# SUPPLIER VERIFICATION REPORT

## XXX (Beijing) Co., Ltd.
## XX（北京）XX 有限公司

**REPORT OWNER: XXX**
**REPORT RELEASE DATE: 17-04-2020**
**REPORT NUMBER: QA-S-00529-00031-01**

.

Scope:
Business License review
Export License review
Management and Products Certificates

QCADVISOR
SHIP BETTER PRODUCTS

Published by: Vita Consulting Ltd. Room D8, 7/F, Block 3, Golden Dragon Ind. Center, 172-180 Tai Lin Pai Road, Kwai Chung, N.T. Hong Kong

Email: contact@qcadvisor.com Website: www.qcadvisor.com

| CLIENT (REPORT OWNER) | |
|---|---|
| COMPANY NAME | **XXX** |
| ADDRESS | XXX<br>XXX<br>SP<br>13412227<br>BRAZIL |
| CONTACT | XXXX |

| INFORMATION PROVIDED BY THE CLIENT | |
|---|---|
| PROVIDED COMPANY NAME (EN) | **XXX(Beijing) Co., Ltd.** |
| PROVIDED COMPANY NAME (CN) | Not provided |
| PROVIDED ADDRESS | XXX |
| PROVIDED CONTACT DETAILS | Tel:86-XXX Fax:86-XXX |
| PRODUCT(S) REQUIRED | - |
| BUSINESS LICENCE COPY | ☐ PROVIDED ☒ NOT PROVIDED |
| REMARKS | None |
| OTHER DOCUMENTS AND CERTIFICATES PROVIDED BY CLIENT (REPORT OWNER) | |
| None | |





Published by: Vita Consulting Ltd. Room D8, 7/F, Block 3, Golden Dragon Ind. Center, 172-180 Tai Lin Pai Road, Kwai Chung, N.T. Hong Kong

| REVIEW SUMMARY | | |
|---|---|---|
| **SECTION** | **FINDINGS AND REMARKS** | **FURTHER ACTIONS** |
| **FACTORY INFORMATION** | Legal Chinese name of the company registered in China is XX（北京）XX 有限公司<br>Business License is available and verified against government database.<br>Export License is not provided for review. Registration certificate of customs declaration unit and Export Certification for Patient Monitor were provided.<br>For Business scope see the details below. | Waiting for Export License copy for final review. |
| **QUALITY MANAGEMENT CERTIFICATES** | Company provided ISO 13485 certificate for Patient Monitor<br>The certificate provided by XX (Beijing) Co., Ltd. Contact is under another company name (see details below).<br>XXX (Beijing) Co., Ltd. contact confirmed this company was their company subsidiary.<br>Company Name: Shenzhen XX Co., Ltd.<br>Floor 5, XX<br>XXX Industrial Park<br>XXX Street<br>Nanshan District<br>518110 Shenzhen<br>People's Republic of China | They can provide other certificates upon request based on the product category. |
| **PRODUCT CERTIFICATES** | Company provided CE (Directive 93/42/EEC on Medical Devices (MDD)) certificate for Patient Monitor (they can provide other certificates upon request based on the product category).<br>The certificate provided by XXX (Beijing) Co., Ltd. Contact is under another company name (see details below). XXX (Beijing) Co., Ltd. contact confirmed this company was their company subsidiary.<br>Company Name: Shenzhen XX Co., Ltd.<br>Floor 5, XX<br>XXX Industrial Park<br>XXX Street<br>Nanshan District<br>518110 Shenzhen<br>People's Republic of China | They can provide other certificates upon request based on the product category. |
| **OTHER CERTIFICATES** | Company also provided CE Technical Documentation Review Report and FDA Pre Emergency Use Authorization for SARS-CoV-2 Antibody Test. These documents are not final certificate of conformance. | - |
| **OTHER REMARKS** | PLEASE SEE CATALOGS AND ADDITIONAL DOCUMENTS ATTACHED TO THIS REPORT | - |

| **ACTUAL FINDINGS REVIEW** | | | |
|---|---|---|---|
| VERIFIED COMPANY NAME (EN) | XXXX (Beijing) Co., Ltd. | | |
| VERIFIED COMPANY NAME (CN) | XXX□ □ □ □ XX□ □ □ □ | | |
| VERIFIED ADDRESS | □ □ □ XXXX □ 37 □ | | |
| SUPPLIER CONTACT PERSON | XXXX | | |
| SUPPLIER CONTACT DETAILS | +86 XXX | | |
| EMAIL | XXX@XXXX.com | | |
| WECHAT | +86 XXX | | |
| WHATSAPP | N/A | | |
| **Business License verified information** | | ☒ PROVIDED ☐ NOT PROVIDED | |
| Company Name on the B.L | XX□ □ □ □ XXX□ □ □ □ | B.L Registration Number | XXXXXXXXXXXX |
| Issue/Expiry Date | 1999/06/11 to 2057/06/10 | City of Issuance | Beijing |
| Legal Representative | XXX<br>XXX | Status | ☒ Valid<br>☐ Invalid |
| Address | □ □ □ XXXX □ 37 □ | Verified against government database | ☒ YES<br>☐ NO<br>☐ N/A |
| Scope of Business in Chinese (Original) | □ 产□ 销□ □ 疗□ □ □ □ □ □ □ □ 疗<br>□ □ □ □ □ □ □ □ 术□ 发□ □ □ □ 产<br>产□ □ □ 术□ 询□ 务□ □ □ 产□ □ 进<br>□ □ □ □ 术进□ □ □ □ □ □ □ □ □ □<br>□ 卖□ □ □ □ 额许□ 证□ □ □ 专项规<br>□ □ □ □ □ □ □ □ □ □ □ 规□ 办<br>□ □ □<br>□ □ □ 须经□ □ □ 项□ □ 经□ □ □ 门<br>□ □ □ □ □ □ □ □ □ □ □ 经营□ 动 | Scope of Business. Translation from Chinese to English | Production and sale of medical devices and their accessories; technical development of medical devices and their accessories; provision of technical consulting services for self-produced products; import and export of the above products; technology import and export; commission agency (excluding auctions, management of quota licenses, The commodities managed under special regulations shall be handled in accordance with relevant national regulations). (Projects that need to be approved according to law will carry out business activities according to the approved content after approval by the relevant departments. |
| Remarks | Registered Capital □ □ 资□ : XXX □ □ □ □ □ □ IPO□ | | |
| **Export License (E.L)** | | ☐ PROVIDED ☒ NOT PROVIDED | |
| Company Name on the E.L | - | E.L Registration Number | - |
| Issue/Expiry Date | - | City of Issuance | - |
| Scope of Business (Products that can be exported under this license) | - | Verified against government database | ☐ YES<br>☐ NO<br>☒ N/A |
| Remarks | - | | |
| **Registration certificate of customs declaration unit** | | ☒ PROVIDED ☐ NOT PROVIDED | |
| Company Name on the document | XX□ □ □ □ XXX□ □ □ □ | Reference | XXXXX |
| Issue/Expiry Date | 1999/09/14 | City of Issuance | Beijing |
| Scope of Business (Products that can be exported under this license) | N/A | Verified against government database | ☐ YES<br>☐ NO<br>☒ N/A |
| Remarks | - | | |

| | | | |
|---|---|---|---|
| **Export Certification for Patient Monitor** | | ☒ PROVIDED ☐ NOT PROVIDED | |
| Company Name on the document | Shenzhen XXX Co., Ltd. | Reference | XXXX |
| Issue/Expiry Date | 2019/07/01 to 2020/04/08 | City of Issuance | XXX |
| Scope of Business (Products that can be exported under this license) | Patient Monitor<br>Pulse Oximeter<br>Spot Check Monitor | Export License verified against government database | ☐ YES<br>☐ NO<br>☒ N/A |
| Remarks | - | | |
| **ISO 13485-Patient Monitor** | | ☒ PROVIDED ☐ NOT PROVIDED | |
| Issuing Body | TUV SUD | Reference | Q5 049076 0015 Rev. 01 |
| Issue/Expiry Date | 10 Oct. 2019<br>02 Oct. 2022 | Status | ☒ Valid<br>☐ Invalid |
| Applied Standard / Legislation / Directive | EN ISO 13485 :2016<br>Medical devices – Quality management systems | Certificate verified and consistent against Issuing body database | ☒ YES<br>☐ NO<br>☐ N/A |
| Scope | Design and Development, Production and Distribution of Patient Monitor, Vital Signs Monitor, Fingertip Oximeter, Handheld Pulse Oximeter, Wrist Oximeter, Easy ECG Monitor, Spot-Check Monitor, SpO2 Probe, Sleep Screener, Multi Parameter Monitors for Capnography and Pulse Oximetry. | | |
| Remarks | The certificate provided by XXX (Beijing) Co., Ltd. Contact is under another company name (see details below).<br>XXX (Beijing) Co., Ltd. contact confirmed this company was their company subsidiary.<br>Company Name: Shenzhen XX Co., Ltd.<br>Floor 5, XX<br>XXX Industrial Park<br>XXX Street<br>Nanshan District<br>518110 Shenzhen<br>People's Republic of China | | |
| **EC CERTIFICATE - Patient Monitor** | | ☒ PROVIDED ☐ NOT PROVIDED | |
| Issuing Body | TUV SUD | Reference | G1 049076 0016 Rev. 02 |
| Issue/Expiry Date | 07 Jan. 2020<br>26 May. 2024 | Status | ☒ Valid<br>☐ Invalid |
| Applied Standard / Legislation / Directive | Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III) | Certificate verified and consistent against Issuing body database | ☒ YES<br>☐ NO<br>☐ N/A |
| Scope | Patient Monitor, Vital Signs Monitor, Fingertip Oximeter, Handheld Pulse Oximeter, Wrist Oximeter, Easy ECG Monitor, Spot-Check Monitor, SpO2 Probe, Sleep Screener, Multi Parameter Monitors for Capnography and Pulse Oximetry. | | |
| Remarks | The certificate provided by XXX (Beijing) Co., Ltd. Contact is under another company name (see details below).<br>XXX (Beijing) Co., Ltd. contact confirmed this company was their company subsidiary.<br>Company Name: Shenzhen XX Co., Ltd.<br>Floor 5, XX<br>XXX Industrial Park<br>XXX Street<br>Nanshan District<br>518110 Shenzhen<br>People's Republic of China | | |
| **CE Technical Documentation Review Report - InVitro** | | ☒ PROVIDED ☐ NOT PROVIDED | |
| Issuing Body | TUV SUD | Reference | XXX |
| Issue/Expiry Date | 07 Jan. 2020<br>26 May. 2024 | Status | ☐ Valid<br>☐ Invalid<br>☒ Not verified |
| Applied Standard / Legislation / Directive | Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III) | Certificate verified and consistent against Issuing body database | ☐ YES<br>☐ NO<br>☒ N/A |
| Scope | Sars-Cov2 Antibody test kit | | |
| Remarks | This document is not a final compliance certificate but a Documentation Review report only.<br>Final Certificate of conformance is not available yet. | | |

| **Pre Emergency Use Authorization** | | ☒ PROVIDED ☐ NOT PROVIDED | |
|---|---|---|---|
| Issuing Body | FDA | Reference | XXX |
| Issue/Expiry Date | 07 Jan. 2020<br>26 May. 2024 | Status | ☐ Valid<br>☐ Invalid<br>☒ Not verified |
| Applied Standard / Legislation / Directive | CFR - Code of Federal Regulations Title 21 | Certificate verified and consistent against Issuing body database | ☐ YES<br>☐ NO<br>☒ N/A |
| Scope | Sars-Cov2 Antibody test kit | | |
| Remarks | This document is not a final compliance certificate but an acknowledgment Letter of submission only.<br>Submission Number: XXX<br>Received: 3/26/2020<br>Applicant: XXX (Beijing) Co., LTD<br>Device: SARS-CoV-2 Antibody Test (Colloidal Gold Immunochromatography) | | |

Business License provided by supplier

Registration certificate of customs declaration unit

QG07

# 中华人民共和国海关
# 报关单位注册登记证书

海关注册编码:
组织机构代码:
企 业 名 称:

企 业 住 所:

企业经营类别:
注册登记日期:
法定代表人:
有 效 期:

中华人民共和国海关总署监制

Export Certification for Patient Monitor


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


ATTACHMENT OF
EXPORTATION C

| SN | Product (s) |
|---|---|
| 1 | 多参数监护仪 Patient Monitor |
| 2 | 脉搏血氧饱和度仪 Pulse Oximter |


| SN | Product (s) |
|---|---|
| 3 | Patient Monitor |
| 4 | Spot-Check Monitor |
| / | / |

| ISO 13485-Patient Monitor | Verification against Issuing body database |
|---|---|

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

TÜV SÜD Product Service

**Certificate**

No. [redacted]

**Holder of Certificate:** Shenzhen [redacted]

**Facility(ies):** [redacted]

**Certification Mark:**

**Scope of Certificate:** **Design and Development, Production and Distribution of Patient Monitor, Vital Signs Monitor, Fingertip Oximeter, Handheld Pulse Oximeter, Wrist Oximeter, Easy ECG Monitor, Spot-Check Monitor, SpO2 Probe, Sleep Screener, Multi Parameter Monitors for Capnography and Pulse Oximetry**

**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.:** [redacted]

**Valid from:** [redacted]
**Valid until:** [redacted]

**Date,** 2019-10-10

Stefan Preiß
Head of Certification/Notified Body

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

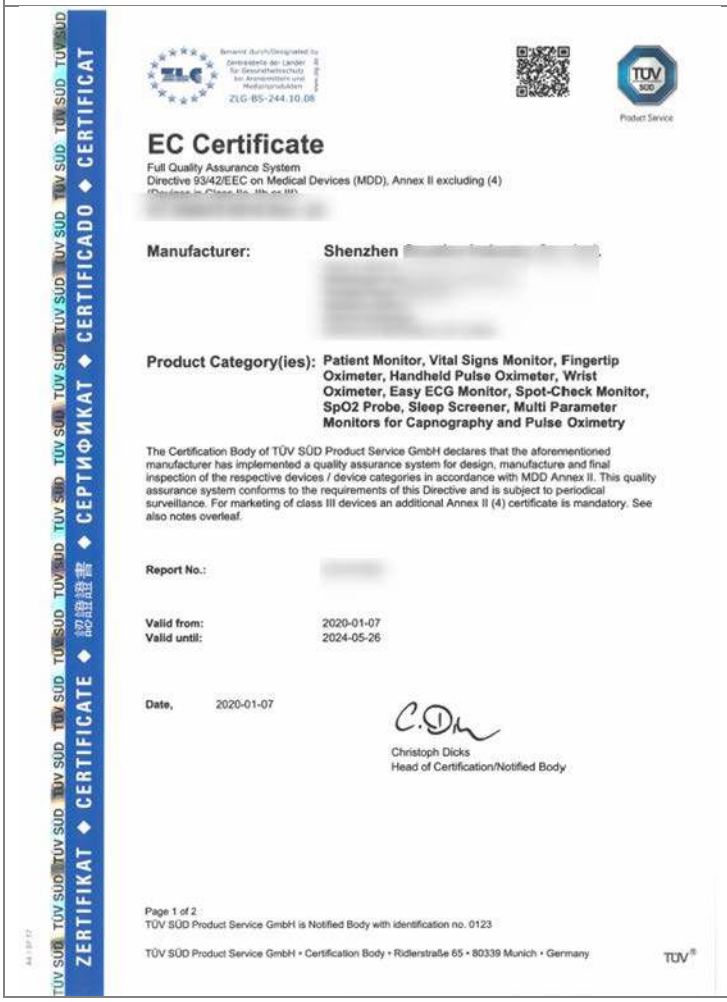
TÜV®

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

Q5 049076 0015 Rev. 01 X

| | |
|---|---|
| Certificate | [redacted] |
| Type | QM Certificates |
| Type name | QM System ISO 13485 |
| Certification body | TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany |
| Certificate holder | [redacted] |
| Product | General Medical Devices |
| Models | Design and Development, Production and Distribution of Patient Monitor, Vital Signs Monitor, Fingertip Oximeter, Handheld Pulse Oximeter, Wrist Oximeter, Easy ECG Monitor, Spot-Check Monitor, SpO2 Probe, Sleep Screener, Multi Parameter Monitors for Capnography and Pulse Oximetry |
| Issued | 10.10.2019 |
| State | Valid |

| EC CERTIFICATE - Patient Monitor | Verification against Issuing body database |
|---|---|



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

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)

**Manufacturer:** Shenzhen

**Product Category(ies):** **Patient Monitor, Vital Signs Monitor, Fingertip Oximeter, Handheld Pulse Oximeter, Wrist Oximeter, Easy ECG Monitor, Spot-Check Monitor, SpO2 Probe, Sleep Screener, Multi Parameter Monitors for Capnography and Pulse Oximetry**

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.:**

**Valid from:** 2020-01-07
**Valid until:** 2024-05-26

**Date,** 2020-01-07

Christoph Dicks
Head of Certification/Notified Body

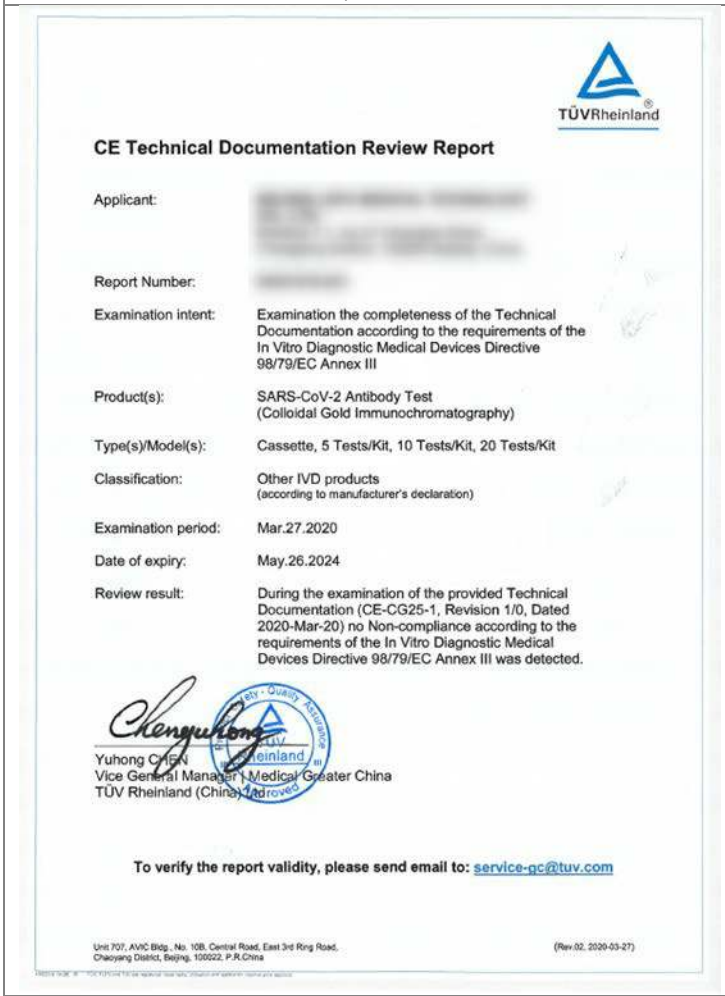
Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

G1 049076 0016 Rev. 02

| | |
|---|---|
| Certificate | |
| Type | Directive Certificates for Systems |
| Type name | EC Certificate - MDD - Annex II excluding (4) |
| Certification body | TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany |
| Certificate holder | |
| Product | Patient Monitoring Equipment |
| Models | Patient Monitor, Vital Signs Monitor, Fingertip Oximeter, Handheld Pulse Oximeter, Wrist Oximeter, Easy ECG Monitor, Spot-Check Monitor, SpO2 Probe, Sleep Screener, Multi Parameter Monitors for Capnography and Pulse Oximetry |
| Issued | 07.01.2020 |
| State | Valid |

| CE Technical Documentation Review Report - InVitro | Pre Emergency Use Authorization |
|---|---|



TÜVRheinland

**CE Technical Documentation Review Report**

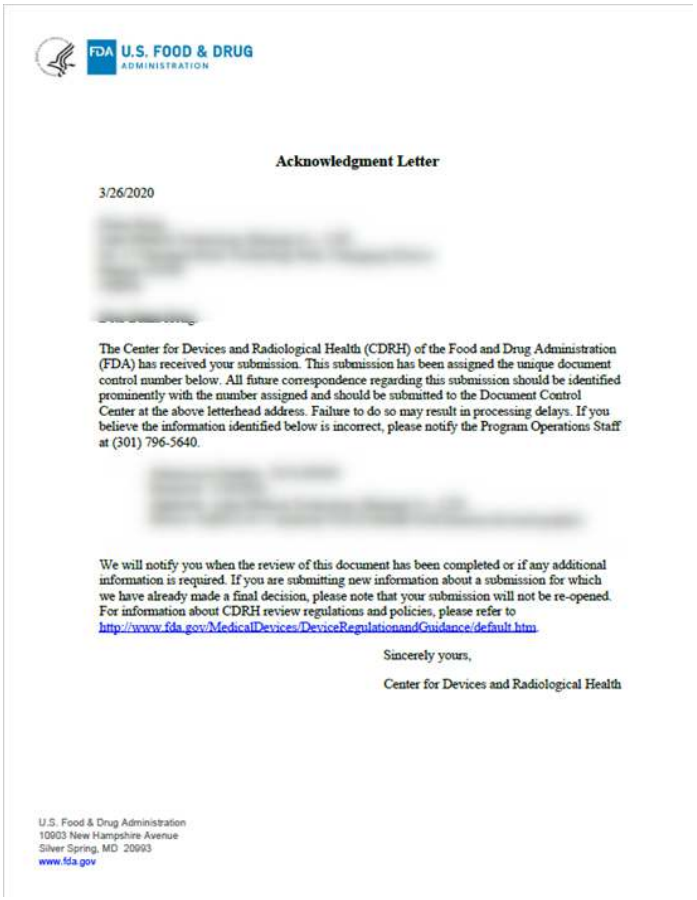
| | |
|---|---|
| Applicant: | [redacted] |
| Report Number: | [redacted] |
| Examination intent: | Examination the completeness of the Technical Documentation according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III |
| Product(s): | SARS-CoV-2 Antibody Test (Colloidal Gold Immunochromatography) |
| Type(s)/Model(s): | Cassette, 5 Tests/Kit, 10 Tests/Kit, 20 Tests/Kit |
| Classification: | Other IVD products (according to manufacturer's declaration) |
| Examination period: | Mar.27.2020 |
| Date of expiry: | May.26.2024 |
| Review result: | During the examination of the provided Technical Documentation (CE-CG25-1, Revision 1/0, Dated 2020-Mar-20) no Non-compliance according to the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC Annex III was detected. |

Yuhong CHEN
Vice General Manager | Medical Greater China
TÜV Rheinland (China) Ltd.

**To verify the report validity, please send email to: service-gc@tuv.com**

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing, 100022, P.R.China

(Rev.02, 2020-03-27)



FDA U.S. FOOD & DRUG ADMINISTRATION

**Acknowledgment Letter**

3/26/2020

[redacted]

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

[redacted]

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

Sincerely yours,

Center for Devices and Radiological Health

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

| List of attached documents to this report |
|---|
| XX business Licence-CN |
| XX BUSINESS LICENCE-NEW |
| ISO 13485-Patient Monitor |
| CE-Patient Monitor |
| XXX Company Profile 2020_XXX |
| UP-7000 |
| Covid-19-SARS-CoV-2 Antibody XXX |
| Infrared Forehead Thermometer_XXX |
| FDA Pre-Emergency Use Authorization |
| Export Certification |
| Registration certificate of customs declaration unit |
| CE certification |

| **REPORT RELEASE INFORMATION** | | | |
|---|---|---|---|
| SERVICE DATE* | 17-04-2019 | REVIEW DONE BY | Nancy Wan |
| REPORT RELEASE DATE* | 17-04-2019 | REPORT RELEASED BY | Habib Rkha |

*China Time