

What must the Technical documentation contain? 需要哪些技术文件?



1. Detailed description of the design & manufacture
设计和制造的详细描述
2. Safety assessment(s)
安全评估
3. Conformity assessment procedure followed
遵循的合格评定程序
4. EC declaration of conformity
EC符合性声明
5. Addresses of the places of manufacture and storage
生产和储存的地址
6. copies of documents that the manufacturer has submitted to a notified body (if involved)
制造商向欧盟通报机构提交的文件副本（如涉及）



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7. Test reports
测试报告
8. EC-type examination certificate or copies of the documents that the manufacturer submitted to the appropriate notified body
EC型式试验证书或制造商向欧盟通报机构提交的文件副本



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