# 房山周边北京医疗器械三类经营许可证，医疗器械二类备案提供进销存软件人员专业快捷包下证。

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| 产品名称 | 房山周边北京医疗器械三类经营许可证，医疗器械二类备案提供进销存软件人员专业快捷包下证。 |
| 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<br>医疗器械二类:注册<br>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 |
| 联系电话 | 15501182773 15501182773 |

# 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；1、经营企业提交的《医疗医疗器械经营许可证。

医疗企业经营许可证一共有三类，其中办理一类医疗器械许可证可以直接办理，经营二类产品是需要办理二类医疗器械经营备案凭证，经营三类产品则需要办理三类医疗器械经营许可证。首先，经营企业必须明确申请三类医疗器械经营许可证的条件并满足相关要求。（一）具有与经营规模和经营范围相适应的质量管理机构或者质量管理人员两个。质量管理人员应当具有国家认可的相关专业学历或者职称，质量管理人应在职在岗，不

(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); (5) clinical evaluation data; product description and label samples; (6) quality management system documents related to product development and production; 1. Business license of medical and medical devices submitted by the operating enterprise. There are three types of medical enterprise business licenses, among which the first class medical device license can be directly handled, the operation of second class products needs to apply for the record certificate of second class medical devices, and the operation of third class products needs to apply for the busines