QualiDefender
Soluções e Produtos de Higiene Profissional

Catalog of Medical Supplies

QualiDefender

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Rapid Tests

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Soluções e Produtos de Higiene Profissional

COVID-19 (SARS-CoV-2)

Antibody Test

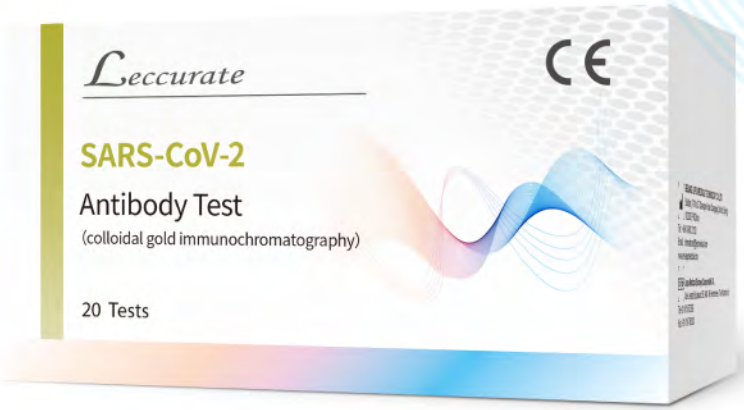
COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY

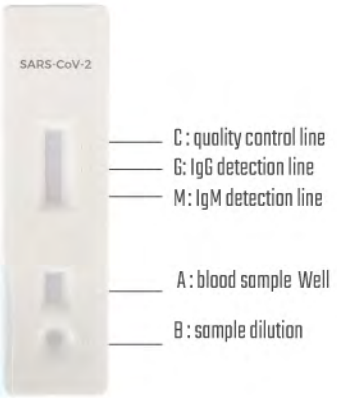
LEPU MEDICAL

PRECISION
High purity antibody with high precision

EFFICIENT
Test result in only 15 minutes

CONVENIENT
Appropriate for finger blood





[Sample Type] Blood/Plasma/Serum

[Sample Volume] 20ul/10ul/10ul

[Reaction Time] 15 minutes

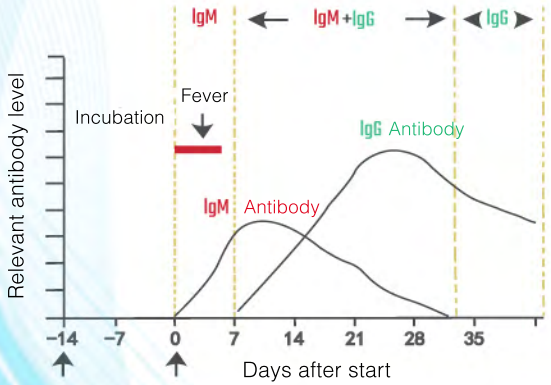
[Quantity per Package] 20 tests

[Storage Condition] 39,2 to 86°F

[Lifespan] 12 months

QualiDefender
Soluções e Produtos de Higiene Profissional

Antibody Test

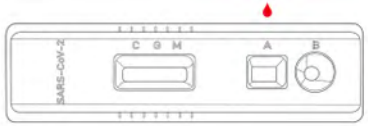


Antibodies are secreted after the virus has invaded.
Immunoglobulin M (IgM) is released initially, acting as an early sign of infection.
And Immunoglobulin G (IgG) later, due to a more specific and stronger reaction against the virus.

Usage Steps

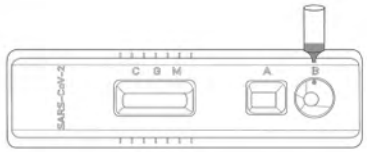
Step 1

Add 20ul blood sample or 10ul serum or plasma sample to sample compartment A



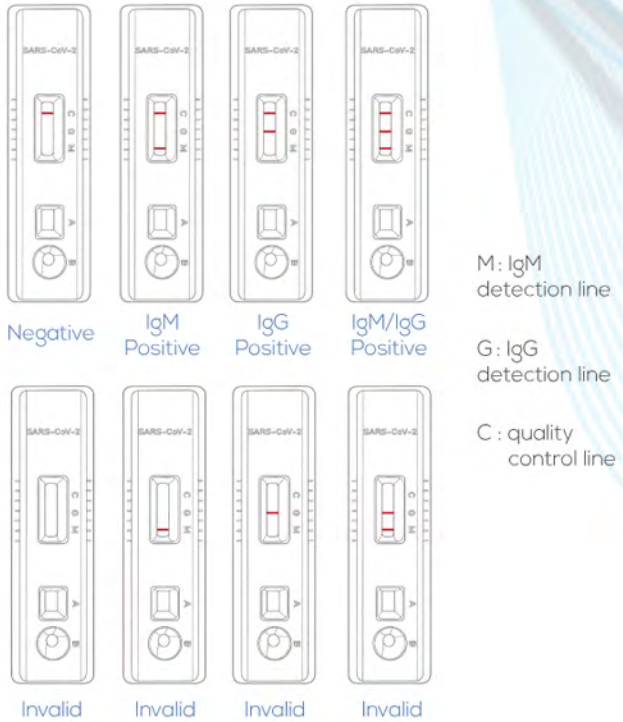
Step 2

Add two drops (about 80ul) of sample dilution to compartment B and start timing



Step 3

The test results should be read within 10-20 minutes.
DO NOT read the result after 20 minutes.



Lepu Medical Technology (Beijing) Co., Ltd.
Please contact regional sales for more information about this product.
Address: 37 Chaoqian Road, Changping District, Beijing, China 102200, Email: international@lepu-medical.com, Website: en.lepumedical.com

QualiDefender
Soluções e Produtos de Higiene Profissional

LEPU MEDICAL

Declaration of Conformity

Endereço de fabricação:	Beijing Lepu Medical Technology Co., Ltd. Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China
Representante europeu:	Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The Netherlands
Informações do produto:	SARS-CoV-2 Antibody Test (colloidal gold immunochromatography) Modelo: 20 tests por caixa
Classificação:	Outros
Rota de avaliação da conformidade:	Annex III of IVDD 98/79/EC Declaramos que os produtos acima mencionados atendem às disposições das seguintes Diretivas e Normas do Conselho EC. Todas as documentações comprobatórias são retidas sob a premissa do fabricante.
Diretiva Geral Aplicável:	Diretiva 98/79/EC DO PARLAMENTO EUROPEU E DO CONSELHO de 27 de outubro de 1998 em dispositivos médicos de diagnóstico in vitro.
Normas aplicadas:	Todas as normas harmonizadas aplicáveis (publicadas no diário oficial das Comunidades Europeias em 17 de novembro de 2017).
Place, date of issue	Beijing, P.R. China, 11 de março de 2020
Local, data de emissão	Qin Xiaowei

Beijing Lepu Medical Technology Co., Ltd.
Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China

CE

QualiDefender
Soluções e Produtos de Higiene Profissional

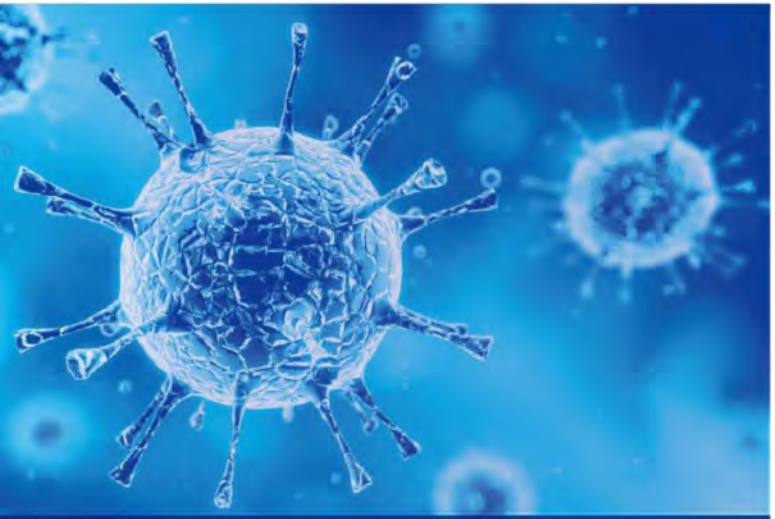
BIOHIT 必欧瀚
立足预防医学·创新诊疗路径

SARS-CoV-2IgM/IgG ANTI-BODOY TEST KIT (COLLOIDAL GOLD METHOD)

BRIEF INTRODUCTION

QualiDefender
Soluções e Produtos de Higiene Profissional

BIOHIT HealthCare
Innovating for Health



Background

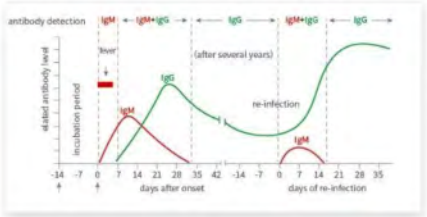
SARS-CoV-2

Coronaviruses are single-stranded, positive-sense RNA viruses with outer membrance, which are important pathogens of vertebrates, and can cause many acute and chronic diseases.

On February 1, 2020, the International Committee on the Taxonomy of Viruses named the new coronavirus as SARS-CoV-2. The infected people will have acute and severe respiratory diseases, accompanied by fever, cough, shortness of breath and dyspnea, and severe cases will lead to renal failure and even death.

SARS-CoV-2 IgM/IgG ANTIBODY DETECTION

When body is infected with the new coronavirus, the specific protein of the virus stimulates the immune system and lead to an antibody response, the first antibody to appear is IgM, and then the IgG antibody. From the general process of acute infection, when the IgG antibody appears, the concentration will continue to increase, the IgM will continue to decrease or even disappear, and the IgG antibody will exist for a long time. The simultaneous dynamic monitoring of IgM and IgG antibody can be used in the auxiliary diagnosis of new coronavirus infection.

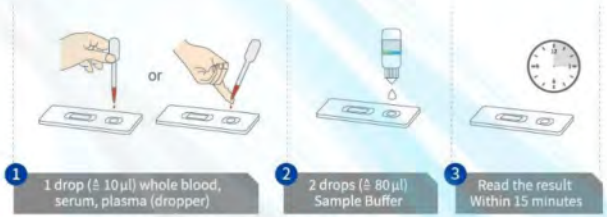


SPECIFICATION

- Sample volume: 10μl
- Rapid test time : 15mins
- Two result : IgM and IgG antibody

Product Name	Sample type	Storage temperature	Packaging size
SARS-CoV-2 IgM/IgG antibody test kit	Serum, Plasma, Whole blood, Peripheral blood	2°C-30°C	20 tests/kit 25tests/kit 50tests/kit 100tests/kit

Operation Procedure



Result Interpretation

Interpretation of the results	A	IgM(−) & IgG(−)	Negative
	B	IgM(+) & IgG(−)	Positive, indication of an acute infection
	C	IgM(+) & IgG(+)	Positive, indication of an ongoing infection
	D	IgM(−) & IgG(+)	Positive, indication of a past infection

Company Qualification

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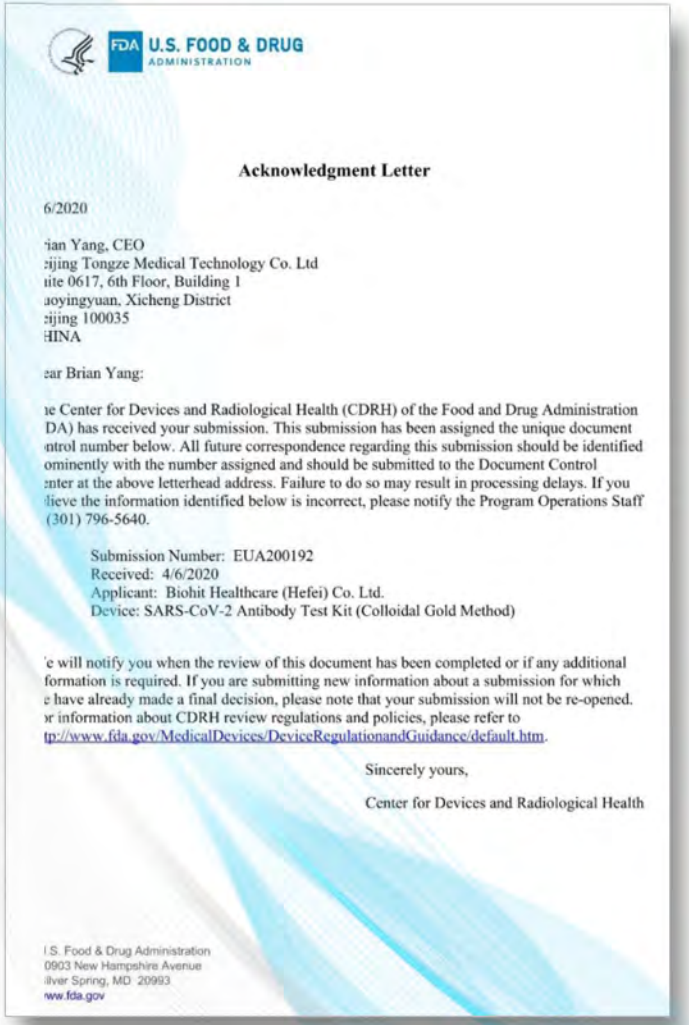
Soluções e Produtos de Higiene Profissional

BIOHIT HealthCare
Innovating for Health



U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

6/2020

ian Yang, CEO
ijing Tongze Medical Technology Co. Ltd
uite 0617, 6th Floor, Building 1
aoyingyuan, Xicheng District
ijing 100035
HINA

ear Brian Yang:

ie Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration DA) has received your submission. This submission has been assigned the unique document ntrol number below. All future correspondence regarding this submission should be identified ominently with the number assigned and should be submitted to the Document Control nter at the above letterhead address. Failure to do so may result in processing delays. If you lieve the information identified below is incorrect, please notify the Program Operations Staff (301) 796-5640.

Submission Number: EUA200192
Received: 4/6/2020
Applicant: Biohit Healthcare (Hefei) Co. Ltd.
Device: SARS-CoV-2 Antibody Test Kit (Colloidal Gold Method)

e will notify you when the review of this document has been completed or if any additional formation is required. If you are submitting new information about a submission for which e have already made a final decision, please note that your submission will not be re-opened. r information about CDRH review regulations and policies, please refer to tp://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

I.S. Food & Drug Administration
0903 New Hampshire Avenue
ilver Spring, MD 20993
ww.fda.gov

EC Declaration of Conformity

According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer: BIOHIT HealthCare (Hefei) Co., Ltd.
Address: Building D9 floor 1-4,Innovation Park,No.800 West Wangjiang Road, High-Tech Zones, Hefei, Anhui,PR China

European Representative: Wellkang Ltd
Address: 16 Castle St,Dover,CT16 1PW, UK

Product: SARS-CoV-2 IgM/IgG antibody test kit (Colloidal Gold Method)
Classification: Others

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

General Applicable Directive DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

The above declaration of conformity is issued under the sole responsibility of the manufacturer.

General Manager: Liu Feng

CE

Hefei, March 18th, 2020
(Place and Date of Issue)

Liu Feng
(Signature and Seal)

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

TÜV SÜD Product Service

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

Certificate

No. Q5 094093 0003 Rev. 01

Holder of Certificate: Biohit Healthcare (Hefei) Co., Ltd
Building D9 floor1-4, Innovation Park
West Wangjiang Road No.800
High-Tech Zones
230088 Hefei, Anhui
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Biohit Healthcare (Hefei) Co., Ltd
Building D9 floor1-4, Innovation Park, West Wangjiang Road No.800, High-Tech Zones, 230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of Assay kits and related Control solutions based on ELISA, Immunochromatographic and Chemiluminescent Method, and Fluorescence Immunoassay Analyzer**

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.: SH20103205

Valid from: 2020-05-04
Valid until: 2022-04-05

Date, 2020-05-04

Christoph Dicks
Head of Certification/Notified Body

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Page 1 of 1
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QualiDefender
Soluções e Produtos de Higiene Profissional

Masks KN95 and 3 Layered Surgical

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Soluções e Produtos de Higiene Profissional

International Certification Registrar International Certification Registrar International Certification Registrar

Certificate

No. ICR Polska/P6301813

CE

Name and address of certificate owner: [redacted]

Name and address of manufacturer: [redacted]

Product name: [redacted]

Product types: [redacted]

Product trademark: [redacted]

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 United Testing Technology (Hong Kong) Limited

No. of test reports: A20032602SR-01

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

Fiscal Year 2020

CERTIFICATE OF REGISTRATION

This Certifies that:

Was registered with US **FDA** (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:

Shenzhen PTSI Testing Co., Ltd.

Owner/Operator Number: **10064861**
Product Name: **Single-Use Medical Face Mask**
Product Listing Number: **D380196**
Date of verification: **March 27, 2020**

This Certificate affirms that Shenzhen PTSI Testing 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 stated above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. Shenzhen PTSI Testing Co., Ltd. assume no liability to any person or entity in connection with the foregoing. Shenzhen PTSI Testing Co., Ltd. is a private revocation agent and is not affiliated with the US Food and Drug Administration.

Shenzhen PTSI Testing Co., Ltd.
http://www.ptsi-lab.com
4008-516-519
FDA website: www.fda.gov

SHENZHEN PTSI TESTING CO., LTD. Approved

(James Liu, Deputy General Manager)
March 27, 2020

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Soluções e Produtos de Higiene Profissional

Infrared Thermometer

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Soluções e Produtos de Higiene Profissional

Product name	Infrared thermometer
Product category	Human body thermometer
weight	**100g(Battery free)**
Measuring distance	3-5CM
measurement accuracy	±0.2℃
Automatic shutdown time	30second
Measuring time	0.5second
Battery type	AAA-Dry battery(Battery No.7)
Service life	More than 100 thousand
temperature range	**Body model：32℃-42.5℃(89.6℉ -108.5℉)**
Authentication	CE RoHS FC FDA

Company Qualification

BCTC Building & 1-2F, East of 6 Building, Pengzhou Industrial Park, Bao'an District, Shenzhen,

Certificate of Compliance

Certificate Number: BCTC2003001499CN1

Applicant : Medical Equipment Co., Ltd
Building 15, smart terminal mobile phone industrial park, intersection of Renmin Road and Xingang Avenue , Zhengzhou airport economic ... zone, Zhengzhou City, Henan Province , China

Manufacturer : Medical Equipment Co., Ltd
... terminal mobile phone industrial park, intersection of Renmin Road and Xingang Avenue , Zhengzhou airport economic comprehensive test zone, Zhengzhou City, Henan Province , China

Product : Infrared thermometer

M/N :

Trademark :

Test Standard : EN 60601-1-2:2015

The EUT described above has been tested according to the listed standards and found in compliance with the council EMC directive 2014/30/EU. The manufacturer should consider this device meets requirement of MDD directive 93/42/EEC. The observations and test results referenced from this Certificate are relevant only to the sample tested. This Certificate is for the exclusive use of BCTC's Client and is provided pursuant to the ... BCTC and its Client. This Certificate is part of the full test report(s) and should be rea... report No. : BCTC2003001499E.

CE

Zero Zhou/Manager
Mar. 27, 2020

This certificate is for the exclusive use of BCTC's client and is provided pursuant to agreement between BCTC and its client. BCTC's responsibility and liability are limited to the terms and conditions of the agreement. The observation and test results referenced from this certificate are relevant only to the sample tested. This Certificate by itself does not imply that the material, product, or service is or has ever been a BCTC certification program.

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

... Community Industrial Avenue,
Fuhai Street, Bao'an District, Shenzhen, China

Certificate of Compliance

Certificate Number: ZKT-2020030275C

Certificate's Holder : ... Medical Equipment Co., Ltd
Building 16, smart terminal mobile phone industrial park, intersection of Renmin Road and Xingang Avenue, Zhengzhou airport economic comprehensive test zone, Zhengzhou City, Henan Province, China

Manufacturer : Hen... cal Equipment Co., Ltd
Buil... rminal mobile phone industrial park, inte... in Road and Xingang Avenue, Zhe... conomic comprehensive test zone, Zhengzhou City, Henan Province, China

Trade Mark

Product : Infrared thermometer
Model(s)

Test Method : IEC 62321-3-1:2013& IEC 62321-5:2013&
IEC 62321-4:2013+A1:2017& IEC 62321-7-1:2015
&IEC 62321-7-2:2017 & IEC 62321-6:2015

The following products have been tested by us and found in ... with the (RoHS) Directive 2011/65/EU Annex II amending ... and amending Annex (EU)2017/2102. It is possible to use CE ... the conformity with this Directive.It is only valid in connection wi... er. ZKT-2020030275R.

CE

Manager
Mar. 25, 2020

This Certificate of Conformity is based on 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 to be observed.

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

... Community Industrial Avenue,
China

SUPPLIER'S DECLARATION OF CONFORMITY

Certificate Number: ZKT-2020030261C

Certificate's Holder : ... Medical Equipment Co., Ltd
Building 16, smart terminal mobile phone industrial park, intersection of Renmin Road and Xingang Avenue, Zhengzhou airport economic comprehensive test zone, ... Province, China

Manufacturer : ... Equipment Co., Ltd
Building 16, smart terminal mobile phone industrial park, intersection of Renmin Road and Xingang Avenue, Zhengzhou airport economic comprehensive test zone, Zhengzhou City, Henan Province, China

Trade Mark :

Product : Infrared thermometer
Model(s)

Test Standard : FCC Part 15 B,
ANSI C63.4:2014

This Attestation of Compliance is issued on a voluntary basis for electrical equipment below the voltage limits of FCC standard. The essential requirement are fulfilled accordingly based on the technical specifications applicable at the time of issuance. See also notes overleaf. It is only valid in connection with the test report number: ZKT-2020030261E.

FC

Luke Xie
Manager
Mar. 25, 2020

This Certificate of Conformity is based on 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 to be observed.

QualiDefender
Soluções e Produtos de Higiene Profissional

Fingertip Pulse Oximeter

Fingertip Pulse Oximeter

QualiDefender
Soluções e Produtos de Higiene Profissional

MAIN FEATURES:

- OLED color display, easy to read
- SpO_2, PR, PI and bar graph can be displayed on the screen
- Automatically power off within 8 seconds when no finger detected
- Low power indicator
- 4 Kinds of color available (Blue, Green, Cyan and Yellow)

SPECIFICATIONS:

Oxygen Saturation	Measuring Range	70%~99%
	Accuracy	80%~99%, ±2% 70%~79%, ±3% No requirement for below 70%
	Resolution	1%
Pulse Rate	Measuring Range	30bpm~240bpm
	Accuracy	30bpm~240bpm,±2bpm or ±2% (select larger)
	Resolution	1bpm
Blood Perfusion Index	Measuring Range	0.3%~20%
Battery Model		2 AAA Batteries
Power Consumption		< 30mA
Battery Life		Continuous use for 25 hours

Blue

Green

Cyan

Yellow

QualiDefender
Soluções e Produtos de Higiene Profissional

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

TÜV SÜD Product Service

Certificate

No. Q5 101251 0001 Rev. 00

Holder of Certificate: [redacted] Intelligent Medical Equipment Co.,Ltd.
North side of floor 3, BLD 9
BaiWangxin High-Tech Industrial Park
[redacted] Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): [redacted] Intelligent Medical Equipment Co.,Ltd. [redacted] High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518055 Shenzhen, Guangdong Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Fingertip pulse oximeter, Digital ultrasonic imaging scanner.**

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.: BJ1812101

Valid from: 2018-12-03
Valid until: 2021-12-02

Date, 2018-12-03

Stefan Preiß

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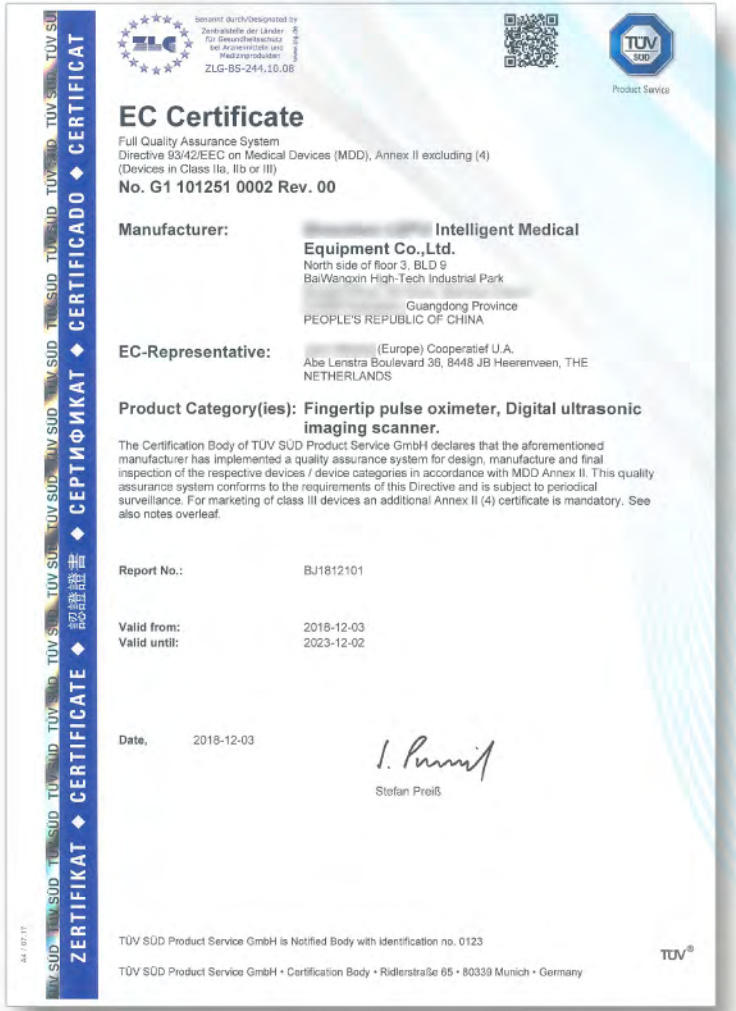
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



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

TÜV SÜD 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 101251 0002 Rev. 00

Manufacturer: [redacted] Intelligent Medical Equipment Co.,Ltd.
North side of floor 3, BLD 9
BaiWangxin High-Tech Industrial Park
[redacted] Guangdong Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: [redacted] (Europe) Coöperatief U.A.
Abe Lenstra Boulevard 36, 8448 JB Heerenveen, THE NETHERLANDS

Product Category(ies): **Fingertip pulse oximeter, Digital ultrasonic imaging scanner.**

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.: BJ1812101

Valid from: 2018-12-03
Valid until: 2023-12-02

Date, 2018-12-03

Stefan Preiß

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

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

TÜV®

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