新冠病毒检测试剂CE认证需要提供什么资料

产品名称	新冠病毒检测试剂CE认证需要提供什么资料
公司名称	超越检测技术（深圳）有限公司
价格	1000.00/件
规格参数	
公司地址	深圳市宝安区燕罗街道洪桥头社区兆福达工业区综合楼B栋一单元502检测实验室
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产品详情

II.新冠病毒检测试剂企业申请CE需要提供的资料清单：文件备注说明书根据EN ISO18113及EN ISO 15223等标准标签英文的（产品名称，规格型号，批号，效期，生产日期，生产信息（企业名称，地址，联系方式等信息），欧代信息，CE标识，外包装包含基本的标识）技术要求只需要技术指标及检验方法性能评估根据EN 13612:2002标准，试验举例：交叉试验，干扰试验，分析灵敏度，分析特异性试验，包括连续三批产品的检验记录，企业参考品的建立。稳定性研究：根据标准EN 13640:2002，包含加速稳定性、实时稳定性、开瓶稳定性、模拟运输试验，等临床评价不需要临床试验，类似于国内的免临床试验（需要方案及报告）风险报告根据EN ISO 14971:2012，特别是Annex H。人源性组织或物质的说明关键原料的供应商，关于生物安全性的说明生产工艺流程图/III.新冠病毒检测试剂需要符合的欧盟协调标准清单Standard/Directive ReferenceTitle98/79/EC（IVD）Directive 98/79/EC of the European Parliament and of the council of 27EN ISO 13485: 2016Medical devices-Quality management systems – Requirement for regulatory purposes.EN 13612:2002Performance evaluation of in vitro diagnostic medical devicesEN 13641: 2002Elimination or reduction of risk of infection related to in vitro diagnostic reagentsEN 13975: 2003Sampling Procedures used for Acceptance testing of in vitro diagnostic medical devices - Statistical aspectsEN ISO 14971:2012Medical Devices - Application of Risk management to medical devicesEN ISO 15223-1: 2016Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirementsEN ISO18113-1:2011In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirementsEN ISO18113-2:2011In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional useEN 13640:2002Stability testing of in vitro diagnostic reagentsEN ISO 23640:2015In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic