体外诊断试剂欧盟CE认证详解-IVDD 98/79/EC要求

产品名称	体外诊断试剂欧盟CE认证详解-IVDD 98/79/EC要求
公司名称	深圳市实测通技术服务有限公司
价格	.00/件
规格参数	测试周期:5-7天 寄样地址:深圳宝安 价格费用:电话详谈
公司地址	深圳市罗湖区翠竹街道翠宁社区太宁路145号二单元705
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产品详情

体外诊断试剂欧盟CE认证详解-IVDD 98/79/EC

体外诊断试剂欧盟法规

体外诊断试剂出口欧盟需按照体外诊断器械指令IVDD 98/79/EC要求进行认证

98/79/EC Scope法规范围：

This Directive shall apply to in vitro diagnostic medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as in vitro diagnostic medical devices in their own right. Both in vitro diagnostic medical devices and accessories shall hereinafter be termed devices.

体外诊断试剂CE认证要求

1 工厂要满足ISO 13485医疗体系的要求

2 准备CE技术文件：产品介绍，使用说明书、风险分析报告、包装标签样本等

3 按照IVDD 98/79/EC 附录III的要求签发EC合格声明

EC DECLARATION OF CONFORMITY下载

4 制造商需去成员国的主管当局competent authorities
注册，若制造商非欧盟公司，需委托欧盟代表帮助制造商完成注册

98/79/EC Article 10 Registration of manufacturers and devices

1. Any manufacturer who places devices on the market under his own name shall notify the competent authorities of the Member State in which he has his registered place of business:

— of the address of the registered place of business,

— of information relating to the reagents, reagent products and calibration and control materials in terms of common technological characteristics and/or analytes and of any significant change thereto including discontinuation of placing on the market; for other devices, the appropriate indications,

— in the case of devices covered by Annex II and of devices for self-testing, of all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Annex I, part A, section 3, the outcome of performance evaluation pursuant to Annex VIII, certificates and any significant change thereto, including discontinuation of placing on the market.

关于‘ ’欧代‘ ’请见：医疗器械、医疗体外诊断试剂等欧盟代表EC Representative如何申请？

5 按照98/79/EC Article 16要求加贴CE标识

98/79/EC Article 16 CE marking

Devices, other than devices for performance evaluation, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.