

# 声 明

## Declaration

### 申请组织声明 **Application Organization Declaration:**

- ☐ 质量管理体系认证 Quality Management System Certification (GB/T19001/ISO9001)
- ☐ 质量管理体系认证 Quality Management System Certification (GB/T42061/ISO13485)
- ☐ 环境管理体系认证 Environmental Management System Certification (GB/T24001/ISO14001)
- ☐ 职业健康安全管理体系认证 Occupational Health and Safety Management System Certification (GB/T45001/ISO45001)
- ☐ 信息安全管理信息系统认证 Information Security Management System Certification (ISO/IEC 27001)
- ☐ 产品认证 *Product Certification*
- ☐ 服务认证 *Service Certification*

本组织自愿申请以上认证事项,已详细阅读了北京国医械华光认证有限公司提供的认证规范(公开文件),了解申请组织的权利及义务。本组织承诺,遵守北京国医械华光认证有限公司认证规范(公开文件)的规定和认可机构的要求,认真履行有关认证的义务,并对申请及认证过程中所出示材料的真实性负责。

Our organization voluntarily applies for the above certification items and has read in detail the certification specifications (public documents) provided by Beijing Hua Guang Certification of Medical Devices Co., Ltd., understanding the rights and obligations of the applying organization. Our organization commits to comply with the certification specifications (public documents) of Beijing Hua Guang Certification of Medical Devices Co., Ltd. and the requirements of the accreditation body, diligently fulfilling the obligations related to certification and being responsible for the authenticity of the materials presented during the application and certification process.

适用时,涉及认证范围变更等,本组织声明,已了解认证范围变更的有关规定,并对申请及认证过程中所出示材料的真实性负责。

Where applicable, regarding changes to the scope of certification, we declare that we understand the relevant regulations concerning changes to the scope of certification and is responsible for the authenticity of the materials presented during the application and certification process.

申请组织代表（签字）/申请组织（盖章）：

**Representative of the applicant (signature)/Applicant (seal):**

年 Year      月 Month      日 Day