医疗器械CE认证MDR法规技术文档要求

产品名称	医疗器械CE认证MDR法规技术文档要求
公司名称	国瑞中安集团-CRO服务机构
价格	.00/件
规格参数	
公司地址	深圳市光明区光源五路宝新科技园一期2#一层
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产品详情

MDR法规下的CE技术文档主要内容如下：

1、产品名称、分类

2、产品概述（包括类型和预期用途）

(1)产品的历史沿革

(2)技术性能参数

(3)产品配合使用的附件、配合件和其它设备清单

(4)产品的图示与样品

(5)产品所用原材料及供应商

3、使用该产品的调和标准/或其它标准

4、风险分析评估结论和预防措施

5、生产质量控制

(1)产品资料和控制文档（包括产品生产工艺流程图）

(2)产品的灭菌方法和确认的描述

(3)灭菌验证

(4)产品质量控制措施

(5)产品稳定性和效期的描述

6、包装和标识

(1)包装材料说明

(2)标签

(3)使用说明书

7、技术评价

(1)产品检验报告及相关文献

(2)技术概要及权威观点

8、风险管理

(1)产品潜在风险报告及相关文献

(2)潜在风险的概要及权威观点

9、临床评价

(1)产品临床测试报告及相关文献

(2)临床使用概述及权威观点

1)产品出厂检测报告

2)产品型式检测报告

3)基本要求检查表备注

(3)临床研究包括：物理性能，生化、药理、药动及毒性研究，功效测试，灭菌合格证明，药物相容性等）

(4)生物兼容性测试（A）第 一部分要求：细胞毒性、感光性、刺激-皮内反应、急性全身中毒、致热性、亚急性中毒、遗传毒性、植入溶血性；（B）支持测试：慢性中毒、致癌性、再生性/生长性毒素、生物动因退化。）

(5)临床资料（需要临床研究或描述临床研究）

(6)包装合格证明

(7）标签、使用说明

(8）结论（设计档案资料的接受、利益对应风险的陈述）

10、欧盟授权代表信息及协议

11、符合基本要求表

12、协调标准

13、警戒系统程序

新的MDR（EU 2017/745）指令相对MDD(93/42/EEC)对CE技术文件要求更加系统化、全面化，更加注重以风险管理为策略，要求对医疗器械全生命周期进行管控，进而确保器械安全、有效，并符合欧盟法规要求。

The main contents of CE technical documents under MDR regulations are as follows:

1. Product name and classification

2. Product overview (including type and intended use)

(1) Historical evolution of products

(2) Technical performance parameters

(3) List of accessories, mating parts and other equipment used with the product

(4) Illustrations and samples of products

(5) Raw materials and suppliers for products

3. Harmonized standards/or other standards for using the product

4. Risk analysis and assessment conclusions and preventive measures

5. Production quality control

(1) Product data and control documents (including product production process flow chart)

(2) Description of product sterilization method and confirmation

(3) Sterilization validation

(4) Product quality control measures

(5) Description of product stability and expiry date

6. Packaging and identification

(1) Description of packaging materials

(2) Label

(3) User Manual

7. Technical evaluation

(1) Product inspection report and relevant documents

(2) Technical overview and authoritative views

8. Risk management

(1) Product potential risk report and relevant literature

(2) Summary of potential risks and authoritative views

9. Clinical evaluation

(1) Product clinical test report and relevant literature

(2) Overview of clinical use and authoritative views

1) Product delivery test report

2) Product type test report

3) Remarks of basic requirements checklist

(3) Clinical studies include: physical properties, biochemistry, pharmacology, pharmacokinetics and toxicity studies, efficacy tests, sterilization certificates, drug compatibility, etc.)

(4) Biocompatibility test (A) Part I requirements: cytotoxicity, photosensitivity, stimulation intradermal reaction, acute systemic poisoning, pyrogenicity, subacute poisoning, genetic toxicity, implantation hemolysis; (B) Supporting tests: chronic poisoning, carcinogenicity, regenerative/growth toxins, and degradation of biological agents.)

(5) Clinical data (clinical study or description of clinical study is required)

(6) Packaging certificate

(7) Labels and instructions

(8) Conclusion (acceptance of design archives and statement of risks corresponding to interests)

10. EU Authorized Representative Information and Agreement

11. Table of basic requirements

12. Harmonized standards

13. Warning system procedure

Compared with MDD (93/42/EEC), the new MDR (EU 2017/745) directive has more systematic and comprehensive requirements for CE technical documents. It pays more attention to risk management as a strategy and requires management and control over the whole life cycle of medical devices, so as to ensure that the devices are safe and effective and comply with EU laws and regulations.