



China National Accreditation Service for Conformity Assessment
LABORATORY ACCREDITATION CERTIFICATE
(Registration No. CNAS L13309)

Lab of STERIS Sterilization Technologies (Suzhou) Ltd.

(Legal Entity: STERIS Sterilization Technologies (Suzhou) Ltd.)

No.26, Xinchang Road, Wuzhong District, Suzhou, Jiangsu, China

is accredited in accordance with ISO/IEC 17025: 2017 General Requirements for the Competence of Testing and Calibration Laboratories(CNAS-CL01 Accreditation Criteria for the Competence of Testing and Calibration Laboratories) for the competence to undertake the service described in the schedule attached to this certificate.

The scope of accreditation is detailed in the attached schedule bearing the same registration number as above. The schedule forms an integral part of this certificate.

Effective Date: 2026-04-27

Expiry Date: 2032-04-26

Signed on behalf of China National Accreditation Service for Conformity Assessment

陳建良

China National Accreditation Service for Conformity Assessment (CNAS) is authorized by Certification and Accreditation Administration of the People's Republic of China (CNCA) to operate the national accreditation schemes for conformity assessment. CNAS is a signatory of the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) and the Asia Pacific Accreditation Cooperation Mutual Recognition Arrangement (APAC MRA).

The validity of the certificate can be checked on CNAS website at <https://www.cnas.org.cn/english/index.html>

Name: Lab of STERIS Sterilization Technologies (Suzhou) Ltd.

Address: No.26, Xinchang Road, Wuzhong District, Suzhou, Jiangsu,
China

Registration No. CNAS L13309

Effective Date: 2026-07-06 Expiry Date: 2032-04-26

SCHEDULE 2 ACCREDITED SIGNATORIES AND SCOPE

No	Name	Authorized Scope of Signature	Note	Effective Date
1	Sophie Yu	all test files of application for accreditation		2026-07-06
2	Sally Yu	Chemical test filed of application for accreditation		2026-07-06
3	Karen Xu	all test filed of application for accreditation		2026-07-06
4	Eva Chen	all test filed of application for accreditation (Except for chemical test filed)		2026-07-06



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The scope of the accreditation in Chinese remains the definitive version.

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Accreditation Criteria: ISO/IEC 17025:2017 and relevant requirements of CNAS

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SCHEDULE 3 ACCREDITED TESTING SCOPE

№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
1	Medical Devices	1	Ethylene oxide residuals(EO)	Biological evaluation of medical devices —Part 7:Ethylene oxide sterilization residuals (EO) ISO10993-7:2008	the ECD detector is not used in residual test.	2026-07-06
		2	Ethylene chlorohydrin residuals(ECH)	Biological evaluation of medical devices —Part 7:Ethylene oxide sterilization residuals ISO10993-7:2008	the ECD detector is not used in residual test.	2026-07-06
		3	Ethylene glycol residuals (EG)	Biological evaluation of medical devices —Part 7:Ethylene oxide sterilization residuals ISO10993-7:2008	the ECD detector is not used in residual test.	2026-07-06
		4	Sterility Test	USP-NF General Chapter 71(Official prior to 2013)		2026-07-06

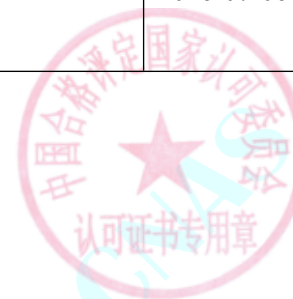


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№	Test Object	Item/Parameter		Standard or Method	Note	Effective Date
		№	Item/ Parameter			
				Sterilization of health care products-----Microbiological methods----- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process ISO 11737-2:2019		2026-07-06
		5	Bioburden test	Sterilization of health care products -Microbiological methods - Part 1: Determination of a population of microorganisms on products ISO 11737-1:2018/Amd 1:2021		2026-07-06
		6	BACTERIAL ENDOTOXINS TEST	USP-NF General Chapter 85 (Official prior to 2018)	Only Gel-Clot limit method	2026-07-06
				China Pharmacopoeia 2025 edition Part 4 General Chapter 1143	Only Gel-Clot limit method	2026-07-06
		7	Spore Verification Count on Biological Indicators	Sterilization of health care products — Biological indicators Part 1: General requirements ISO 11138-1:2017 Annex A		2026-07-06
				USP-NF General Chapter 55 (official prior to 2019)	Only Total Viable Spore Count	2026-07-06
		8	Sterilization biological monitoring	Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results ISO 11138-7:2019		2026-07-06



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