CATALOG

Disposable medical masks

Protective equipment

Rapid Tests

Remote infrared thermometers

Ventilators

VIRUTAN

Delivery by plane

Ilyushin Il-76
Volume: 160 m3
Cost: 335 000 USD

McDonnell Douglas MD-11
Volume: 200 m3
Cost: 300 000 USD

An 124 "Volga-Dnepr"
Volume: 900 m3
Cost: 747 750 USD

*Aircraft must be reserved
one week before departure

VIRUTAN

Disposable Medical Masks

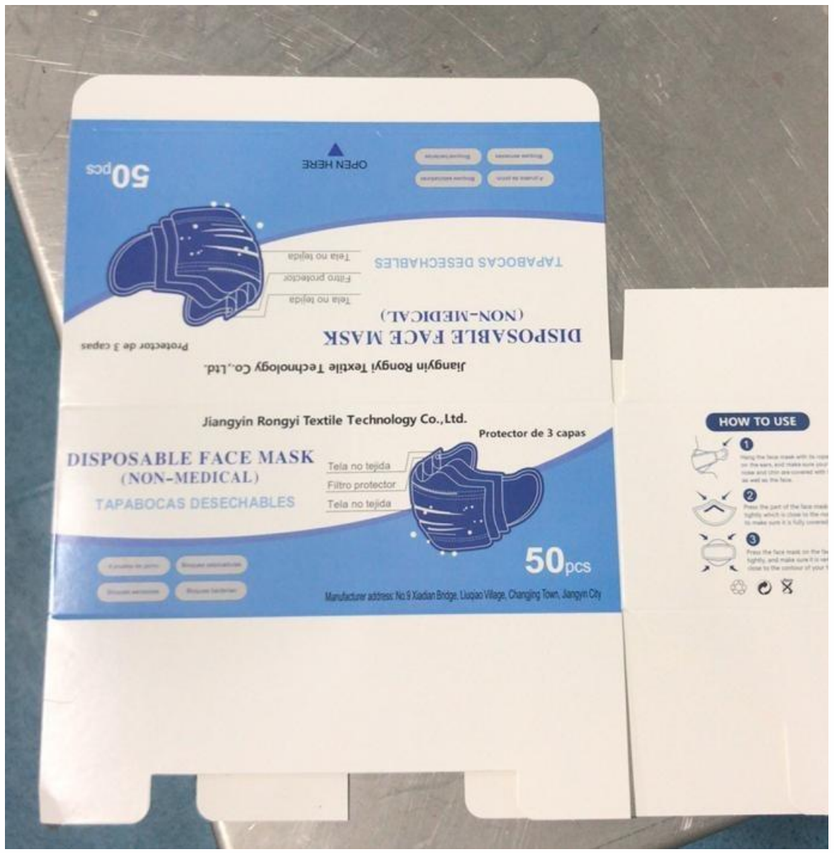
VIRUTAN

Disposable face mask

Specifications:

Type: Disposable face mask
Layer: 3
Filter media:Melt blown
Earloops: Knitted Polyester
Nose-piece: Yes
Visor piece: No
Bacterial Filtration Efficiency (BFE): BFE ≥ 95%
Cytotoxicity: Grade = 0
Skin Irritation & Dermal Sensitization:
Negligible Expiration: 5 years

Producing capacity: 10,000,000PCS per day



Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Disposable face mask

CERTIFICATE OF CONFORMITY

Certificate No.: VIC200318-CJR-4174

The Certification Body of

VIC TESTING AND CERTIFICATION LTD

Certifies that

Applicant: Jiangyin Rongyi Textile Technology Co., Ltd.
Add: No.9 Xiadian bridge, Tonggang Road, Changjing Town, Jiangyin, China

Manufacturer: Jiangyin Rongyi Textile Technology Co., Ltd.
Add: No.9 Xiadian bridge, Tonggang Road, Changjing Town, Jiangyin, China

Product: Disposable Face Mask
Model No.: 175*90mm 175*95mm
Report No.: VIC20200317-JRY06-CE-S

Complies with the requirements of the **Regulation (EU)2016/425 Personal Protective Equipment (PPE).** The submitted products have been tested by us and found in compliance with the following European Standards:
EN 149:2001+A1:2009.

This certificate of conformity is based on an evaluation of a sample of the above mentioned products. It does not imply an assessment of the whole production. The CE marking as shown below can be affixed on the product after preparation of necessary technical documentation.

Signature: Steven White
Steven White
Date of issue: March 18, 2020
Expiry Date: March 17, 2025

VIC TESTING AND CERTIFICATION LTD
Add: CHASE BUSINESS CENTRE (CHD) 39-41 CHASE SIDE LONDON, N14 5BP, U.K.
Email: Info@victesting.com Website: www.victesting.com

EU Declaration of Conformity

(No.: CJRY20200318-1)

We,

Jiangyin Rongyi Textile Technology Co., Ltd.

Address: No.9 Xiadian bridge, Tonggang Road, Changjing Town, Jiangyin, China

as the manufacturer declare under our sole responsibility that the product

Product: Disposable Face Mask
Model No.: 175*90mm 175*95mm

to which this declaration relates is in compliance with **Regulation (EU)2016/425 Personal Protective Equipment (PPE)** and comply with the standards listed below:
EN 149:2001+A1:2009.

Signature:
Function: manager
Place of issue : Jiangyin, China
Date of issue : 2020-03-18

VIRUTAN

Disposable Medical Mask

Type A

Specifications:

Mask type:Disposable Medical Mask Layer: 3 Layer
Filter media:Melt blown
Earloops: Knitted Polyester
Nose-piece: Yes
Visor piece:No
Bacterial Filtration Efficiency (BFE): BFE @ 3.0 μm large Bacteria ≥ 95%
Cytotoxicity: Grade = 0
Skin Irritation & Dermal Sensitization:Negligible
Expiration: 5 years
Packing: 37*37*42CM, 2000PCS，9KGS
Producing capacity: 8,000,000PCS per day

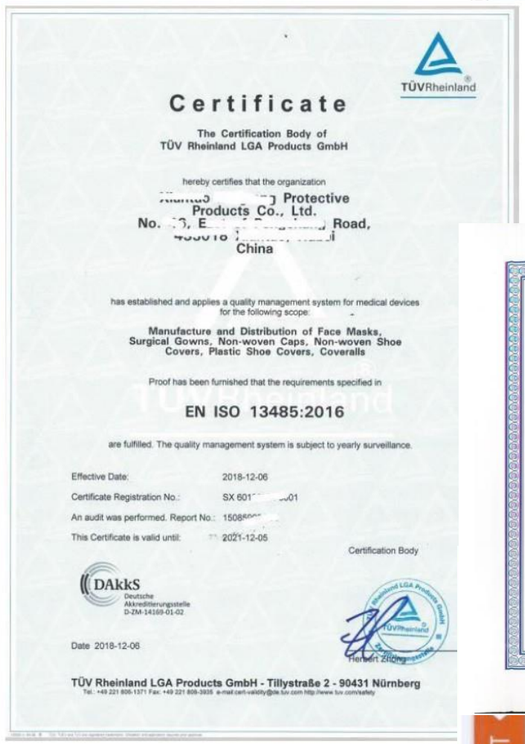
Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

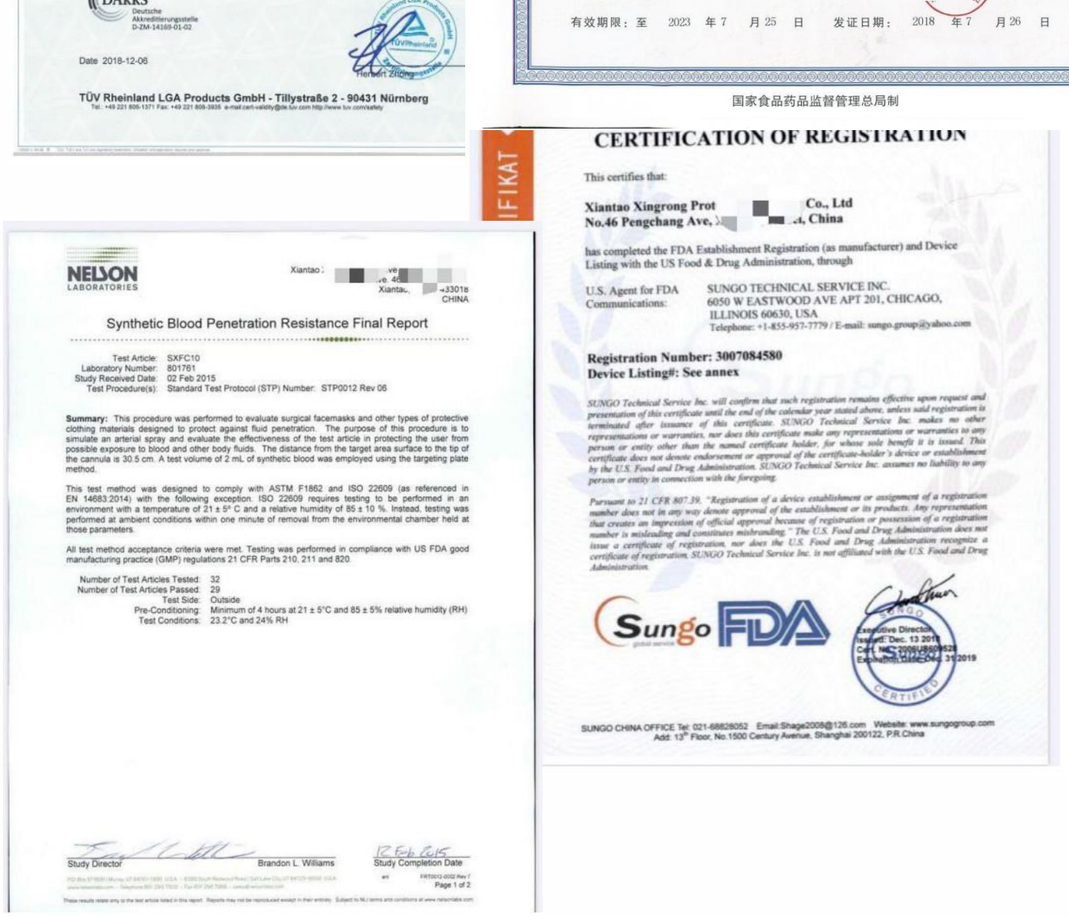
VIRUTAN

Disposable Medical Mask

In the box:

In the pack:





VIRUTAN

Disposable Medical Mask

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

TÜVRheinland

Registration No.: DD 60133273 0001

Report No.: 15085900 005

Manufacturer: Xiantac Protective Products
No. 46, Ea. ang Road,
433018 Xiant
China

Products: Aspects of manufacture concerned with securing and maintaining sterile conditions of Face Masks, Surgical Gowns, Non-woven Caps, Non-woven Shoe Covers, Plastic Shoe Covers, Coveralls

Replaces Approval, Registration No.: DD 60104282 0001

Expiry Date: 2023-12-05

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

Effective Date: 2018-12-06

Date: 2018-12-06

Notified Body
TÜVRheinland
Herbert Zhang

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

TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Protective Products Co., Ltd.
No. Road,
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Face Masks, Surgical Gowns, Non-woven Caps, Non-woven Shoe Covers, Plastic Shoe Covers, Coveralls

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-12-06

Certificate Registration No.: SX 601 01

An audit was performed. Report No.: 1508

This Certificate is valid until: 2021-12-05

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

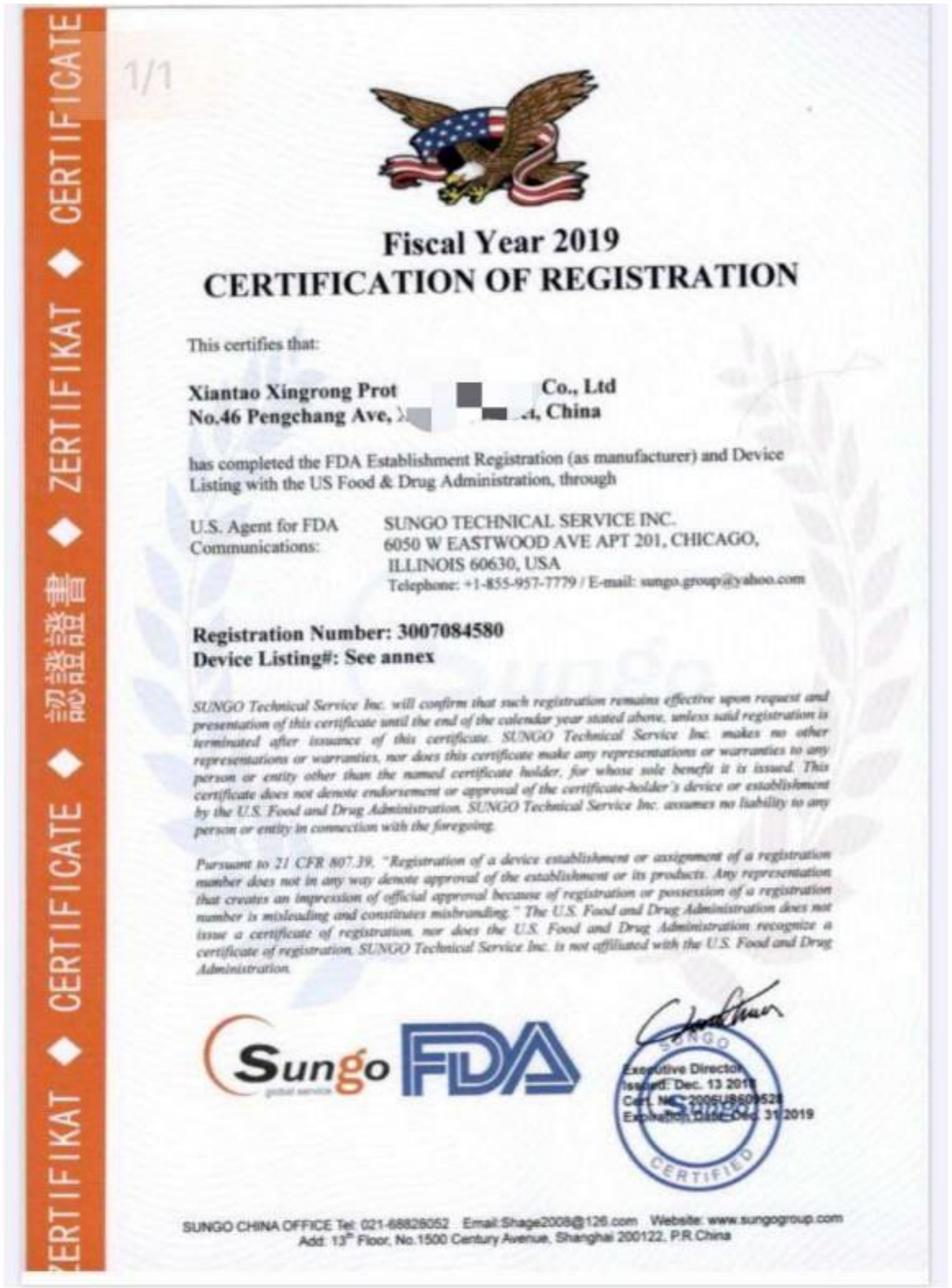
Date 2018-12-06

Herbert Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

VIRUTAN

Disposable Medical Mask



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書

1/1

Fiscal Year 2019
CERTIFICATION OF REGISTRATION

This certifies that:

Xiantao Xingrong Prot [redacted] Co., Ltd
No.46 Pengchang Ave, [redacted], China

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

U.S. Agent for FDA Communications: SUNGO TECHNICAL SERVICE INC.
6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungo.group@yahoo.com

Registration Number: 3007084580
Device Listing#: See annex

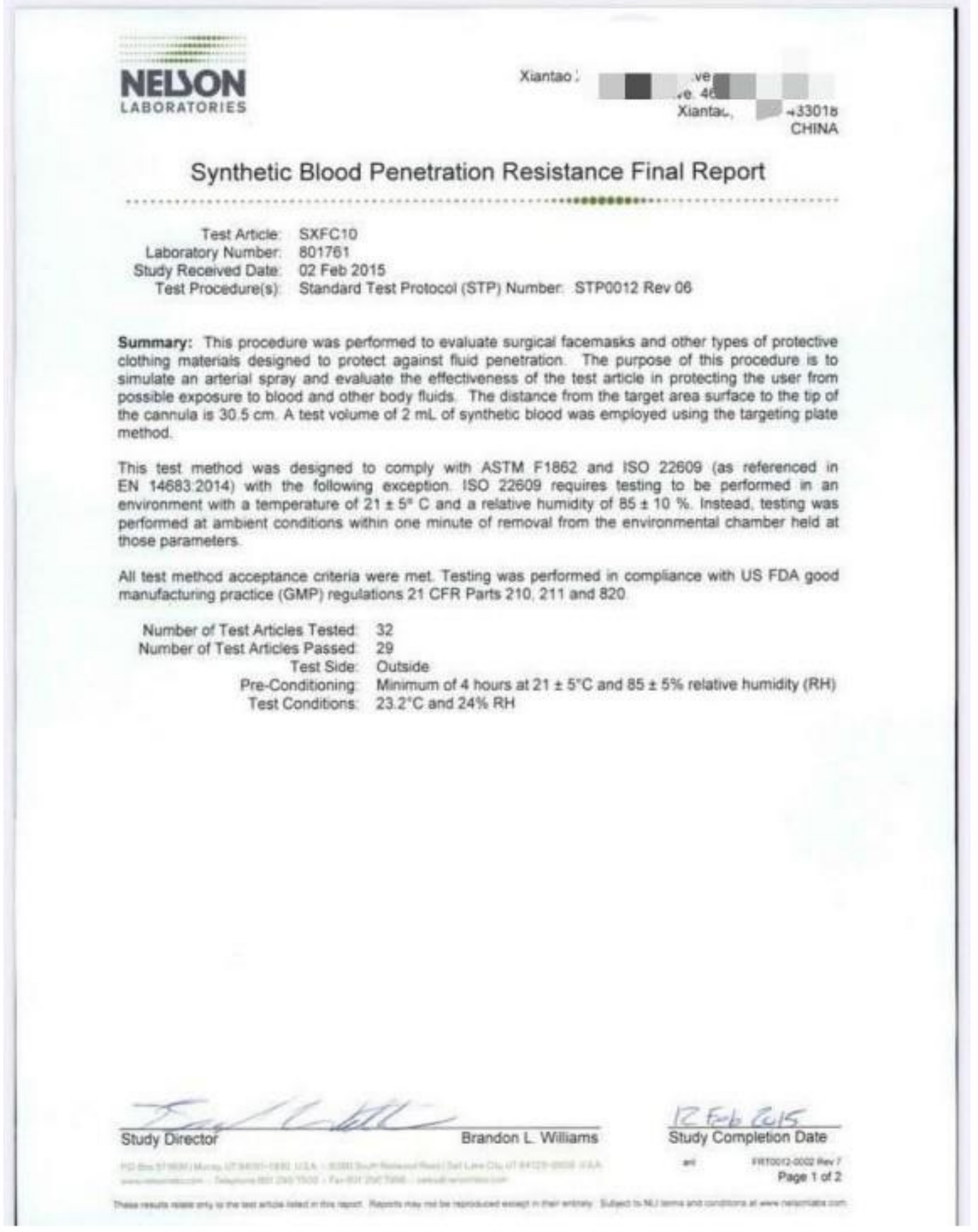
SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SUNGO Technical Service Inc. makes no other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

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

Sungo FDA

SUNGO
Executive Director
Issued: Dec. 13 2018
Cert. No: 2006US8609528
Expiration Date: Dec. 31 2019
CERTIFIED

SUNGO CHINA OFFICE Tel: 021-68828052 Email:Shage2008@126.com Website: www.sungogroup.com
Add: 13th Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China



NELSON LABORATORIES

Xiantao [redacted] 433018
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article: SXFC10
Laboratory Number: 801761
Study Received Date: 02 Feb 2015
Test Procedure(s): Standard Test Protocol (STP) Number: STP0012 Rev 06

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2014) with the following exception. ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5° C and a relative humidity of 85 ± 10 %. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 32
Number of Test Articles Passed: 29
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions: 23.2°C and 24% RH

Study Director: Brandon L. Williams
Study Completion Date: 12 Feb 2015

FRT0012-0002 Rev 7
Page 1 of 2

These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NLI terms and conditions at www.nelsonlabs.com

VIRUTAN

Disposable Surgical Mask

Uses:
It has the effect of resisting liquids, filtering particles and bacteria, etc. can use disposable medical masks in non-personnelintensive public places.

Structure:
PP (25g) + Meltblown (25g) + PP (25g)

Filtration level:
BFE≥99%

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

Full english box:

Carton:

Packing:

Box size: 175x95mm/50pcs/0,2kg
Ctn size: 550x420x430mm/2000pcs/8,5kg
20ft: 260ctns
40HQ: 670ctns

VIRUTAN

Disposable Surgical Mask

Certificate of Registration

This is to Certify that the medical apparatus Quality Management System of

Unify social credit code：91310116MA1JCX8U8F

Address

Apply to

Technical Services, Technical Development, Technical Consulting, Technical Exchanges, Technology Transfer, Technology Promotion; (Non-Medical) Respirators Sales; Labor Protection Supplies Wholesale; Labor Protection Supplies Sales; Needle Textiles Wholesale; Type I Medical Equipment Wholesale; Type II Medical Equipment Wholesale; Disinfectant Sales; Sanitary Ware Retail; Information System Integration Services; other Chemical Products Wholesale; Rubber Products Wholesale; Chemical Products Wholesale (excluding hazardous chemicals); Import & Export of Goods; Import & Export of Technology; (Non-medical) Personal Protective Masks Production.

has been assessed and registered by International Standards Authority,Inc. in accordance with provisions of

ISO13485:2016

this registration is subject to the company maintaining a medical apparatus quality management system, to the above standard, which will be monitored by ISA. if the certificate can't be inquired by www.saia-isa.org it will be invalid certificate or the rescission qualifications.

Certificate Number: ISA/HK/200312

Issued Date: 20 Mar 2020

Valid Until: 19 Mar 2023

Signed by:

INTERNATIONAL STANDARDS AUTHORITY, INC. HONGKONG

Biotech Medical Technology (Shanghai) Co.,Ltd. CE TD

File No.: CE-I-01 Revision: 00 Effective date: 2020.03.23

EC DECLARE OF THE CONFORMITY

Manufacturer:	Name:	B
	Add:	S Jinshan Industrial Park, Shanghai City, PRC
European Representative:	Name:	
	Add:	Mies-van-der-Rohe-Straße 6, 80807 München, Germany
Product Name:	Disposable Medical Face Mask	
Object of the declaration:	Type:	with earloop
	Size:	17.5cm x 9.5cm,17.5cm x 10cm,18cm x 8cm,18cm x 9cm,18cm x9.5cm,18cm x 10cm,19.5cm x 8cm,19.5cm x 9cm,19.5cm x 9.5cm,19.5cm x 10cm
	Lot No.	Pending
	Number of products:	Pending
UMDNS Code:	12-447	
Classification (MDD, Annex IX):	I , rule 1	
Conformity Assessment Route:	Annex VII	

We herewith declare in sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

CE Start of CE Marking: 2020-03-27

Place of Issue: Shanghai, CHINA

Date of Issue: 2020-03-23

Signature:

Mr.XIA MENG

Position: General Manager

VIRUTAN

Disposable Surgical Mask

International Certification Registrar International Certification Registrar

Certificate

No. ICR Polska/P6301786

CE

Name and address of certificate owner: hejian

Name and address of manufacturer: hejian

Province, PRC.

Product name: Non-Sterile Protective Masks

Product types: 17.5cm*9.5cm

Product trademark: BIOT

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 QA Testing Certification Co., LTD

No. of test reports: QA2020031712

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: Rafał Kalinowski

Warsaw, 23. 03. 2020

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

International Certification Registrar International Certification Registrar

Certificate

No. ICR Polska/P6301827

CE

Name and address of certificate owner: ıai City, PRC.

Name and address of manufacturer: ıai City, PRC.

Product name: Disposable Coveralls with Hood Protective Suit

Product types: BTK203001SH

Product trademark: BIOT BIOTECH

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 14126:2003

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 Institute of Textile Technology Testing Center

No. of test reports: ITTT2020032012

Certificate issue date: 25.03.2020
Expiration date: 24.03.2025

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

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

Director: Rafał Kalinowski

Warsaw, 25. 03. 2020

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

VIRUTAN

Disposable Surgical Mask

MedPath

EC-Registration Certificate

Directive 93/42/EEC on Medical Devices (MDD), Article 14

No. R A001 85 Rev. 01

Manufacturer: E .td.

Product Category(ies): See Appendix A

CE

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

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

Date, 2020-03-26 MedPath GmbH

MedPath

Appendix A: Product Category(ies)

Name	Classification	UMDNS Code	Form No.	Registration No.
Disposable Medical Face Mask	I	12-447	00300096	to be issued

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

CE

VIRUTAN

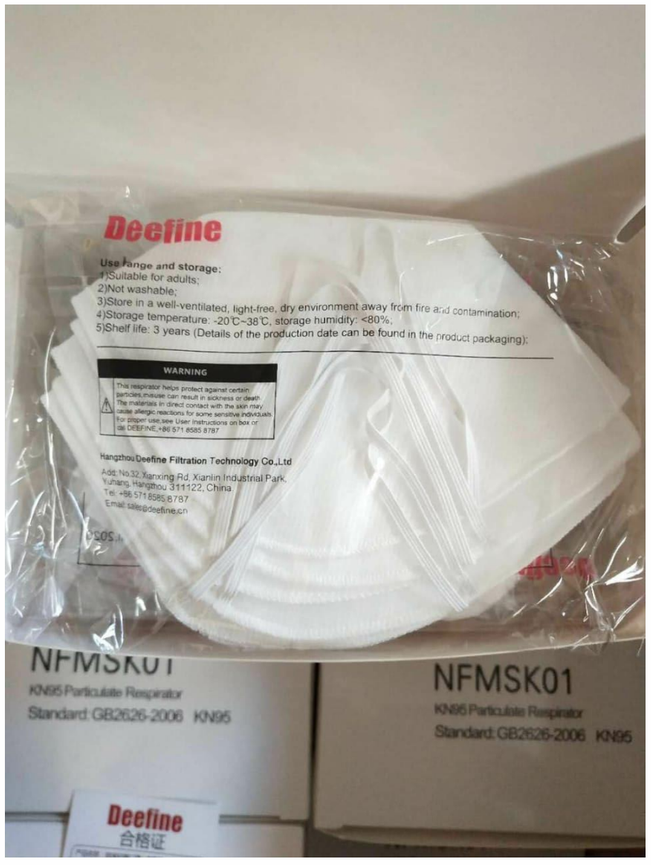
Disposable Surgical Mask

Dust-free purification workshop.

Strict quality control.

VIRUTAN

KN95



Protectionclass: FFP2

Producingcapacity: 800,000PCS per day
Carton size: 670x310x285mm

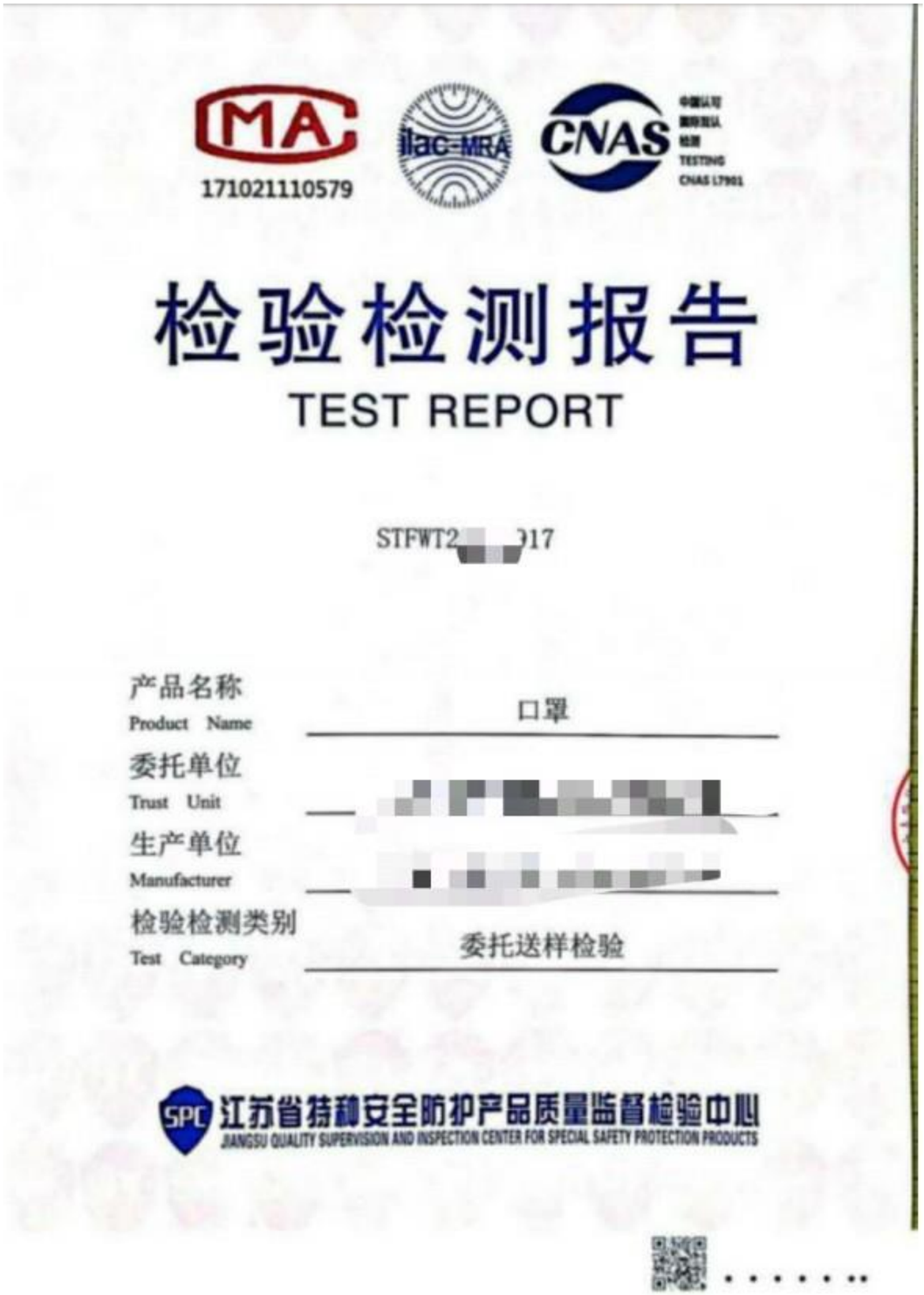
Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

KN95

VIRUTAN

KN95



171021110579

检验检测报告

TEST REPORT

STFWT2[redacted]017

产品名称
Product Name 口罩

委托单位
Trust Unit [redacted]

生产单位
Manufacturer [redacted]

检验检测类别
Test Category 委托送样检验

江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

DEKRA

DEKRA Testing and Certification GmbH
Standort Essen
Persönliche Schutzausrüstungen

Adlerstraße 29
45307 Essen, Germany

Tel +49.201.52319-0
Fax +49.201.52319-401
E-Mail DTC-Support-Essen@dekra.com

Prüfbericht / *Test report*
No. 3417084.10-CPA

Prüfgegenstand *Testsubject*	Corona SARS-CoV-2 Atemschutzmaske *Coroan SARS-CoV-2 respiratory protective mask*
Modell *Type*	Starbuss S-KN 95
Hersteller *Manufacturer*	[redacted]u City, Jiangxi Province, China
Prüfgrundlage *Test requirement*	Prüfgrundsatz für Corona SARS-Cov-2 Pandemie Atemschutzmasken Rev. 1 vom 26.03.2020 *Testing principle for Corona SARS-CoV-2 pandemic respiratory masks rev. 1 of 2020-03-26*
Prüfergebnis *Test result*	Die Pandemie Atemschutzmaske entspricht den Corona SARS-CoV-2 Prüfanforderung *The pandemic respiratory protective mask does meet the Corona SARS-CoV-2 test requirement.*
Datum *Date of issue*	16.04.2020

Dieser Bericht besteht aus 11 Seiten. *This report consists of 11 pages.*
Eine auszugsweise Veröffentlichung dieses Berichtes bedarf der Zustimmung der DEKRA Testing and Certification GmbH. Juristisch bindend ist ausschließlich die deutsche Fassung dieses Berichtes.
Publication of extracts of this report requires agreement of DEKRA Testing and Certification GmbH. We confirm the correctness of the translation of the German original. In the case of arbitration however only the German wording shall be valid and binding.

DEKRA Testing and Certification GmbH, Handwerkstraße 15, 70565 Stuttgart
Zertifizierungsstelle *Certification Body*: Dinnendahlstraße 9, 44809 Bochum
Telefon +49.234.3696-400, Fax +49.234.3696-401, DTC-Certification-body@dekra.com

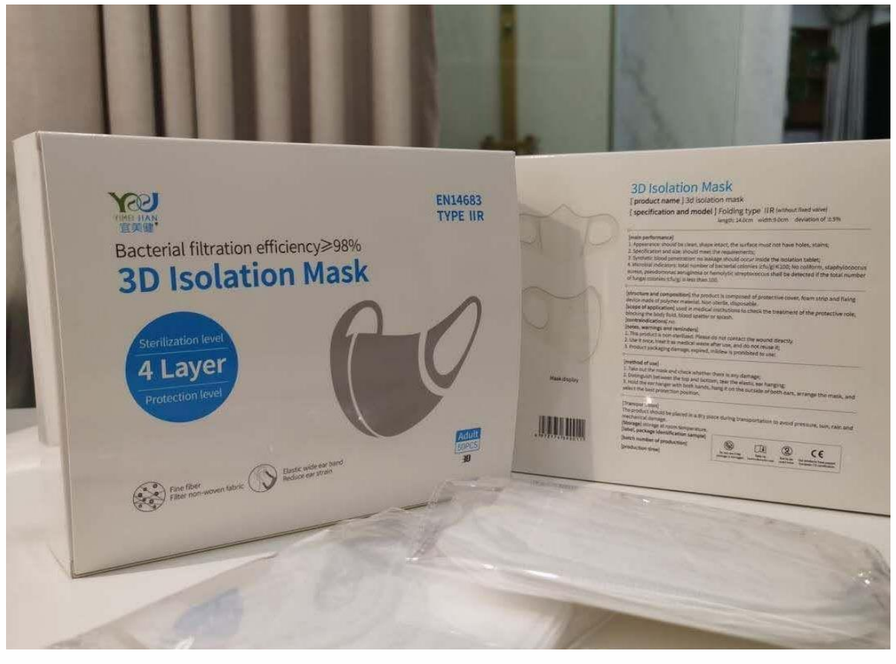
VIRUTAN

N95 FFP3

The most protected type of masks.
Protection class: FFP3

Daily productivity: 1 000 000 pcs

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.



VIRUTAN

N95

Fiscal Year 2020

CERTIFICATE OF FDA REGIST

This certifies that:

[redacted]

523000, CHINA

has completed the FDA Establishment Registration and Device Listi
Administration, through UCL-REG SERVICE

Owner/Operator Number: 10064623

Listing No.	Product Code:	Device
D379546	MSH	Respirator

Medical materials series, protec
mask/disposable surgical mask,
equipment ,disposa
gloves,disinfectant,glasses,Clear
materials (environ

*UCL-REG SERVICE INC. will confirm that such registration remains effective u
this certificate until the end of the calendar year stated above, unless said re
issuance of this certificate. UCL-REG SERVICE INC. makes no other representa
certificate make any representations or warranties to any person or entity other t
for whose sole benefit it is issued. This certificate does not denote endor
certificate-holder's device or establishment by the U.S. Food and Drug Administ
assumes no liability to any person or entity in connection with
Pursuant to 21 CFR 807.39, " Registration of a device establishment or assignm
not in any way denote approval of the establishment or its products. Any re
impression of official approval because of registration or possession of a regist
constitutes misbranding."
The U.S.Food and Drug Administration does not issue a certificate of registrati
Drug Administration recognize a certificate of registration, UCL-REG SERVICE
Food and Drug Administration.*

For and on beh
UCL-REG

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

Cert. No
Issued
Expirati

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

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

CE Documentation Review

No. [redacted]

Holder: [redacted]

Manufacturer:

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

Product: N95,KN95, FPP2,FPP3,KF94

Model(s): A1,A2,A3,A4 ,A5,A6,A7,A8,A9/11.5cmX12 cm-5P

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. 20ZCTS0317015SP.
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 24 March 2020
Approver
ECM Service Director
Luca Redonni

Expiry date 23 March 2025
Technical Expert
Amanda [redacted]

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

TÜVRheinland

Report

plies Co., Ltd.
njie Town,
ui Province, China

ss of the Technical
the requirements of
5, Annex II

declaration)

the provided Technical
1, Version A/0, Dated
liance according to the
TION (EU) 2017/745,

il to: service-gc@tuv.com

(Rev.02, 2020-03-27)

VIRUTAN

N95

广微测 sting

MA 201819000883 ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L1747

广东省微生物分析检测中心

GUANGDONG DETECTION CENTER OF MICROBIOLOGY

分 析 检 测 报 告

REPORT FOR ANALYSIS

报告编号 Report №.	2020FM04579R01D
样品名称 Name of Sample	灭菌新材料（环保） New sterilization materials (environmental protection)
委托单位 Applicant	[redacted]
检测类型 Test Type	委托检测 Entrustment Test

单位地址：广州市先烈中路 100 号大院 66 号楼
Address: Building 66, No.100 Central Xianlie Road, Guangzhou, China
邮政编码：510070
Postcode:
电话号码：(020)87137666
Tel:
传真号码：(020)87137668
Fax:
网　　址：www.gddcm.com
Website:

广微测 Gmicro Testing

MA 201819000883 ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L1747

广东省微生物分析检测中心

GUANGDONG DETECTION CENTER OF MICROBIOLOGY

分 析 检 测 报 告

REPORT FOR ANALYSIS

报告编号（Report №.）2020FM04579R01D 校验码（Verification Code）：50623918

样品名称 Name of Sample	灭菌新材料（环保） New sterilization materials (environmental protection)	检测类型 Test Type	委托检测 Entrustment Test
委托单位 Applicant	[redacted]	地　址 Address	[redacted]
样品来源 Sample Source	委托方送检 Submitted for Testing by the Applicant	样品数量 Sample Quantity	1 片
样品规格和批号 Spec and Lot №. of Sample	——	样品状态和特性 State and Characteristic	片状 Flaky
接样日期 Sample Received Date	2020-03-08	检测完成日期 Completion Date	2020-03-15
检测依据和方法 Test Standard and Method	GB/T 20944.3-2008 振荡法 GB/T 20944.3-2008 Oscillation method		
检测项目 Item Tested	抗（抑）菌试验 Antibacterial efficacy		
检测结论 Test Conclusion	该样品所检项目的实测数据见本检测报告续页。 The test data of the sample(s) is attached to the page(s) of this report. 签发日期 Issue Date: 2020-03-17 （机构盖章 Official Seal）		
备注 Remarks			

制 表 Editor　　审 核 Verifier　　批 准 Approver

3M™ Particulate Respirator 8210, N95

Key Features
- NIOSH approved N95 rating
- Adjustable nose clip
- Nose foam
- Ultrasonically welded headbands

Approvals and Standards
- NIOSH approved N95 particulate respirator
- Meets NIOSH 42 CFR 84 N95 requirements for a minimum 95% filtration efficiency against solid and liquid aerosols that do not contain oil.
- NIOSH approval number: TC-84A-0007
- Assigned Protection Factor (APF 10) per US OSHA and Canada CSA

Price on request

17 000 000 pcs in stock

VIRUTAN

3M™ Health Care Particulate Respirator and Surgical Mask, 1860, N95

Key Features
- NIOSH approved N95 rating
- FDA cleared for use as a surgical mask
- Fluid Resistant 120 mmHg
- Flammability Rating Class I
- Adjustable nose clip
- Braided and stapled headbands

Approvals and Standards
- NIOSH approved N95 respirator
- Meets NIOSH 42 CFR 84 N95 requirements for a minimum 95% filtration efficiency against solid and liquid aerosols that do not contain oil.
- NIOSH approval number: TC-84A-0006
- FDA cleared for use as a surgical mask
- Health Canada Class I medical device
- Bacterial Filtration Efficiency F2101 >99% BFE
- Assigned Protection Factor (APF 10) per US OSHA and Canada CSA

Price on request

155 000 000 pcs in stock

VIRUTAN

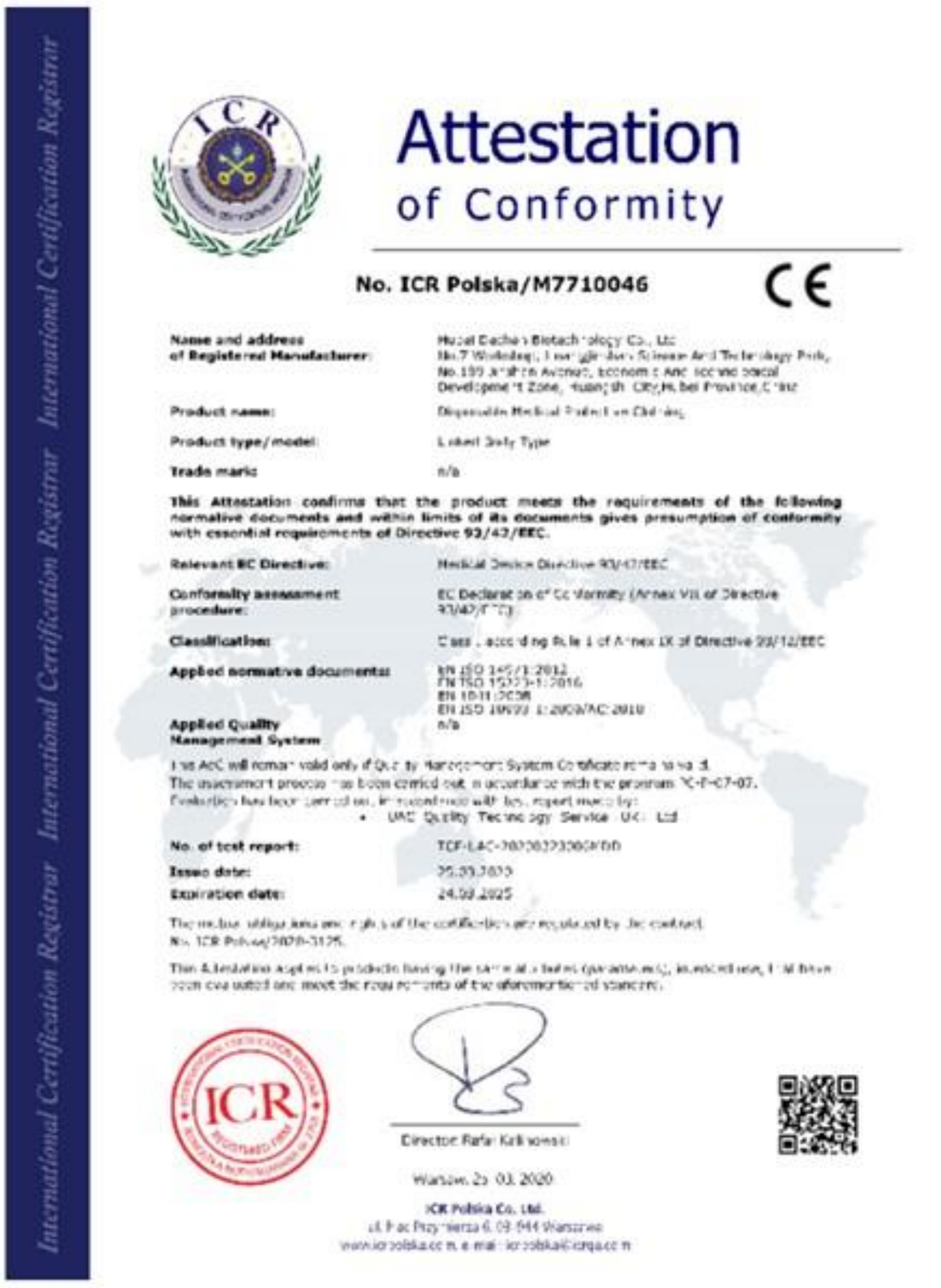
PROTECTIVEEQ UIPMENT

VIRUTAN

Isolation clothing

Protective clothing (42gsm), non-sterile

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.


International Certification Registrar International Certification Registrar

Attestation of Conformity

No. ICR Polska/M7710046 CE

Name and address of Registered Manufacturer:	Hubei Dachen Biotechnology Co., Ltd. No.7 Workshop, Luonglin Jiuxin Science And Technology Park, No.199 Jinfeng Avenue, Economic And Technical Development Zone, Huangshi City, Hubei Province, China
Product name:	Disposable Medical Protection Clothing
Product type/model:	Coverall Body Type
Trade mark:	n/a

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

Relevant EC Directive:	Medical Device Directive 93/42/EEC
Conformity assessment procedure:	EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)
Classification:	Class I, according Rule 1 of Annex IX of Directive 93/42/EEC
Applied normative documents:	EN ISO 14971:2012 EN ISO 15223-1:2016 EN 1041:2008 EN ISO 10993-1:2009/AC:2010
Applied Quality Management System	n/a

This AoC will remain valid only if Quality Management System Certificate remains valid.
The assessment procedure has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out, in accordance with test report issued by:
- UAC Quality Technology Service UAC Ltd

No. of test report:	TCF-LAC-20200323006/P00
Issue date:	25.03.2020
Expiration date:	24.03.2025

The exclusive obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3125.

This Attestation applies to products having the same data sheet (parameters, construction, material) which was used and meet the requirements of the aforementioned standard.

ICR

Director Rafał Kaliszewski

Warsaw, 25.03.2020

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

VIRUTAN

Disposable isolation gown

Material: PE + PP Size:L
Weight:42g
Quantity/mon:2 000 000PC

Packing:
100pc/carton
Carton size:57*35*44cm
Gross weigt:12KG
Net weight:11KG

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Disposible PE robe

Material: PE
Size:L
Weight:43g
Quantity:2 000 000PC

Packing:
200pc/carton
Carton size: 43*34*34cm
Gross weigt:10,6KG
Net weight:9,8 KG

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

Medical disposable protective clothing

Applications
It is suitable for medical staff to work in contact with potentially infectious patients when they are in contact with blood, body fluids, secretions, airborne particles, etc. to provide barriers and protection.

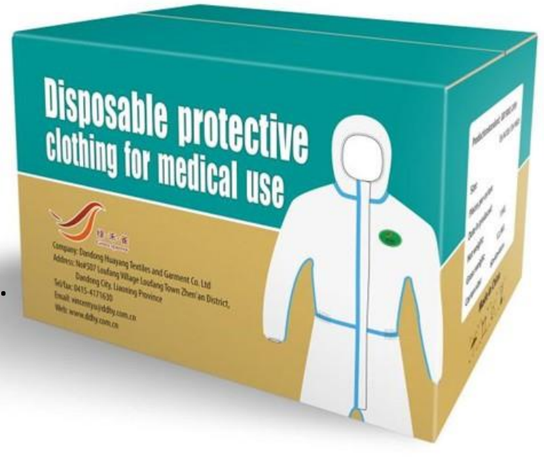
Main features
1. The product is sterile an non-sterile available.
2. The main performance indicators comply with GB 19082-2009;

Model specifications
Length： 160,165,170,175,180,185cm

Maintenance methods
For disposable use

Packaging and others
This product is packed in PE bags
1piece/bag, 40bag/carton

Box sizes:
Gross weight： 10.28 KG/ carton
Net weight： 8.47 KG/ carton
Volume： 0.6*0.4*0.4m



Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Last 4 items (Disposable)

CE Technical Documentation Review Report

TÜVRheinland

Applicant: [redacted]
Dongguan, Chiang'an Town, Xinle City, Hebei Province,050701,China

Report Number: 16806072.001

Examination Intent: Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII

Product(s): Please see attachment

Type(s)/Model(s): Please see attachment

Classification: Class I
(according to manufacturer's declaration)

Examination period: Aug.18.2016

Date of expiry: Aug.17.2021

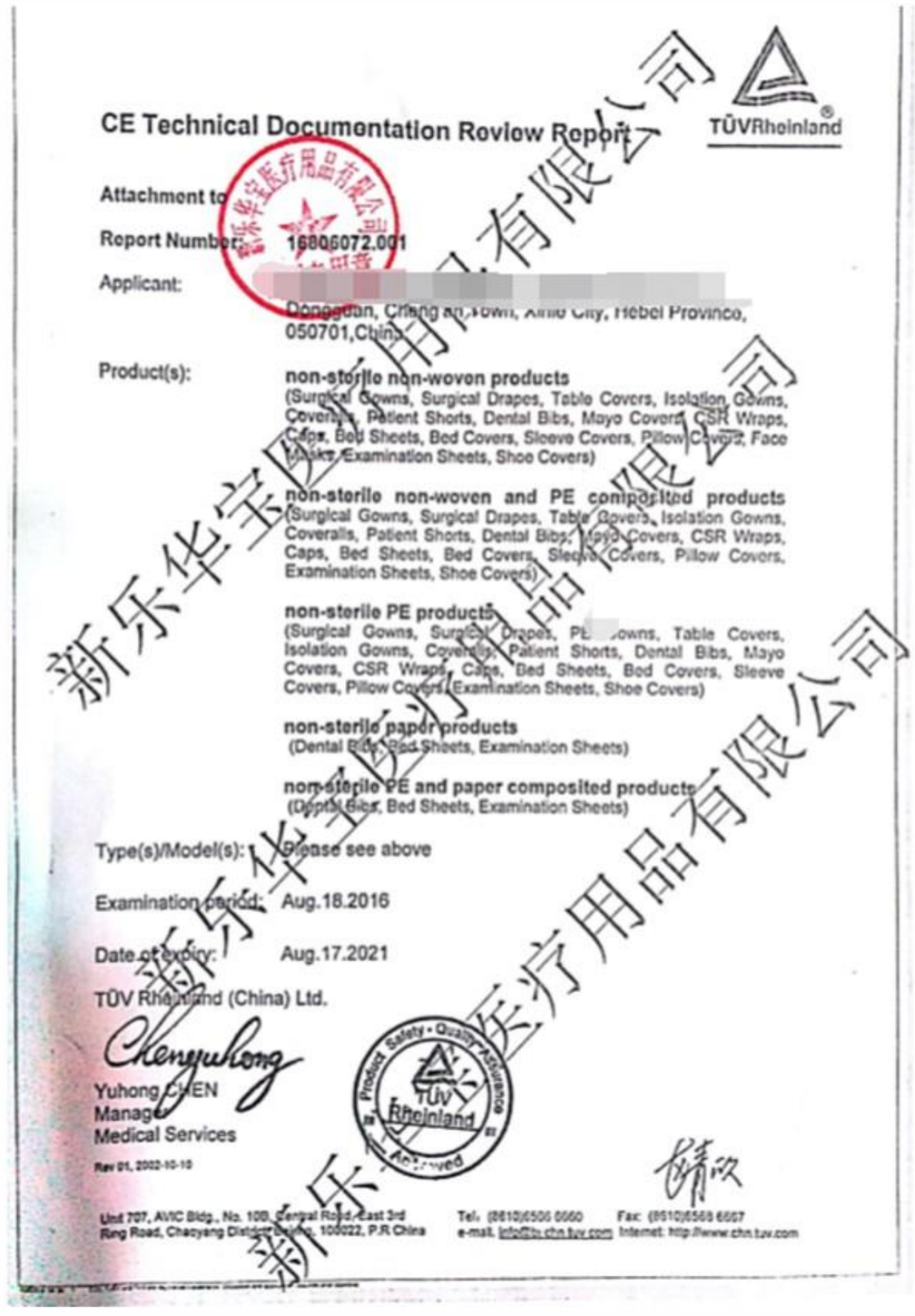
Review result: During the examination of the provided Technical Documentation (No.: Q/HBMP06.36-2015, Revision A/1, dated 2015-04-20), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd.

Yuhong CHEN
Manager
Medical Services

Rev 01, 2002-10-10

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China
Tel: (8610)6566 6660 Fax: (8610)6566 6667
e-mail: info@tc.chn.tuv.com Internet: http://www.chn.tuv.com



CE Technical Documentation Review Report

TÜVRheinland

Attachment to

Report Number: 16806072.001

Applicant: [redacted]
Dongguan, Chiang an Town, Xinle City, Hebei Province, 050701,China

Product(s):

non-sterile non-woven products
(Surgical Gowns, Surgical Drapes, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Face Masks, Examination Sheets, Shoe Covers)

non-sterile non-woven and PE composited products
(Surgical Gowns, Surgical Drapes, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Examination Sheets, Shoe Covers)

non-sterile PE products
(Surgical Gowns, Surgical Drapes, Table Covers, Isolation Gowns, Coveralls, Patient Shorts, Dental Bibs, Mayo Covers, CSR Wraps, Caps, Bed Sheets, Bed Covers, Sleeve Covers, Pillow Covers, Examination Sheets, Shoe Covers)

non-sterile paper products
(Dental Bibs, Bed Sheets, Examination Sheets)

non-sterile PE and paper composited products
(Dental Bibs, Bed Sheets, Examination Sheets)

Type(s)/Model(s): Please see above

Examination period: Aug.18.2016

Date of expiry: Aug.17.2021

TÜV Rheinland (China) Ltd.

Yuhong CHEN
Manager
Medical Services

Rev 01, 2002-10-10

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R China
Tel: (8610)6566 6660 Fax: (8610)6566 6667
e-mail: info@tc.chn.tuv.com Internet: http://www.chn.tuv.com

VIRUTAN

Medical disposable protective clothing

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

[redacted]

Was registered with US Food and Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807, by Shenzhen Huacetong Testing and Certification Co., ltd

Owner/Operator Number: 10063913
Device Listing#: See annex
Expiration Date: December. 31, 2020

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

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

Executive Director
Issued: Mar. 24, 2020
Expiration Date: Dec.31, 2020

FDA

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Owner/Operator Number: 10063913

Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
ACCESSORY, SURGICAL APPAREL	*LYU*	*1*	*D377349*	*Manufacturer Repackager/Relabeler*
Non-surgical isolation gown	*OEA*	*1*	*D377350*	*Manufacturer Repackager/Relabeler*

Executive Director
Issued: Mar. 24, 2020
Expiration Date: Dec.31, 2020

FDA

END OF THE ANNEX

VIRUTAN

Medical disposable protective clothing

Certificate – Certificat – 證明書 – Сертификат – 인증서 – شهادة

Certificate of Compliance

No. 0P200310.DHT0W97

Technical Construction File no. TPUH2000P22065

Certificate's Holder:

Certification ECM Mark:

Type Approved

Product: Disposable Protective Clothing for Medical Use

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

Verification to: Standard: EN 14126:2003

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

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.enteceemo.it. This Certificate of Compliance can be checked for validity at www.enteceemo.it

This 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 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).

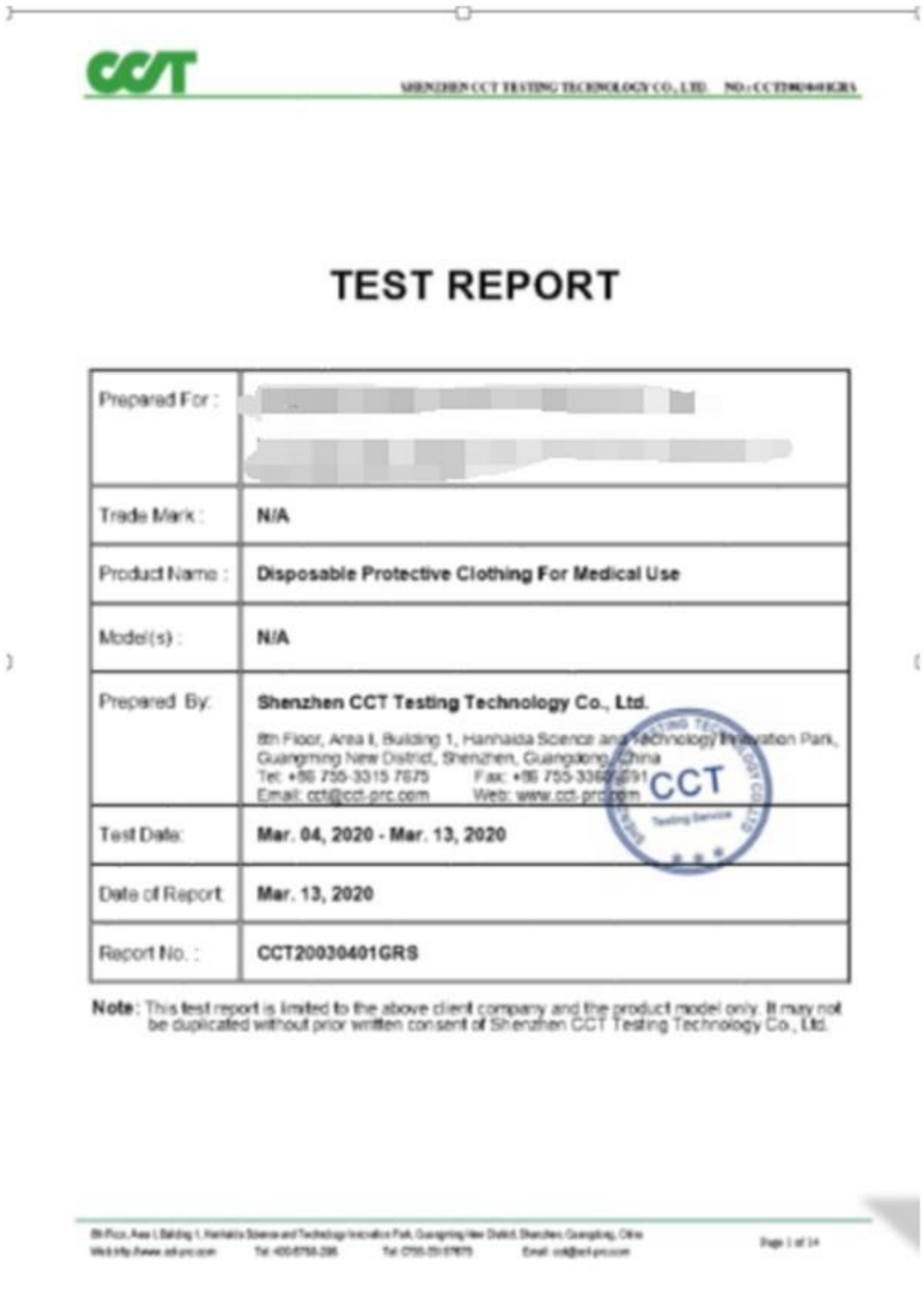
Date of issue 10 March 2020

Chief Manager
Matteo Monici

Expiry date 09 March 2025

Deputy Manager
Amanda Payne

Ente Certificazione Macchine Srl
Via Ca' Bella, 345 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
☎ +39 051 6705141 🖷 +39 051 6705156 ✉ info@enteceemo.it 🌐 www.enteceemo.it



CCT SHENZHEN CCT TESTING TECHNOLOGY CO., LTD. NO.: CCT20030401GRS

TEST REPORT

Prepared For :	
Trade Mark :	N/A
Product Name :	Disposable Protective Clothing For Medical Use
Model(s) :	N/A
Prepared By:	Shenzhen CCT Testing Technology Co., Ltd. 8th Floor, Area I, Building 1, Hannaida Science and Technology Innovation Park, Guangming New District, Shenzhen, Guangdong, China Tel: +86 755-3315 7675 Fax: +86 755-3369 6991 Email: cct@cct-prc.com Web: www.cct-prc.com
Test Date:	Mar. 04, 2020 - Mar. 13, 2020
Date of Report:	Mar. 13, 2020
Report No. :	CCT20030401GRS

Note: This test report is limited to the above client company and the product model only. It may not be duplicated without prior written consent of Shenzhen CCT Testing Technology Co., Ltd.

8th Floor, Area I, Building 1, Hannaida Science and Technology Innovation Park, Guangming New District, Shenzhen, Guangdong, China
Web: http://www.cct-prc.com Tel: 400-8756-288 Tel: 0755-33157675 Email: cct@cct-prc.com

Page 1 of 14

Isolation clothes

Applications
It is suitable for medical staff to work in contact with potentially infectious patients when they are in contact with blood, body fluids, secretions, airborne particles, etc. to provide barriers and protection.

Main features
3. The product is sterile;
4.The main performance indicators comply with GB 19082-2009;

Model specifications
Size: 160XS,165S,170M,175L,180XL,185XXL
Material: PP + PE impermeable non-woven film 60g

Maintenance methods
For disposable use

Packaging and others
This product is packed in PE bags 1piece/bag

Period of use
One month after the sterilization date

Box sizes:

Pcs/carton:50pcs
G.W.： 14.35KG ;
N.W. : 12.65KG

Caron size： 0.6*0.4*0.4
Carton volume： 0.096CBM

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Isolation clothes

HUACETONG

Declaration of Conformity

Certificate No.: WUXC2020031606629SC

Applicant:

Address:

Manufacturer:

Address:

Product Name: ISOLATION GOWN

Model No.: 169,165,170,175,180,185

Trade Mark: /

Test Standard: **EN 14126:2003**

Test Report Number(s): WUXC2020031606629S

PPE directive (EU) 2016/425

Remarks:

The **CE** markings as shown below can be affixed on the product after preparation of necessary conformity documentation, as stipulated in article 10 of the Council Directive **(EU) 2016/425.**

CE

Tony Bi
Technical Director

Mar. 24, 2020

Shenzhen Huacetong Testing and Certification Co., Ltd.
Building B, Xinbaosheng, No.233, Xixiang Street, Bao' an District, Shenzhen, China.
Web: www.szcttlab.com Tel: 86-755-23592524 E-mail: ctt_lab@foxmail.com

HUACETONG

TEST REPORT

EN 14126:2003
Protective clothing —
Performance requirements and tests methods for protective clothing against infective agents

Report Number	WUXC2020031606629S
Test by (name+signature)	Sally Liu
Compiled by (+signature)	Lucy Ni
Approved by (+signature)	Tony Bi
Date of issue	Mar. 24, 2020
Total number of pages	
Testing laboratory	Shenzhen Huacetong Testing and certification Co., Ltd.
Address	Building B, Xinbaosheng, No.233, Xixiang Street, Bao'an District, Shenzhen, China
Testing location	As above
Applicant's name	DANDONG HUAYANG TEXTILES AND GARMENTS CO.,LTD
Address	Loufang Village Loufang Town Zhen'an District Dandong City
Test specification:	
Standard	**EN 14126:2003**
Test procedure	N/A
Non-standard test method	N/A
Test Report Form No.	EN 14126
Test Report Form(s) Originator	Huacetong
Master TRF	N/A
Test item description	ISOLATION GOWN
Trade Mark	--
Manufacturer:	
Model/Type reference	169,165,170,175,180,185

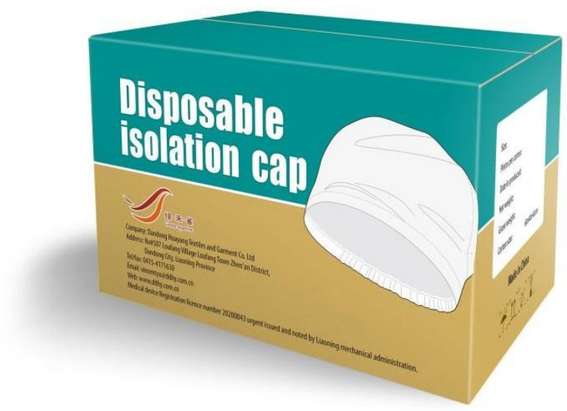
Medical cap

Size
S M L

Expected usage
For general isolation in clinics and inspection rooms of medical institutions.

Main structure
It is made of non-woven fabric as the main material.

Box sizes:
240pc/carton
Gross weight： 7.02 KG/ carton
Net weight： 5.21 KG/ carton Volume：
0.6*0.4*0.4m



VIRUTAN

Medical cap

第一类医疗器械生产备案凭证

备案编号：辽丹食药监械生产备20200002号

企业名称			
住　所			
生产地址			
法定代表人	于文福	企业负责人	于文福
生产范围	2002分类目录 18:6864-1-防护用品 2017分类目录 18:14-14-医护人员防护用品		

生产产品列表

产品名称	产品备案号	登载日期	备注
隔离衣	辽丹械备20200002号	2020-01-30	
医用帽	辽丹械备20200043号	2020-03-23	
医用隔离鞋套	辽丹械备20200044号	2020-03-23	

备案部门（盖章）：辽宁省丹东市[illegible]管理局

备案日期：2020年3月23日

HUACETONG

	The marking of protective clothing against infective agents shall contain the following additional information: a) the number of this European Standard; b) the type of protective clothing, as specified in Table 5, with the suffix "-B", e.g. type 3-B; c) the pictogram "protection against biological hazard"	EN 14126:2003	P
			--
6	Information supplied by the manufacturer		P
	The information for the user shall be worded clearly and unambiguously and be understandable by a trained person.		P
	The information for the user of protective clothing against infective agents shall contain all the information required by EN 340 and by the relevant standard for that specific type of chemical protective clothing. In addition it shall contain the following information:	EN 340	P
	a) the number of this European Standard;	EN 14126:2003	P
	b) the type designation, e.g. type 3-B;		P
	c) the biological agents against which the protective clothing has been tested. This information shall be expressed as performance levels, as specified in 4.1.4.1 to 4.1.4.4 for the relevant types of biological challenge;		P
	d) all other relevant information on performance levels, preferably as a Table;		P
	e) the information necessary for trained persons about:		P
	[illegible]		P

VIRUTAN

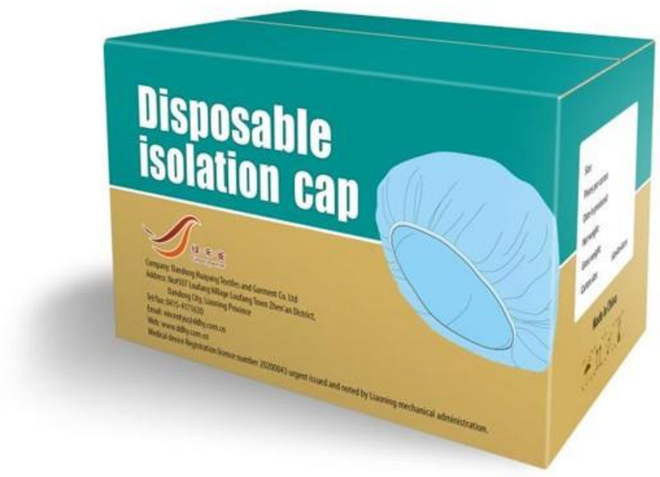
Medical cap 2

Size
S M L

Expected usage
For general isolation in clinics and inspection rooms of medical institutions.

Main structure
It is made of non-woven fabric as the main material.

Box sizes:
800pc/carton
Gross weight： 7KG/ carton
Net weight： 5.3 KG/ carton Volume：
0.6*0.4*0.4m



VIRUTAN

Medical cap 2

HUACETONG

Declaration of Conformity

Certificate No.: WUXC2020031636SC

Applicant:

Address:

Manufacturer:

Address:

Product Name: protective cap

Model No.: All code

Trade Mark: /

Test Standard: **EN 14126:2003**

Test Report Number(s): WUXC2020031636SS

PPE directive (EU) 2016/425

The CE marking is as shown below can be affixed on the product after preparation of necessary conformity documentation, as stipulated in article 19 of the Council Directive **93/65/EEC.**

CE

Tony Bi
Technical Director

Mar. 24, 2020

Shenzhen Huacetong Testing and Certification Co., Ltd.
Building B, Xinbaosheng, No.233, Xixiang Street, Bao' an District, Shenzhen, China
Web: www.szcttlab.com Tel: 86-755-23592524 E-mail: ctt_lab@foxmail.com

第一类医疗器械生产备案凭证

备案编号：辽丹食药监械生产备20200002号

企业名称			
住　所			
生产地址			
法定代表人	于文福	企业负责人	于文福
生产范围	2002分类目录 Ⅰ类:6864-1-防护用品 2017分类目录 Ⅰ类:14-14-医护人员防护用品		

生产产品列表	产品名称	产品备案号	登载日期	备注
	隔离衣	辽丹械备20200002号	2020-01-30	
	医用帽	辽丹械备20200043号	2020-03-23	
	医用隔离鞋套	辽丹械备20200044号	2020-03-23	

备案部门（盖章）：辽宁省丹东市食品药品监督管理局

备案日期：2020年3月23日

VIRUTAN

Nitrile gloves

Powder free nitrile examination gloves
Size:XS,S,M,L.XL

Packing
50pair/box
1000 Pairs/carton
Carton weight 14kg
Carton volume 0,05388CBM

Production capacity
500000/day

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Nitrile gloves

TÜVRheinland®

CE Technical Documentation Review Report

Applicant:	[redacted]
Report Number:	**50149149-001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII
Product(s):	**Powder-free Nitrile Examination Gloves**
Type(s)/Model(s):	XS,S,M,L,XL
Classification:	Class I (according to manufacturer's declaration)
Examination period:	Jun.21.2018
Date of expiry:	Jun.20.2023
Review result:	During the examination of the provided Technical Documentation (No.: TS-02, Revision: A2, dated 2018-04-10), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd.

Yuhong CHEN
Manager
Medical Services

Rev.01, 2002-10-10

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China
Tel: (8610)6566 6660 Fax: (8610)6566 6667
e-mail: info@tuv.cn.tuv.com Internet: http://www.chn.tuv.com

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 9, 2016

[redacted]
c/o Mr. Chu Xiaoan
Room 1606 Bldg. 1, Jianxiang [redacted]
Bei Si Huan Zhong Road, Haidian District
Beijing 100083
CHINA

Re:
Trade/Device Name: Nitrile Powder Free Patient Examination Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: January 28, 2016
Received: February 1, 2016

Dear Mr. Xiaoan:

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. 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

VIRUTAN

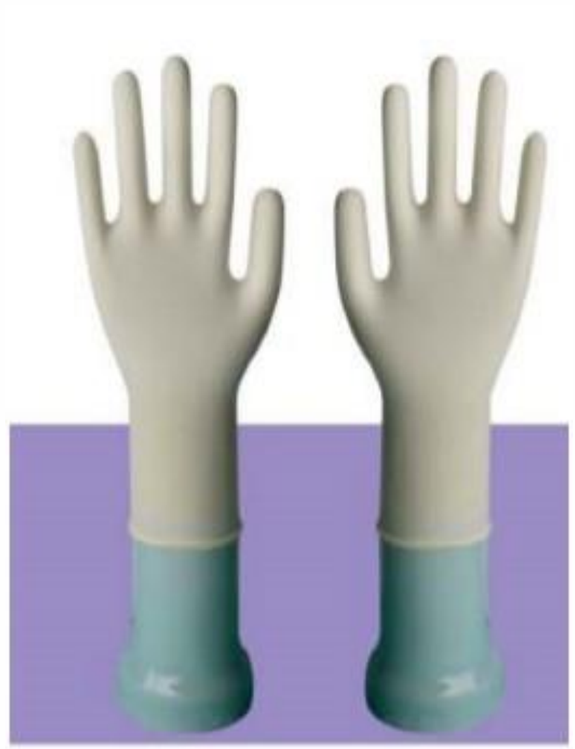
Latex Gloves

Certification: ISO,FDA, CE

Size: XS,S,M,L,XL

Powdered/ Powder-free

Protection from unwanted or dangerous substances Easy donning and helps prevent roll back
Softness provides superior comfort and natural fit
Beaded cuff makes donning easy
Ambidextrous and straight fingers



Conforms to ASTM D3578(05) and EN 455(09) Standards.

Manufactured under QSR(GMP), ISO 9001:2008 Quality Management System

Packing
100pcs/50pairs/box
500pairs/10box/1carton
Carton size:59*34*23cm， G.W.8kg Min
Order 1600carton/800 000pairs

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Vinyl Gloves

Certification: ISO,FDA, CE

Size: XS,S,M,L,XL

Powdered/ Powder-free

Conforms to ASTM D5250 and EN 455 Standards.

Manufactured under QSR(GMP), ISO 9001:2008 & ISO 13485:2003(Medical Device) Quality Management System

Packing
100pcs/50pairs/box
500pairs/10box/1carton
Carton size:59*34*23cm，G.W.8kg Min
Order 1600carton/800 000pairs

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Disposable Vinyl Gloves

SGS

Test Report No. SHAEC1918773402 A01 Date: 16 Sep 2019 Page 1 of 4

[redacted] TECH INDUSTRIAL DEVELOPMENT ZONE

THIS REPORT IS TO SUPERSEDE TEST REPORT NO.SHAEC1918773401.

The following sample(s) was/were submitted and identified on behalf of the clients as : VINYL GLOVES

SGS Job No. :	[redacted] - SH
Supplier :	[redacted]
Date of Sample Received :	22 Aug 2019
Testing Period :	22 Aug 2019 - 28 Aug 2019
Test Requested :	Selected test(s) as requested by client.
Test Method :	Please refer to next page(s).
Test Results :	Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
US California Proposition 65- Lead content	PASS
US California Proposition 65- Cadmium content	PASS
US California Proposition 65- Phthalate	PASS

SGS质量认证

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Dora Hu

Dora Hu
Approved Signatory

皮肤致敏报告

第一类医疗器械备案信息表

第一类医疗器械备案凭证

江苏宏红工贸有限公司：

根据相关法规要求，对你单位第一类医疗器械：检查手套予以备案。备案号：苏宗械备20180059号。

宿迁市食品药品监督管理局

（盖章）

日期：2018年07月02日

VIRUTAN

Protective glasses

PVC:

Daily productivity

10 000 pcs

Box sizes:
100pc/carton

Gross weight 12,2kg
Carton 52x38.5x54cm

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Protective glasses

10pc/box
200pc/carton
Carton size: 64*52*35cm
Net weight: 15.8KG Gross weight: 17KG


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

Certificate of Compliance

只限用于本公

Holder: Co., Ltd.
No. 124, Zhenqianlu, Shan Hou Pan Village, Hengjie Town, Luqiao District, Taizhou City Zhejiang, China

Certification ECM Mark:

Type Approved

Product: Protection glasses
Model(s): WZ- YZ8, WZ- YZ7, WZ- YZ6, WZ- YZ5

Verification to: Standard:
EN 166:2001+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, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 05 April 2020

Expiry date: 04 April 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

Certificate – Certificat – 证明书 – Сертификат – شهادة

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

Protective glasses

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Registration Number: 3010875283

Listing No	Code	Device Name	Proprietary Names	Activities
D304044	HQY	Sunglasses (non-prescription including photosensitive)	Sun glasses	Manufacturer Foreign Exporter
D304045	HOY	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydriatic eyewear)	Protective goggles SKI GOGGLES	Manufacturer Foreign Exporter
D304046	IWS	Shield, eye, radiological	Radiation glasses	Manufacturer Foreign Exporter
D304047	HQG	Lens, spectacle, non-custom (prescription)	Myopic glasses Presbyopic glasses	Manufacturer Foreign Exporter

END OF THE ANNEX

Chief engineer

Issued: January 15, 2020

Expiration Date: December 31, 2020

CERTIFICATE

With EU Directive of PPE 2016/425

Certificate No.: CE-20-0325-04

Applicant: Guangzhou Shuaipu Sport Goods Co.,ltd
No.9 Industrial Road,XinZhuang Village,Shilingtown,Huadu District,Guangzhou (self declaration)

Manufacturer: Guangzhou Shuaipu Sport Goods Co.,ltd
No.9 Industrial Road,XinZhuang Village,Shilingtown,Huadu District,Guangzhou (self declaration)

Product: Medical goggles

Model(s): SP05

Trademark: DEX

Standards: EN 166:2001

Based upon the voluntary assessment of the product sample and Technical Construction File, the apparatus is deemed to meet the requirements of the above standards and EC directives.
The manufacturer has the responsibility for ensuring that all serial manufacture of the products are in compliance with the specification of the sample submitted for assessment and detailed in the technical file.

CE

Date: 25/03/2020

Stamp: EuroScene Business Solutions GmbH

The CE marking may be used if all relevant and effective EC directives are complied with.

EuroScene Business Solutions GmbH

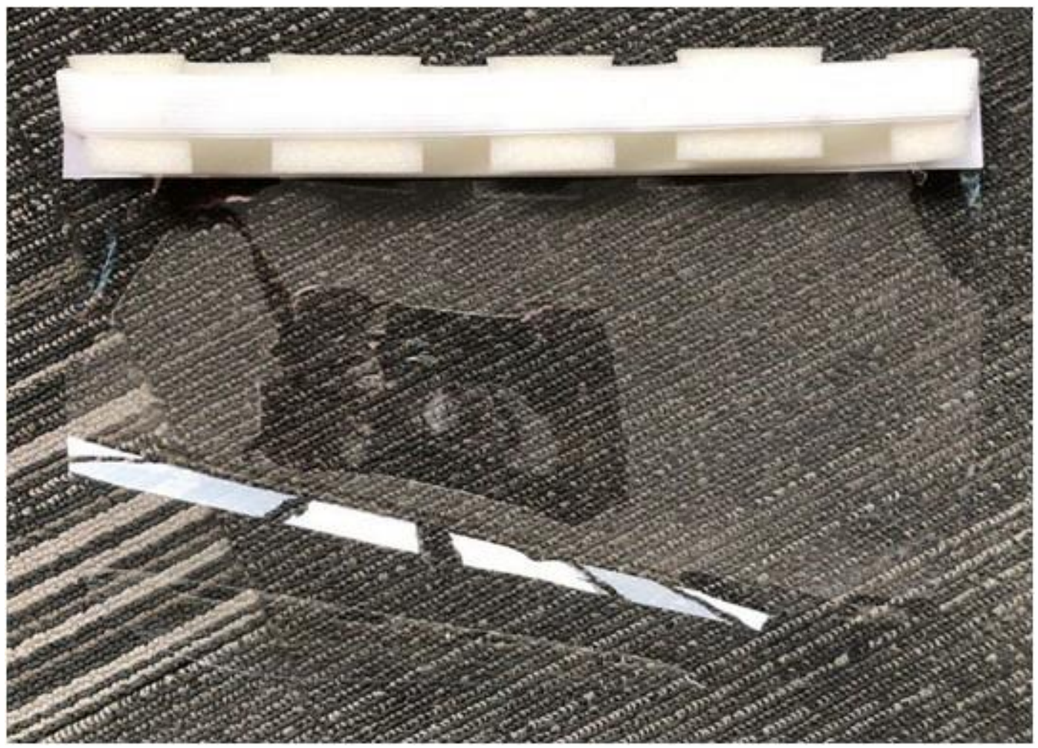
Annastrasse 9B 64347 Griesheim Germany

VIRUTAN

Face shield SP06

Daily productivity
25 000 pcs

Box sizes:
60pcs/carton
Gross weight： 3kg/ carton Volume：
74x46x55cm



Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Face shield SP06

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Device Listing# for Registration Number: 3010875283

Listing No	Code	Device Name	Proprietary Names	Activities
D304044	HQY	Sunglasses (non-prescription including photosensitive)	Sun glasses	Manufacturer Foreign Exporter
D304045	HOY	Shield, eye, ophthalmic (including sunlamp protective eyewear and post-mydriatic eyewear)	Protective goggles SKI GOGGLES	Manufacturer Foreign Exporter
D304046	IWS	Shield, eye, radiological	Radiation glasses	Manufacturer Foreign Exporter
D304047	HQG	Lens, spectacle, non-custom (prescription)	Myopic glasses Presbyopic glasses	Manufacturer Foreign Exporter

END OF THE ANNEX

GTB TESTING TECHNOLOGY

Chief engineer

Issued: January 15, 2020
Expiration Date: December 31, 2020

CERTIFICATE

With EU Directive of PPE 2016/425

Certificate No.: CE-20-0325-05

Applicant: Guangzhou Shuaipu Sport Goods Co.,ltd
No.9 Industrial Road,XinZhuang Village,Shilingtown,Huadu District,Guangzhou (self declaration)

Manufacturer: Guangzhou Shuaipu Sport Goods Co.,ltd
No.9 Industrial Road,XinZhuang Village,Shilingtown,Huadu District,Guangzhou (self declaration)

Product: Medical goggles

Model(s): SP06

Trademark: DEX

Standards: EN 166:2001

Based upon the voluntary assessment of the product sample and Technical Construction File, the apparatus is deemed to meet the requirements of the above standards and EC directives.
The manufacturer has the responsibility for ensuring that all serial manufacture of the products are in compliance with the specification of the sample submitted for assessment and detailed in the technical file.

CE

Date: 25/03/2020

Stamp: EuroScene Business Solutions GmbH

The CE marking may be used if all relevant and effective EC directives are complied with.

EuroScene Business Solutions GmbH

Annastrasse 9B 64347 Griesheim Germany

VIRUTAN

Protective glasses BA3023

1. Clear PC frame
2. Clear PC lens，anti-fog
3. Clear PC temple

Daily productivity

25 000 pcs

Box sizes:

Gross weight： 3kg/carton

Volume：64x35x38.5cm

/150pcs

Other products in same category and all Incoterms available.

Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

COVID-19
Rapid Test

VIRUTAN

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

Price on request

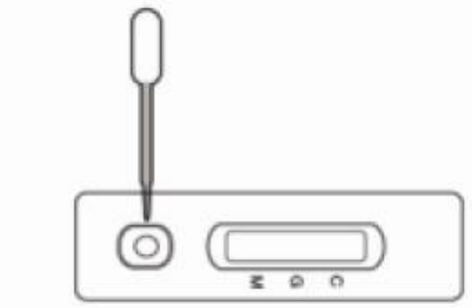
VIRUTAN

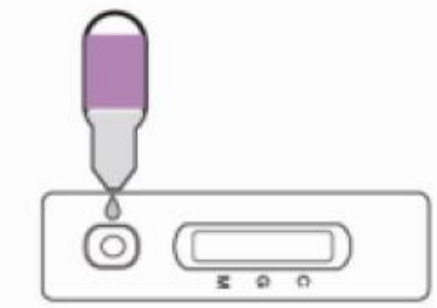
COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

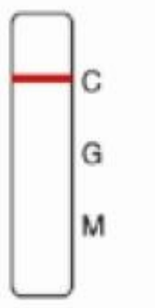
COMPONENT	20Test Kit/Box	40Test Kit/Box	Main components
Test Kit	20Test Kit/Box (1Test/Bag ×20 Bags)	40Test Kit/Box (1Test/Bag ×40Bags)	The detection lines were coated with mouse anti-human IgM antibody and mouse anti-human IgG antibody, the quality control lines were coated with sheep anti-chicken antibody, and the colloidal gold pad contained recombinant COVID Antigen labeled colloidal gold .
Dryer	20Bags	40Bags	Silica Gel
Specimen Diluent	1Bottle(5mL)	1Bottle(8mL)	Solution of trimethylaminomethane hydrochloride(0.02M Tris-HCl)

2.Plasma and serum :Collect the specimen with a pipettor, Add 10μl plasma and serum into sample well,Add 1~2 drops diluent into sample well .Whole blood: Collect the specimen with a pipettor, Add 20μl whole blood into sample well,Add 1-2drop diluent into sample well .

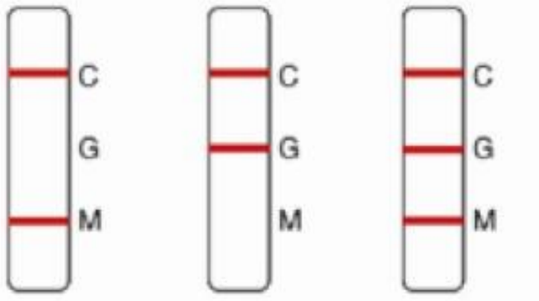
3.Start timing .The result should be read at 15-20minutes.The result is invalid after 20 minutes.


Add specimen into sample well

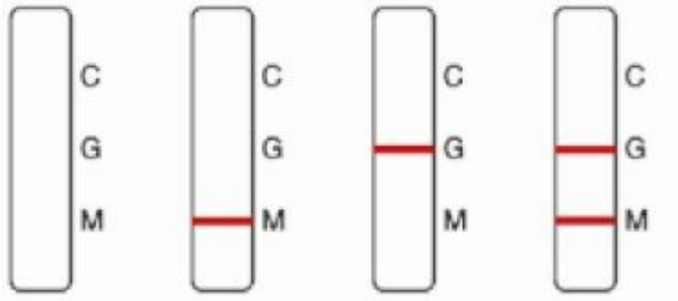

Add diluent into sample well



Negative (-)



Positive (+) Positive (+) Positive (+)



Invalid(x) Invalid(x) Invalid(x) Invalid(x)

VIRUTAN

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

Declaration of Conformity

Manufacturer : [redacted]

Whose single Authorized EU-Representative:
Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMID: DE/0000047791
Lin Sun
Tel: 0049-1715605732
E-mail: info.m@luxuslw.de

Product Name: COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards: EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 23640:2015, EN13975:2003, EN13612:2002

Signature: Sen Wang 王森 2020.3.18

Name: Wang Sen

Title: General Manager

Position: TEDA Tianjin, China

正元盛邦(天津)生物科技有限公司

EC Declaration of Conformity
Page 1/1

CE

天津市医疗器械出口备案凭证

备案号：津滨20200006

生产企业名称	正元盛邦（天津）生物科技有限公司		
生产地址	天津市开发区洞庭路220号天津市国际生物医药联合研究院实验楼九层		
是否具有生产许可证或者备案	是	生产许可/备案编号	津食药监械生产许20100326
是否具有第三方认证	是	第三方认证机构	TUV莱茵检测认证服务（中国）有限公司
联系方式	13821759311		
出口产品名称	COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)		
是否境内注册/备案	否	注册号/备案号	
出口企业名称	自营出口		
出口企业地址	自营出口		
销往国家（地区）	盟成员国：法国、德国、意大利、荷兰、比利时、卢森堡、丹麦、爱尔兰、希腊、葡萄牙、西班牙、奥地利、瑞典、芬兰、马耳他、塞浦路斯、波兰、匈牙利、捷克、斯洛伐克、斯洛文尼亚、爱沙尼亚、拉脱维亚、立陶宛、罗马尼亚，保加利亚、克罗地亚。EEA、瑞士、和土耳其，挪威，柬埔寨，越南，韩国，日本，菲律宾，黎巴嫩，泰国，新加坡，巴基斯坦，伊朗，澳洲，马来西亚，印度尼西亚，沙特，尼泊尔		
是否境外委托境内生产	否	是否获准境外上市	是
境外委托企业名称			
境外委托企业地址			
出口合同编号	无	出口合同期限	2021-03-31
产品规格	卡型、条型		
包装规格	20人份/盒（1人份/袋×20袋）、40人份/盒（1人份/袋×40袋）50条（1人份/袋×50袋）100条（1人份/袋×100袋）		
出口数量	2000000		
本企业承诺保证所生产出口的医疗器械符合进口国（地区）的要求，所提交的全部备案资料真实有效，并承担一切法律责任。 法定代表人（签字）：　　（企业盖章）			
备案部门（公章）： 正元盛邦(天津)生物科技有限公司 医疗器械备案专用章 备案日期：2020年03月20日			

VIRUTAN

COVID-19 lgG/lgM Rapid Test Kit (Colloidal Gold)

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

China

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-06-11
Certificate Registration No.:	SX 60134013 0001
An audit was performed. Report No.:	16806278 003
This Certificate is valid until:	2020-06-06

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2019-06-11

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: SX 60134013 0001
Report No.: 16806278 003

Organization:

China

Scope: Design and development, manufacture and distribution of in vitro diagnostic test kits used in the detection of Cancer, Cardiac Markers, fertility testing, pregnancy testing, Drugs of abuse, Sexually transmissible agents, Infection Diseases including home use in-vitro diagnostic medical devices

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2019-06-11

Fuxiu Sheng

VIRUTAN

COVID-19 lgG/lgM Rapid Test Kit (Colloidal Gold)

TÜVRheinland®

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60114453 0001

Report No.: 16806278 001

Manufacturer:

China

Products:

- Pregnancy Urine Tests for self testing
- Ovulation Urine Tests for self testing
- Fecal Occult Blood Tests for self testing

Expiry Date: 2021-10-12

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC 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 IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2017-06-07

Date: 2017-06-07

Notified Body
TÜV Rheinland LGA Products GmbH
X. Ren
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

TÜVRheinland®

CE Technical Documentation Review Report

Applicant:

Report Number:	**50271688.001**
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III
Product(s):	**Treponema Pallidum Antibody Test Kit (Colloidal Gold)** **Tuberculosis Antibody Test Kit (Colloidal Gold)** **Mycoplasma Pneumonia IgM Antibody Test Kit (Colloidal Gold)** **Morphine/Methamphetamine/Ketamine Test Kit (Colloidal Gold)**
Type(s)/Model(s):	------
Classification:	Other IVD products (according to manufacturer's declaration)
Examination period:	Sep.25.2019
Date of expiry:	Sep.24.2024
Review result:	During the examination of the provided Technical Documentation (No.: CE-JSWD-005, Revision 0.0, Dated 2019-Sep-20, CE-JSWD-006, Revision 0.0, Dated 2019-Sep-20, CE-JSWD-007, Revision 0.0, Dated 2019-Sep-20, CE-JSWD-011, Revision 0.0, Dated 2019-Sep-20) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected.

TÜV Rheinland (China) Ltd.
Yuhong CHEN
Manager
Medical Services

Rev.01, 2002-10-10

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China
Tel: (8610)6588 6860 Fax: (8610)6568 6667
e-mail: info@bj.chn.tuv.com Internet: http://www.chn.tuv.com

VIRUTAN

SARS-CoV-2 Antibody Test (Lateral Flow Method)

The First Officially Approved Product in China for SARS-CoV-2 Antibody Rapid Test

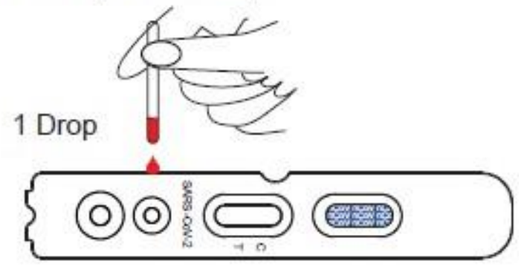
- An auxiliary test for the diagnosis of coronavirus infection disease（COVID-19）.
- Easy to use, instant result in 15 minutes.

Antibodies will be secreted after intruders invasion. Immunoglobulin M (IgM) comes out first, becoming the early sign of infection. Immunoglobulin G (IgG) comes out later, arising a more specific and stronger reaction against the intruders.

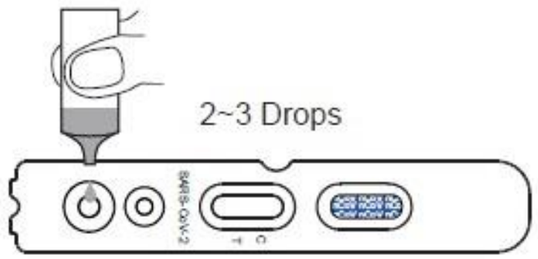
VIRUTAN

SARS-CoV-2 Antibody Test
(Lateral Flow Method)

1 **For whole blood or serum or plasma specimen**
Transfer 1 drop (10 µL) of whole blood or serum or plasma specimen to the sample well (small well) and then add 2~3 drops (80 µL) of buffer solution to the buffer well (large well).



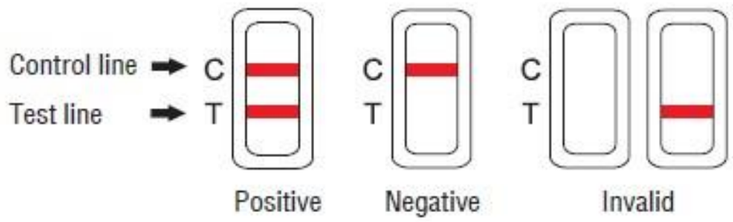
2 Add 80 µL (approximately 2~3 drops) of buffer to the buffer well (large well).



3 Wait for 15 minutes and read the results.
Note: Do not read results after 20 minutes, as the result can be inaccurate.

15 minutes

4 Interpretation of Results



VIRUTAN

SARS-CoV-2 Antibody Test (Lateral Flow Method)

qarad
European Regulatory Services

DECLARATION OF NOTIFICATION

Date: March 5, 2020

The undersigned, Sara Van Wouwe, Device Compliance Assistant of Qarad BVBA, hereby declares that:

N ct,
PR China

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

Name Device	Catalogue numbers
SARS-CoV-2 Antibody Test (Lateral Flow Method)	W195
Finecare™ SARS-CoV-2 IgM Test	W277
Finecare™ SARS-CoV-2 Antibody Test	W276

The notification to the Belgian Competent Authorities has been carried out on March 5, 2020 by Qarad BVBA, the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

Information on the notification to the competent Authorities of other European countries is available upon request.

Sara Van Wouwe

Device Compliance Assistant

Qarad BVBA
Authorized Representative

Qarad BVBA | Office Address: Pas 257, B-2440 Geel, Belgium | Social Siege: Cipalstraat 3, B-2440 Geel, Belgium
Tel. +32 (0)14 49 04 22 | ECREP@qarad.com | www.qarad.com

People's Republic of China Medical Device Registration Certificates

(In Vitro Diagnosis Test)

Registration No.: GuoXieZhuZhun20203400176

Registrant Company	C
Registrant Address	N C
Manufacturing Address	N C
Agent's Name	/
Agent's Address	/
Product Name	One Step COVID-19 Antibody Test（Colloidal Gold Method）
Package Specification	1 test cassette in one pouch, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 40 tests/kit, 50 tests/kit.
Main Content	The test kit consists of test cassettes, detection buffer, droppers. (See the instructions for details)
Intended Use	The test is for *in vitro* detecting COVID-19 antibodies in human whole blood, serum or plasma sample. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19). The test is only for medical institutions.
Appendix	Technical requirement and operation instruction.
Storage and Shelf Life	Store at 2-30℃, the shelf life is 6 months.
Other content	/
Remark	1.The test can only be used as an aid or emergency reserve in the diagnosis. The registration certificate is valid for one year 2. A summary report of the clinical data should be submitted as required for continuation of registration 3. The enterprise shall, at the time of continuous registration, complete all registration declaration materials in accordance with the *in vitro* diagnostic reagent registration regulation

Approved by: China Food and Drug Administration

Approval Date: 22th February 2020
Valid Until: 21th February 2021

FOR BUSINESS ONLY

VIRUTAN

SARS-CoV-2 Antibody Test (Lateral Flow Method)

Guangzhou Wondfo Biotech Co., Ltd.
RF-008-00

Effective date：2017-11-2

EC DECLARATION OF CONFORMITY
According the In Vitro Diagnostic Medical Device Directive 98/79/EC

Manufacturer:		
Address:	District, P.R. China	
In vitro diagnostic device(s):	**Product Name:**	**Cat. No.:**
	Wondfo SARS-CoV-2 Antibody Test (Lateral flow method)	W195
	Finecare™ SARS-CoV-2 IgM Test	W277
	Finecare™ SARS-CoV-2 Antibody Test	W276
	IVDD Classification: Other, for professional use	

This declaration of conformity is issued under the sole responsibility of the manufacturer that that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices.

The following (harmonized) standards have been applied:

EN ISO 13485: 2016	EN ISO 14971: 2012	EN 13612:2002
EN ISO 15223-1:2016	EN ISO 18113-1: 2011	EN ISO 18113-2: 2011
EN ISO 23640: 2015	EN 13641: 2002	EN 62366: 2008
EC 1272/2008		

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: Annex III**, excluding 6**

Notified Body (if consulted):	Not applicable.

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:

Qarad b.v.b.a., Cipalstraat 3, B-2440 GEEL, Belgium

Guangzhou, Feb 28, 2020	Yaqin Chi, Regulatory Affairs Director Yaqin Chi
(Place and date of issue)	(name and signature or equivalent marking of authorized person)

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：粤食药监械出 20200183 号
Certificate NO.：粤食药监械出 20200183 号

产品名称：新型冠状病毒（2019-nCoV）抗体检测试剂盒（胶体金法）
Product(s)：SARS-CoV-2 Antibody Test (Lateral Flow Method)

规格型号：卡型：1 人份/袋、1 人份/盒、10 人份/盒、20 人份/盒、25 人份/盒、30 人份/盒、40 人份/盒、50 人份/盒。
Model: Cassette: 1 test/pouch, 1 test/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 40 tests/kit, 50 tests/kit.

产品注册或备案凭证号：国械注准 20203400176
Registration certificate(s)：国械注准 20203400176

生产企业：广州万孚生物技术股份有限公司
Manufacturer:

生产企业住所：广州市萝岗区科学城荔枝山路 8 号
Address of m
Guangzhou, P.R. China

生产许可或备案凭证号：粤食药监械生产许 20030645 号
Manufacturing License(s)：粤食药监械生产许 20030645 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2021 年 02 月 21 日
This certification valid until: 21/02/2021

备注：/
Remark: /

广东省药品监督管理局
2020 年 03 月 09 日
（出具单位盖章）
出口销售证明专用章

VIRUTAN

SARS-CoV-2 Antibody Test (Lateral Flow Method)

Package:

Box： 20 pcs/box

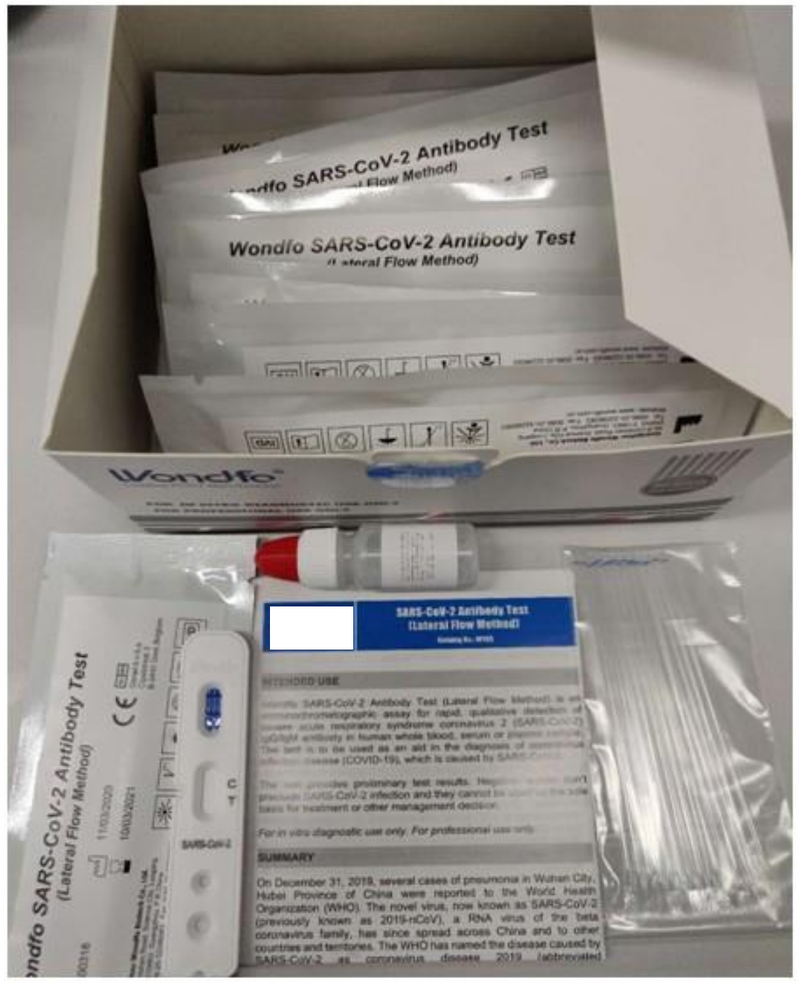
Dimenson of the carton： 60*44*44cm

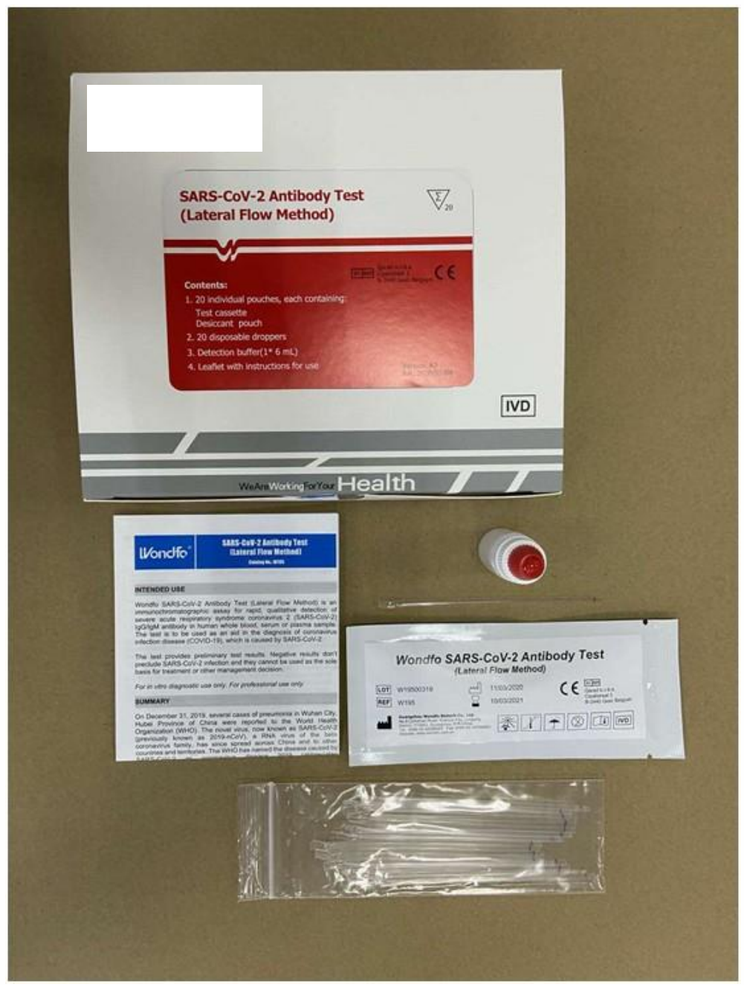
weigth： 14.6KGS

Carton： 60 boxes/carton

HS code： 38220010

Price on request





VIRUTAN

Diagnostic Kit for SARS-CoV-2 IgM/IgG Antibody (Colloidal Gold) R-423-25-C-CE

Kit:

Cassette:

Dilute:

Safety Lancet:

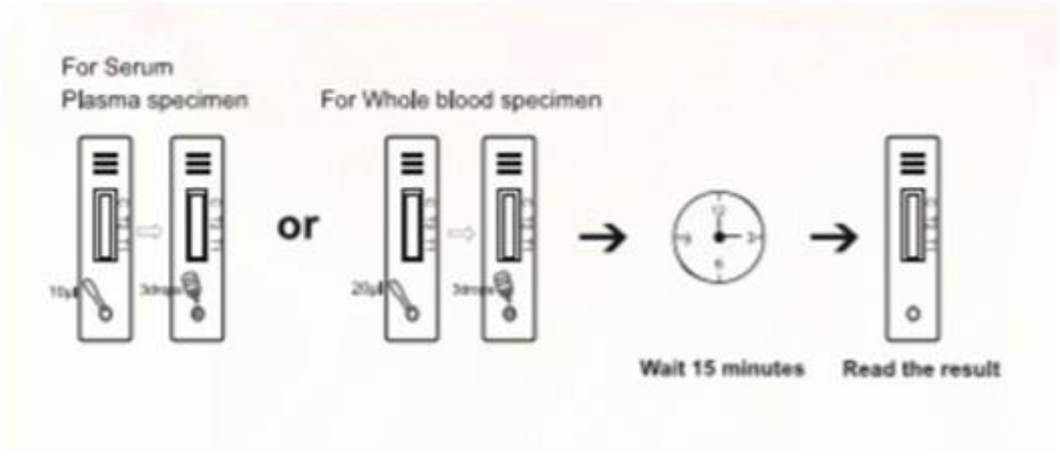
Alcohol Pad:

Pipette:

VIRUTAN

Diagnostic Kit for SARS-CoV-2 IgM/IgG Antibody (Colloidal Gold) R-423-25-C-CE

The Diagnostic Kit for SARS-CoV-2 IgM/IgG Antibody (Colloidal Gold) from KHB adopts the solid phase colloidal gold immunochromatographic technology for the qualitative determination of IgM/IgG antibodies against SARS-CoV-2 in human serum, plasma, and whole blood. The gold SARS-CoV-2 antigen conjugate and the gold chicken IgY conjugate are coated to the conjugate pad in advance. The test line T1 (antibodies against human IgM), the test line T2 (SPA) and the control line (chicken IgY antibodies) are pre-coated on the surface of Nitrocellulose (NC) membrane. When the specimen is added to the sample pad, it migrates through the conjugate pad, the gold SARS-CoV-2 antigen conjugate - IgM antibodies against SARS-CoV-2- antibody against human IgM complex is formed and test line T1 will be visible in the strip if there are enough IgM antibodies against SARS-CoV-2 (IgM Positive) in the specimen; the gold SARS-CoV-2 antigen conjugate - IgG antibodies against SARS-CoV-2 – SPA complex is formed and test line T2 will be visible in the strip if there are enough IgG antibodies against SARS-CoV-2 (IgG Positive) in the specimen. If the specific IgM/IgG antibodies are absent, or present at a very low level, no test line appears (Negative).



Production capacity: 500 thousand test/ Day

Quantity 10 000pcs
Price FOB *5,5*USD

Quantity 100 000pcs
Price FOB *5,2*USD

Packing:
25pc/box
18box/carton
Carton size:555*425*270mm
Carton gross weight:9Kg

VIRUTAN

Diagnostic Kit for SARS-CoV-2 IgM/IgG Antibody (Colloidal Gold) R-423-25-C-CE

CE

EC DECLARATION OF CONFORMITY

According to Directive 98/79/EC on *in vitro* diagnostic medical devices, Annex III

Manufacturer: [redacted] Qinzhou Road, 200233, Shanghai, China

EC- Representative: DIAneering® Diagnostics Engineering & Research GmbH
Friedrichstrasse 26, D-69221 Heidelberg-Dshm, Germany

Product: Diagnostic Kit for SARS-CoV-2 IgM/IgG Antibody (Colloidal Gold)

Product code: R-423-20-C-CE, R-423-25-C-CE

EDMA code: 15-04-80-19

Classification: Other device (all devices except Annex II and self-testing devices)

We, manufacturer, herewith declare under our sole responsibility that the above-mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer.

List of Directive and Standard Applied:

- Directive 98/79/EC
- EN ISO 14971:2012
- EN ISO 13485:2016
- EN 13612:2002/AC:2002
- EN13975:2003
- EN ISO 15223-1:2016
- EN ISO 18113-1:2011
- EN ISO 18113-2:2011
- EN 13641:2002
- EN ISO 23640:2015
- 1272/2008/EC

Place, Date of Issue: Shanghai, P.R. China, 2020-03-09

Signature of RA Director

KHB

СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICAT

TÜV SÜD Product Service

CERTIFICATE

No. Q5 18 03 52591 010

Holder of Certificate: [redacted] Co., Ltd.
1189 North Qinzhou Road
200233 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: Design and Development,
Production and Distribution of
In Vitro Diagnostic Reagents using ELISA,
PCR, Clinical Chemistry,
Chemiluminescence and Rapid Test Technologies

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1831907

Valid from: 2018-05-20
Valid until: 2021-05-19

Date, 2018-04-27

Stefan Preiß

Page 1 of 2

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

VIRUTAN

Diagnostic Kit for SARS-CoV-2 IgM/IgG Antibody (Colloidal Gold) R-423-25-C-CE

003157220000506

上海市电子证照库
zwdtcert.sh.gov.cn

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：沪食药监械出 20200077 号
Certificate NO.：沪食药监械出 20200077 号

产品名称：见附件
Product(s): see attachment

规格型号：见附件
Model: see attachment

生产企业：上海科华生物工程股份有限公司
Manufacturer:

生产企业住所：上海市徐汇区钦州北路 1189 号
Address of manufacturer: No. 1189 North Qinzhou Road, Shanghai

医疗器械出口备案凭证号：20200004
Exportation Registration certificate(s): 20200004

兹证明上述产品未在中国注册，尚未进入中国市场，该产品出口不受限制。出口医疗器械的企业应当保证其出口的医疗器械符合进口国（地区）的要求。
This is to certify that the above products are not registeredin China and not distributed on the Chinese market. The exportation of the product(s) is not restricted. The enterprise exporting medical devices should guarantee that the exported medical devices should comply with the requirments of the import country(region).

证明有效日期至：2021 年 05 月 19 日
This certification valid until: May, 19, 2021

备注：/
Remark: /

上海市药品监督管理局

2020 年 03 月 19 日
（出具单位盖章）

KHB

Business License

Unified Social credict Code: 91310000132660318J
License No: 00000002201807240048

Company Name
Company Type: Company Limited (Joint venture by Taiwai,Hongkong and Macao with China Mainland, Listed company.)
Registered address: 1189 North Qinzhou Road, Xuhui District, Sh ghai
Legal representative: Yongming HU
Registered capital: RMB 515,079,193
Date of Establishment: 22 Noverber 1981
Term of Business: 22 Noverber 1981 to Non-prescribed deadline
Businiss scope: Biochemistry reagent, Clinical diagnostic reagent, Medical instruments, Veterinary injection, Biochemistry reagent testing tool, Genetic engineering drug, Biological environmental-friend products' development, production, commercialization, own produced instrument rent and related technical service, commercialized own products exporting and importing mechanical instrument, spare parts and raw material which required for own company (products and technical service restricted by company regulation is exclusive.)

Registration office: Shanghai Administration for Industry and Commerce
Date: 24 July 2018

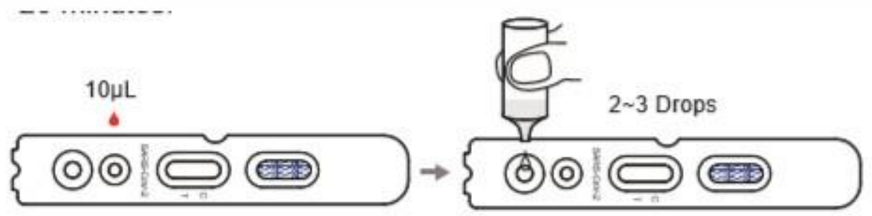
VIRUTAN

SARS-CoV-2 Antibody Test

SARS-CoV-2 Antibody Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2) IgG/IgM antibody in human whole blood, serum or plasma sample. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2. The test provides preliminary test results.
Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision. For in vitro diagnostic use only. For professional use only.

MATERIAL
Material Provided
1.20 Individual sealed pouches, each pouch contains: 1 x Test cassette, 1 x Desiccant pouch
2. 20 disposable droppers
3. Detection buffer (1*6 mL)
4. Instructions for use

Price on request



VIRUTAN

SARS-CoV-2 Antibody Test

qarad

DECLARATION OF NOTIFICATION

Date: March 5, 2020

The undersigned, Sara Van Wouwe, Device Compliance Assistant of Qarad BVBA, hereby declares that:

[redacted]
Guangzhou 510663
PR China

has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

Name Device	Catalogue numbers
Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method)	W195
Finecare™ SARS-CoV-2 IgM Test	W277
Finecare™ SARS-CoV-2 Antibody Test	W276

The notification to the Belgian Competent Authorities has been carried out on March 5, 2020 by Qarad BVBA, the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

Information on the notification to the competent Authorities of other European countries is available upon request.

Sara Van Wouwe
Device Compliance Assistant
Qarad BVBA
Authorized Representative

Qarad BVBA | Office Address: Pas 257, B-2440 Geel, Belgium | Social Siege: Cipalstraat 3, B-2440 Geel, Belgium
Tel. +32 (0)14 49 04 22 | ECREP@qarad.com | www.qarad.com

VIRUTAN

Alcohol Pads

The soft, absorbent, non-woven pads are saturated with 70% isopropyl alcohol;
Sterile in unopened, undamaged package;
Discard after single use

For disinfection use.

Packing:
100pc/box
100box/carton
Production capacity: 1 000 000pc/day

VIRUTAN

Alcohol Pads

CFL CERTIFICATION CENTER

CERTIFICATION OF QUALITY MANAGEMENT SYSTEM

Registration No: 06518Q32670R0S

[redacted] Medical Instrument Co., Ltd.

Registered Address: Concentrated Area Of Xiaoguanzhuang Industrial Town Christmas Road, Baoying County, Yangzhou City, Jiangsu Province, China

Office Address: Bustling road No.1 Economic Development Zone Baoying county, Yangzhou City, Jiangsu Province, China

Unified social credit code/Organization code: 913210230601860038

Complies with the requirements of

GB/T19001-2016/ISO 9001: 2015

The scope of certification business covers:

Cleaning wet wipes sales

the 1st qualified identification	the 2nd qualified identification	the 3rd qualified identification

The certified organization should paste a new attendance tag within 12 months from the last site audit, otherwise the certificate will be invalid.

The validity period: 2018-11-16 to 2021-11-15 The issued date: 2018-11-16

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

CNAS 中国认可 国际互认 管理体系 MANAGEMENT SYSTEM CNAS C065-M

Add:A301,Dehui Edifice,No.A39,Xingfu Avenue Dongcheng District,Beijing,100061,P.R.C.

Inquiring Website:www.bjzwl.org Inquiring Telephone:010-67161955

Administration Supervision Commitee Official Website (www.cnca.gov.cn) Inquiry

Version 2018 No: 1811260

Certificate – Certificat – 인증서 – شهادة – Certificate – Сертификат – 證明書

Certificate of Compliance

No. 0D60701.YSMDC92

Technical Construction File no. SX-16000602

Certificate's Holder: [redacted] Medical Instrument Co., Ltd.
Baoying County Concentrated Area Of Xiaoguanzhuang Industrial Town Christmas Road

Certification ECM Mark: Type Approved

Product: Alcohol pad, Povidone-Iodine Pre Pad, Cleaning wipe, Medical sterilizing cotton ball, Medical sterilizing cotton swab, Cotton ball, Cotton swab, PBT Bandage, Gauze Bandage, Gauze Swab

Model(s): 30~200mmX30~200mm, 30~200mmX30~200mm, 30~200mmX30~200mm, 0.1g~3.0g/1~100pcs, 7cm~20cm/1~3pcs, 0.1g~3.0g, 7cm~20cm, 4~12cmX3-5m, 4~12cmX3-5m, 4.5~10cmX4.5~10cm-8~16

Verification to: related to CE Directive(s): 93/42/EEC amended by 2007/47/EC (Medical Devices) Annex V Devices Production Quality Assurance System

Remark The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:

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

Date of issue 01 July 2016 Expiry date 30 June 2021

Chief Manager Tim Mahon

Deputy Manager Viola Miller

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

VIRUTAN

Alcohol Pads 2

The soft, absorbent, non-woven pads are saturated with 70% isopropyl alcohol;
Sterile in unopened, undamaged package;
Discard after single use

For disinfection use

Size:3*6,5 cm MOQ:
500 000pc

Packing:
100pc/box
100box/carton
Carton size 42.5*28.5*28.5
Net weight 10KG
Gross weight 11 KG
Production capacity: 2 000 000pc/day

VIRUTAN

Alcohol Pads 2

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q6 17 07 01075 001

Holder of Certificate: [redacted]

225300 Taizhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): [redacted]

Development Zone, 225300 Taizhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Absorbent Cotton Wool, Absorbent Cotton Ball, Dental Cotton Roll, Sterile Pad (Alcohol Pad)**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH17120001

Valid from: 2017-10-26
Valid until: 2020-10-25

Date, 2017-10-26

Stefan Preiß

Page 1 of 1

DAkkS Deutsche Akkreditierungsstelle D-ZM-11323-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 07 01075 002

Manufacturer: [redacted]

225300 Taizhou, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: [redacted]

Effestraße 80
20537 Hamburg
GERMANY

Product Category(ies): **Sterile Pad (Alcohol Pad)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH17120001

Valid from: 2017-10-26
Valid until: 2022-10-25

Date, 2017-10-26

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2

DAkkS Deutsche Akkreditierungsstelle D-ZM-11323-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

VIRUTAN

Instant sanitizer 1

Alcohol gel
99,9% strerilization disinfection
Disposable quick-drying
Long-term bacteriostasis
Safety protection Medical household
75% alcohol
MOQ 10 000pc
Production capacity: 200 000pc/day

Packing 100pc/carton
Carton size: 36*36*19cm
Gross weight:11KG

Packing 360pc/carton
Carton size: 55*28*32.2cm
Gross weight:20KG

Packing 144pc/carton
Carton size: 49*30.5*29.5cm
Gross weight:21KG

Packing 30pc/carton
Carton size: 43*35*22.2cm
Gross weight:16KG

Packing 386pc/carton
Carton size: 61*31.5*34.3cm
Gross weight:26KG

VIRUTAN

Instant sanitizer 1

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

[redacted]

CHINA

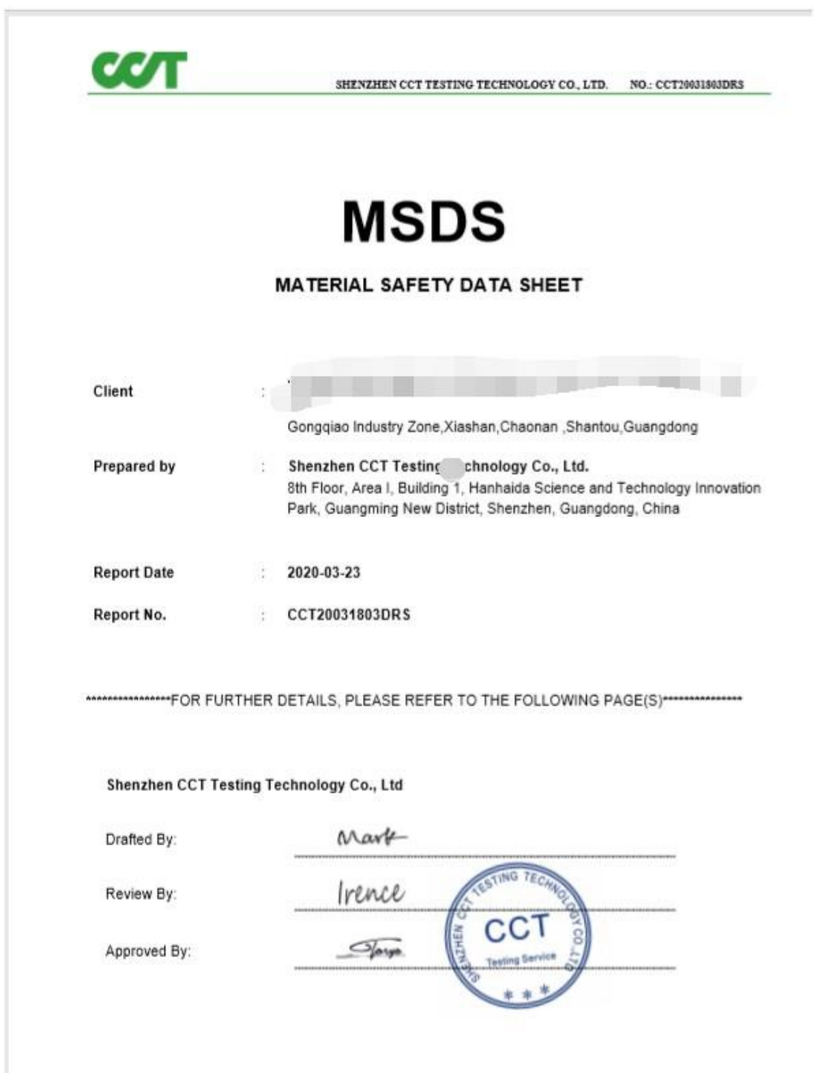
has completed the FDA Establishment Registration and Device Listing.

Owner/Operator Number: 10066538

Listing No.	Code	Device Name	Proprietary Names	Activities
D384153	LRJ	Disinfectant, medical devices	INSTANT HAND SANITIZER 30ml, 50ml , 60ml, 80ml, 100ml, 120ml, 200ml, 250ml, 300ml, 500ml, 1000ml, 5000ml, 3.8L, 20L, 25L	Manufacturer
			DISINFECTANT SPRAY 30ml, 50ml , 60ml, 80ml, 100ml, 120ml, 200ml, 250ml, 300ml, 500ml, 1000ml, 5000ml, 3.8L, 20L, 25L	

FDA

Initial Registration Date:April 2, 2020
Expiration Date: December 31, 2020



CCT SHENZHEN CCT TESTING TECHNOLOGY CO., LTD. NO.: CCT20031803DRS

MSDS

MATERIAL SAFETY DATA SHEET

Client : [redacted]
Gongqiao Industry Zone,Xiashan,Chaonan ,Shantou,Guangdong

Prepared by : Shenzhen CCT Testing Technology Co., Ltd.
8th Floor, Area I, Building 1, Hanhaida Science and Technology Innovation Park, Guangming New District, Shenzhen, Guangdong, China

Report Date : 2020-03-23

Report No. : CCT20031803DRS

**********FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)**********

Shenzhen CCT Testing Technology Co., Ltd

Drafted By: Mark

Review By: Irence

Approved By: Steve

SHENZHEN CCT TESTING TECHNOLOGY CO.,LTD. CCT Testing Service

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

Form QAT_10-M05, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 4Q200327.GMTDT12
Test Report no. CCT20031017ZRS

Certificate's Holder: [redacted]
Gongqiao Industry Zone, Xiashan, Chaonan, Shantou, Guangdong

Certification ECM Mark: Type Approved

Product: Instant Hand Sanitizer
Trade Mark: MIDINGQI
Model(s): MDQ-001, MDQ-002, MDQ-003, MDQ-004, MDQ-005, MDQ-006, MDQ-007, MDQ-008, MDQ-009, MDQ-010, MDQ-011, MDQ-012, MDQ-013, MDQ-014, MDQ-015, MDQ-016, MDQ-017, MDQ-018, MDQ-019, MDQ-020

Verification to: Standard: EN 1499:2013, EN 1500:2013

related to CE Directive(s): 2001/95/EC (General Product Safety)

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.entecerma.it

Issuance date: 27 March 2020

Expiry date: 26 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

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

VIRUTAN

Remote infrared thermometer

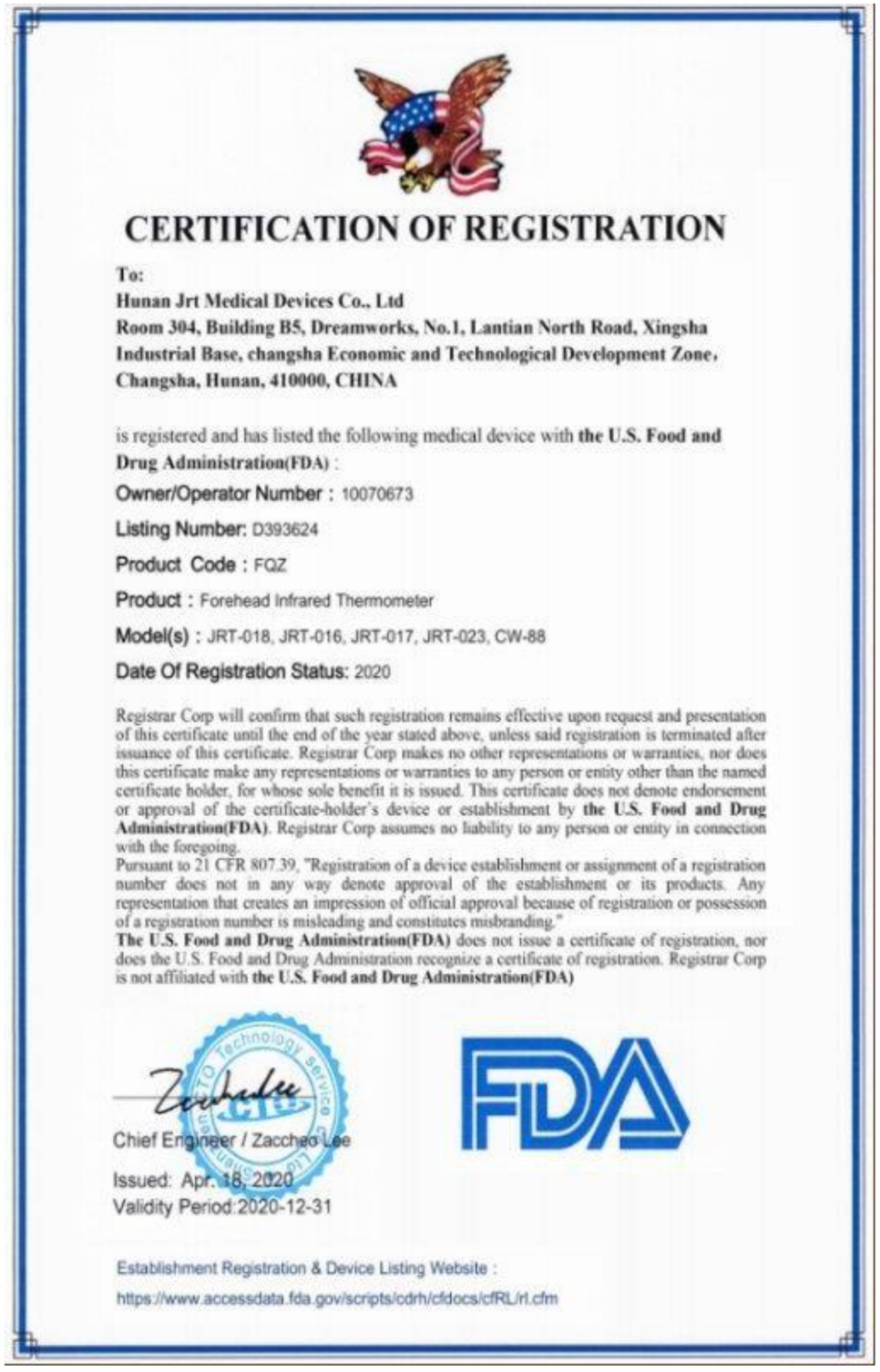
Measured temperature : 32 - 42,9℃ (0 - 100℃)

Producing capacity: 40,000PCS per day

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Remote infrared thermometer



CERTIFICATION OF REGISTRATION

To:
Hunan Jrt Medical Devices Co., Ltd
Room 304, Building B5, Dreamworks, No.1, Lantian North Road, Xingsha Industrial Base, changsha Economic and Technological Development Zone, Changsha, Hunan, 410000, CHINA

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

Owner/Operator Number : 10070673

Listing Number: D393624

Product Code : FQZ

Product : Forehead Infrared Thermometer

Model(s) : JRT-018, JRT-016, JRT-017, JRT-023, CW-88

Date Of Registration Status: 2020

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

Chief Engineer / Zaccheo Lee

Issued: Apr. 18, 2020
Validity Period:2020-12-31

Establishment Registration & Device Listing Website :
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

LST

Shenzhen LST Technology Co.,Ltd.
HOTLINE: 400-090-8010
WWW.LST-LAB.COM

Certificate of Compliance

Certificate No.	:	LST200378039E-2
Applicant	:	Hunan JRT Medical Devices Co.,Ltd
Applicant Address	:	Room 304, Building B5, Dreamworks, No. 1, Lantian North Road, Xingsha Industrial Base, Changsha Economic and Technological Development Zone, Hunan Province, China
Manufacturer	:	Hunan JRT Medical Devices Co.,Ltd
Manufacturer Address	:	Room 304, Building B5, Dreamworks, No. 1, Lantian North Road, Xingsha Industrial Base, Changsha Economic and Technological Development Zone, Hunan Province, China
Product	:	Non-contact Infrared Thermometer
M/N	:	JRT-023 JRT-016,JRT-017,JRT-018,JRT-019,JRT-029
Trademark	:	JRTYL
Test Standard	:	EN 60601-1-2:2015 (CISPR 11:2015;IEC 61000-3-2:2014;IEC 61000-3-3:2013; IEC 61000-4-2:2008;IEC 61000-4-3:2006;IEC 61000-4-4:2012; IEC 61000-4-5:2014;IEC 61000-4-6:2013;IEC 61000-4-8:2009; IEC 61000-4-11:2004)

The EUT described above has been tested by us with the listed standards and found in compliance with the council MDD directive 93/42/EEC. It is possible to use CE marking to demonstrate the compliance with this MDD Directive. It is only valid in connection with the test report number: LST200378039ER-2.

CE

Manager
Issue Date: Apr. 07, 2020

LST

Shenzhen LST Technology Co.,Ltd.
HOTLINE: 400-090-8010
WWW.LST-LAB.COM

Certificate of Compliance

Certificate No.	:	LST200378039F-2
Applicant	:	Hunan JRT Medical Devices Co.,Ltd
Applicant Address	:	Room 304, Building B5, Dreamworks, No. 1, Lantian North Road, Xingsha Industrial Base, Changsha Economic and Technological Development Zone, Hunan Province, China
Manufacturer	:	Hunan JRT Medical Devices Co.,Ltd
Manufacturer Address	:	Room 304, Building B5, Dreamworks, No. 1, Lantian North Road, Xingsha Industrial Base, Changsha Economic and Technological Development Zone, Hunan Province, China
Product	:	Non-contact Infrared Thermometer
M/N	:	JRT-023 JRT-016,JRT-017,JRT-018,JRT-019,JRT-029
Trademark	:	JRTYL
Test Standard	:	

The submitted sample of the equipment has been tested and found to comply with the following standards:

- FCC Part 15 B
- ANSI C63.4:2014

This verification is part of the full test report(s) and should be read in conjunction with it. The referred test report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified FCC standard. This Verification does not imply assessment of the production of the product.It is only valid in connection with the test report number: LST200378039FR-2.

FC

Manager
Issue Date: Apr. 07, 2020

VIRUTAN

Remote infrared thermometers

Type A

Specifications:

Measure temperature : 32 - 42,9℃

Size 150*85,5*43mm Batteries : 2x AAA

Producing capacity: 30,000PCS per day

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

医疗器械生产许可证

许可证编号：粤食药监械生产许 20101869 号

企业名称：深圳市家康科技有限公司　生产地址：深圳市龙华区观湖街道观城社区大和村 596-4 号 301；东莞市塘厦镇蛟乙路社区银湖工业区银湖路 16 号 A 栋

法定代表人：梁艺平　生产范围：见医疗器械生产产品登记表

企业负责人：梁艺平

住　　所：深圳市龙华区观湖街道观城社区大和村 596-4 号 301　发证部门：广东省药品监督管理局

有效期限：至 2024 年 10 月 14 日　发证日期：2019 年 10 月 15 日

国家食品药品监督管理总局制

VIRUTAN

Remote infrared thermometers

Type B

Specifications:

Error: 0,1 ℃

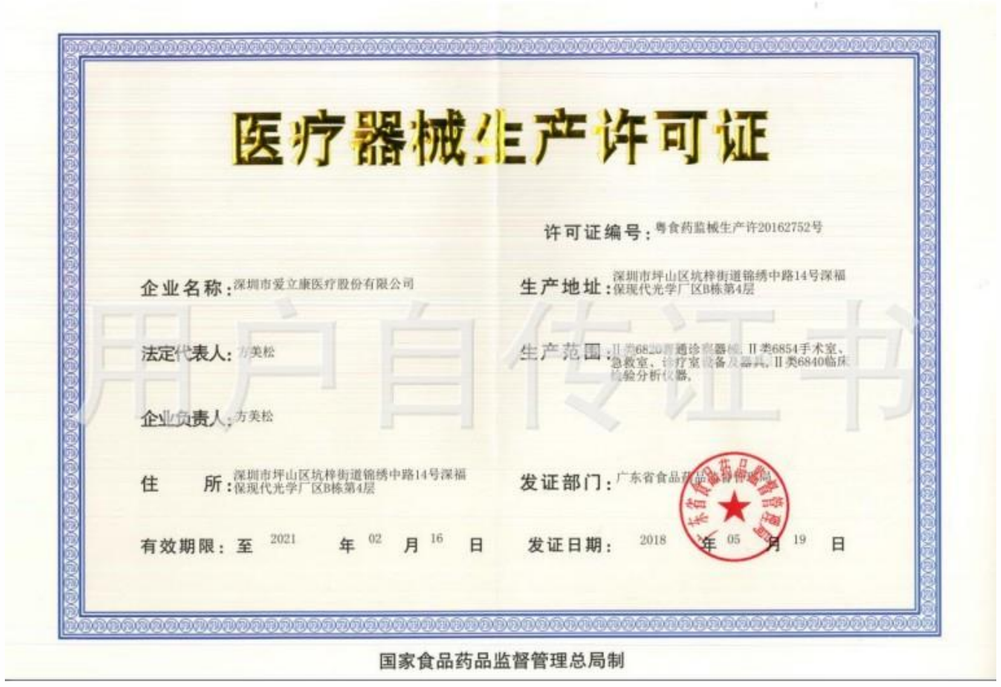
Measured temperature : 32 - 42,2℃

Size : 138*37*37mm

Batteries : rechargeable battery

Producing capacity: 30,000PCS per day

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.



医疗器械生产许可证

许可证编号：粤食药监械生产许20162752号

企业名称：深圳市爱立康医疗股份有限公司

生产地址：深圳市坪山区坑梓街道锦绣中路14号深福保现代光学厂区B栋第4层

法定代表人：方美松

生产范围：Ⅱ类6820普通诊察器械，Ⅱ类6854手术室、急救室、诊疗室设备及器具，Ⅱ类6840临床检验分析仪器。

企业负责人：方美松

住　　所：深圳市坪山区坑梓街道锦绣中路14号深福保现代光学厂区B栋第4层

发证部门：广东省食品药品监督管理局

有效期限：至 2021 年 02 月 16 日　　发证日期：2018 年 05 月 19 日

国家食品药品监督管理总局制

·CE/FDA证书

VIRUTAN

Remote infrared thermometers 3

LCD Backlight 1s
fast
reading Beep
alarm 99
memories Unit
switchable
MOQ 1000pc

Packing:
1pc/color box
30box/carton
Carton volume: 0,05m3
Gross weight:0,7KG

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Remote infrared thermometers 3

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

CERTIFICATE

Certificate Number **UCN** : **802792330465**
Job : *J29855*
Date of Issue : *2020-03-25*
Certificate valid up to : *2024-03-24*

Brand Name : *Tida*
Type : *Infrared Thermometer*
Model N : *TD133, TD238, TD338*

Manufacturer
Address : No. 20, Changsha road,Dalong street, Panyu District, Guangzhou China

Standard Used : EN 60601-1:2006+A1:2013+AC:2010, EN 60601-1-2:2015, EN 71:2012

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

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

Presence of Declaration of conformity template	✔ OK
Presence of test report using standards as indicated in the declaration of conformity Test report reference : 80391031707A/2020	✔ OK
Presence of CE symbol in the product label.	✔ OK
Presence of instruction manual	✔ OK
Use of valid Harmonized standard in the declaration of conformity	✔ OK
Presence of product description in the technical construction file	✔ OK

Massimiliano Bertoldi
General Manager – CELAB
www.celab.com

SGS

Test Report No.T31920261824SC Date: JUL 30, 2019 Page 1 of 4

KONG

The following samples were submitted and identified by/on behalf of the client as:
0.%HG 9VOLTS 6F22, CARBON ZINC BATTERY, METAL JACKET

Style No. : CA319202629019
Manufacturer : NEW LEADER
Country of Origin : CHINA
Sample Receiving Date : JUL 18, 2019
Test Performing Date : JUL 18 – 24, 2019

Test Requested		Conclusion
1.	European Directive 2006/66/EC and its amendments (Directive 2013/56/EU) – Lead, Cadmium and Mercury Content	PASS (SEE REMARK)
2.	Mercury requirement in compliance with various USA States requirement	PASS

Remark: According to 2006/66/EC, the corresponding chemical symbol beneath the cross-out wheeled bin logo is required if the heavy metal content in batteries and accumulators exceeded the values specified under labeling requirements.

********* FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S) *********

Signed for and on behalf of
SGS Hong Kong Ltd.

Che Wai Leuk, Jerry
Technical Manager

SGS HONG KONG LIMITED

VIRUTAN

Remote infrared thermometers 4

Technical parameters:
Transport&storage- Temperature -20C-55C
Atmospheric Pressure:70kpa-106kpa Indicating Unit
Resolution: 0,1C
Accuracy: Body temperature mode:35.0C-42.0C
Within range +-0.2C
Body temperature mode:35.0C-42.0C Out of
range +-0.3C
Measuring Range:Body Temperature Mode
32.0C-42.9C
Measuring Distance: 5-15cm
Power supply: DC9V
Battery Automatic Power Off :90
sec Product
size:100*46*160mm Product
weight:125g(no battery)

Production capacity: 10 000pc/week

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Remote infrared thermometers 4

International Certification Registrar · International Certification Registrar

Attestation of Conformity

No. ICR Polska/M6330127

CE

Name and address of Registered Manufacturer:	[redacted] g District, Luzhou City
Product name:	Medical infrared thermometer
Product type/model:	SK-T008, SK-T008A, SK-T008B, SK-T008C, SK-T006, SK-T007, SK-T009, SK-T100, SK-T200, SK-T300
Trade mark:	CLOC

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 Devices Directive 93/42/EEC
Conformity assessment procedure:	EC Declaration of conformity (Annex VII of Directive 93/42/EEC)
Classification:	Class IIa according Rule 1 of Annex IX of Directive 93/42/EEC
Applied normative documents:	EN 60601-1:2006+A12:2014, EN 60601-1-2:2015
Applied Quality Management System	N/A

This AoC will remain valid only if Quality Management System Certificate remains valid.
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 report made by:

- TMC Testing Services (Shenzhen) Co., Ltd.

No. of test report:	TMC200313115-E, TMC200313115-S
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/2020-3125.

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. 03. 2020.

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 证书证书 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TMC

Declaration of Conformity

Certificate No.:	TMC200313115-ES
Applicant/ Address:	[redacted] Block 28, No.9 Chuangxin Road, Jiangyang District, Luzhou City
Manufacturer/ Address:	[redacted] Chuangxin Road, Jiangyang District, Luzhou City
Product Name:	Medical infrar[redacted]hermometer
Trade Name:	CLOC
Model/Item Number:	SK-T008, SK-T008A, SK-T008B, SK-T008C, SK-T006, SK-T007, SK-T009, SK-T100, SK-T200, SK-T300
Rated:	Input: DC9V
Date and Number of Test Report:	March 14, 2020-March 17, 2020 TMC200313115-E TMC200313115-S
EC-Directive:	Medical Devices Directive 93/42/EEC
Test Standard:	EN 60601-1-2:2015 EN 60601-1-2:2006+A12:2014

Conclusion

The Declaration of EMC Compliance has been granted to applicant based on the results of tests performed by Laboratory of TMC Testing Services (Shenzhen) Co., Ltd. on sample of the above-mentioned product in accordance with the provisions of the relevant specific standards and the Medical Devices Directive 93/42/EEC. It is possible to use CE marking to demonstrate the compliance with this Directive.

Place and date of issue: Shenzhen, March 18, 2020

TMC Testing Services (Shenzhen) Co., Ltd.
1/F., Block A, Xinshida Gongrong Industrial Park, No. 2, Shihuan Road, Shiling Community, Shiyan Street, Baoan District, Shenzhen, China
Tel: +86-755- 86642861
Email:cert@tmc-lab.com Http://www.tmc-lab.com

CE

TMC

Remote infrared thermometers 4

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TMC

Access to global market

Certificate of Compliance

Certificate No.:	TMC200316121-C
Applicant/ Address:	Block 28, No.9 Chuangxin Road, Jiangyang District, Luzhou City
Manufacturer/ Address:	Block 28, No.9 Chuangxin Road, Jiangyang District, Luzhou City
Product Name:	**Medical infrared thermometer**
Trade Name:	CLOC 云和家
Model/Item Number :	SK-T008, SK-T008A, SK-T008B, SK-T008C, SK-T006, SK-T007, SK-T009, SK-T100, SK-T200, SK-T300
Date and Number of Test Report:	March 16, 2020-March 18, 2020 TMC200316121-C
EC-directive:	RoHS 2.0 Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU
Test Standard:	IEC 62321-1:2013 IEC 62321-3-1:2013 IEC 62321-4:2017 IEC 62321-5:2013 IEC 62321-6:2015 IEC 62321-7-1:2015 IEC 62321-7-2:2017 IEC 62321-8:2017

Conclusion

This Certification of RoHS Compliance has been granted to applicant based on the results of tests, performed by Laboratory of TMC Testing Services (Shenzhen) Co., Ltd on sample of the above-mentioned product in accordance with the provisions of the relevant specific standards and the RoHS 2.0 Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU. It is possible to use RoHS marking to demonstrate the compliance with this directive.

Place and date of issue: Shenzhen, March 18, 2020

TMC Testing Services (Shenzhen) Co., Ltd.
1/F., Block A, Xinshidai Gongrong Industrial Park, No. 2,
Shihuan Road, Shilong Community, Shiyan Street,
Baoan District, Shenzhen, China
Tel: +86-755- 86642861
Email:cert@tmc-lab.com
Http://www.tmc-lab.com

Bauart geprüft Product Safety

CE

TMC

TMC

TMC Testing Services (Shenzhen) Co., Ltd

Report No.: TMC200324129-E

FC

APPLICATION FOR EMC DIRECTIVE

On Behalf of

Medical infrared thermometer

Trade Name: CLOC 云和家

Model: SK-T008, SK-T008A, SK-T008B, SK-T008C, SK-T006, SK-T007, SK-T009, SK-T100, SK-T200, SK-T300

Prepared For : **Luzhou Skinod Technology Co., Ltd**
Block 28, No.9 Chuangxin Road, Jiangyang District, Luzhou City

Prepared By : **TMC Testing Services (Shenzhen) Co., Ltd.**
1/F., Block A, Xinshidai Gongrong Industrial Park, No. 2, Shihuan Road, Shilong Community, Shiyan Street, Baoan District, Shenzhen, China
Tel: +86-755- 86642861
Web: www.tmc-lab.com
E-mail: Cert@tmc-lab.com

Date of Test	March 24, 2020-March 26, 2020
Date of Report	March 26, 2020
Report Number	TMC200324129-E

Remote infrared thermometers 4

2020

CERTIFICATE OF REGISTRATION

This Certifies that:

[redacted]

Luzhou City, Sichuan, 646000,CHINA

Was registered with US Food & Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807. Such registration has been verified, with the registrant's authorization, by TMC Testing Services (Shenzhen) Co., Ltd.

Owner/Operator Number:		
Listing Number:	Product Code(s):	Device Name(s):
10384139	FQZ	THERMOMETER, CLINICAL COLOR CHANGE
Proprietary Name:	Infrared thermometer, SK-T008, SK-T008A, SK-T008E, SK-T008C, SK-T006,SK-T007	

Issued: April 02, 2020
Expiration Date: Dec.31, 2020

The Compliance (previously TMC Testing Services (Shenzhen) Co., Ltd. has verified that the above stated facility is registered with the US Food & Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807, on the date noted above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other persons or entity other than the name certificate holder, for whose sole benefit it is issued. TMC Testing Services (Shenzhen) Co., Ltd. assumes no liability to any person or entity in connection with the foregoing. TMC Testing Services (Shenzhen) Co., Ltd. is a private registration agent and are not affiliated with the US Food and Drug Administration.

FDA

TMC Testing Services (Shenzhen) Co., Ltd.
CHINA OFFICE: 086-755-86642861
Web: http:www.fda.gov

Director

CERTIFICATION EUROPE HONG KONG

Certificate of Registration

Certificate NO: 10136652M

This is to Certify that the Medical Devices Industry Management System of

[redacted]

ngyang District, Luzhou City, Sichuan Province, China

Has been audited to the following Medical Devices Industry Management System standard:

ISO13485:2016

This system is valid for the

R&D, Production and sales of Medical infrared thermometer, temperature monitoring bracelet, temperature monitoring watch, temperature detection mobile phone, temperature detection assess control system, temperature detection attendance machine, door frame type temperature detector and other temperature detection equipment, medical protective mask

Date of issue: Mar. 24, 2020 **Date of expiry: Mar. 23, 2023**

This certificate will not remain valid only if the certified organization accepts at least one surveillance audit annually within the validity period of the certificate in which the surveillance audit conforming mark is in the designated position on the certificate.

Medical Device Management

IAF

UKAS

Issued by:

12months	24months

CERTIFICATION EUROPE(HONGKONG)LIMITED WWW.CCE-HK.COM

VIRUTAN

Infrared Human Temperature Detect Door

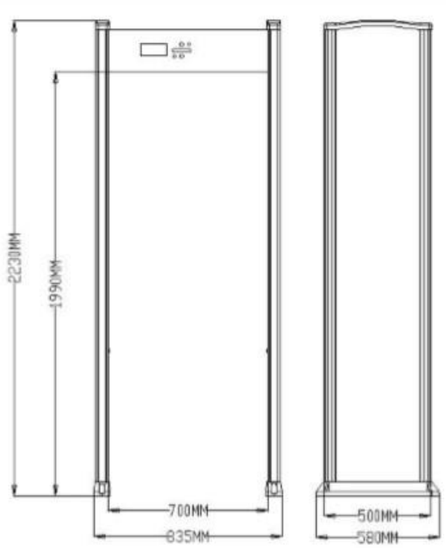
Non-contact temperature detection: the temperature of the forehead of a passing person is tested by an adjustable infrared sensor.

Test accuracy: ± 0.3-0.5℃, test distance: 5cm-30cm.

Adjustable settings: People of different heights can adjust the sensor angle by themselves to find a suitable angle for measurement.

Metal detection and temperature detection function: Metal detection function and temperature detection function exist at the same time. Wider range of use.

Multi-zone technology: 18 detection zones, the sensitivity of each detection zone can be adjusted arbitrarily (with adaptive adjustmenttechnology), and there is a high-brightness LED alarm location indication to accurately locate hidden contraband areas.



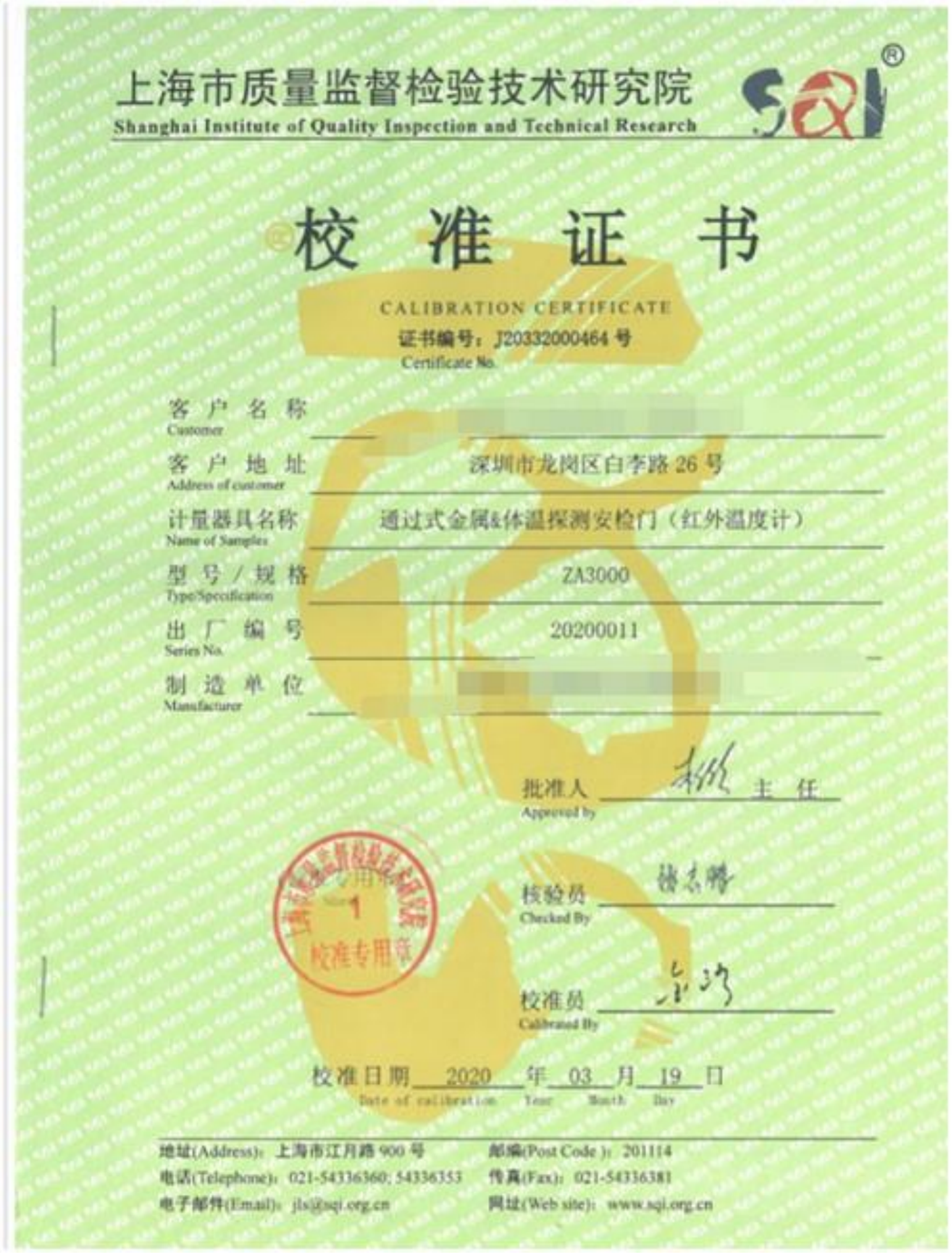
MOQ-10pcs (in stock)

Packing:
1pc-2carton Total
weight 65kg
1carton： 76*25.5*39cm
2carton： 231*65*19.5cm

Other products in same category and all Incoterms available.
Prices are updated daily. Please ask for current prices and discounts.

VIRUTAN

Infrared Human Temperature Detect Door



上海市质量监督检验技术研究院
Shanghai Institute of Quality Inspection and Technical Research

校 准 证 书

CALIBRATION CERTIFICATE

证书编号：J20332000464 号
Certificate No.

客户名称 Customer

客户地址 Address of customer：深圳市龙岗区白李路 26 号

计量器具名称 Name of Samples：通过式金属&体温探测安检门（红外温度计）

型号/规格 Type/Specification：ZA3000

出厂编号 Series No.：20200011

制造单位 Manufacturer

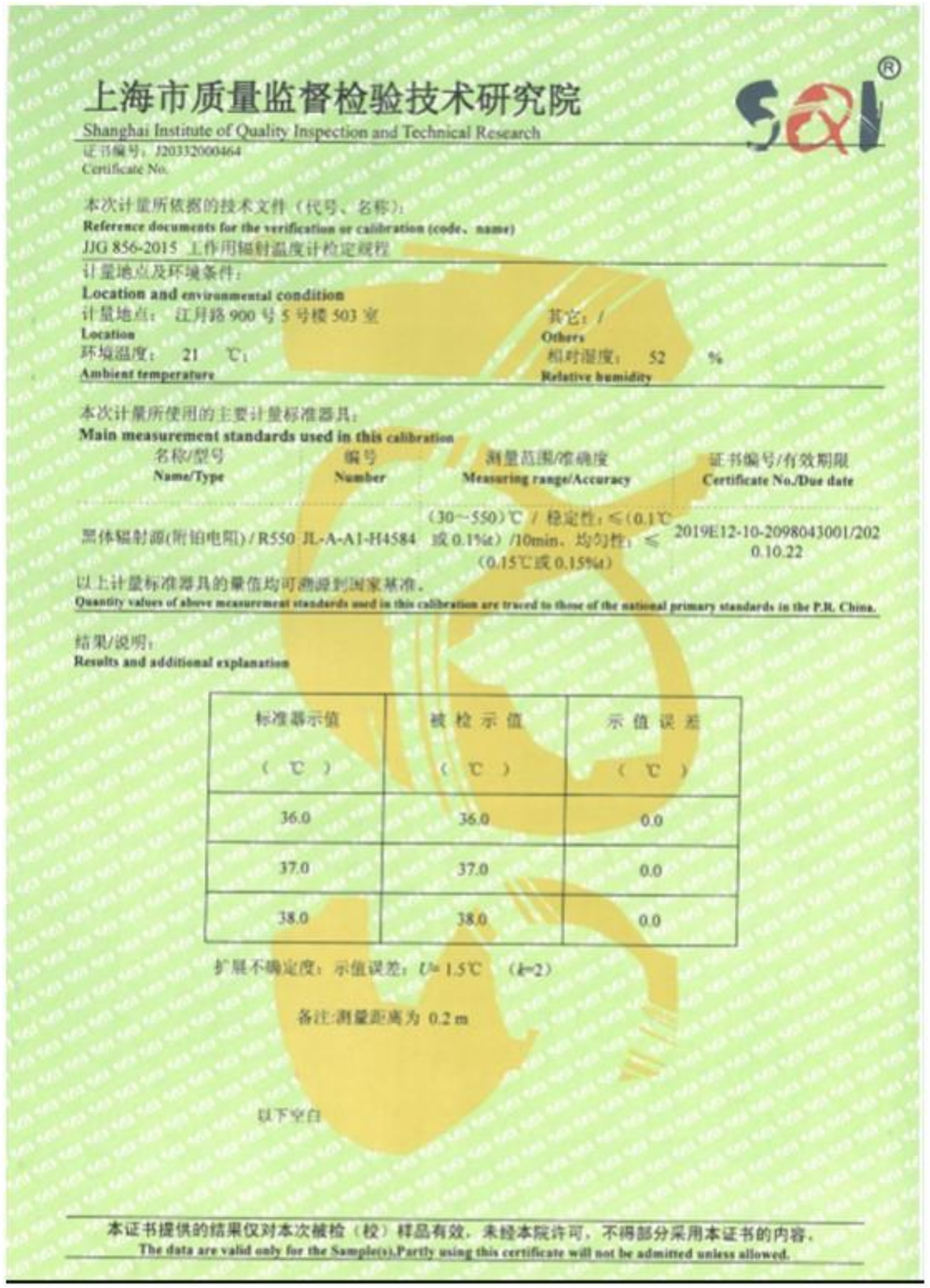
批准人 Approved by：主任

核验员 Checked By

校准员 Calibrated By

校准日期 Date of calibration 2020 年 03 月 19 日

地址(Address)：上海市江月路 900 号　邮编(Post Code)：201114
电话(Telephone)：021-54336360; 54336353　传真(Fax)：021-54336381
电子邮件(Email)：jls@sqi.org.cn　网址(Web site)：www.sqi.org.cn



上海市质量监督检验技术研究院
Shanghai Institute of Quality Inspection and Technical Research

证书编号：J20332000464
Certificate No.

本次计量所依据的技术文件（代号、名称）：
Reference documents for the verification or calibration (code、name)
JJG 856-2015 工作用辐射温度计检定规程

计量地点及环境条件：
Location and environmental condition
计量地点：江月路 900 号 5 号楼 503 室　其它：/
Location　Others
环境温度：21 ℃　相对湿度：52 %
Ambient temperature　Relative humidity

本次计量所使用的主要计量标准器具：
Main measurement standards used in this calibration

名称/型号 Name/Type	编号 Number	测量范围/准确度 Measuring range/Accuracy	证书编号/有效期限 Certificate No./Due date
黑体辐射源(附铂电阻)/R550	JL-A-A1-H4584	（30～550）℃ / 稳定性：≤（0.1℃ 或 0.1%t）/10min、均匀性：≤（0.15℃或 0.15%t）	2019E12-10-2098043001/202 0.10.22

以上计量标准器具的量值均可溯源到国家基准。
Quantity values of above measurement standards used in this calibration are traced to those of the national primary standards in the P.R. China.

结果/说明：
Results and additional explanation

标准器示值（℃）	被检示值（℃）	示值误差（℃）
36.0	36.0	0.0
37.0	37.0	0.0
38.0	38.0	0.0

扩展不确定度：示值误差：U= 1.5℃ （k=2）

备注:测量距离为 0.2 m

以下空白

本证书提供的结果仅对本次被检（校）样品有效，未经本院许可，不得部分采用本证书的内容。
The data are valid only for the Sample(s).Partly using this certificate will not be admitted unless allowed.

VIRUTAN

Infrared Human Temperature Detect Door

Certificate of Conformity

Certification Number: HY20CC-399E

Shenzhen HuaYu Test Technology Co.,Ltd. hereby declares that testing has been completed and reports have been generated for:

Applicant:	
Address:	A403 QIFENG DIGITAL TECHNOLOGY PARK, 26BAILI ROAD, XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, P.R.CHINA
Manufacturer:	
Address:	A403 QIFENG DIGITAL TECHNOLOGY PARK, 26BAILI ROAD, XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PR[illegible] CHINA
Factory:	
Address:	A403 QIFENG DIGITAL TECHNOLOGY PARK, 26BAILI ROAD, XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, P.R.CHINA
Product:	**Walk through body temperature metal detector**
Model:	ZA3000, ZA3000A, ZA3000B, ZA3000C, ZA3000[illegible]A3000E, ZA-3000BX
Rating:	Input: 220V~240Vac 50Hz 1.0A Output: 24V⎓ 2.0A
Note:	All models share same circuit diagram, just different with appearance and power. All test performance on: ZA-3000D
Test standard:	**EN 55032:2015+A11:2020** **EN 55035:2017** **EN 61000-3-2:2014** **EN 61000-3-3:2013**

The EUT described above has been consolidate by us and found in compliance with the council Electromagnetic Compatibility (as amended) -- 2014/30/EU. It is only valid in connection with the report number: HY20CR-399E

Senior Manager
March 19, 2020

This certificate of conformity is based on a single evaluation of the submitted sample(s) of the above mentioned product. It does not imply an assessment of the whole product and relevant. Directives have to be observed.

No. D880, 4th Floor, Building 1, Detai Industrial Park, Huarong Road No. 460, Dalang Street, Longhua New District, Shenzhen

Tell: +86-755-85293110 Fax: +86-755-21014842 http://www.hyjctest.com

Attestation of Conformity

Attestation number: HY20CC-399F Report number: HY20CR-399F

The device, as described herewith, was tested pursuant to applicable test procedure and complies with the requirements of FCC Part15 B Rules

All measurements contained in this report were conducted with ANSI C63.4-2014, American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the range of 9 kHz to 40 GHz

Applicant:	
Address:	A403 QIFENG DIGITAL TECHNOLOGY PARK, 26BAILI ROAD, XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, P.R.CHINA
Manufacturer:	
Address:	A403 QIFENG DIGITAL TECHNOLOGY PARK, 26BAILI ROAD, XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, P.R.CHINA
Factory:	
Address:	A403 QIFENG DIGITAL TECHNOLOGY PARK, 26BAILI ROAD, XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, P.R.CHINA
Product:	**Walk through body temperature metal detector**
Rating:	Input: 220V~240Vac 50Hz 1.0A Output: 24V⎓ 2.0A
Model:	ZA3000, ZA3000A, ZA3000B, ZA3000C, ZA3000D, ZA3000E, ZA-3000BX
Note:	All models share same circuit diagram, just different with appearance and power. All test performance on: ZA-3000D
Laboratory Name:	Shenzhen HuaYu Test Technology Co.,Ltd.

The results in this report are applicable only to the equipment tested.
This report shall not be re-produced except in full without the written approval of Shenzhen HuaYu Test Technology Co.,Ltd.

Attestation by:

Senior Manager

Date of Issue: March 19, 2020

No. D880, 4th Floor, Building 1, Detai Industrial Park, Huarong Road No. 460, Dalang Street, Longhua New District, Shenzhen

Tell: +86-755-85293110 Fax: +86-755-21014842 http://www.hyjctest.com

VIRUTAN

Infrared Human Temperature Detect Door

Certificate of Conformity

Certification Number: HY20CC-399S

Shenzhen HuaYu Test Technology Co.,Ltd. hereby declares that testing has been completed and reports have been generated for:

Applicant:	
Address:	A403 QIFENG DIGITAL TECHNOLOGY PARK, [illegible], XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, P.R.CHINA
Manufacturer:	
Address:	AL TECHNOLOGY PARK, 26BAILI ROAD, XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, P.R.CHINA
Factory:	
Address:	A403 QIFENG DIGITAL TECHNOLOGY PARK, 26BAILI ROAD, XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, P.R.CHINA
Product:	**Walk through body temperature metal detector**
Model:	ZA3000, ZA3000A, ZA3000B, ZA3000C, ZA3000D, ZA3000E, ZA-3000BX
Rating:	Input: 220V~240Vac 50Hz 1.0A Output: 24V⎓ 2.0A
Note:	All models share same circuit diagram, just different with appearance and power. All test performance on: ZA-3000D
Test standard:	**EN 60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013**

The EUT described above has been consolidate by us and found in compliance with the council Low Voltage Directive -- 2014/35/EU. It is only valid in connection with the report number: HY20CR-399S.

CE

Senior Manager
March 19, 2020

This certificate of conformity is based on a single evaluation of the submitted sample(s) of the above mentioned product. It does not imply an assessment of the whole product and relevant. Directives have to be observed.

No. D880, 4th Floor, Building 1, Detai Industrial Park, Huarong Road No. 460, Dalang Street, Longhua New District, Shenzhen

Tell: +86-755-85293110 Fax: +86-755-21014842 http://www.hyjctest.com

Attestation of Conformity
RoHS

Certification number: HY20CC-399R

The device, as described herewith, was tested and/or verified on the basis of samples and/ or RoHS test reports provided by the Applicant, and to be certified that the hazardous substance are in compliance with the Directive:

2011/65/EU Restriction of Hazardous Substance

The test results are traceable to the international or national standards

Applicant:	
Address:	A403 QIFENG DIGITAL TECHNOLOGY PARK, 26BAILI ROAD, XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, P.R.CHINA
Manufacturer:	
Address:	A403 QIFENG DIGITAL TECHNOLOGY PARK, 26BAILI ROAD, XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, P.R.CHINA
Factory:	
Address:	A[illegible] PARK, 26BAILI ROAD, XIALILANG COMMUNITY, NANWAN STREET, LONGGANG DISTRICT, SHENZHEN CITY, GUANGDONG PROVINCE, P.R.CHINA
Product:	**Walk through body temperature metal detector**
Model:	ZA3000, ZA3000A, ZA3000B, ZA3000C, ZA3000D, ZA3000E, ZA-3000BX
Test standard:	IEC 62321-4:2013+AMD1:2017, IEC 62321-5:2013, IEC 62321-6:2015, IEC 62321-7-2:2017, IEC 62321-8:2017

The results in this report are applicable only to the devices tested and/or test reports verified. This report shall not be re-produced except in full without the written approval of the undersigned. This report is valid only companied with the RoHS report verified and identified by the undersigned.

Attestation by:

Senior Manager

Date of Issued: March 19, 2020

No. D880, 4th Floor, Building 1, Detai Industrial Park, Huarong Road No. 460, Dalang Street, Longhua New District, Shenzhen

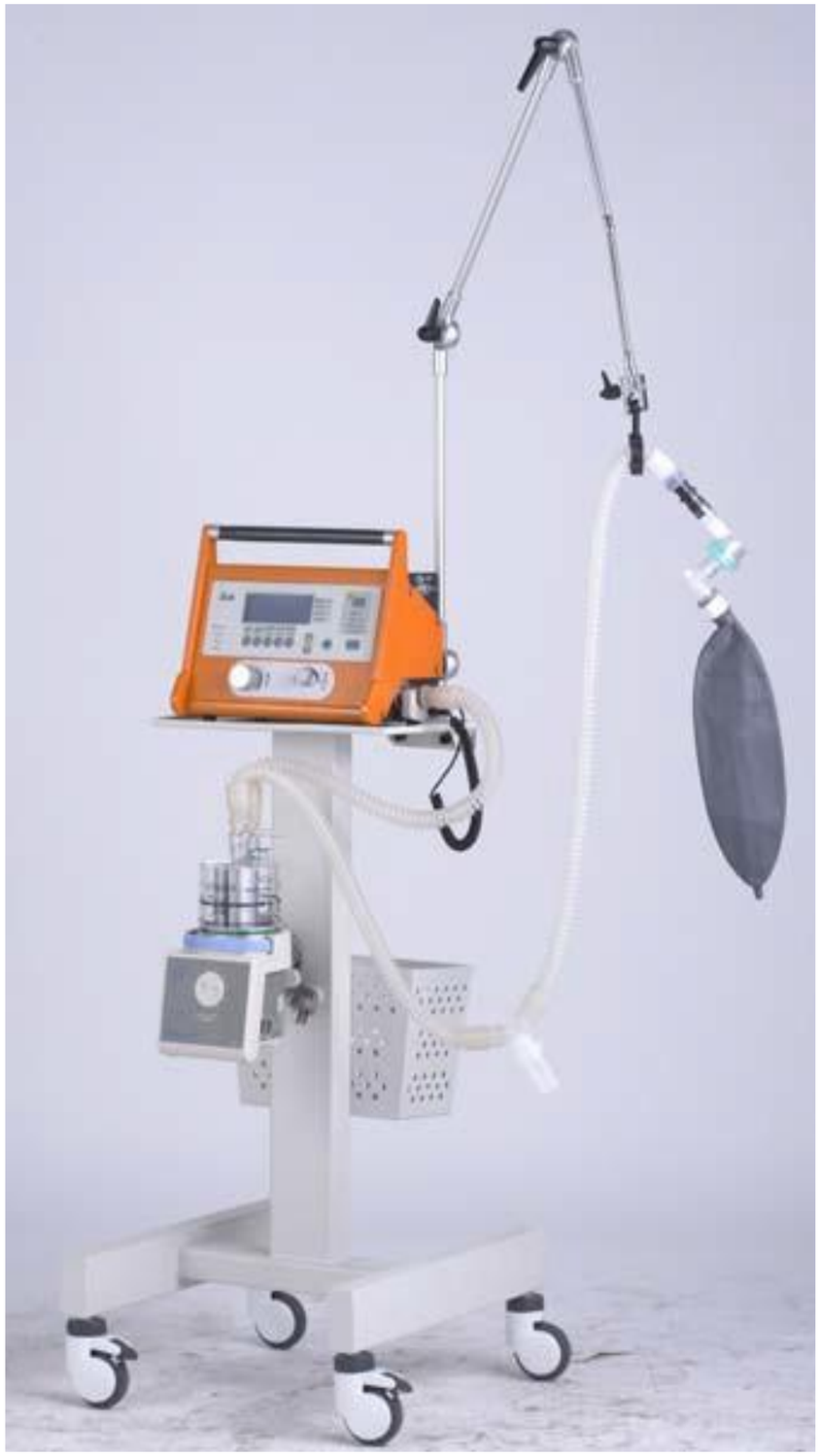
Tell: +86-755-85293110 Fax: +86-755-21014842 http://www.hyjctest.com

VENTILATORS

VIRUTAN

VENTILATOR **ASM812A**

- Suitable for adult and child
- For various treatment environments such as emergency room, operating theater, ambulance, patient transfer and first-aid
- Unique invasive and non-invasive ventilation modes to meet the different patients' needs
- Inspiration halt, convenient for sucking phlegm
- Oxygen mixing technique to adjust oxygen concentration and meet the oxygen therapy need
- Alarm and monitoring system which meet the international safety standard
- TFT screen, displaying various respiration parameters and waveforms
- With built-in battery and on-vehicle power connector for A/C and D/C power supply
- **PEEP valve, humidifier, trolley, supporting arm and other accessories as optional**



VIRUTAN

VENTILATOR **ASM812A**

Main parameters

Applications: Adult, child

Control mode: Pneumatic driven and electric controlled, timeswitch, pressure limit, volume control, apnea ventilation

Ventilation modes: A/C, SIMV, SPONT, SIGH, NIPPV, manual

Respiratory rate: 4bpm～80bpm

Tidal volume: 0，50ml～1500ml

I:E ratio: 1: 0.3, 1: 0.5, 1: 0.7, 1: 1, 1: 1.5, 1: 2, 1: 2.5, 1: 3, 1: 3.5, 1: 4

Trigger sensitivity: -2kPa～2kPa, continuously adjustable

Oxygen concentration: 48-100%

Display mode: LCD screen display

Waveform: Airway pressure waveform display

Monitoring parameters

Tidal volume, Minute volume, Respiratory rate, Peak airway pressure

Alarm parameters

Upper airway pressure limit
Lower airway pressure limit
Low battery alarmLo Power supply failurePow Silence for alarm

Note: This machine can be a portable one with oxygen cylinder.

VENTILATOR **ASM812A**

TÜVRheinland®

EC Certificate

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

Registration No.: HD 60130281 0001

Report No.: 16802111 006

Manufacturer:
[redacted]
100039 Beijing
China

Products: Medical devices

(see attachment for site and products included)

Replaces Certificate, Registration no.: HD 60124191 0001

Expiry Date: 2023-07-11

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

Effective Date: 2018-07-12

Date: 2018-06-13

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
III
S. Liu
Zertifizierungsstelle

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

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: HD 60130281 0001
Report No.: 16802111 006

Manufacturer:
[redacted]
100039 Beijing
China

Products:

- Anaesthetic Units
- Anaesthetic Vaporizers
- Ventilators
- Medical Ultrasound Diagnostic Systems

Site included:

[redacted]

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
III
S. Liu
Zertifizierungsstelle

Date: 2018-06-13

VIRUTAN

VENTILATOR **ASM812A**

100+ pcs in stock
30 April - 300 pcs in stock

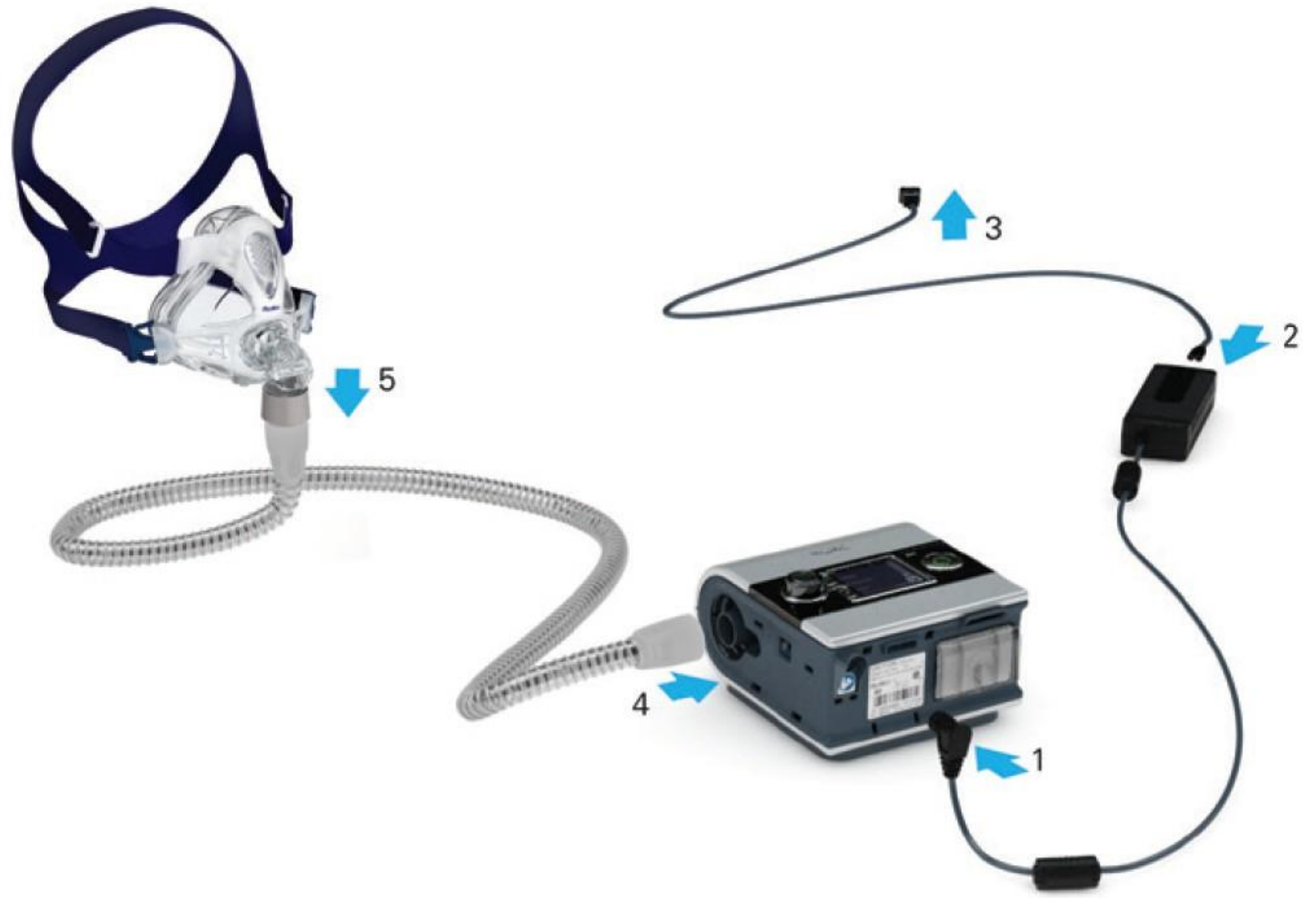
Price on request

VIRUTAN

VENTILATOR **S9**

!NONINVASIVE VENTILATOR!

This model is designed for home use with minor respiratory failure. But in emergency cases, this model is certified to perform the functions of medical ventilation.



100 pcs in stock

Price on request

VIRUTAN

VENTILATOR **S9**

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 049861 0154 Rev. 00

Holder of Certificate: **ResMed Limited**
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153
AUSTRALIA

Facility(ies):
ResMed Limited
1 Elizabeth Macarthur Drive, Bella Vista
NSW 2153, AUSTRALIA

ResMed Asia Pacific Limited
1 Elizabeth Macarthur Drive, Bella Vista
NSW 2153, AUSTRALIA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution, Installation and Servicing of Positive Airway Pressure Devices, Ventilators, Humidifiers, Masks, Tubes and associated Accessories, Patient Data Recorders (Respiratory).**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: **JAQ235034455**

Valid from: **2018-11-23**
Valid until: **2021-11-22**

Date, **2018-10-15**

Stefan Preiß

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV Product Service

EC Certificate

Full Quality Assurance System

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

No. G1 16 06 49861 115

Manufacturer: **ResMed Limited**
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153
AUSTRALIA

EC-Representative: **ResMed (UK) Ltd**
96 Jubilee Avenue
Milton Park, Abingdon, Oxfordshire
OX14 4RW
UNITED KINGDOM

Product Category(ies): **Positive Airway Pressure Devices, Ventilators, Humidifiers, Masks, Tubes and associated Accessories, Patient Data Recorders (Respiratory).**

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

Report No.: **JAQ235024313**

Valid from: **2016-10-04**
Valid until: **2021-10-03**

Date, **2016-09-29**

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A1 / 04.11

VENTILATOR **S9**

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 12678-7-2019

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(Three Pages)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from August 01, 2019 to July 31, 2021.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 12678-7-2019
Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer
Manufacturer
ResMed Asia Pte. Ltd.
8 Loyang Crescent
No. 05 - 01
Singapore, SINGAPORE 509016

Legal Manufacturer/Manufacturer
RESMED LTD.
1 ELIZABETH MACARTHUR DRIVE
BELLA VISTA, New South Wales AUSTRALIA 2153

Name of Distributor
Distributor
RESMED CORP
9001 Spectrum Center Boulevard
San Diego, CA USA 92123

---END OF MANUFACTURER/DISTRIBUTOR LIST---

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 12678-7-2019
Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 3

Name of Manufacturer
Manufacturer
ResMed Asia Pte. Ltd.
8 Loyang Crescent
No. 05 - 01
Singapore, SINGAPORE 509016

Legal Manufacturer/Manufacturer
RESMED LTD.
1 ELIZABETH MACARTHUR DRIVE
BELLA VISTA, New South Wales AUSTRALIA 2153

Name of Distributor
Distributor
RESMED CORP
9001 Spectrum Center Boulevard
San Diego, CA USA 92123

Name of Product(s)
POSITIVE AIRWAY PRESSURE DEVICES
S9 Escape Auto
S9 Elite
S9 AutoSet
S9 Auto25
S9 AutoSet CS
S9 VPAP S
S9 VPAP ST
S9 VPAP ST-A
S9 VPAP TX
AirMini
AirStart 10 APAP
AirSense 10 Elite
AirSense 10 AutoSet
AirSense 10 AutoSet for Her
AirCurve 10 Vauto
AirCurve 10 CS Pacewave
Lumis 100 VPAP S
Lumis 150 VPAP ST
Lumis 150 VPAP ST-A
INVASIVE AND NON-INVASIVE VENTILATOR
Stellar 100
Stellar 150
Astral 100
Astral 150
HUMIDIFIERS
H4i
H5i
CPAP MASKS
NV AcuCare F1-0 Full Face Mask
NV AcuCare F1-1 Full Face Mask
NV AcuCare F1-4 Full Face Mask
AcuCare High Flow Nasal Cannula
AirFit F10 Full Face Mask
AirFit P10 Nasal Pillows Mask
AirMini P10 Setup Pack
AirFit N10 Nasal Mask
AirFit F20 Full Face Mask
AirMini F20 Setup Pack

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 12678-7-2019
Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 3
AirTouch F20 Full Face Mask
AirFit N20 Nasal Mask
AirMini N20 Setup Pack
AirFit N30i
AirFit F30 Full Face Mask
AirFit P30i
Mirage FX Nasal Mask
Mirage Softgel Nasal Mask
Mirage Micro Nasal Mask
Mirage Quattro Full Face Mask
Quattro FX Non-Vented Full Face Mask System
Quattro Air Non-Vented Full Face Mask System
Mirage Non-Vented Full Face Mask System
Ultra Mirage Non-Vented Full Face Mask System
Ultra Mirage Non-Vented Nasal Mask System
Pixi Pediatric Mask
Quattro FX Full Face Mask
Quattro Air Full Face Mask
Swift FX Nano Nasal Mask
Swift LT Nasal Pillows Mask
Hospital Nasal Mask
Hospital Full Face Mask
ACCESSORIES
ApneaLink Air
Adapter
Breathing Circuit
Cables
Cannula
Card Reader
Carry Bag
Circuit
ClimateLine Heated Tube
ClimateLine Max Oxy Heated Tube
ClimateLineAir Heated Tube
ClimateLineAir Oxy Heated Tube
Effort Belt
Mask Elbow
Filter
Filter Heater
FIO2
Gecko Pad
Heated Humidifier Base
HumidAir Cleanable Tub
Humidifier
Humidifier with Water Chamber
HumidX, Humid X Plus
Leakport / Leak Valve
Mask Headgear, Cushion, Frame, Chin Strap, Loops, Clips, Elbows
Mounting
Mouth Piece
Oximetry
Oxygen Monitoring Kit
Passover or Circulating Water Chamber
Power Cable
Power Supply Station / Unit (RPS)
Pressure Transducing System
Remote Alarm
RPS – Power Supply

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 12678-7-2019
Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 3
Sensors
SD Card
Temperature Probe
Tubing
Tubing Wrap
TX Link
USB Stick
Water Chamber
Water Trap
Wireless Module
XPOD
EasyCare Online/AirView/MyAir
ResScan, ResTraxx
---END OF PRODUCT LIST---

VIRUTAN

VENTILATOR **Stellar 100**

!NONINVASIVE VENTILATOR!

This model is designed for home use with minor respiratory failure. But in emergency cases, this model is certified to perform the functions of medical ventilation.

Leak (Lk):
0–120 L/min (1 L/min)

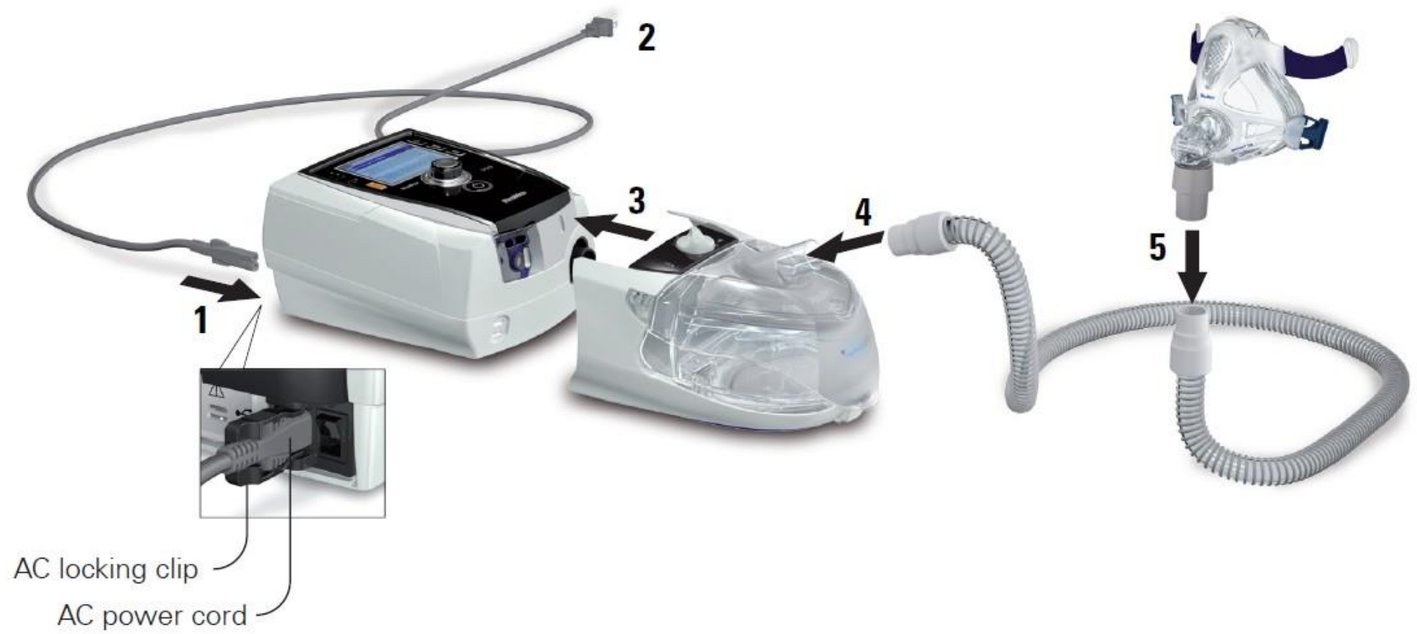
Respiratory Rate (RR)
5–60 bpm (1 bpm)

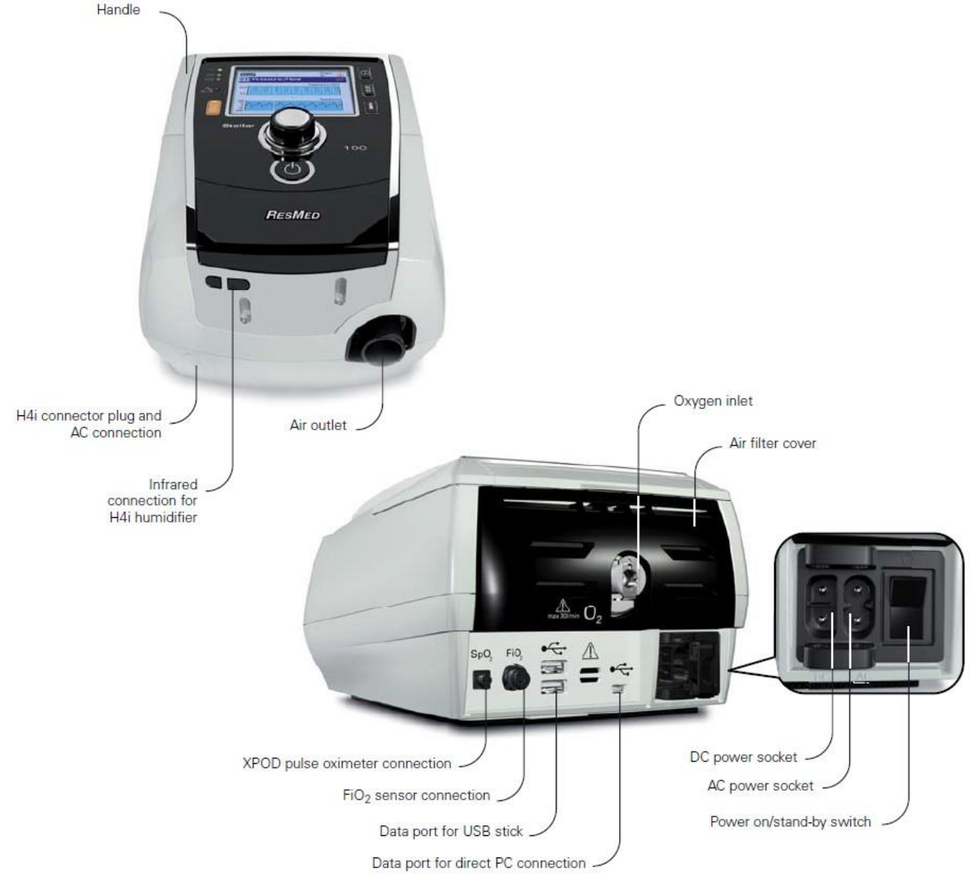
Inspiration Time (Ti):
0.1–4 sec (0.1 sec)

Tidal Volume (Vt): 50–3000 mL (10 mL)

Minute Ventilation (MV):
0.6–60 L/min (0.1 L/min)

Price on request





VIRUTAN

VENTILATOR **Stellar 100**

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

Product Service

EC Certificate

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

No. G1 049861 0158 Rev. 01

Manufacturer: **ResMed Pty Ltd**
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153
AUSTRALIA

Product Category(ies): **Positive Airway Pressure Devices, Ventilators, Humidifiers, Masks, Tubes and associated Accessories, Patient Data Recorders (Respiratory).**

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

Report No.: **JAQ235040503**

Valid from: **2019-12-04**
Valid until: **2024-05-26**

Date, **2019-12-04**

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

Product Service

EC Certificate

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

No. G1 049861 0158 Rev. 01

Facility(ies): **ResMed Pty Ltd**
1 Elizabeth Macarthur Drive, Bella Vista NSW 2153,
AUSTRALIA

-/-

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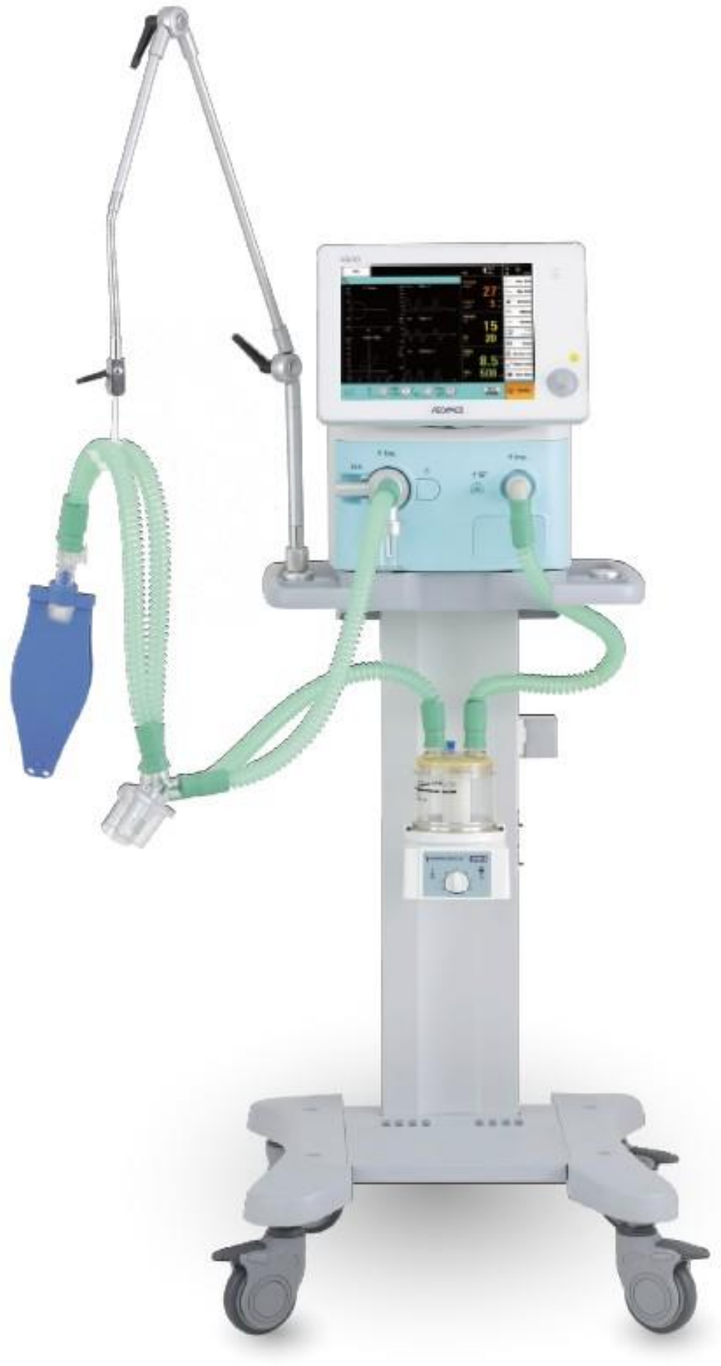
VIRUTAN

VENTILATOR **VG70**

Ventilation Modes				
	VCV(A/C)	PCV(A/C)	PRVC	SIMV(VCV)+PSV
	SIMV(PCV)+PSV	SIMV(PRVC)+PSV	SPONT/CPAP+PSV	
	BIVENT+PSV	NIV/CPAP	NIV-T	NIV-S/T
Parameters				
• Tidal Volume:	20~2000 ml			
• Respiration Rate:	1~80 bpm			
• Tinsp:	0.2~9 s			
• Tslope:	0~2 s			
• Tpause:	0~4 s			
• I:E Ratio:	1:10~4:1			
• FiO_2:	21%~100%			
• Trigger Sensitivity:	Pressure (-20~0 cmH_2O, above PEEP)			
	Flow (0.5~20 LPM)			
• PEEP:	0~35 cmH_2O			
• Psupport:	0~70 cmH_2O			
• Pinsp:	5~70 cmH_2O			
Special Procedures				
	Apnea Ventilation	Smart Suction	Manual Breath	
	Insp/ Exp Hold	$ETCO_2$ Measurement		
	Nebulization	Waveform Freeze		
Monitoring				
• Pressure Value:	Ppeak, Pplat, Pmean, Pmin, PEEP			
• Volume / Flow Value:	Vti, Vte, MV, MVspont			
• Time Value:	ftotal,fspont, I:E			
• Real Time Curves:	Pressure-Time, Flow-Time, Volume-Time waveforms			
	Pressure-Volume, Volume-Flow, Flow-Pressure loops			
• Gas Monitoring:	FiO_2, $ETCO_2$			
• Calculated Values:	Compliance(C)			
	Resistance(R)			
	MVleak			
	RSBI			
	WOB			
	PEEPi			
Alarm				
	Paw high / low	MVe high / low	Circuit disconnnect	
	FiO_2 high / low	Inspiration / Expiratory tidal volume low		
	High Respiration Rate	Apnea AC Failure	Nebulizer On	
	Low Battery	Air /O_2 supply down	High / Low PEEP	
	Leakage out of range	Occlusion		
Technical Data				
• Screen:	12" TFT color touch screen (detachable)			
• Supply Gas:	O_2, 0.28~0.6 MPa			
• Power Supply:	AC100~240 V, 50 Hz/60 Hz			
• Communication Interface:	RS-232 Port, Nurse call Port, Ethernet Port			
• Dimension (WxDxH):	322 mm x 375 mm x 366 mm (Main Unit)			
	547 mm x 675 mm x 950 mm (Cart)			
• Weight:	12.5 kg (Main Unit)			
	25 kg (Cart)			



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VENTILATOR **VG70**

Packing list:

1. VG70 Main Unit1
2. VG70-02 Connecting Plate for cart
3. Filter Assembly 1
4. VG70-03-EN Humidifier
7. VG70-04 Expiratory Valve Diaphragm
8 VG70-05 Check Diaphragm 1
9 Hinged Arm 1
10. O2 sensor 1
11. O2 sensor wrench 1
12. Power cord
    1 13
    Fuses 2
13. O2 high pressure pipeline
14. Air high pressure pipeline

Accessory parts:

1. Silicon Tube System, adult
2 Silicone Tube
3 Test Lung
4 Respiratory bag
5 Face mask

Price on request

Production time:
1000pcs - 40 days
2000pcs - 60 days

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VENTILATOR **VG70**

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EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)
No. G1 065725 0019 Rev. 01

Manufacturer: **Beijing Aeonmed Co., Ltd.**
Room 405
Basement 1 to 4th Floor of 901 Unit
Building 9, No.26 Outer Ring West Road
Fengtai District
100070 Beijing
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): **Anaesthetic Workstation, Vaporizer, Ventilator, Medical Air Compressor, Infusion Pump, Ceiling Pendant, Multi-Parameter Patient Monitor, Videoscope System, Patient Warming System.**

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

Report No.: BJ19859044

Valid from: 2019-07-16
Valid until: 2022-05-03

Date, 2019-07-16

Stefan Preiß
Head of Certification/Notified Body

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(Devices in Class IIa, IIb or III)
No. G1 065725 0019 Rev. 01

Facility(ies): Beijing Aeonmed Co., Ltd.
Room 405, Basement 1 to 4th Floor of 901 Unit, Building 9, No.26 Outer Ring West Road, Fengtai District, 100070 Beijing, PEOPLE'S REPUBLIC OF CHINA

Beijing Aeonmed Co.,Ltd.
No. 10 Chaobai Street, Yingbin Road West, Yanjiao Development Zone, 065201 Langfang City, Hebei Province, PEOPLE'S REPUBLIC OF CHINA

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VENTILATOR **YH830**

Specification	BreathCare PAP II				
Product Number	YH-450	YH-480	YH-820	YH-825	YH-830
Mode	CPAP	CPAP、Auto CPAP	CPAP、S、T、ST、VGPS	CPAP、S、T、ST、VGPS	CPAP、S、T、ST、VGPS
Pressure	4-20cmH_2O	4-20cmH_2O	4-20cmH_2O	4-25cmH_2O	4-30cmH_2O
Efficient humidifier	●	●	●	●	●
Smart Start/Stop	●	●	×	×	×
FPS-Tech	●	●	×	×	×
High Pressure Reminder	×	×	●	●	●
Leak Reminder	●	●	●	●	●
Asphyxiation Reminder	×	×	●	●	●
Trigger Adjustment	×	×	●	●	●
Cycle Adjustment	×	×	●	●	●
Slope Adjustment	×	×	●	●	●
Tidal Volume Adjustment	×	×	●	●	●
Altitude Adjustment	●	●	●	●	●
Leak Compensation	●	●	●	●	●
Data Management	●	●	●	●	●
Central Apnea Detection	●	●	×	×	×
Smart Humidification	●	●	●	●	●

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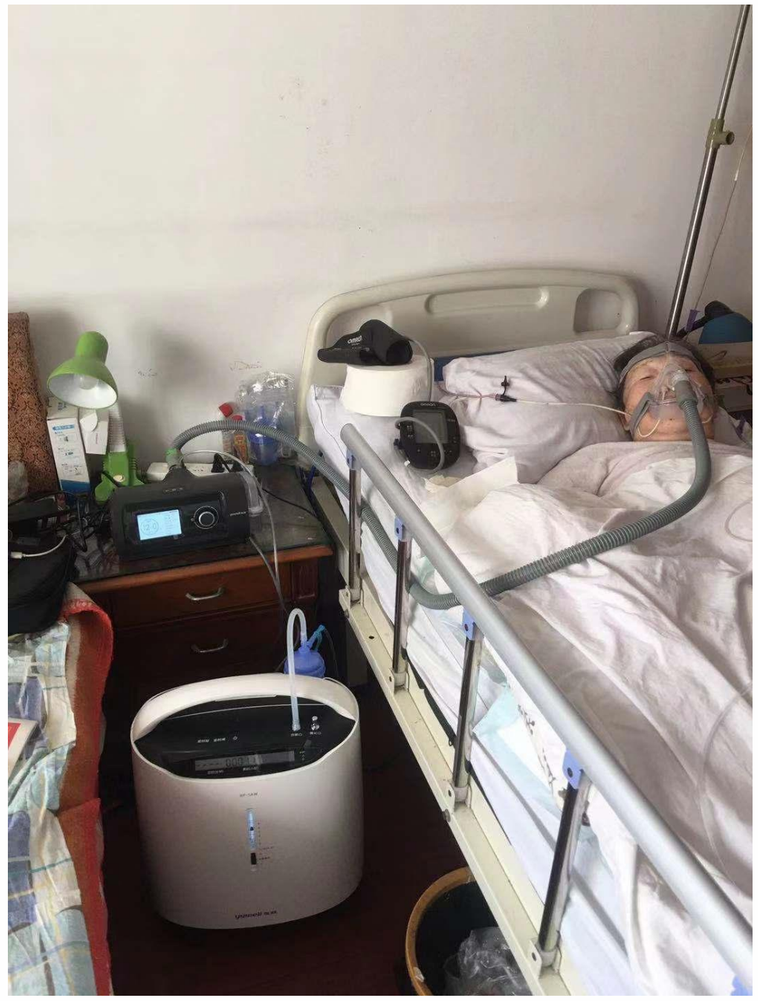
VENTILATOR **YH830**

!NONINVASIVE VENTILATOR!

This models is designed for home use with minor respiratory failure. But in emergency cases, this model is certified to perform the functions of medical ventilation.



Price on request
Min. 300 pcs in stock

VIRUTAN

VIRUTAN

A brand of – Global Trading GmbH
Wiesendamm 17, 13597 Berlin
Germany

Fon: **+49 30 863287990**
Mail: info@virutan.de

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