

**Background note on the relationship between  
MDCG 2020-6  
and  
MEDDEV 2.7/1 rev. 4 on clinical evaluation**

MDCG 2020-6 document *Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC - A guide for manufacturers and notified bodies*, references in Appendix I the sections of [MEDDEV 2.7/1 rev. 4](#) which are still relevant under the MDR for the application of the MDCG 2020-6.

For your convenience MEDDEV 2.7/1 rev. 4 is embedded below



2\_7\_1\_rev4\_en.pdf



医课汇  
公众号  
专业医疗器械资讯平台  
WECHAT OF  
HLONGMED



hlongmed.com  
医疗器械咨询服务  
MEDICAL DEVICE  
CONSULTING  
SERVICES



医课培训平台  
医疗器械任职培训  
WEB TRAINING  
CENTER



医械宝  
医疗器械知识平台  
KNOWLEDG  
ECENTEROF  
MEDICAL DEVICE



MDCPP.COM  
医械云专业平台  
KNOWLEDG  
ECENTEROF MEDICAL  
DEVICE