

VERIFICATION OF CONFORMITY

S/N: 005574

No.: ICR/VC/HM230686

Name and address of

Applicant

Infitek Co., Ltd.

Rm. 2014, Bldg. 3, Ligaoguojihuayuan, No. 1222, West Aoti Road, Lixia District, Jinan,

Shandong, China

Name and address of

manufacturer:

Infitek Co., Ltd.

Rm. 2014, Bldg. 3, Ligaoguojihuayuan, No. 1222, West Aoti Road, Lixia District, Jinan,

Shandong, China

Product name:

Autoclaves & Sterilizers

Product types:

BCS Series, BGS Series, STGB Series, STP-A Series, STP-E Series, STP-M Series,

STC Series, STB-N Series, STB-BZ Series, STB-BB Series, STB-B-2A Series, STB-B-2B Series, STB-B-3A Series, STB-B-3C Series, STB-NA Series, STB-B-3D Series,

STB-B-3B Series, STB-N Series, STH Series, STH-ND Series, STV Series, STV-All Series, STV-II Series, STV-II Series, STV-IV Series, STV-APV Series, DOF-HAS II Series, DOF-HAS E Series, DOF-HAS Series, STV-PV Series, STB Series, STP Series, BII Series, BIK Series, STA Series,

STA-FM Series, STA-WM Series, BR Series, BI Series, BI-S Series, BI-H Series, BI-EO Series, STP-Series, STP-A Series, STP-M Series, STP-E Series, BCS-A Series,

BCS-B Series, STUV Series

Product trademark:

Infitek

Verification was carried within following scope:

Information on the Declaration of Conformity:

Result: Legislation: Standard:

✓ LVD EN 61010-1:2010+A1:2019
✓ EMC EN IEC 61326-1:2021

The assessment process has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test report: EC.INFI.20230626-R111

EC.INFI.20230626-R112

Tests conducted by: Infitek Co., Ltd.

Issue date: 29.06.2023 **Expiration date:** 28.06.2028

Remarks:

• VoC was issued on voluntary basis and does not imply meeting all essential requirements listed in Declaration of Conformity.

ICR Co. Ltd. www.icrqa.com www.icrpolska.com cert@icrqa.com



CEO, ICR Co., Ltd.





CERTIFICATE OF CONFORMITY ENVIRONMENTAL MANAGEMENT SYSTEM CERTIFICATION

NO. 10424E00415R0S

This is to certify that the Environmental Management System of

INFITEK CO., LTD.

(Registered Address: Rm. 2014, Bldg. 3, Ligaoguojihuayuan, No.1222, West Aoti Road, Lixia District, Jinan, Shandong Audit Address: 17th Floor, Mingsheng Building, No. 2117 Xinluo Street, High-tech Zone, Jinan City, Shandong Province Unity Social Credit Code:91370102MA3WDYWA0B Postal Code:250100)

is in conformity with:

GB/T 24001-2016/ISO 14001:2015

This system is valid to:

* SALES OF CLASS I AND CLASS II MEDICAL DEVICES, LABORATORY EQUIPMENTS AND ANALYZERS, ECOLOGICAL ENVIRONMENT MONITORING, TESTING, ANALYSIS INSTRUMENTS AND METERS, GAS AND LIQUID SEPARATION AND PURIFICATION EQUIPMENT AND RELATED OHS MANAGEMENT ACTIVITIES BY INFITEK CO., LTD. LOCATED AT 17TH FLOOR, MINGSHENG BUILDING, NO. 2117 XINLUO STREET, HIGH-TECH ZONE, JINAN CITY, SHANDONG PROVINCE (ACCORDING TO THE SCOPE OF MEDICAL DEVICE BUSINESS RECORD CERTIFICATE FOR THOSE REQUIRING QUALIFICATION) *

Further clarifications regarding the scope of this certificate and the applicability of GB/T 24001-2016/ISO 14001:2015 requirements may be obtained by this body organization. Certificate in the state regulations administrative license, qualification, mandatory product certification received within the validity period, the regular supervision review of the case effectively. This certificate information is available on the official website of the agency and Certification & Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

Issue

date:04-25-2024

Term of validity: 04-25-2024 TO 04-24-2027

Representative of the company (Director):

S. p. chua





中国认可 国际互认 管理体系

> **MANAGEMENT SYSTEM** CNAS C104-M

labeling

inspection place inspection place
The certified organization shall accept supervision and audit in accordance with the regulations, and the certificate shall remain valid after being verified as qualified Address: NO.2 Zhuyuan Road, High-tech Zone, Qingdao City, China

Web: www.seatone.net.cn

Wechat certificate query



CERTIFICATE OF CONFORMITY OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEM CERTIFICATION NO. 10424S00108R0S

This is to certify that the Occupational Health And Safety Management System of

INFITEK CO., LTD.

(Registered Address: Rm. 2014, Bldg. 3, Ligaoguojihuayuan, No.1222, West Aoti Road, Lixia District, Jinan, Shandong Audit Address: 17th Floor, Mingsheng Building, No. 2117 Xinluo Street, High-tech Zone, Jinan City, Shandong Province Unity Social Credit Code:91370102MA3WDYWA0B Postal Code:250100)

is in conformity with:

GB/T 45001-2020/ISO 45001:2018

This system is valid to:

* SALES OF CLASS I AND CLASS II MEDICAL DEVICES, LABORATORY EQUIPMENTS AND ANALYZERS, ECOLOGICAL ENVIRONMENT MONITORING, TESTING, ANALYSIS INSTRUMENTS AND METERS, GAS AND LIQUID SEPARATION AND PURIFICATION EQUIPMENT AND RELATED OHS MANAGEMENT ACTIVITIES BY INFITEK CO., LTD. LOCATED AT 17TH FLOOR, MINGSHENG BUILDING, NO. 2117 XINLUO STREET, HIGH-TECH ZONE, JINAN CITY, SHANDONG PROVINCE (ACCORDING TO THE SCOPE OF MEDICAL DEVICE BUSINESS RECORD CERTIFICATE FOR THOSE REQUIRING QUALIFICATION) *

Further clarifications regarding the scope of this certificate and the applicability of GB/T 45001-2020/ISO 45001:2018 requirements may be obtained by this body organization. Certificate in the state regulations administrative license, qualification, mandatory product certification received within the validity period, the regular supervision review of the case effectively. This certificate information is available on the official website of the agency and Certification & Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

Issue

date:01-26-2024

Term of validity: 01-26-2024 TO 01-25-2027

Representative of the company (Director):

S. p. chua







中国认可 国际互认 管理体系

labeling

MANAGEMENT SYSTEM CNAS C104-M

inspection place inspection place
The certified organization shall accept supervision and audit in accordance with the regulations,

and the certificate shall remain valid after being verified as qualified Address: NO.2 Zhuyuan Road, High-tech Zone, Qingdao City, China

Vechat certificate quer





CERTIFICATE OF CONFORMITY **OUALITY MANAGEMENT SYSTEM CERTIFICATION**

NO. 10424Q00652R1S

This is to certify that the Quality Management System of

INFITEK CO., LTD.

(Registered Address: Rm. 2014, Bldg. 3, Ligaoguojihuayuan, No.1222, West Aoti Road, Lixia District, Jinan, Shandong Audit Address: 17th Floor, Mingsheng Building, No. 2117 Xinluo Street, High-tech Zone, Jinan City, Shandong Province Unity Social Credit Code:91370102MA3WDYWA0B Postal Code:250100)

is in conformity with:

GB/T 19001-2016/ISO 9001:2015

This system is valid to:

* SALES OF CLASS I AND CLASS II MEDICAL DEVICES, LABORATORY EQUIPMENTS AND ANALYZERS, ECOLOGICAL ENVIRONMENT MONITORING, TESTING, ANALYSIS INSTRUMENTS AND METERS, GAS AND LIQUID SEPARATION AND PURIFICATION EQUIPMENT (ACCORDING TO THE SCOPE OF MEDICAL DEVICE BUSINESS RECORD CERTIFICATE FOR THOSE REQUIRING QUALIFICATION) *

Further clarifications regarding the scope of this certificate and the applicability of GB/T 19001-2016/ISO 9001:2015 requirements may be obtained by this body organization. Certificate in the state regulations administrative license, qualification, mandatory product certification received within the validity period, the regular supervision review of the case effectively. This certificate information is available on the official website of the agency and Certification & Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

Issue

date:04-25-2024

Term of validity: 04-25-2024 TO 11-11-2027

Representative of the company (Director):

S. p. chua







中国认可 国际互认 管理体系

MANAGEMENT SYSTEM CNAS C104-M

labeling

inspection place inspection place
The certified organization shall accept supervision and audit in accordance with the regulations, and the certificate shall remain valid after being verified as qualified Address: NO.2 Zhuyuan Road, High-tech Zone, Qingdao City, China

Wechat certificate query

Web: www.seatone.net.cn



13485



Certificate NO: 2335ES02103M

Award

Infitek Co., Ltd.

Rm. 2014, Bldg. 3, Ligaoguojihuayuan, No. 1222, West Aoti Road, Lixia District, Jinan, Shandong

The Medical management system of the above

organizations has been reviewed and complied with

ISO 13485:2016

Requirements of applicable clauses of Medical management system standards

This system is valid for the

R&D, production and sales of class I and class II medical device, laboratory device, ecological environment monitoring and testing device, gas and liquid separation and purification device

Under the condition that the certificate holder's management system continues to Meet the management system standards, the certification deadline is three years. And query on www.cce-iso.com. The validity of this certificate must be confirmed by the center through regular supervision and review.

Date of issue: July 12, 2023

Valid period: July 11, 2026











Spain European Certified organization Limited

WWW.CCE-ISO.COM