Zhongsheng Deshang Inspection and Certification (Chengdu) Co., Ltd. Management System Certification Rule A Medical Device Quality Management System

CRC-A001-05 A/2

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Revision and Change

prepared by	Review	approve	Version number	
Drafting Group	Review Panel	Cha Zhengbing	A/2	
Revision Notes		Revision Pages	Revision Date	approve
According to the Certification and Accreditation Administration of China (CNCA) Order No. 9 of 2025 Announcement regarding revisions to the implementation rules			2025.6.2	Cha Zhengbing
According to the requirements of the Certification and Accreditation Administration of China, the implementation regulations Then revisions will be made.			2026.5.6	Cha Zhengbing

Head

Medical Device Quality Management System Certification Rules

1Purpose and Scope

1.1This rule is used to regulate the certification activities of Medical Device Quality Management System (MDQMS).

1.2This rule, based on relevant laws and regulations on certification and accreditation and in conjunction with relevant technical standards, makes specific provisions for standardizing the MDQMS certification process, clarifies the relevant responsibilities in the MDQMS certification process, and ensures the standardization and effectiveness of
MDQMS certification activities.

1.3 These rules are the basic requirements for this organization in MDQMS certification activities, and MDQMS certification activities shall comply with them.

2Management requirements of this organization

2.1This organization followsGB/T 27021/ISO/IEC 17021-1Requirements for Conformity Assessment Management System Audit and Certification Bodies Manage the capabilities and processes involved in MDQMS certification;

2.2Our organization has established internal checks and balances, oversight, and accountability mechanisms to separate the MDQMS training,
certification, and certification decision-making processes to ensure impartiality.

2.3The MDQMS certification offered by our organization can be combined with a Quality Management System (QMS).(EMSThe organization conducts certification activities for Occupational Health and Safety Management System (OHSMS).

3Certification personnel requirements

3.1Personnel participating in MDQMS certification activities should possess the necessary personal qualities and education, training, and/or work
experience in areas such as quality management systems.

3.2Certification personnel participating in MDQMS certification should meet the following criteria:

(1) obtained certification from the China Certification and Accreditation Association (CCAAQuality registration auditor qualification.

(2Professional certification personnel should possess the relevant industry expertise (assessed in accordance with the professional competence evaluation criteria for medical device quality management systems).

(3(Having received training on MDQMS related standards)**4**

Certification basis

4.1MDQMS certification criteria include:

GB/T 42061-2022/IOS13485:2016 "Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes"

For more detailed information on the rules, please contact CRC headquarters at 028-83555628 or email ChinaCRC@VIP.163.com .