

Form RG2 has to be completed and submitted to MDA

A short Technical file should be held in the UK comprising

- ◆ Description
- ◆ Function of the device
- ◆ Classification rationale
- ◆ MSDS chemical and material data sheets
- ◆ Specification
- ◆ Tests carried out : Clinical trials : efficacy
- ◆ Cleaning and sterilisation
- ◆ Labels
- ◆ Instructions for use
- ◆ Risk analysis
- ◆ Biocompatibility
- ◆ Essential requirements

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