

Contents of Technical Documentation

Please find below a sample of how a technical product file as required by the European Directive may look like:

1.1 EC declaration of conformity and classification according to ANNEX IX.

1.2 Name and address of the manufacturer/European Representative

1.3 Product description including:

- all variants
- intended clinical use
- indications / contraindications
- operating instructions / instructions for use
- warnings / precautions
- photographs highlighting the product
- photographs highlighting the usage
- brochures, advertising, catalogue sheets, marketing claims (if available)

2. Product specification

- Parts list, list of components
- Drawings, assembly drawings
- sub-assembly drawings, drawings of components
- Specifications of materials used incl. data sheets
- List of standards applied
- Details of substance(s) used (in the event of drug + device combination)
- Manufacturing specifications
- Sterilisation specifications
- Packaging specifications
- QA specifications (QC specs., in-process controls etc.)
- Labelling, accompanying documents, package insert (DIN EN 389, EN 980)
- Instructions for Use (EN 1041)
- Service Manual

3. Product verification

- Testing data and reports, functionality studies, wet lab or bench top testing
- Materials certificates / reports on biological tests
- EMC testing and certificates
- Validation of the packaging / ageing studies
- Compatibility studies (connection to other devices)
- Risk analysis (EN ISO 14971)
- Clinical data (Article 15/ Annex 10, DIN EN 540)
- List of requirements (Annex 1) indicating cross-reference with documentation