他	
√	√	√	甲	

红外额温计白名单生产企业，浙械注准20162200312
白名单编号41#



yangyuan@czitc.cn

NO.T-05

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

其他

√

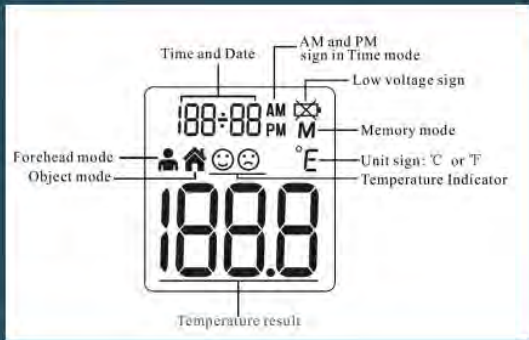
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代理“红外额温计”产品生产厂家为白名单企业“温州博康医疗科技有限公司”
白名单编号154#

Product Image



October 29, 2018
 JOYTECH Healthcare Co., Ltd.
 Yunhua Ren
 General Manager
 No. 365 Wuzhou Road, Yuhang Economic Development Zone
 Hangzhou City
 Zhejiang, 311100
 China

Re: K181239
 Trade/Device Name: Infrared Forehead Thermometer, Infrared Ear/Forehead Thermometer, Models: DET-205, DET-206, DET-305, DET-306, DET-315
 Regulation Number: 21 CFR 880.2910
 Regulation Name: Clinical Electronic Thermometer
 Regulatory Class: Class II
 Product Code: FLL
 Dated: August 29, 2018
 Received: September 28, 2018

Dear Yunhua Ren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/cdrh/cdrh/510k/pmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

U.S. Food & Drug Administration
 1085 Farmington Avenue
 Silver Spring, MD 20912
www.fda.gov



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

Registration No.: DD 60128148 0001
 Report No.: 15095961 002

Manufacturer: JOYTECH Healthcare Co., Ltd.
 No. 365, Wuzhou Road
 Yuhang Economic Development Zone
 Hangzhou City
 311100 Zhejiang
 China

Products:
 - Digital Thermometers
 - Blood Pressure Monitors
 - Infrared Ear Thermometers
 - Infrared Forehead Thermometers
 - Infrared Ear/Forehead Thermometers
 - Electric Breast Pumps
 (Reference Approval, Registration No.: DD 60114333 0001)

Expiry Date: 2021-03-10

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 8 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 93 is required.

Effective Date: 2017-04-20

Date: 2019-08-20



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.



yangyuan@czitc.cn

NO.T-06

企业名称 Company

产品名称 Product

型号

国药器械浙江医疗器材有限公司 (浙江健拓医疗仪器科技有限公司)

Sionpharm Zhejiang Medical Device Co.,Ltd.

红外额温枪

Infrared Thermometer

DET-306

是否白名单企业

国内批准文号

CE

其他

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√

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代理产品生产企业为白名单企业：“浙江健拓医疗仪器科技有限公司”，浙械注准20202071031
 白名单序号：162#



yangyuan@czitc.cn

NO.T-07

企业名称 Company		产品名称 Product		型号
浙江红相科技股份有限公司	Zhejiang ULIRVISION Technology Co., LTD.	红外人体表面温度快速筛查仪 (红外热像仪)	Thermal imaging camera for rapid body temperature screening	TI160-P1
是否白名单企业	国内批准文号	CE	其他	
----	√	√	甲	

Zhejiang ULIRVISION Technology Co., LTD, founded in 2005, focus on the R&D and production of infrared thermal imaging cameras. We have a core research team of more than 100 people in the fields of optical design, image algorithm, information processing, precision machinery and system integration, and have been certified by the national high-tech enterprise and national key software enterprise. At present,ULIRVISION have provided more than 30,000 sets of infrared thermal imagers in more than 60 countries



yangyuan@czitc.cn

NO.T-08

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	Infrared Thermometer	A66
是否白名单企业	国内批准文号	CE	其他	
√	√	√	丙	

代理“红外额温计”产品生产厂家为白名单企业,赣械注准20202070071
白名单编号167#



NO.T-09

企业名称 Company		产品名称 Product		型号
杭州天翔供应链管理有限公司	SINOSKY LTD	红外额温计	Infrared Thermometer	
是否白名单企业	国内批准文号	CE	其他	
----	√	√	乙	

红外体温计代理产品，生产企业为白名单企业：粤械注准20192070969
白名单序号;35#



Rapid Test Device

新冠病毒监测试剂盒

产品Product		区间价格Price (Eur) / pc	起订量MOQ
新型冠状病毒2019-nCoV核酸检测试剂盒	New Coronavirus(COVID-19) IgG/IgM Rapid Test Device	€ 5.17	50000 Pcs
新型冠状病毒IgG/IgM抗体检测试剂 (胶体金法)	COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)	€2.73 ~ €3.18	



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NO.S-01-1

企业名称 Company	产品名称 Product	型号
杭州优思达生物技术有限公司 Ustar Biotechnologies(Hangzhou)Ltd	新型冠状病毒2019-nCoV核酸检测试剂盒 (恒温扩增-实时荧光法) Diagnostic Kit for Novel-Coronavirus(2019-nCoV) RNA(Isothermal Amplification-Real Time Fluorescence Assay)	
是否白名单企业	CE	其他
√	√	甲

国械注准20203400241
白名单序号：20#



yangyuan@czitc.cn

NO.S-01-2

企业名称 Company	产品名称 Product	型号
杭州优思达生物技术有限公司 Ustar Biotechnologies(Hangzhou)Ltd	核酸扩增检测分析仪 Automatic extraction, amplification and detection of virus (POCT)	
是否白名单企业	CE	其他
	√	甲

For healthy persons:

The 2019-nCoV IgG/IgM Rapid Test Device was compared with RT-PCR Reagent using clinical specimens from 100 healthy persons.

Result	2019-Ncov IgG Rapid	2019-Ncov IgM Rapid	RT-PCR
Positive	0	0	0
Negative	100	100	100
Accuracy	100%	100%	100%



For identified persons:

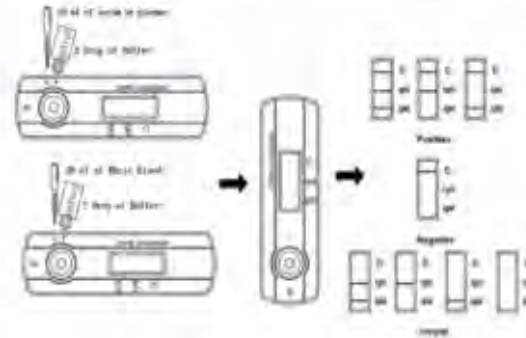
The 2019-nCoV IgG/IgM Rapid Test Device was compared with RT-PCR Reagent using clinical specimens from 200 2019-nCoV identified patients.

Result	2019-Ncov IgG Rapid	2019-Ncov IgM Rapid	RT-PCR
Positive	190	183	200
Negative	10	17	0
Accuracy	95%	91.5%	100%

For susceptible persons:

The 2019-nCoV IgG/IgM Rapid Test Device was compared with RT-PCR Reagent using clinical specimens from 200 susceptible 2019-nCoV patients, the results of RT-PCR are all negative.

Result	2019-Ncov IgG Rapid	2019-Ncov IgM Rapid	RT-PCR
Positive	148	142	0
Negative	52	58	200
Accuracy	74%	71%	0%



EC Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer:

Name: HANGZHOU REALY TECH CO., LTD.
Address: No.28.3 Main Street, Hangzhou Economic and Technological Development Area, 310018 Hangzhou, P.R.China

Products	Model
New Coronavirus(COVID-19) IgG/IgM Rapid Test Device	Device

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III, except Point 6, of Directive (Model A)

Applicable Standards: EN ISO 13485:2016; EN ISO 15223-1:2016;
EN ISO 14971:2012; EN ISO 13612:2002; EN ISO 17511:2003;
EN ISO 18113-1:2011; EN ISO 18113-2:2011; EN ISO 18113-3:2011;
EN ISO 23640:2015; EN 62366:2008.

We, the Manufacturer, herewith declare with sole responsibility that our products mentioned above meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd, located at Suite B,29 Harley Street, London W1G 9QR, England, United Kingdom to act as our European Authorised Representative as defined in the aforementioned Directive.

Hangzhou, February 25th, 2020
Place, date

Ding Pengfei General Manager
Legally binding signature, Position



yangyuan@czitc.cn

NO.S-02

企业名称 Company

产品名称 Product

型号

杭州睿丽科技有限公司

HANGZHOU REALY
TECH CO., LTD.

新型冠状病毒IgG/IgM快
速检测试剂盒 (胶体金
法)

COVID-19 IgG/IgM Test
Kit (Colloidal Gold
Method)

DYFK039

是否白名单企业

国内批准文号

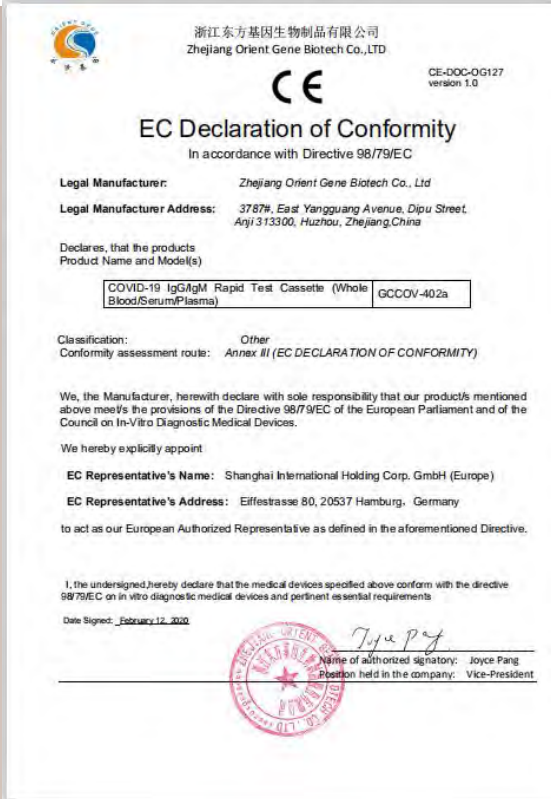
CE

其他

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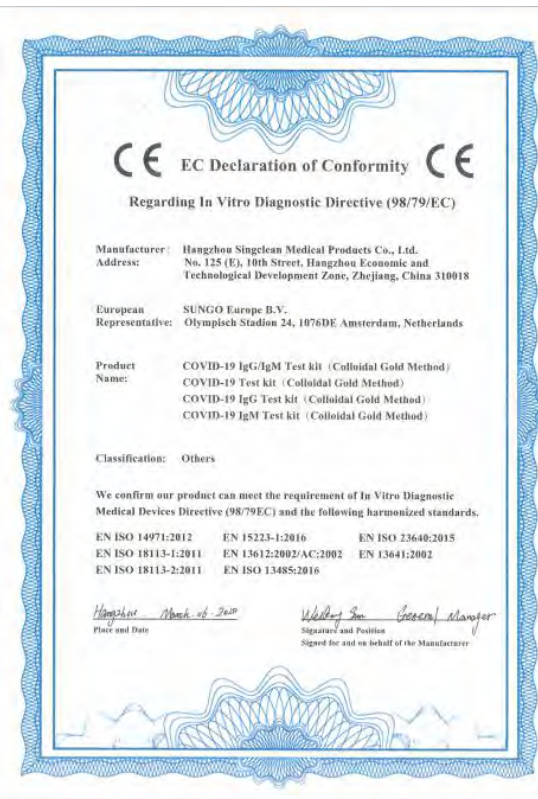
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企业名称 Company	产品名称 Product	型号
浙江东方基因生物制品股份有限公司 Zhejiang Orient Gene Biotech Co., Ltd.	新冠病毒监测试剂 COVID-19 IgM/IgG Rapid Test Cassette (Whole Blood/Serum/Plasma)	DYFK039
是否白名单企业 ----	国内批准文号 √	CE √
	其他 甲	

Zhejiang Orient Gene Biotech Co., Ltd has developed and cultivated the International market for more than ten years, with the focus on POCT Real Time Diagnostic Product, we have been widely sold to the market of North America, Asia, Africa, Europe, South America and the Oceania. We also established Wholly-owned Subsidiary in America and Canada. Our International Sales takes 90% of the total turnover. Parts of our products has passed the WHO Evaluation. and worked together with some World top 500



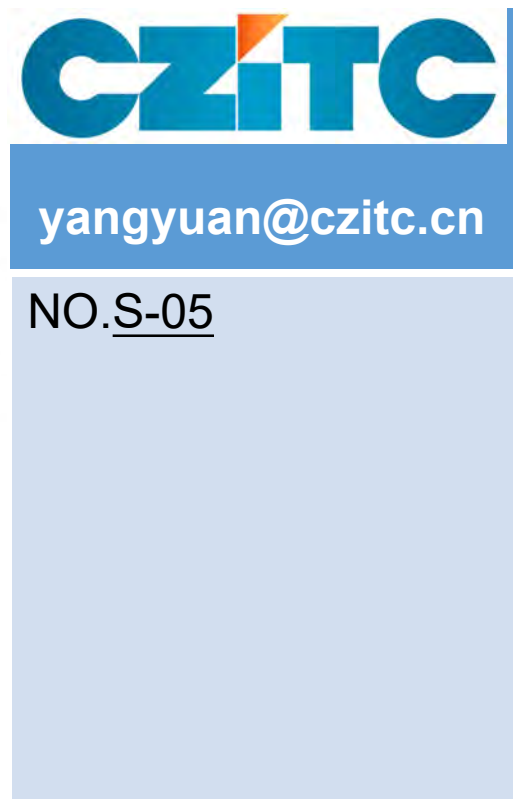
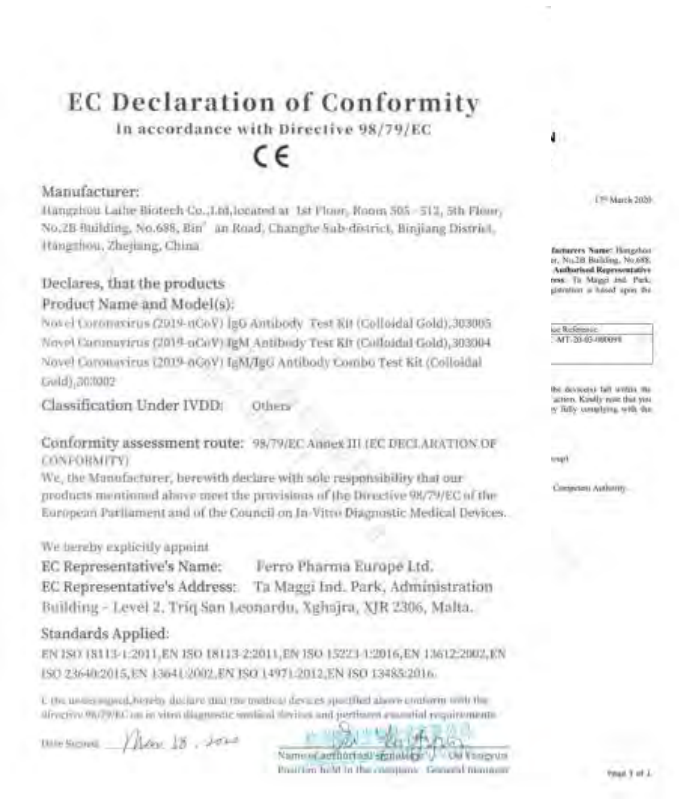
yangyuan@czitc.cn

NO.S-04

企业名称 Company	产品名称 Product	型号
杭州协合医疗用品有限公司 Hangzhou Singclean Medical Products Co.,Ltd.	新型冠状病毒IgG/IgM抗体检测试剂 (胶体金法) COVID-19 IgG/IgM Test Kit (Colloidal Gold Method)	
是否白名单企业	CE	其他
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Hangzhou Singclean Medical Products Co., Ltd., established in March 2003 with registered capital of 80, 000, 000 RMB. Committing herself to develop new types of composite and smart biomaterials, the company majors in producing biodegradable bio-materials and their derivatives, and has at present products of 7 series (chitosan, medical sodium hyaluronate gels, cross-linked hyaluronic acidsodium gels, microporous polysaccharide, oxidized regenerated cellulose, basic materials of tissue engineering, in vitro diagnostic reagents), 50 varieties.

The company passed the ISO9001 quality management system certification and ISO13485 medical device quality management system certification in 2007. In 2007, Hangzhou Singclean was awarded the title of Hangzhou high-tech enterprise. In 2008, it was recognized as a high-tech enterprise in Zhejiang Province.



企业名称 Company	产品名称 Product	型号
杭州莱和生物技术有限公司 Hangzhou Laihe Biotech Co., Ltd	新型冠状病毒 (2019-nCoV) IgM/IgG抗体联合检测试剂 (胶体金法) Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	
是否白名单企业	CE	其他
----	√	甲

Founded in February 2012, Hangzhou Laihe Biotech Co., Ltd (hereafter referred to as “Laihe Biotech”) is a national high-tech enterprise specialized in R & D, manufacturing and marketing of In Vitro Diagnostic (IVD) products. Laihe Biotech is always focusing on POCT instant diagnosis, monitoring and health information technology, committing to provide fast, accurate and reliable health detection products and services to our customers.

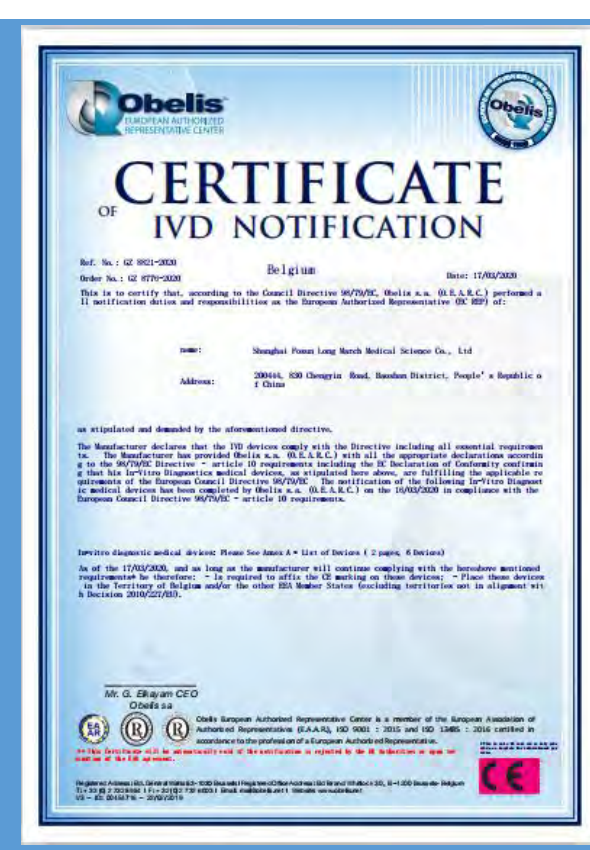
With our dedication for quality, Laihe Biotech is certified by CE and ISO 13485 quality system. And our urine and saliva drug testing products have been listed in “Ministry of Public Security Drug Test Kit recommended Purchasing Catalogue”



yangyuan@czitc.cn

NO.S-06

企业名称	Company	产品名称	Product	型号
杭州金溪生物技术有限公司	HANGZHOU GENESEA BIOTECHNOLOGY CO., LTD.	新型冠状病毒检测试剂	SARS-CoV2 (COVID-19) IgG/IgM Rapid Test	DYFK039
是否白名单企业	国内批准文号	CE	其他	
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NO.S-07

企业名称 Company	产品名称 Product	型号
杭州天翔供应链管理有 限公司	新型冠状病毒 (2019- nCoV) 核酸检测试剂盒 (荧光PCR法)	New Coronavirus(COVID-19) IgG/IgM Rapid Test Device
是否白名单企业	CE	其他
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代理产品检测试剂盒，生产企业为白名单企业：上海复星长征医学科学有限公司，国械注准20203400299
白名单序号;22#

Invasive Ventilator

呼吸机及配件



产品Product		区间价格Price (Eur) / pc	起订量MOQ
高流量无创呼吸湿化治疗仪	Heated Humidified High Flow Nasal Cannula Oxygen Therapy Device(HFNC)	€ 7266.00	10 Pcs
无创呼吸机	Non-invasive ventilator	€ 12421.00	10 Pcs
有创呼吸机	Invasive ventilator	€ 41522.00	100Pcs
相关配件	Accessories	----	

ACM812A Ventilator



yangyuan@czitc.cn

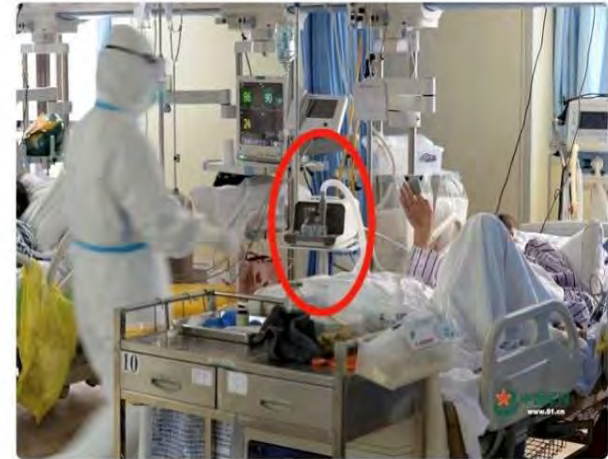
NO.H-01

企业名称 Company	产品名称 Product	型号
杭州天翔供应链管理 有限公司	有创呼吸机 Invasive ventilator	
是否白名单企业	CE	其他
√	√	甲

代理产品呼吸机，生产企业为白名单企业：北京航天长峰股份有限公司，国械注准20183541592
白名单序号;39#



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



yangyuan@czitc.cn

NO.H02-1

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	Micomme Medical Technology Development Co.,Ltd	高流量无创呼吸湿化治疗仪	Heated Humidified High Flow Nasal Cannula Oxygen Therapy Device(HFNC)	OH-70C
是否白名单企业	国内批准文号	CE	其他	
√	√	√	甲	

SEPRAY[®] ST-30H

Non-invasive Ventilator



CFDA

Letter of thanks from national government for contribution during the epidemic

中央赴湖北等疫情严重地区指导组

指导组保 C2020J 166 号

感谢信

湖南明康中锦医疗科技发展有限公司：
 新冠肺炎疫情爆发以来，在以习近平总书记为核心的党中央坚强领导下，按照党中央、国务院决策部署和中央应对疫情防控工作领导小组、国务院联防联控机制要求，全国上下全面落实“坚定信心、同舟共济、科学防治、精准施策”总要求，坚持全国一盘棋，经过艰苦努力，当前已初步呈现疫情形势持续向好、生产生活秩序加快恢复的态势。
 疫情防控期间，贵单位对中央赴湖北等疫情严重地区指导组物资保障工作给予了大力支持，以“战时状态”，迅速反应，快速支援，在医用防护用品、医疗救治设备、重要生活物资等的生产、调拨、采购、运输、清关、质检等各个环节发挥了重要作用，有效保障了湖北省、武汉有抗击疫情所需重要物资设备，为全国打赢疫情防控阻击战、总体战、阻击战作出了重要贡献。
 在此，谨向贵单位致以崇高敬意和衷心感谢！

中央赴湖北等疫情严重地区指导组物资保障组
 2020年3月9日



During the epidemic, SEPRAY provided devices more than

5000 pcs



yangyuan@czitc.cn

NO.H02-2

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

其他

√

湘械注准20192080049

—

丁

名单序号：12#



yangyuan@czitc.cn

NO.H03-1

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

普通氧气面罩

Simple oxygen mask

A0106

是否白名单企业

国内批准文号

CE

其他

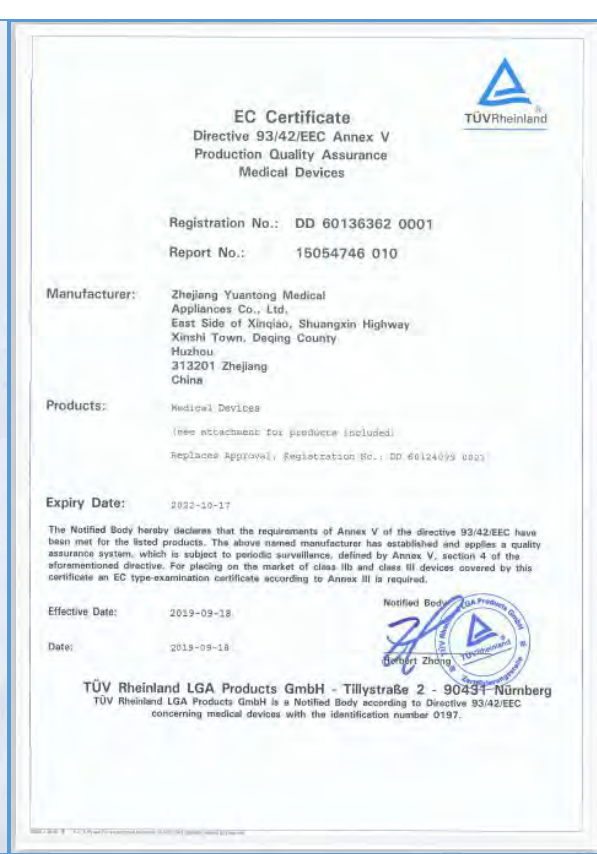
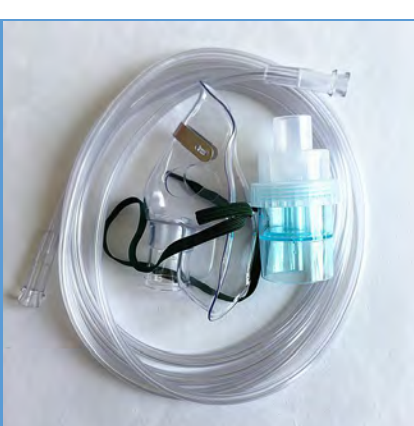
--

浙械注准20162560069

√

甲

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, idt ISO9001-2000 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



NO.H03-2

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	CE	其他
--	国内批准文号 浙械注准20162540070	甲

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, idt ISO9001-2000 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



NO.H03-3

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	一次性使用鼻氧管 Disposable Nasal oxygen cannula	
是否白名单企业	CE	其他
--	国内批准文号 浙械注准20162560068	甲

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, idt ISO9001-2000 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



NO.H03-4

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 with 7 dihuters	
是否白名单企业	CE	其他
--	国内批准文号 浙械注准20162560069	甲

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, idt ISO9001-2000 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



Medical isolation goggles

护目镜产品

产品Product		区间价格Price (Eur) / pc	起订量MOQ
医用隔离眼罩	Medical isolation goggles	€1.56~2.99	2000 Pcs
隔离面罩	Face Shield	€1.10~1.95	2000 Pcs



501#



502#

amtre veritas

Certificate of Compliance
With European Directives

Applicant Manufacturer: Taizhou City Jixing Safety Protection Products Co.,Ltd.
Addr.: Banyang Village , Daqiao 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 mopod 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 Hatoraffhouse Ingrave street london
Tel: 0044 020 780 10996 Fax: 0044 020 7501 4189
Http://www.amtre-veritas.com P.C: SW11 2SQ
E-mail: amtreveritas@gmail.com

Module B EU Type-Examination Certificate
For the requirements of PPE Regulation 2016/425
Certificate No.: PP-GB-201903-01-008

Product: Protective eyewear
Model(s): Goggles
Manufacturer(s): Linhai City Jixing Safety Protection Products Co., Ltd.
Issue date: 2019-03-08
Revision date: 2019-08-05
Expiry date: 2024-03-07

Module B EU Type-Examination Certificate Annex
For the requirements of PPE Regulation 2016/425
Certificate No.: PP-GB-201903-01-008

Model reference	Product description
K3101	Specification with polycarbonate clear lens and frame with UV filtering lens, 20 x 10 mm ILO, 1.0, color energy impact (PI), Optical Class 1
K3102	Specification with clear lens and frame, impact frame and temple, lens energy impact (PI), Optical Class 1
K3103	Specification with polycarbonate clear lens and frame with UV filtering lens, 20 x 10 mm ILO, 1.0, color energy impact (PI), Optical Class 1
K3104	Specification with polycarbonate clear lens and frame with color temple, lens and nose piece, lens energy impact (PI), Optical Class 1

Beijing Zhongliantianrun Certification Center

Certificate of Approval
Certificate No.: 10116015449805
Awarded to
Linhai City Raul Machinery Co.,Ltd.
Organisational Code Certificate No.: Unified Social Credit Code: 9133102611595863
Addr.: Banyang Village, Daqiao Town, Linhai City, Zhejiang, China P.C. 317016

Beijing Zhongliantianrun Certification Center (ZLTC) 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: Jan 27th, 2018
The effectiveness of this Certificate shall be Validated by periodic surveillance audit of ZLTC 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 Zhongliantianrun Certification Center (http://www.zltc.com.cn)

Beijing Zhongliantianrun Certification Center
Room 2023, 22nd Floor, 2nd Unit, Block 1, No. 4 First, Qiang Road, Chaoyang District, Beijing, P.R. China 100010

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	CE	其他
--	√	甲
国内批准文号		
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	其他	
√	√	√	乙	

“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#



yangyuan@czitc.cn

NO.G-03

企业名称 Company	产品名称 Product	型号
杭州启硕进出口有限公司 Hangzhou Qishuo IMP&EXP Co., Ltd.	医用护目镜 Medical isolation goggles	
是否白名单企业	CE	其他
----	√	甲

代理“护目镜”产品生产厂家为白名单企业”桂食药监生产许20100012号



Certificate - Сертификат - 證明書 - 증명서 - 證書

Form GAT_16/004, version 00, effective since March 09th, 2020

Certificate of Compliance

No.: 0P2004026.YC60701

Technical Construction file no.: 177,0003123715

Certificate's Holder: Yiwu Guanyong Bags Co., Ltd.
2F, Building 3, No.518 Shuanglong Road, Fobang Town, Yiwu City

Certification ECM Mark:

Product: FACE SHIELD

Model(s): This certificate certifies only the product without its own specific models.

Verification to: Standard: EN 166:2001, EN 166:2001
related to CE Directive(s): 89/391/EEC (Personal Protective Equipment)

CE

Expiry date: 02 April 2025

Reviewer: Technical expert Amanda Payne

Approver: SQA Service Director Isaac Balfour

Printed Certificate Moulding Set

Via CE Mark 242-121, Certificate of Conformity - 4003, Via Somoglia (BO) - ITALY
☎ +39 051 6792141 ☑ +39 051 6791152 ✉ info@certecmark.it www.certecmark.it



Test Report
No. TPZ20081223715 Date: 2020/04/02

The following sample(s) was/were submitted and identified by the client as:

Applicant	Yiwu Guanyong Bags Co., Ltd.
Address	2F, Building 3, No.518 Shuanglong Road, Fobang Town, Yiwu City
Sample Description	FACE SHIELD
Main Model	-
Sample Receiving Date	Mar. 31, 2020
Testing Period	Mar. 31, 2020 to April 02, 2020
Testing Performed	SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	EN 166:2001, EN 166:2001
Test Results	FOR FURTHER DETAILS PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion	THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT

For and on behalf of

Authorized Signature:
Shi Lixiwen
General Manager - GTS(SHO)

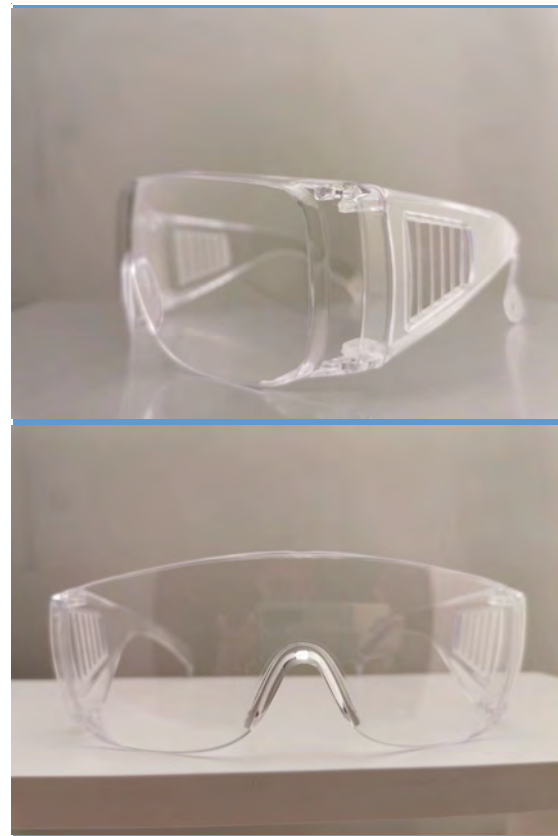
Test Conducted:
Personal eye protection - Specifications



yangyuan@czitc.cn

NO.G-04

企业名称 Company	产品名称 Product	型号
绍兴上虞澳璞特国际贸易有限公司 Shaoxing Shangyu Allbranded International Trading Company Limited	防护面罩 Face shield	
是否白名单企业	CE	其他
国内批准文号	√	丙



NO.G-05

企业名称 Company	产品名称 Product	型号
国药器械浙江医疗器材有限公司	护目镜 SAFETY GLASSES	JJI-YSA-5
是否白名单企业	CE	其他
国内批准文号	√	甲
浙金械备 20200010 号		

代理产品生产企业为“金华市景蓝工贸有限公司”浙金械备 20200010 号



Form GAT_10-M04, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 08200319.NGMUS72

Certificate's Holder: Ningbo Gele Medical Apparatus Co., Ltd.
No.10, Zhejiang Road, Lanjiang Street, Yuyao, Zhejiang Province, China.

Certification ECM Mark: 

Product: Face Shield
Model(s): 12cm*10.5cm \ 13cm*11cm \ 13.5cm*10cm \ 13.5cm*12cm \ 14.5cm*10.5cm \ 14.5cm*12cm \ 15.2cm*10.5cm \ 16cm*13cm \ 32.5cm*25cm

Verification to: Standard: EN 149:2001+A1:2009
related to CE Directive(s): R 2016/425 (Personal Protective Equipment)

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 qualification about the Marking:
The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of product. #G01_ECM rev.3 available at: www.entecerma.it

CE

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

Reviewer: Technical expert Amanda Payne
Approver: ECM Service Director Luca Segondi

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



yangyuan@czitc.cn

NO.G-06-1

企业名称 Company		产品名称 Product		型号
杭州天翔供应链管理有 限公司	SINOSKY LTD	隔离面罩	Isolation Face Shield	
是否白名单企业	国内批准文号	CE	其他	
----	√	√	乙	

代理产品医用隔离面罩生产厂家为: 宁波吉丽医疗器械有限公司白名单序号;浙甬械备20200065号



yangyuan@czitc.cn

NO.G-06-2

企业名称 Company		产品名称 Product		型号
杭州天翔供应链管理有 限公司	SINOSKY LTD	隔离眼罩	Safety Goggles	
是否白名单企业	国内批准文号	CE	其他	
----	√	√	乙	

代理产品医用隔离眼罩生产厂家为：宁波吉丽医疗器械有限公司白名单序号;浙甬械备20200006号



Anti Fog Goggles

شهادة - 증명서 - 證明書 - Сертификат - Certificat - Certificate

Form GAT_10/M04, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 4Q200402G_JEW0709

Certificate's Holder: **Jinhua Enjoy&Wonderful Inc.**
Fuhou Road Xiaoshun Town Jinhua Zhejiang China

Certification ECM Mark:  Type Approved

Product: Protective Goggles
Model(s): HMJ001, HMJ002, HMJ003

Verification to: Standard: EN 166:2001
related to CE Directive (s): R 2016/425 (Personal Protective Equipment)

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.entecema.it

Issuance date: 02 April 2020
Expiry date: 01 April 2025

Reviewer: Technical expert Amanda Payne 
Approver: ECM Service Director Luca Beoloni 

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



yangyuan@czitc.cn

NO.G-07

企业名称 Company	产品名称 Product	型号
金华万得福日用品股份有限公司 Jinhua Enjoy&Wonderful Inc.	护目镜 Protective goggles	
是否白名单企业	CE	其他
国内批准文号	√	丙
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Hand Sanitizer

消毒类产品

产品Product		区间价格Price (Eur) / pc	起订量MOQ
洗手液消毒剂	Hand Sanitizer	€ 0.32~3.00	Online negotiation
等离子体空气消毒器	Plasma Air Sterilizer	€ 910.00~1040.00	50 Pcs

景维康免洗手消毒凝胶



Ningbo Syton Testing & Technology Service Co., Ltd.
 F5 No. 5 Building Zhongshuanghui No. 128 Jinyuan Road, Ningbo
 National Hi-Tech Zone, 315040, China
 Tel: +86-574-87248329 Fax: +86-574-87042953
 http://www.syton.com.cn



Verification of Conformity

On the basis of the referenced the sample(s) of the below product has been found to comply with the relevant harmonized standard(s) to the directive(s) listed on this verification.

Verification No.: SYT20200316001
 Applicant: Zhejiang Ludao Technology Co.,Ltd.
 Manufacturer: Zhejiang Ludao Technology Co.,Ltd.
 Address: No.5,Industry Avenue ,Hairun Street ,Sanmen County ,Taizhou City,Zhejiang Province,China
 Product Description: Hand Hygiene Washing Gel
 Model No.: 53ML/70ML/100ML/237ML/375ML/500ML/1000ML
 Brand Name: N/A
 Relevant Standard(s): EN13445-1:2008

NOTE: This verification should be read in conjunction with it.

This verification is for the exclusive use of SYT's clients and is provided pursuant to the agreement between SYT and its clients. SYT's responsibility and liability are limited to the terms and conditions of the agreement. SYT assumes no liability to any party, other than to the client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Verification. The observations and test results referenced from this Verification are relevant only to the sample tested. This verification by itself does not imply that the material, product, or service is or has ever been under an SYT verification program.



Winy Hu
 Winy Hu
 Manager
 16th March 2020



yangyuan@czitc.cn

NO.X-01-1

企业名称

Company

产品名称 Product

型号

浙江绿岛科技有限公司

Zhejiang Ludao
 Technology Co.,Ltd.

无水洗手液

hand sanitiser

是否白名单企业

国内批准文号

CE

其他

√

√

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Ningbo Syton Testing & Technology Service Co., Ltd
 F5 No. 9 Building Zhonghuangshu No. 128 Jinyuan Road, Ningbo
 National Hi-Tech Zone, 315040, China
 Tel: +86-574-87248323 Fax: +86-574-87042953
 http://www.syton.com.cn



Verification of Conformity

On the basis of the referenced the sample(s) of the below product has been found to comply with the relevant harmonized standard(s) to the directivel(s) listed on this verification.

Verification No.: SYT20200317001
 Applicant: Zhejiang Ludao Technology Co.,Ltd.
 Manufacturer: Zhejiang Ludao Technology Co.,Ltd.
 Address: No.5Industry Avenue Jiairun Street Sanmen County,Taizhou City,Zhejiang Province,China
 Product Description: Alcohol spray
 Model No.: 100ML
 Brand Name: N/A
 Relevant Standard(s): EN13445-1:2008

NOTE: This verification should be read in conjunction with it.

This verification is for the exclusive use of SYT's clients and is provided pursuant to the agreement between SYT and its clients. SYT's responsibility and liability are limited to the terms and conditions of the agreement. SYT assumes no liability to any party, other than to the client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this verification. The observations and test results referred from this verification are relevant only to the sample tested. This verification by itself does not imply that the material, product, or service is or has ever been under an SYT certification program.



Winy Hu
 Manager
 17th March 2020



yangyuan@czitc.cn

NO.X-01-2

企业名称

Company

产品名称 Product

型号

浙江绿岛科技有限公司

Zhejiang Ludao
 Technology Co.,Ltd.

酒精喷雾

Alcohol spray

是否白名单企业

国内批准文号

CE

其他

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√

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Zhejiang Ludao Technology Co., Ltd is under China Ludao Technology Co.,Ltd, which has invested 73.35 million HK dollars in China. This company founded in July, 2002 located in Taizhou, Zhejiang, covers 35,500 m2, owns 10 fully-automatic aerosol filling production lines, 3 fully-automatic liquid filling production lines, one professional gas station, 4 tiered warehouse facility, 5 workshop, modern office building and the national research and Development Center with the annual production capacity of 100million aerosol cans and 100,000Ton liquid filling product.



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

Form CAI_10A104, version 00, effective since March 6th, 2020

CE Documentation Review

No. 08.200319.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.enteceerma.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 Cò Bella, 243 - 40053 Volturno Loc. Castello di Serravalle (Bo) Italy
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yangyuan@czitc.cn

NO.X-02

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 Quick-dry wash-free Sanitizing gel	
是否白名单企业	CE	其他
--	√	乙

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.



Hand Sanitizer (Washing Free) Product Statement

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

شهادة - Certificate - 증명서 - 証明書

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

Certificate of Compliance



No. DH200329_HSF0Q_66
Test Report no. XMT020200132_ILY/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, 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:

CE 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.enlecemait

Issuance date: 29 March 2020
Expiry date: 28 March 2025

Reviewer: Technical expert Amanda Payne
Approver: ECM Service Director Luca Bernardi

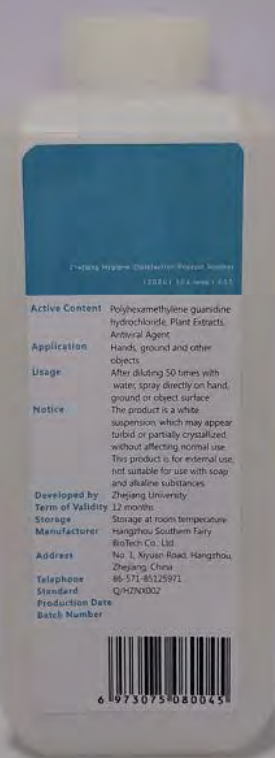
Enf Certificazione Macchine Srl
Via Ca' Bella, 2/43 - Loc. Castello di Serravalle - 40053 Valsamoggia (BO) - ITALY
+39 051 6705141 +39 051 6705156 info@enlecemait www.enlecemait



yangyuan@czitc.cn

NO.X-03-1

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	CE	其他
--	√	乙



شهادة - Certificate - 증명서 - 證明書 - Сертификат

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

Certificate of Compliance

No. OH200329-HSFDQ66
Test Report no. XMT020200132 ILY/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:

CE 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.enftecemail.it

Issuance date: 29 March 2020
Expiry date: 28 March 2025



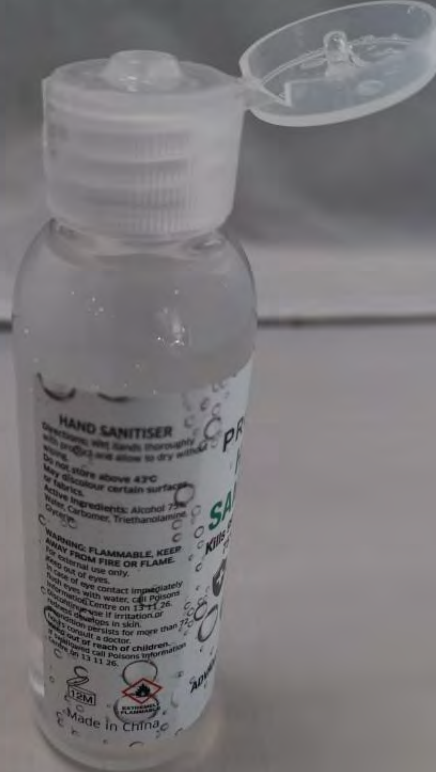

Enfe Certificazione Macchine Srl
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yangyuan@czitc.cn

NO.X-03-2

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	CE	其他
--	√	乙



NO.X-04

企业名称 Company	产品名称 Product	型号
绍兴上虞澳璞特国际贸易有限公司 Shaoxing Shangyu Allbranded International Trading Company Limited	酒精消毒水和免洗手液 75% Alcohol Sanitizer and Spray	
是否白名单企业	CE	其他
----	√	乙



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NO.X-05-1

企业名称	Company	产品名称	Product	型号
杭州启硕进出口有限公司	Hangzhou Qishuo IMP&EXP Co., Ltd.	消毒洗手啫喱	Hand Sanitizer Gel	
是否白名单企业	国内批准文号	CE	其他	
----	√	√	甲	



NO.X-05-2

企业名称 Company	产品名称 Product	型号
杭州启硕进出口有限公司 Hangzhou Qishuo IMP&EXP co., Ltd.	消毒喷雾 Disinfectant Spray	
是否白名单企业	CE	其他
----	√	甲

圖片



GTS

Test Report

Report No. TCZJ20031722737EN Job No.:22737 Date: March 31, 2019

The following information was/were submitted and identified by/on behalf of the client:

Applicant: Zhejiang Disinfekt Biotechnology Co., Ltd
 Address: Building B-2, No. 288, Yansan Road, Jiuguan Town, Nanxun District, Huzhou City, Zhejiang Province
 Sample Name: Disinfekt disinfectant
 Sample Model: 50ml, 100ml, 250ml, 300ml, 500ml, 5L, 10L, 20L, 200L, 1000L
 Sample Receive Date: March 25, 2020
 Sample Testing Period: March 25, 2020 - March 31, 2020
 Test Result Summary:

As requested by the applicant, for details refer to attached page(s).

TEST ITEM(S)	TEST REQUESTED	RESULT(S)
Two hundred and five(205) substances content in SVHC	ECHA's SVHC candidate on and before Oct. 18, 2019 of European Commission Regulation 1907/2006/EC concerning the REACH	LESS THAN 0.1% (w/w)

Forwarded on behalf of
Shanghai Global Testing Services Co., Ltd.

Authorized Signature:
Shi LeiKevin
General Manager -GTS/SHO

Page 1 of 12

This report is only responsible for the tested samples from the client, the testing results is used for scientific research, teaching or internal quality control. Within the testing agreement of the contract, the client must allow us to copy the report information to our website.
 Shanghai Global Testing Services Co., Ltd.
 Floor 2nd, Building D-1, No. 128 Shenyi Road, Minhang District, Shanghai, China, 201104 China
 Tel: (86-21) 3102 7900 Fax: (86-21) 3102 7858 E-mail: info@gts-lab.com Web Site: http://www.gts-lab.com

Certificate - 證明書 - 증명서 - Сертификат

Certificate of Compliance

No. OP200327.ZDBDD78
 Technical Construction File no. TCZJ20031722737

Certificate's Holder: Zhejiang Disinfekt Biotechnology Co., Ltd.
 Building B-2, No. 288, Yansan Road, Jiuguan Town, Nanxun District, Huzhou City, Zhejiang Province

Certification ECM Mark:

Product: Disinfekt disinfectant
 Model(s): 50ml, 100ml, 250ml, 300ml, 500ml, 5L, 10L, 20L, 200L, 1000L

Verification to: Standard: EN 1650:2019

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.entecema.it. This Certificate of Compliance can be checked for validity at www.entecema.it. This verification doesn't imply assessment of the production of the product(s).

Date of Issue 27 March 2020 Expiry date 24 March 2025

Service Manager:
 Deputy Manager:

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NO.X-06

企业名称 Company	产品名称 Product	型号
浙江德茵菲科生物科技 股份有限公司	手部消毒液	DYFK039
是否白名单企业	CE	其他
----	√	甲

Zhejiang Disinfekt Biotechnology Co.,Ltd is an innovation-oriented technology enterprise focusing on scientific life,health,environmental protection and green health.To provide the public with a solution to keep away from bacteria and viruses, Disinfekt produces a new generation of safe disinfection products, which have been awarded the title of "Safety, Energy-saving and Green product". Disinfekt's facilities and equipment have reached the production line of purifying medical care.



NO.X-07-1

企业名称 Company	产品名称 Product	型号
浙江丽芙秀化妆品有限公司 ZHEJIANG RIFESHOW COSMETICS CO., LTD.	洗手液 Hand Sanitizer	
是否白名单企业	CE	其他
国内批准文号	甲	
----	√	

Founded in 1996, Zhejiang Rifeshow Cosmetics Co.,Ltd is located in Fotang Industrial Park in Yiwu ,with a 70,000 square meters GMPC certified factory building and a set complete of corresponding supporting production R & D and testing equipment and precision instruments. At the same time, it has production qualifications with national level, independent research and development laboratory, raw material storage room, emulsification workshop, filling workshop, disinfection workshop. The company has strong production capacity and strong technical force. Its main production includes perfume, cosmetics, disinfectants and other supplies.

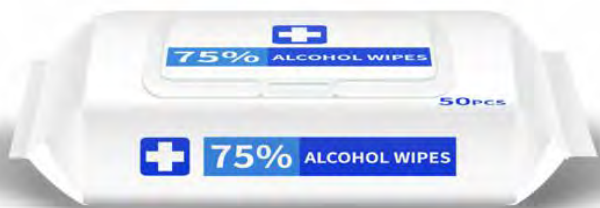


yangyuan@czitc.cn

NO.X-07-2

企业名称 Company	产品名称 Product	型号
浙江丽芙秀化妆品有限公司 ZHEJIANG RIFESHOW COSMETICS CO., LTD.	酒精消毒液 Alcohol Disinfectant	
是否白名单企业	CE	其他
----	√	甲

Founded in 1996, Zhejiang Rifeshow Cosmetics Co.,Ltd is located in Fotang Industrial Park in Yiwu ,with a 70,000 square meters GMPC certified factory building and a set complete of corresponding supporting production R & D and testing equipment and precision instruments. At the same time, it has production qualifications with national level, independent research and development laboratory, raw material storage room, emulsification workshop, filling workshop, disinfection workshop. The company has strong production capacity and strong technical force. Its main production includes perfume, cosmetics, disinfectants and other supplies.



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

CE Documentation Review Report 

No. 30171113.ZYCTW54

Holder: Zhejiang Youquan Care Products Technology Co., Ltd.
Changxing Economic and Technological Development Zone, Huzhou City, Zhejiang Province, China

Review goal: Review of the Technical Documentation in regards of the requirements of the Medical Devices Directive 93/42/EEC Annex VII

Product: Wet Wipes, Dry Wipes

Model(s): Wet Wipes: Barrel, Bag or Box
Dry Wipes: Barrel, Bag or Box

Classification: Class I (accordingly to the Manufacturer's declaration)

Review output: The output of the Review of the Test Report identified with the no. CE/MDD-ZHYQ-2017-11 is that no Non-Conformity in regards to the requirements of Directive 93/42/EEC Annex VII has been detected.

Date of Issue 13 November 2017 Expiry date 12 November 2022

Chief Manager  Deputy Manager 

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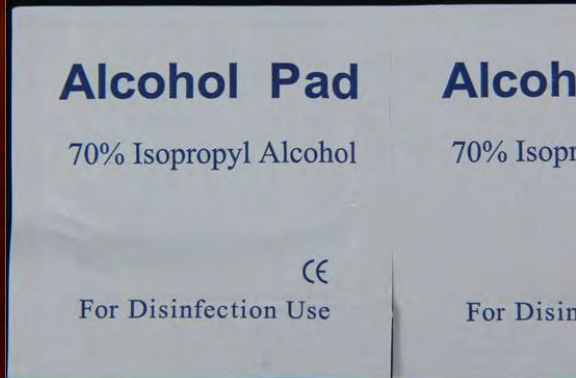
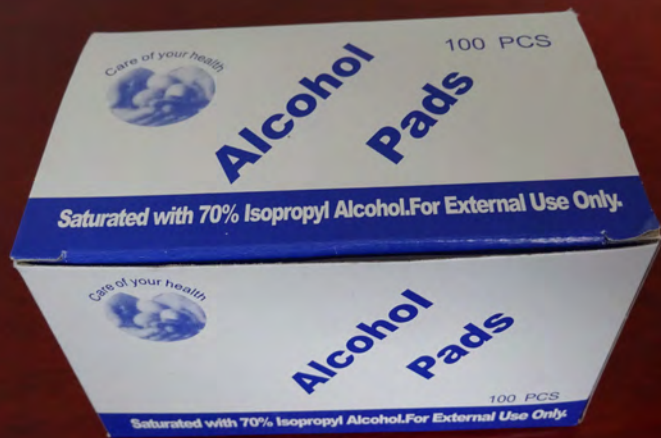


yangyuan@czitc.cn

NO.X-08

企业名称 Company	产品名称 Product	型号
浙江优全护理用品科技股份有限公司 Zhejiang Youquan Care Products Technology Co., Ltd.	酒精湿巾 Alcohol Wipes	
是否白名单企业	CE	其他
----	√	甲

Zhejiang Youquan Care Products Technology Co., Ltd. (Youquan Care) was set up in 1987 in Changxing county, north of Zhejiang province and close to Shanghai. It targets at hygiene and medical products market with nonwoven fabrics like spunlace, spunbond, themalbond and hot air through fabric, wet and dry wipes, and diapers. The company covers an area of 300,000 m², in which 30,000m²is 100,000 grade purification GMP certified workshop. The company with 30 nonwoven machines producing about 10,000 tons nonwoven fabrics per month is No. 1 in Asian Nonwoven Industry and No. 13 all over the world. With 35 wet and dry wipe machines and 15 diaper machines, the company is one of the biggest suppliers in this industry. Our company supplies different kinds of products. High quality and favorable price. We're pleased to get your Inquiry and we will come back to as soon as possible. We stick to the principle of "quality first, service first, continuous improvement and innovation to meet the customers" for the management and "zero defect, zero complaints" as the quality objective. To perfect our service, we provide the products with good quality at the reasonable price. The company with ISO9001, ISO14001, ISO13485, GMPC, FDA and CE certified, can provide OEM and ODM for customers with qualified and price-competitive products.



yangyuan@czitc.cn

NO.X-09-1

企业名称 Company	产品名称 Product	型号
杭州经成进出口贸易有限公司 Hangzhou Golden City Import and Export Trade Co., Ltd.	酒精棉片 Alcohol Prep Pads	
是否白名单企业	CE	其他
----	√	丙



yangyuan@czitc.cn

NO.X-09-2

企业名称	Company	产品名称		Product	型号
杭州经成进出口贸易有限公司	Hangzhou Golden City Import and Export Trade Co., Ltd.	消毒湿巾	Disinfection Wipes		KCL-2033
是否白名单企业	国内批准文号	CE	其他		
----	√	√	丙		



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NO.X-10

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

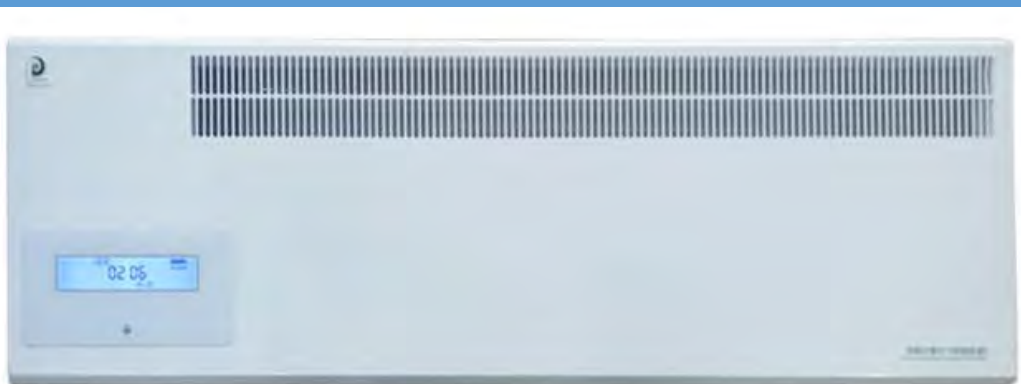
CE

其他

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



PM-B1000D2



PM-L1200D2



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NO.X-11

企业名称 Company

浙江佩洁尔医疗科技有
限公司

ZHEJIANG PEIJIEER
MEDICAL TECHNOLOGY
CO.,LTD.

产品名称 Product

等离子体空气消
毒器

Plasma Air Sterilizer

型号

PM-B1000D2
PM-L1200D2

是否白名单企业

国内批准文号

CE

其他

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