THE TECHNICAL FILE OR DESIGN DOSSIER

1. GENERAL

All medical devices are required to conform to the essential requirements contained in the directive. The information concerning this conformity is held in a technical file by the manufacturer which is available for inspection by a Competent Authority should an incident be reported, or by a Notified Body should the product be subject to an audited quality system. Products falling into Class III and manufactured under Annex 2 are required to have a summary of the file submitted to the Notified Body for separate examination as a "Design Dossier".

2. SCOPE OF FILE OR DOSSIER

To avoid duplication of information and the creation of large numbers of files it is recommended that devices be grouped into families of similar design and construction and that files are prepared around these families.

It is for the manufacturer to decide on the most suitable groupings, however, examples include heart valves and catheters made in different sizes, similarly patient monitoring systems with a range of options based around common modules.

3. CONTENT OF FILE

3.1 General

The content of a generalised file is laid out in the following section, those parts not applicable to particular devices should be deleted when preparing the files. The layout proposed is not mandatory, the final form is at the clients discretion.

3.2 Identification

The file should clearly identify itself as a technical file or design dossier for a given product or family of products, name the directive and give the date of compilation.

3.3 Introduction

- Index
- Identification of family and individual devices covered by file including accessories
- Identification of function of device
- Identification of design location and manufacturing locations for the devices in the dossier

3.4 Device Information

Device Specifications:

- Device family common features
- Individual device specifications
- Accessories supplied with the device
- Reference to other accessories required to use the device, if any

Document Supplied With The Device:

- Device user / patient information
- Device physicians information
- Other documentation supplied in connection with the device
- Sample labels

Brief Summary Device Features eg:

- Type of construction
- Technology used and reason for choice
- Results of tests performed to prove claimed specification is met

Compliance With Essential Requirements

- Data must be provided to show how the device conforms with all of the relevant essential requirements. Where an essential requirement is claimed not applicable a justification of this statement must be given
- Clinical aspects of device uses must be addressed including:
  - Report on trials or clinical experience
  - Inclusion of medicinal substances, verification as in directives
  - Basis for identification of any undesirable side effects
  - Basis for information on implantation risks

The Use Of Standards

Where harmonised standards are used to demonstrate compliance with the essential requirements the relevant standard must be clearly identified and the results of tests provided. It is the manufacturer's responsibility to ensure that all the essential requirements are satisfied.

If other standards are used they should preferably be International standards agreed by the IEC or ISO, or failing that, European national standards, or other nations standards. Alternatively, the manufacturer may use his own test methods and procedures. In all of these cases, it is for the manufacturer to show that the tests performed demonstrate compliance with the essential requirements.

It is recommended that for clarity and completeness, the manufacturer include in his file a cross reference list, such as that shown in Appendix II, showing the means, that is the standard or specification, by which he demonstrates compliance with each essential requirement.

3.5 Procedural and Manufacturing

- Brief manufacturing process description including sterilisation method
- Identification of sub-contractor usage
- Software development process and design validation, reference to procedures covered by quality system

PRESENTATION OF FILE

4.1 Language

The language used to prepare the file is at the choice of the client. Normally it will be prepared either in the local language or in English. If information is needed form this file by a Competent Authority or by BSI then some translation may be required. Any translation cost will be charged to the client.

For normal audit purposes and for discussions on particular issues it will generally be sufficient to provide a concise review in English of each section of
the file. An example is to have the complete clinical investigation available in the local language of the country in which it was performed but covered by a summary statement reviewing the major points and conclusions in English.

4.2 Summary File

Whilst the manufacturer is required to hold all the information demanded by the directive, it is not essential for that information to be all located in one place. To enable access for review during assessment visits, a summary file should be held with the systems documentation.

The summary file should have a cross-reference in it to the location of the full information and to the language of the text if not in English.

4.3 Reference Files

In the preparation of the technical files many manufacturers will find that certain subjects are repeated identically in many dossiers, for example common test methods, common trials for biocompatibility of materials or common processes such as sterilisation. In these cases it may be advantageous to extract these common matters from the technical file and place them in a separate reference file to which the technical files cross-refer as necessary. If this is done this reference file should be available with the summary technical files for ease of use.

5. UPDATING THE FILES

During the life of a product many changes are likely to be made. A significant number of these will be for reasons which have no impact on the essential requirements, for example modifications made for ease of manufacture. Some changes will however. It is the manufacturer's responsibility to ensure that all aspects of the technical file are checked to reflect these changes.

6. DESIGN DOSSIER

A design dossier is a document derived from the technical file which is supplied to the Notified Body for agreement prior to the launch of a Class III product where the manufacturer has a quality system in compliance with Annex II of the directive.

The design dossier should contain in summary all the evidence presented in a technical file. It is strongly recommended by BSI that the dossier is not made too large. When examining the dossier BSI will, if necessary, request more information. However, the file should not be too empty of fact and must contain sufficient information for a reasoned judgement to be made of compliance with the essential requirements. An example of the required contents could be with the reference to the clinical trial where only the original scope and purpose of the trial, the number of centres and participants plus the summary of results need to be included.

7. FILES FOR EXISTING PRODUCTS

Where products are already in existence and have a proven record of use then this may be used as evidence for compliance with the essential requirements.

An example is biocompatibility. There is no need to consider additional trials or the inclusion of old test data in the technical file when data on the use of the device is

available. This should be presented as the total number of devices concerned, the uses of the devices, the record of success and the identification of failures. The information must be presented in a meaningful way to withstand scrutiny by the Competent Authority in the event of an investigation. Similarly compliance with other matters may be reasonably so demonstrated, for example, the adequacy of packaging to withstand transport stresses whilst maintaining sterility or the adequacy of performance in use.

Many existing products will have been subject to type test by a regulatory body in a European country, where this has resulted in a report this should be included in the file. If only a certificate is available then this too should be included, it is however, of lesser value if there is no indication of the scope of the work which lies behind it.

A note of caution should be sounded at this point since standards do change and what was considered acceptable in the past is not always acceptable now. In this regard attention is drawn particularly to EMC requirements which are being introduced formally across Europe and also to certain other matters of a technical nature such as allowable leakage currents, insulation levels and creepage distances which are now all being given values. Devices not satisfying such clearly given parameters will not be considered to satisfy the essential requirements.

8. FILES FOR PRODUCTS DEVELOPED FROM EXISTING DEVICES

Where a device is developed from an already existing device, then its technical file may be based on the technical file developed for the earlier device. It is important that the new file clearly identifies all matters referred to in the description given under point 3, however, where no differences exist from the earlier device the manufacturer may refer back to the relevant file. Where there are differences an explanation of these must be made together with a description of how the essential requirements are met.

9. AUDIT OF FILES

Where a manufacturer has selected Annex 2 as his route to conformity with the directive, BSI will audit his full quality system including his design and test procedures and the technical files.

In performing these audits BSI will pay particular attention to the following matters:

- Class of product
- The use of harmonised standards
- The results of the risk analysis
- The clarity of the file and particularly the clarity of compliance with each of the essential requirements
- Formal reports from known bodies
- For existing products - the presented history