附件1

**渭南市第三类医疗器械经营企业**

**质量管理年度自查报告**

**（ 年度）**

企业名称：

报告日期： 年 月 日

所属辖区：

联 系 人：

电 话：

手 机：

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| **一、企业主体情况** | | | | | | | | | | | | | | | | | | | | | | |
| 企业名称 | |  | | | | | | | | | | | 许可证编号 | | | | | |  | | | |
| 住 所 | |  | | | | | | | | | | | 发证日期 | | | | | |  | | | |
| 经营地址 | |  | | | | | | | | | | | 统一社会  信用代码 | | | | | |  | | | |
| 库房地址： | | | | | | | | | | | | | | | | | | | | | | |
| 法定代表人 | | |  | | | | 联系电话 | | |  | | | | | | | | 固定电话 | |  | | |
| 企业负责人 | | |  | | | | 联系电话 | | |  | | | | | | | | 固定电话 | |  | | |
| 质量负责人 | | |  | | | | 联系电话 | | |  | | | | | | | | 固定电话 | |  | | |
| 经营面积 | | | ㎡ | | | | 仓库面积 | | | 常温库 ㎡; 冷库 m³ | | | | | | | | | | | | |
| 经营方式 | | | □批发 □批零兼营 ☑零售  □第三方配送或储存 □异地设库 | | | | | | | | | | | | | | | | | | | |
| 经营场所、库房条件、设施设备  情况简述 | | | 经营场所条件  （包括用房性质、 设施设备情况等） | | | | | | |  | | | | | | | | | | | | |
| 计算机信息管理系统  (名称）建立和运行情况 | | | | | | |  | | | | | | | | | | | | |
| 经营范围(只填写类代码)： | | | | | | | | | | | | | | | | | | | | | | |
| 经营产  品种类 | 无菌类□ 植入材料和人工器官类□ 体外诊断试剂类□ 设备仪器类□  计生类□ 角膜接触镜类(软性) □ (硬性)□ (塑形角膜接触镜)□ | | | | | | | | | | | | | | | | | | | | | |
| **二、经营活动基本情况** | | | | | | | | | | | | | | | | | | | | | | |
| 从事器械经营的人员总数： 名 | | | | | | | | | | | 质量管理人员总数: 名 | | | | | | | | | | | |
| 年度销售总额: 万元 | | | | | | | | | | | 年度纳税总额: 万元 | | | | | | | | | | | |
| 不良事件上报数量： 件 | | | | | | | | | | | 严重伤害或死亡不良事件上报数量： 件 | | | | | | | | | | | |
| 主要产品经营情况 | | | | | | | | | | | | | | | | | | | | | | |
| 主营产品名称 | | | | | 类代码 | | | | 注册证号 | | | | | | 生产企业 | | | | | | | |
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| 进口代理情况 | | | | | | | | | | | | | | | | | | | | | | |
| 代理类别 | | | | 全国总代□ 陕西省总代□ 区域总代□ | | | | | | | | | | | | | | | | | | |
| 进口产品名称 | | | | 注册证号 | | | | | | | | 原产地 | | | | 生产企业名称 | | | | | | |
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| 医疗器械产品抽验情况 | | | | | | | | | | | | | | | | | | | | | | |
| 抽验时间 | | | | | | | | 抽验品种 | | | | | | | | | 抽验结果 | | | | | |
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| 企业是否自行停业： 是□ 否□  如自行停业一年以上，重新经营时，是否书面报告辖区市场监督管理局，并经核查符合要求后恢复经营： 是□ 否□ | | | | | | | | | | | | | | | | | | | | | | |
| **三、经营许可(登记)事项变更情况** | | | | | | | | | | | | | | | | | | | | | | |
| 变更事项 | | | | | | 变更前内容 | | | | | | 变更后内容 | | | | | | | | | | 变更日期 |
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| 四、年度监督检查情况 | | | | | | | | | | | | | | | | | | | | | | |
| 检查时间 | | | | | | 检查类型（日常检查、  飞行检查、专项检查） | | | | | | | | 检查结果 | | | | | | | 是否完成整改 | |
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| 本企业按照《医疗器械监督管理条例》等法规，以及医疗器械经营质量管理规范进行自查，所报告的内容真实有效，并愿承担一切法律责任。    法定代表人（负责人）签名：    企业盖章：      年 月 日 | | | | | | | | | | | | | | | | | | | | | | |

**注：空格不够可自行添加**