CERTIFICATE OF ACCREDITATION

This is to attest that

MDS TESTING TECHNOLOGY (SHANGHAI) CO., LTD.

UNIT 612, BLOCK 6, NO. 799 HULAN RD, BAOSHAN DISTRICT
200431, SHANGHAI, CHINA

Testing Laboratory TL-1084

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories*, and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories.* This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date March 27, 2025

International Accreditation Service
Issued under the authority of IAS management

Visit www.iasonline.org for current accreditation information.

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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MDS TESTING TECHNOLOGY (SHANGHAI) CO., LTD.

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Accredited to ISO/IEC 17025:2017 *Effective Date March 27, 2025*

Validation of Cleaning, Disinfection and Sterilization of Medical Devices	
AAMI TIR12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
AAMI TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
ANSI/AAMI ST79	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
ANSI/AAMI ST91	Flexible and semi-rigid endoscope processing in health care facilities
ANSI/AAMI ST98	Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices
ASTM F3208-20	Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices
EN 285	Sterilization - Steam sterilizers - Large sterilizers
EN 556-1	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN 13060	Small steam sterilizers
EN ISO 11737-1	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14937	Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
EN ISO 15883-1	Washer-disinfectors – Part 1: General requirements, terms and definitions and tests
EN ISO 15883-2	Washer-disinfectors – Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
EN ISO 15883-3	Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers
EN ISO 15883-4	Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
EN ISO 15883-5	Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy

EN ISO 15883-6	Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment
EN ISO 15883-7	Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare
EN ISO 17664-1	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
EN ISO 17664-2	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices
EN ISO 17665-1	Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices
GB 8599	Technical requirements for large steam sterilizers - Automatic type
GB 18278.1	Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
GB 18281.1	Sterilization of health care products—Biological indicators—Part 1: General requirements (ISO 11138, IDT)
GB 18281.3	Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes
GB 27955	Hygienic requirements for low-temperature hydrogen peroxide gas plasma sterilizer
GB 30689	Hygienic requirements for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
GB/T 33417	Test method of biological indicator for hydrogen peroxide vapour sterilization processes
GB/T 35267	Endoscopes washer-disinfectors
ISO 11138-1	Sterilization of health care products — Biological indicators
ISO 11138-3	Sterilization of health care products—Biological indicators—Part 3: Biological indicators for moist heat sterilization processes
ISO 22441	Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
YY/T 0802	Processing of medical devices — information to be provided by the medical device manufacturer

AAMI: Association for the Advancement of Medical Instrumentation