国药集团河南省医疗器械有限公司
SINOPHARM HENAN MEDICAL DEVICE CO., LTD.
国药器械成员企业

AGICO GROUP

Catelogue

National Pharmaceutical Group Henan Medical Equipment Co.,Ltd

Anyang General International Co., Ltd.

*Product List

1. Non-contact Infrared Body Thermometer1. Face Mask
2. Face mask
3. Protective goggles
4. Protective uniform
5. SARS-CoV-2 Nucleic Acid Detection Kit

*Certificate

*Company Picture

Non-contact Infrared Body Thermometer

Picture
Non-contact Infrared Body Thermometer

Face Mask

Picture
Face Mask FFP3

Picture
Face Mask N95

Picture
Face Mask FFP2

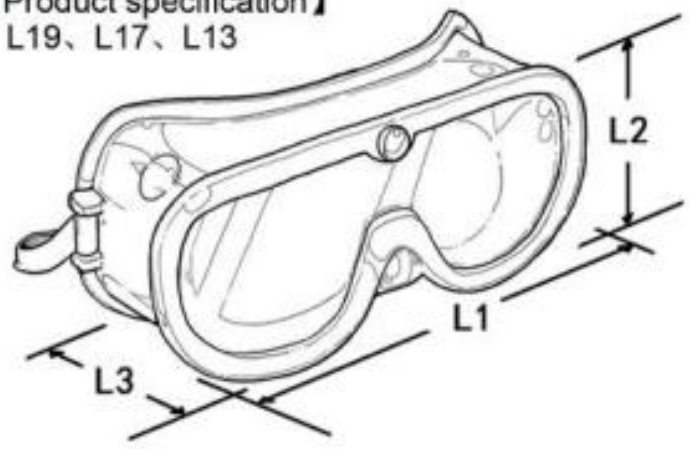
Picture
Disposable Surgical Mask

Protective Goggles

Picture
Protective Goggles

Specification
Protective Goggles

【Product specification】
L19、L17、L13



Unit: cm

Specifications	L1	L2	L3
L19	19±1	9±0.5	6±0.5
L17	17±1	8±0.5	6±0.5
L13	13±1	7±0.5	5±0.5

Protective Uniform

Picture

Disposable Medical Protective Clothing (Sterile)

Size:160,165,170,175,180,185

Picture

Disposable Medical Protective Clothing (Non-Sterile)

Size: 160,165,170,175,180,185

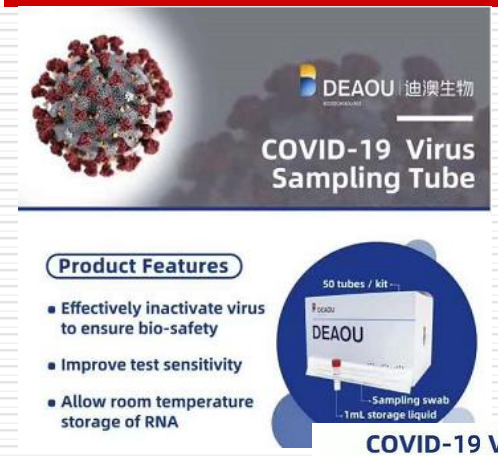
Picture
Gown

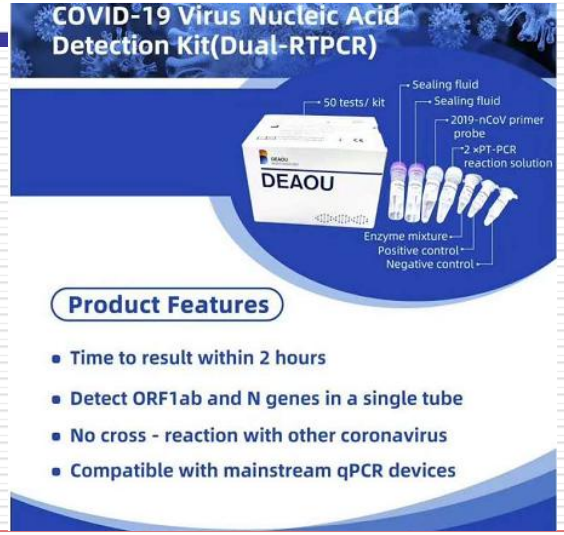
Size:160,165,170,175,180,185

SARS-CoV-2 Nucleic Acid Detection Kit

Picture

SARS-CoV-2 Nucleic Acid Detection Kit





国药集团河南省医疗器械有限公司 SINOPHARM HENAN MEDICAL DEVICE CO., LTD. AGICO GROUP

CE Identification

ZERTIFIKAT ◇ CERTIFICATE ◇ 认证证书 ◇ СЕРТИФИКАТ ◇ CERTIFICADO ◇ CERTIFICAT

CERTIFICATE

DECLARATION OF NOTIFICATION

AS THE EU REPRESENTATIVE, CORDIMAX DEUTSCHLAND GMBH(EUROPE) HEREWITH DECLARE THAT THE MANUFACTURER:

SHANDONG RIENTECH MEDICAL TECH CO., LTD.
BRANDEN INDUSTRIAL PARK, QIHE ECONOMIC &, DEVELOPMENT ZONE, 251100 QIHE, SHANDONG PROVINCE, P.R. CHINA.

HAS SIGNED THE EC DECLARATION OF CONFORMITY IN AGREEMENT WITH THE COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES, INCLUDING AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC, AND HAS SUBMITTED THE REQUIRED TECHNICAL DOCUMENTATION FOR THE FOLLOWING MEDICAL DEVICES:

NAME OF DEVICES	TYPE	REFERENCE NUMBERS
Medical Face Shield	L28、L32、L36	20200009
Medical Safety Goggles	L19、L17、L13	20200015
Disposable Medical Surgical Mask	PKZ-1、BKZ-1	20202140228
Isolation Gown	ONE-PIECE (S, M, L, XL, XXL, XXXL)、SPLIT (S, M, L, XL, XXL, XXXL)	20200013

THE NOTIFICATION TO THE DEUTSCHLAND COMPETENT AUTHORITIES HAS BEEN CARRIED OUT BY CORDIMAX, THE APPOINTED AUTHORIZED REPRESENTATIVE OF RIENTECH.
INFORMATION ON THE NOTIFICATION TO THE COMPETENT AUTHORITIES OF OTHER EUROPEAN COUNTRIES IS AVAILABLE UPON REQUEST.

AUTHORIZED EU REPRESENTATIVE
CORDIMAX DEUTSCHLAND GMBH(EUROPE)

NAME: HAIHONG GUO
POSITION: CEO

CORDIMAX DEUTSCHLAND GMBH

CORDIMAX DEUTSCHLAND GMBH(EUROPE)

CE Identification

FDA

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Name: SHANDONG RIENTECH MEDICAL TECHNOLOGY CO., LTD.

Add: Economic Development Zone, Qihe County, Dezhou, Shandong, China

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

The Owner/ Operator Number for this Registration is : 10063096

Listing No	Code	Device Name
D375314	OEA	Isolation Gown, Protective Clothing
D375316	BYG	Medical Face Shield,
D375313	HOY	Medical Safety Goggles
D375312	KEA	Disposable Medical Surgical Mask

ABmed will confirm that such registration remains effective upon request and presentation of this certificate urtil the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed makes no other representations or warranties, nor does this certificate make any representations or warranties to ary 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.

ABmed assumes nc liability to any person or entity in connection with foregoing.

Date of verification:Mar. 17, 2020

Date of expiration:Dec. 31, 2020

SH OFFICE

TEL:0086-21-50313932 Boyle Wang Phone:0086-18930777676 info@truthful.com.cn

ABMED SERVICE INC.

36 Soyth 18th Avenue, Suite A Brighton,CO USA 80601

TEL:213-375-3998 FAX:213-375-3998 info@abmed.com.cn

CE Certificate - Non-contact Infrared Body Thermometer

TÜVRheinland

EC Certificate

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

Registration No.: HD 60127617 0001

Report No.: 17029954 010

Manufacturer: Shenzhen Jiacom Technology Co., Ltd.
No. A6 Building, Silicon Valley Power, Qinghu Park,
Longhua Street, Bao'an District
518109 Shenzhen
China

Products:
- Blood Pressure Monitors
- Infrared Thermometers
- Compressor Nebulizers

Replaces Approval, Registration No.: HD 60110193 0001

Expiry Date: 2023-04-29

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.

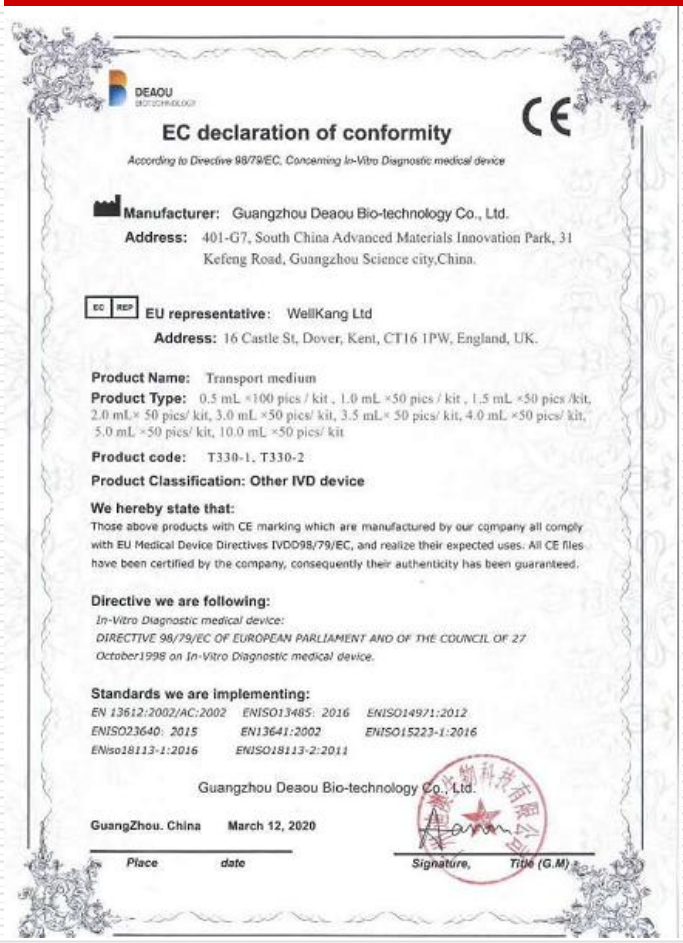
Effective Date: 2018-05-08

Date: 2018-05-08

Notified Body

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.

CE Identification- SARS-CoV-2 Nucleic Acid Detection Kit



DEAOU

EC declaration of conformity

CE

According to Directive 98/79/EC, Concerning In-Vitro Diagnostic medical device

Manufacturer: Guangzhou Deaou Bio-technology Co., Ltd.
Address: 401-G7, South China Advanced Materials Innovation Park, 31 Kefeng Road, Guangzhou Science city,China.

EC REP **EU representative:** WellKang Ltd
Address: 16 Castle St, Dover, Kent, CT16 1PW, England, UK.

Product Name: Transport medium
Product Type: 0.5 mL ×100 pics / kit , 1.0 mL ×50 pics / kit , 1.5 mL ×50 pics /kit, 2.0 mL× 50 pics/ kit, 3.0 mL ×50 pics/ kit, 3.5 mL× 50 pics/ kit, 4.0 mL ×50 pics/ kit, 5.0 mL ×50 pics/ kit, 10.0 mL ×50 pics/ kit
Product code: T330-1, T330-2
Product Classification: Other IVD device

We hereby state that:
Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directives IVDD98/79/EC, and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

Directive we are following:
In-Vitro Diagnostic medical device:
DIRECTIVE 98/79/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 October1998 on In-Vitro Diagnostic medical device.

Standards we are implementing:
EN 13612:2002/AC:2002 ENISO13485: 2016 ENISO14971:2012
ENISO23640: 2015 EN13641:2002 ENISO15223-1:2016
ENIso18113-1:2016 ENISO18113-2:2011

Guangzhou Deaou Bio-technology Co., Ltd.

GuangZhou. China March 12, 2020

Place date Signature, Title (G.M.)

DEAOU

EC declaration of conformity

CE

According to Directive 98/79/EC, Concerning In-Vitro Diagnostic medical device

Manufacturer: Guangzhou Deaou Bio-technology Co., Ltd.
Address: 401-G7, South China Advanced Materials Innovation Park, 31 Kefeng Road, Guangzhou Science city,China.

EC REP **EU representative:** WellKang Ltd
Address: 16 Castle St, Dover, Kent, CT16 1PW, England, UK.

Product Name: Transport medium
Product Type: 0.5 mL ×100 pics / kit , 1.0 mL ×50 pics / kit , 1.5 mL ×50 pics /kit, 2.0 mL× 50 pics/ kit, 3.0 mL ×50 pics/ kit, 3.5 mL× 50 pics/ kit, 4.0 mL ×50 pics/ kit, 5.0 mL ×50 pics/ kit, 10.0 mL ×50 pics/ kit
Product code: T330-1, T330-2
Product Classification: Other IVD device

We hereby state that:
Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directives IVDD98/79/EC, and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

Directive we are following:
In-Vitro Diagnostic medical device:
DIRECTIVE 98/79/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 October1998 on In-Vitro Diagnostic medical device.

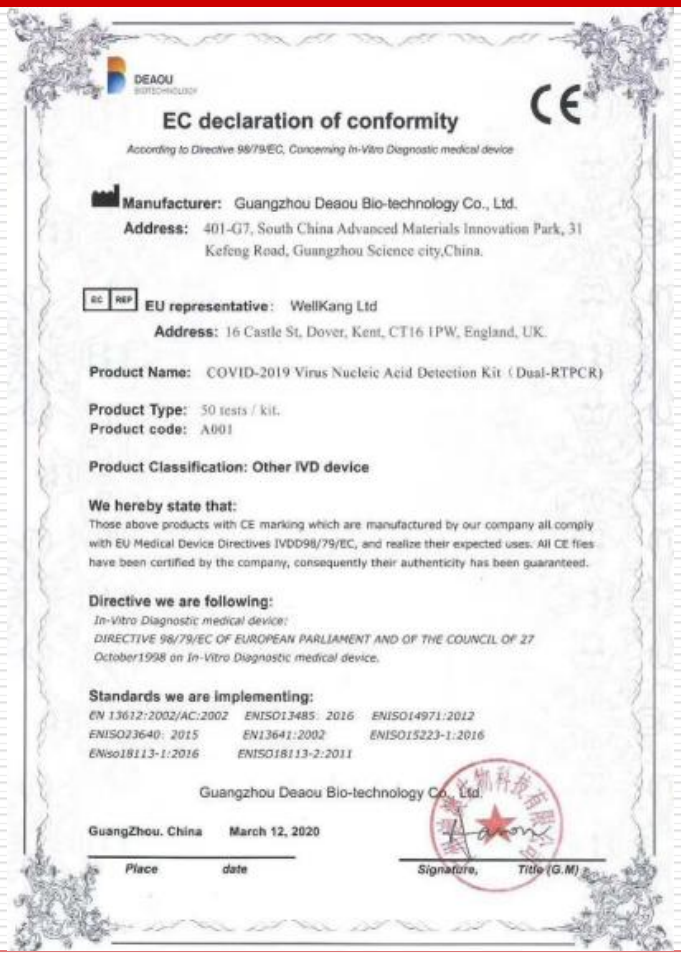
Standards we are implementing:
EN 13612:2002/AC:2002 ENISO13485: 2016 ENISO14971:2012
ENISO23640: 2015 EN13641:2002 ENISO15223-1:2016
ENIso18113-1:2016 ENISO18113-2:2011

Guangzhou Deaou Bio-technology Co., Ltd.

GuangZhou. China March 12, 2020

Place date Signature, Title (G.M.)

CE Identification- SARS-CoV-2 Nucleic Acid Detection Kit



DEAOU

EC declaration of conformity

CE

According to Directive 98/79/EC, Concerning In-Vitro Diagnostic medical device

Manufacturer: Guangzhou Deaou Bio-technology Co., Ltd.
Address: 401-G7, South China Advanced Materials Innovation Park, 31 Kefeng Road, Guangzhou Science city,China.

EC REP **EU representative:** WellKang Ltd
Address: 16 Castle St, Dover, Kent, CT16 1PW, England, UK.

Product Name: COVID-2019 Virus Nucleic Acid Detection Kit（Dual-RTPCR)

Product Type: 50 tests / kit.
Product code: A001

Product Classification: Other IVD device

We hereby state that:
Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directives IVDD98/79/EC, and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

Directive we are following:
In-Vitro Diagnostic medical device:
DIRECTIVE 98/79/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 October1998 on In-Vitro Diagnostic medical device.

Standards we are implementing:
EN 13612:2002/AC:2002 ENISO13485: 2016 ENISO14971:2012
ENISO23640: 2015 EN13641:2002 ENISO15223-1:2016
ENiso18113-1:2016 ENISO18113-2:2011

Guangzhou Deaou Bio-technology Co., Ltd.

GuangZhou. China **March 12, 2020**

Place *date* *Signature,* *Title (G.M)*

DEAOU

EC declaration of conformity

CE

According to Directive 98/79/EC, Concerning In-Vitro Diagnostic medical device

Manufacturer: Guangzhou Deaou Bio-technology Co., Ltd.
Address: 401-G7, South China Advanced Materials Innovation Park, 31 Kefeng Road, Guangzhou Science city,China.

EC REP **EU representative:** WellKang Ltd
Address: 16 Castle St, Dover, Kent, CT16 1PW, England, UK.

Product Name: Virus Sampling Tube

Product Type: 50 tests / kit.
Product code: T310-01, T310-02, T310-03, T310-04, T320-01, T320-02, T320-03, T320-04

Product Classification: Other IVD device

We hereby state that:
Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directives IVDD98/79/EC, and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

Directive we are following:
In-Vitro Diagnostic medical device:
DIRECTIVE 98/79/EC OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 October1998 on In-Vitro Diagnostic medical device.

Standards we are implementing:
EN 13612:2002/AC:2002 ENISO13485: 2016 ENISO14971:2012
ENISO23640: 2015 EN13641:2002 ENISO15223-1:2016
ENiso18113-1:2016 ENISO18113-2:2011

Guangzhou Deaou Bio-technology Co., Ltd.

GuangZhou. China **March 12, 2020**

Place *date* *Signature,* *Title (G.M)*

CE Identification

Attestation of Conformity

No. ICR Polska/M6101120

CE

Director Rafał Kalinowski

Warsaw, 11. 03. 2020.

Attestation of Conformity

No. ICR Polska/M6101020

CE

Director Rafał Kalinowski

Warsaw, 11. 03. 2020.

Quality System Identification

CERTIFICATE

质量管理体系认证证书

注册号：30817QZ0195R0M

兹证明

亿信医疗器械股份有限公司

统一社会信用代码：91410720307780577J

地址：长垣县高科技医疗器械产业园

管理体系符合

ISO13485:2016 标准

证书覆盖范围

类质范围内第Ⅰ类、第Ⅱ类医疗器械的生产

首次发证日期：2017 年 12 月 07 日

本次发证日期：2017 年 12 月 07 日

有 效 期 至：2020 年 12 月 06 日

HNC-China

华纳时代检测认证有限公司

HNC-CHINA
Huana Times Testing and Certification Co., Ltd.

CERTIFICATE

Certificate of Registration

Certificate No. : 30817QZ0195R0M

This is to certify that

ESound Medical Devices Co., Ltd.

Unified Social Credit Code: 91410720307780577J

Address: Changyuan County High-tech Medical Equipment Industrial Park, Henan Province, P.R. China

Has been awarded this certificate for compliance with the standard

ISO13485:2016 standard

Certification Scope

Production of Category I Medical Devices, Category II Medical Devices (Specific Products See Annex for Details)

Date of awarded certificate: Dec 7th,2017
Date of this certificate: Jun 4th,2019
Expired date: Dec 6th,2020

Note: This certificate is valid within the term of validity of administrative license and qualification license in accordance with the regulation of the country.
The certified organization must accept the surveillance audit (s). The audit shall be approved as effective before approving that this certificate can maintain to valid. Or and by Dec 9th,2018.
This certificate shall be used together with notice of maintaining certification and registration.
The validity of this certificate issued on this result from QR code.
Checking the validity from certificate authority website www.hnc-china.cn.
Checking the validity from CNCA website www.cnca.gov.cn.

HNC-China

Huana Times Testing and Certification Co., Ltd.

HNC-CHINA
Huana Times Testing and Certification Co., Ltd.

Inspection Report

No.202000413

河南省医疗器械检验所

检 验 报 告

产品名称:医用一次性防护服

检验类别:应急检验

委 托 方 :亿信医疗器械股份有限公司

河南省医疗器械检验所

检验报告首页

报告编号：202000413
样品编号：急202000029

共 3 页 第 1 页

样品名称	医用一次性防护服	样品数量	8包
	送样（√） 抽样（ ）	规格型号	180
委托方	亿信医疗器械股份有限公司		
生产地址	长垣县高科技医疗器械产业园	生产批号	200206613
		生产日期	2020年2月6日
标示生产单位	亿信医疗器械股份有限公司	产品编号	/
受检单位	亿信医疗器械股份有限公司	有效期	2022年1月
抽样单位	/	检验类型	应急检验
抽样基数	/	样品状态	正常
抽样日期	/	收样日期	2020.02.07
抽样地点	/	检验地点	本检验所试验室
抽样单编号	/	检验日期	2020.02.07-2020.02.08
检验项目	“抗合成血液穿透性”、“断裂强力”、“过滤效率”共3项		
检验依据	豫械注准20182140613《医用一次性防护服》		
检验结论	所检项目符合豫械注准20182140613《医用一次性防护服》的要求。 签发日期：2020年02月10日		
备注	1)报告中的“——”表示此项不适用，报告中“/”表示此项空白或未检。		

报告批准：

报告审核：

检 验：朱改婷

Inspection Report

No. 国20170066

河南省医疗器械检验所

检 验 报 告

产品名称：医用外科口罩

检验类别：国家监督抽验

委 托 方：国家食品药品监督管理总局

河南省医疗器械检验所

检验报告首页

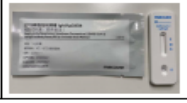
河南省医疗器械检验所

检验报告

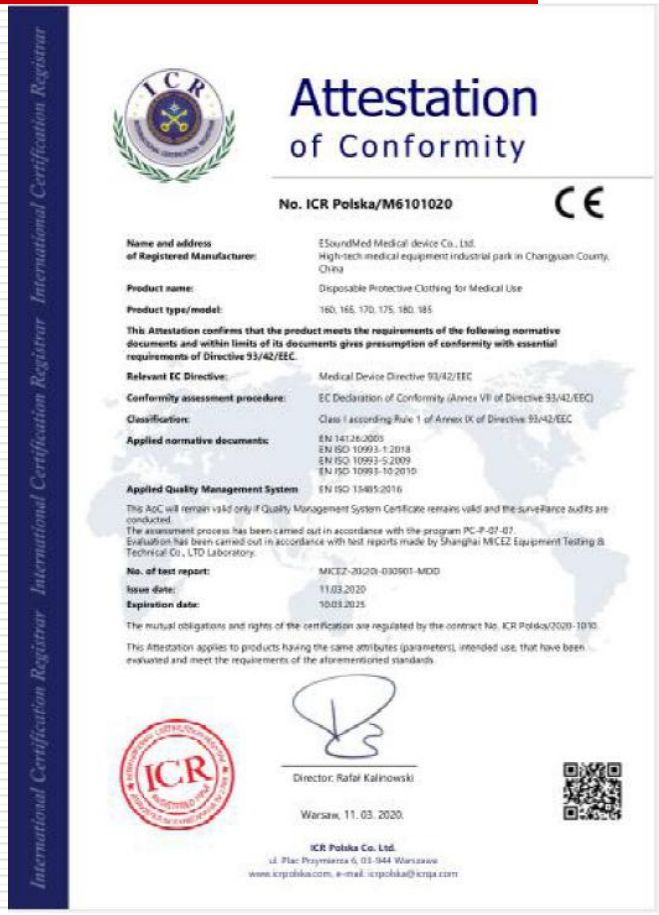
河南省医疗器械检验所

检验报告照片页

Packing Information

NO.	Ref	Description Item	Origin	Unit	Packing/ in paper cartons				
					Qty/carton (unit)	Carton size (cm*cm*cm)	Carton weight (kgs)	Carton qty	Volumn/cbm
1		Face Mask FFP2	China	box	10	69*52*30	5.8	500	53.82
2		Hazmat Suits cat III,	China	PC	40	0.1cbm	10	100	10
3		Protective Safety Goggles		PC	10	19x16.5x19cm	10	20	2
4		Non-contact Infrared Body Thermometer	China	PC	40	41.5*37.5*32cm	6.3	40	1.992
5		SARS-CoV-2 Nucleic Acid Detection Kit	China	box	0.5ml*100pcs 1.0ml*50pcs				
In total								660.00	67.812

CE Certificate



International Certification Registrar International Certification Registrar International Certification Registrar

Attestation of Conformity

No. ICR Polska/M6101020 CE

Name and address of Registered Manufacturer:	ESoundMed Medical device Co., Ltd. High-tech medical equipment industrial park in Changyuan County, China
Product name:	Disposable Protective Clothing for Medical Use
Product type/model:	160, 165, 170, 175, 180, 185

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 14126:2003 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2010
Applied Quality Management System	EN ISO 13485:2016

This AoC will remain valid only if Quality Management System Certificate remains valid and the surveillance audits are conducted.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co., LTD Laboratory.

No. of test report:	MICEZ-20020-030901-MDD
Issue date:	11.03.2020
Expiration date:	10.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-1010.

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

Director: Rafał Kalinowski

Warsaw, 11. 03. 2020.

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

Quality system Identification

CERTIFICATE

质量管理体系认证证书

注册号：30817QZ0195R0M

兹证明

亿信医疗器械股份有限公司

统一社会信用代码：91410728397790577J

地址：长垣县南蚬镇医疗器械产业园

管理体系符合

ISO13485：2016 标准

证书覆盖范围

资质范围内第Ⅰ类、第Ⅱ类医疗器械的生产

首次发证日期：2017 年 12 月 07 日
本次发证日期：2017 年 12 月 07 日
有 效 期 至：2020 年 12 月 06 日

HNC-China

华纳时代检测认证有限公司

HNC-CHINA
Huana Times Testing and Certification Co., Ltd.

CERTIFICATE

Certificate of Registration

Certificate No. : 30817QZ0195R0M

This is to certify that

ESound Medical Devices Co., Ltd.

Unified Social Credit Code: 91410728397790577J

Address: Changyuan County High-tech Medical Equipment Industrial Park, Henan Province, P.R. China.

Has been awarded this certificate for compliance with the standard

ISO13485:2016 standard

Certification Scope

Production of Category I Medical Devices, Category II Medical Devices (Specific Products See Annex for Details)

Date of awarded certificate: Dec 7th,2017
Date of this certificate: Jan 4th,2019
Expired date: Dec 6th,2020

HNC-China

Huana Times Testing and Certification Co., Ltd.

HNC-CHINA
Huana Times Testing and Certification Co., Ltd.

Company Picture

Company Picture

Company Picture

Company Picture

国药集团河南省医疗器械有限公司
SINOPHARM HENAN MEDICAL DEVICE CO., LTD.
国药器械成员企业

AGICO GROUP

Thanks You!

National Pharmaceutical Group Henan Medical Equipment Co.,Ltd

Anyang General International Co., Ltd.