华认标准技术服务（苏州）有限公司
CCATS (SuZhou) Co., Ltd

医疗器械质量管理体系认证规则
MD-QMS Certification Rules

制定修订 Formulate or modify			修订内容摘要 Revision Summary	制定 Formulated	审核 Checked	核准 Approved
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2023 年 2 月 1 日	A	0	新发行 New Issue	汪红	高礼伟	高礼伟
2023 年 11 月 1 日	A	1	YY/T 0287-2017 升级为国标 GB/T42061-2022 YY/T0287-2017 upgraded to national standard GB/T42061-2022	汪红	高礼伟	高礼伟
2025年6月5日	A	2	根据《国家认监委关于加强认证规则管理的公告》修订相关内容 Revise relevant content according to the Announcement of the State Administration for Market Regulation on Strengthening the Management of Certification Rules	汪红	高礼伟	高礼伟
2026年5月30日	A	3	根据整改要求修订相关内容 Revise the relevant content in accordance with the rectification requirements	汪红	高礼伟	高礼伟
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1.目的 Purpose

为满足与医疗器械质量管理体系(MD-QMS)相关认证认可的法规要求，规避认证风险，指导认证管理人员、审核员按照程序要求实施认证活动，特制定本文件。This document is formulated to meet the requirements for certification of medical devices quality management systems (MD-QMS), to avoid certification risks, to guide certification managers and auditors to implement certification activities in accordance with procedural requirements.

2.范围和认证依据 Scope and Certification basis

2.1 本规则用于规范CCATS对申请认证和获证的各类组织按照GB/T42061-2022/ISO 13485《医疗器械质量管理体系用于法规的要求》标准建立医疗器械质量管理体系的认证活动。These rules are used to regulate the certification activities of CCATS for various organizations applying for certification and getting certification to establish a medical device quality management system in accordance with GB/T42061-2022/ISO 13485 "Requirements for Regulatory Application of Medical Device Quality Management System".

2.2 本规则旨在结合认证认可相关法律法规、国家及行业技术标准，对医疗器械质量管理体系认证实施过程作出具体规定，强化本机构对认证过程的管理和责任。The purpose of this rule is to combine the certification and accreditation related laws and regulations, the national and industrial technical standards, the implementation of the medical device quality management system certification process to make specific provisions, strengthen CCATS management and responsibility for the certification process.

2.3 本规则是本机构从事医疗器械质量管理体系认证活动的基本要求，开展医疗器械质量管理体系认证活动时应当遵守本规则。These rules are the basic requirements for the medical device quality management system certification activities of this institution, and shall be observed when carrying out the medical device quality management system certification activities.

3. 对 CCATS 的基本要求 Basic requirements for certification bodies

3.1 获得国家认监委批准、取得从事质量管理体系认证的资质方可开展医疗器械质量管理体系认证。Only with the approval of the CNCA and the qualification of quality management system certification can the medical device quality management system certification be carried out.

3.2 认证能力、内部管理和工作体系符合 GB/T 27021/ISO/IEC 17021-1《合格评定 管理体系审核认证机构要求》。The certification capability, internal management and work system shall comply with GB/T 27021/ISO/IEC 17021-1 *Conformity assessment-Requirements for bodies providing audit and certification of management systems.*

因认证规则属于本公司技术文件，如需获取完整版，请致电我司工作人员获取，联系电话：0512-36626918。