**设计和开发确认评审报告（M5）**

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| 项目名称 | |  | | | | | | |
| 评审申请人 | |  | | | 评审时间 |  | | |
| 评审内容 | | | | | | | | |
| 1. 项目目标及范围是否发生变化？如果是，项目计划是否已相应更新并被批准？ | | | | | | | | |
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| 1. 设计确认活动是否完成？外部确认报告（总结性可用性评价、动物试验、临床评价或临床试验等）的内容和质量是否符合要求？ | | | | | | | | |
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| 1. 设计确认过程是否存在遗留问题？ | | | | | | | | |
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| 1. 是否还有未关闭的工程变更？如果有，是否对已完成的验证及确认活动有影响？ | | | | | | | | |
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| 1. 风险分析是否持续更新？是否已添加确认报告作为相关风险控制措施的有效性证据？ | | | | | | | | |
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| 1. 是否编制IOVV矩阵并保持持续更新？是否对所有客户需求进行了追溯？ | | | | | | | | |
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| 1. 所需的DHF和DMR文件是否完整？ | | | | | | | | |
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| 评审意见及结果 | | | | | | | | |
| 评审意见 | | | 1. 缺陷识别 2. 总体评价及建议 | | | | | |
| 评审结论 | | | 评审通过  评审不通过  评审有条件通过，纠正措施如下 | | | | | |
| 纠正措施及验证 | | | | | | | | |
| 序号 | 整改项 | | | 纠正措施 | | | 结果 | 实施人/日期 |
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**评审人员会签**

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