

北京国医械华光认证有限公司简介

Introduction of Beijing Hua Guang Certification of Medical Devices Co., Ltd.

北京国医械华光认证有限公司（Beijing Hua Guang Certification of Medical Devices Co. Ltd. 简称“CMD”）成立于2002年。前身为1994年经原国家医药管理局批准成立的“中国医疗器械质量认证中心”，是一家由国家认证认可监督管理委员会批准（批准号：CNCA-R-2002-047），具有医疗器械管理体系认证、医疗器械产品认证资格的并经官方认可的专业性认证机构。CMD按照中华人民共和国法律成立并经工商登记注册，是具有独立法人地位的第三方认证机构，服务对象覆盖医疗器械全生命周期产业链所涉及各类组织和外部供方。

Beijing Hua Guang Certification of Medical Devices Co., Ltd. (hereinafter referred to “CMD”) was established in 2002, the predecessor of CMD was “China Medical Device Quality Certification Center” approved by the former National Medical Administration in 1994, which is also approved and accredited by official authority as professional certification body with qualification of QMS and Product Certification referring to Medical Devices (Grant No.: CNCA-R-2002-047). CMD was established in accordance with the laws of the People's Republic of China and registered with the industrial and commercial authorities. It is an independent third-party certification body with legal personality, the service target covers various organizations and external suppliers involved in industrial chain of entire life cycle relating to medical devices.

原国家医药管理局于 1996 年 4 月批准成立全国医疗器械质量管理和通用要求技术委员会（简称 SAC/TC221），该委员会致力于医疗器械领域相关质量管理标准的制修订工作。经主管机构批准，由中国食品药品检定研究院和北京国医械华光认证有限公司共同担任 SAC/TC221 秘书处单位工作，参与医疗器械监管相关标准的立项、起草和发布工作。

The National Technical Committee for Quality Management and General Requirements of Medical Devices (hereinafter referred to SAC/TC221) was established and approved by the former National Medical Administration in Apr. 1996, such committee is dedicated to the development and revision of quality management standards in the field of medical devices, With the approval of the competent authority, the National Institutes for Food and Drug Control and Beijing Hua Guang Certification of Medical Devices Co., Ltd., jointly served as the Secretariat Units of SAC/TC221, participating in the project initiation, drafting, and publication of regulatory standards related to medical device supervision.

国际认可 International Accreditation

CMD为CNAS认可的认证机构，具有国家认监委批准的质量管理体系认证、环境管理体系认证、职业健康安全管理体系认证、信息安全认证及服务认证的医疗器械专业认证资质。CMD所颁发的质量管理体系、环境管理体系和职业健康安全管理体系认证均获得国际互认，带有“IAF”及“CNAS”标识。为助力企业提升管理水平和国际市场竞争力，CMD积极与国际接轨，获得美国IAS国际认可服务公司的认可资质，在满足国内认证需求的同时，致力于为企业提供具有国际认可度的认证服务。IAS国际认可的获得，标志着CMD在认证领域开启了新的篇章，坚定不移地为企业的持续发展保驾护航。

CMD is a Certification body accredited by CNAS, has professional qualification of Medical Devices Certification approved by National Certification and Accreditation Administration including QMS, EHS, IS and service Certification in field of Medical Devices. The QMS & EHS Certification issued by CMD has IAF & CNAS label with international mutual recognition. For the purpose of assistance of improvement in standard of management and competition of International Market to enterprises, CMD actively aligns with international resources and has obtained accreditation from the American IAS International Accreditation Service Company. While meeting domestic certification needs, CMD is committed to providing internationally recognized certification services for enterprises. The attainment of IAS international accreditation marks a new chapter for CMD in the

field of certification, steadfastly safeguarding the sustainable development of enterprises.

业务分布与团队建设 Business Distribution and Team Building

CMD 认真执行国家有关法律法规，按照国家认证机构认可准则的要求规范运行、依法认证。CMD 继承了原中国医疗器械质量认证中心的全部资质，由专家组、国家注册高级审核员、审核员、政府委托项目评估员、产品检查员、技术专家、培训讲师与咨询顾问共同组成了一支服务团队。在多年的认证与培训工作中积累了丰富的经验。

CMD conscientiously implements relevant National laws and regulations, running in accordance with the requirements of the accreditation criteria of national certification bodies, and conducts certification activities in accordance with the law. CMD inherits all the qualifications of the former China Medical Device Quality Certification Center, and has a service team in consist of experts, national registered senior auditors, auditors, government commissioned project evaluator, product assessors, technical expert, training instructor and consultant with comprehensive experience for many years accumulated in certification and training.

CMD总部设立在中国首都北京，服务网络覆盖全国范围，分别在广东省、浙江省、江苏省、山东省成立分子公司，在上海、沈阳、成都、重庆、武汉等中国主要城市设立多个办公室。CMD 不断树立在医疗器械行业认证与培训的权威性，赢得了医疗器械监督管理部门、各类医疗器械生产、经营企业和广大医疗器械用户的信任。

CMD is headquartered in Beijing, the capital of China, with a service network covering the whole country, It has established subsidiaries in Guangdong Province, Zhejiang Province, Jiangsu Province, and Shandong Province, and has set up multiple offices in major cities in China including but not limited in Shanghai, Shenyang, Chengdu and Chongqing etc. CMD has constantly established the

authority of certification and training in the medical device industry, won the trust of the medical device regulatory department, various medical device manufacturers, trading company as well as and the majority of medical device users.

行业优势 Industry Advantages

作为中国医疗器械行业认证、培训与技术服务的领导企业，CMD充分发挥行业优势资源，持续跟踪国内外医疗器械行业发展动态，与科研院所、检测机构、监管机构、行业协会保持深入的合作与交流，旨在建设具有全球影响力的医疗器械创新交流平台，努力推进行业进步与发展，促进技术转让与落地。目前CMD已累计与行业内近万家医疗器械生产、经营、服务企业、医疗器械配套服务企业、医院建立了合作关系，服务内容包括：

As a leading enterprise in field of Medical Device industry certification, training and technical services in China, CMD fully leverages its industry advantages and resources, continuously tracks the development trends of the medical device industry at home and abroad, maintains in depth cooperation and communication with research institutes, testing institutions, regulatory governmental authorities, and industry associations, aiming to build a globally influential medical device innovation exchange platform, strive the promote industry progress and development, and facilitate technology transfer and implementation. At present, CMD has established cooperative relationships with nearly 10000 medical device production, operation, service enterprises and medical device supporting service enterprise in the industry as well as hospital. The service content includes:

- 成为中国企业走出国门的海外信息交流平台，包括提供海外合作区域营商环境咨询、法律法规咨询与辅导以及跨国公司中国法规模拟检查。

Becoming an overseas information exchange platform for Chinese enterprises to abroad, including providing consultation and guidance on the local business environment, legal regulations for overseas cooperation regions as well as Simulation inspection of Chinese regulations for multinational corporations.

- 与中国产业园区建立合作关系，为园区招商引资，产品技术转化与战略落地。

Establishing cooperative relationships with Chinese industrial parks to attract investment, product technology transformation, and strategic implementation for the parks.

公司愿景 Company Vision

CMD 坚持公正、客观、诚信、优质、高效的服务宗旨，以人为本的品牌战略，秉承传递质量信任并服务认证组织发展，聚焦生命、关注健康、倾尽所能、全力以赴的理念，为监管服务、为行业服务、为企业服务，领航中国医疗行业健康发展，努力确保产品认证与管理体系认证的公正性、权威性和有效性。为提高组织管理水平、保障认证产品安全有效、保障认证产品符合标准及法规要求提供诚信、优质的认证与培训服务，提升认证组织在海内外市场竞争力，促进国际贸易发展与合作做出贡献。

CMD adheres to the service tenet of fairness, objectivity, integrity, quality and efficiency, people-oriented brand strategy, aiming at delivering quality trust and serves the development of enterprises of certification, focusing on life and health, “whatever you do, do it a hundred percent” for service of supervision、industry and enterprises, leading development of Chinese Medical Industry in healthy, endeavoring the fairness, authority and effectiveness with respects to CMD product certification and management system certification. CMD provides honest and high-quality certification and training services for organizations to improve their management level, ensure the safety and effectiveness of certified products, and ensure that certified products meet standards and regulatory requirements, enhances the competitiveness of certification organizations in domestic and overseas markets, and contributes to the development and cooperation of international trade.

我们坚信医疗健康行业的进步离不开多边合作与技术创新。我们始终积极与产业链上下游的伙伴建立合作关系，CMD持续努力为合作伙伴之间的对话搭建一座桥梁，

发挥行业优势，加速医疗器械创新步伐，构建医疗器械领域的创新生态体系，确保人类生命健康。

We firmly believe that the progress of the healthcare industry cannot be achieved without multilateral cooperation and technological innovation. We always actively establish cooperative relationships with partners upstream and downstream in the industrial chain. CMD continues to work hard to build a bridge for dialogue between partners, leverage industry advantages, accelerate the pace of medical device innovation, and build an innovative ecosystem in the field of medical devices for purpose of assurance of human life and health.

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