

丰台小屯路没有人员怎么办北京医疗器械三类经营许可证提供人员库房专业安全包下证

产品名称	丰台小屯路没有人员怎么办北京医疗器械三类经营许可证提供人员库房专业安全包下证
公司名称	北京星期三企业管理咨询有限公司业务部
价格	.00/件
规格参数	医疗器械三类:注册 医疗器械二类:注册 注册公司:网络销售备案
公司地址	北京市海淀区清河嘉园东区甲1号楼11层1124
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产品详情

1、三类医疗器械经营许可证办理方式如下：（1）申请人提交申请资料到相关部门；（2）相关部门受理申请人的申请；（3）到实际场地进行勘察以及对产品进行审核；（4）准予颁发三类医疗器械许可证。2、法律依据：《医疗器械监督管理条例》第十四条第一类医疗器械产品备案和申请第二类、第三类医疗器械产品注册，应当提交下列资料：（一）产品风险分析资料；（二）产品技术要求；（三）产品检验报告；（四）临床评价资料；（五）产品说明书以及标签样稿；（六）与产品研制、生产有关的质量管理体系文件；申请人隐瞒有关情况或者提医疗器械经营许可证。

（三）具有与经营规模和经营范围相适应的储存条件，包括具有符合医疗器械产品特性要求的

1) the applicant submits the application materials to the relevant departments; (2) the relevant departments accept the application of the applicant; (3) investigate the actual site and review the products; (4) grant the issuance of the Class III medical device license.2. Legal basis: Article 14 of the Regulations on Supervision and Administration of Medical Devices for the filing of Class I medical devices and the application for the registration of Class II and III medical devices, the following materials shall be submitted: (1) product risk analysis data; (2) product technical requirements; (3) product inspection report; (4) clinical evaluation data; (5) product specification and label samples; (6) quality management system documents related to the product development and production; the applicant conceals the relevant information or gives the medical device business license. (3) It shall have storage conditions suitable for the scale and scope of business, including the requirements for meeting the characteristics of medical device products