CE技术文件清单

01 Device Description and Specification

02 Labeling of device and packaging

03 Instruction for use

04 Design Information

05 Manufacturing Information

06 Applied standards list and GSPR checklist

07 Benefit-risk analysis and risk management

08 Product Verification and validation

09 Device packaging and transportation

10 Sterilization, disinfection, and reprocessing

11 Clinical evaluation

12 PMS plan & PSUR & PMCF

13 Declaration of conformity

14 Other documents