

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
---	---	--

Title:	Technical Documentation
Chapter:	2.5.1 Conformity assessment procedures; General rules

Text:	
Key words:	Design dossier, technical documentation, technical file

1. Introduction

The requirements for the technical documentation are laid down in the various Annexes of the medical devices Directives, as appropriate for the conformity assessment procedure and the products concerned. As a general rule, the documentation should cover the design, manufacture and intended operation of the product.

Note. The 'operation' of the product would include installation, preparation for use, pre-use checks and maintenance, calibration and servicing as appropriate to the particular medical devices involved.

The details included in the documentation will depend on the nature of the product and on what is considered as necessary, from a technical point of view, for demonstrating the conformity of the product to the essential requirements of the medical devices Directives. If the harmonised standards have been applied, the technical documentation should also make clear where these have been used to demonstrate conformity with the particular essential requirements covered by the standards.

Note: This Recommendation has been written particularly to meet the needs for guidance on technical documentation for medical devices and active implantable medical devices. The Recommendation may also be helpful, however, in relation to IVDs, but may need revision in the light of experience of the practical implementation of the IVDD.

2. Purpose of Recommendation

A rationale and history sheet is available; please contact Technical Secretariat.

Reference to Directives:	Article/ Annex:	Reference to standards:
AIMD	Annex: 2, 3, 4, 5	
MDD	Annex: II, III, IV, V, VI, VII	
IVD	Annex: III	

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3		4	03.02.2000	29.02.2000			1/21

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

The purpose of this Recommendation is to provide guidance to Notified Bodies, Competent Authorities and manufacturers on the technical documentation needed to meet the requirements of the medical devices Directives.

Note: It is **not** the purpose of this Recommendation to oblige the manufacturer to re-organise existing technical documentation where this already proves appropriate and sufficient.

3 Technical Information

3.1 General

Subject

- (i) Content of technical documentation

Guidance

This Recommendation is not intended as an exhaustive listing of all the technical documentation that may be required in particular cases. Equally, where particular information indicated by this Recommendation is not included, a justification should be provided.

The manufacturer is required by the Directives to prepare the technical documentation and to determine and justify what is appropriate and sufficient to assure his particular medical devices comply with the relevant Directive(s). This will obviously vary on a case-by-case basis, depending on the type of product, the risk associated with its manufacture, installation, use and servicing, and the period that it has been on the market. For example, it is unlikely that well-established products, regardless of their classification, will have much formal design validation - but the manufacturer will have considerable market experience of use, together with details on how he has responded to any problems that have emerged, and this available data should be used by way of validation.

- (ii) Other

The technical documentation should include the information indicated in sections 3.2 - 3.5

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

3.2 Product Description

Subject

- (i) a general description of the device(s)

Guidance

This should include the intended range of variants (for example, a group of catheters of a particular type differing only in length), and a description of the packaging where this is relevant to the preservation of the intended characteristics and performances of the device(s). All that is needed, however, is a brief description sufficient to allow an understanding of the design, characteristics, and where appropriate, performances of the device(s) and to distinguish between variants. In many cases, the name of the device(s) will be sufficient. Where the ‘technical documentation’ is to be evaluated by a Notified Body, a general pictorial representation of the device(s), e.g. a schematic diagram, photograph or drawing may be of assistance.

Note: For guidance on what constitutes a ‘range’ of product variants, see NB-MED Recommendation NB-MED/2.1/Rec2.

- (ii) a description of the intended use and operation of the device(s)

A short description of the intended purpose/application and/or method of use of the device(s) is needed. This may include, where appropriate, details of the intended patient population(s) and medical condition(s) for which the device is intended. This should also make clear the intended user(s), in particular whether the device is professional use. All of the above may be self-evident from the general description of the device(s). The information may be given by way of reference to the “instructions for use” or operating manual for the device(s). It is not necessary to detail the mechanism by which the device(s) achieves its intended purpose.

The description should make clear the process-

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

ing of important inputs and outputs associated with the intended operation of the device(s). For example, in the case of a pulse oximeter, the inputs and processing are to do with relative absorption of light at different wavelengths. The outputs may include a display of the haemoglobin saturation with oxygen, and a graphical representation of the patient's pulse.

- (iii) device(s) incorporating a medicinal substance

Where the device(s) incorporates a medicinal substance, the 'technical documentation' should make clear the purpose of including the substance and its mode of action in this application. This only applies where the substance is liable to act upon the body with action ancillary to that of the device.

Note: For this reason this will not be relevant to IVDs which do not 'act upon the body'.

The risk analysis should address the additional risks and benefits associated with incorporation of such a substance. The technical documentation should include the data on the tests conducted in this connection.

Note. For guidance on 'borderline products' and regulatory treatment of 'drug/device combinations' see MedDev 2.1/3.

- (iv) device(s) incorporating non-viable materials of animal origin

Where the device(s) incorporates non-viable materials of animal origin, the risk analysis within the technical documentation should address the additional risks and benefits associated with incorporation of such materials, and the measures taken (for example, in sourcing of animals, veterinary controls and measures taken to eliminate/inactivate transmissible agents).

Note: For guidance on measures to eliminate/inactivate transmissible agents see MedDev 2.5/5.

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

Note: IVDs may contain materials of animal [or human] origin. Here, the technical documentation should include relevant details, including sourcing and measures to protect personnel and to preserve the performance of the device.

- | | |
|--|--|
| (v) device(s) requiring special consideration | Where aspects of the device(s) are the subject of emerging concern (for example, the use of latex potentially leading to allergic reaction), the risk analysis within the 'technical documentation' should address these aspects. |
| (vi) description of the methods of manufacture envisaged | A summary is required in general terms of the type of manufacturing method (for example, injection/blow moulding, extrusion, chemical processing, assembly, packaging/labelling) and the method of sterilization, if relevant. This should make clear the technologies involved and means of assuring the intended characteristics and performances of the devices manufactured. What is not required is an exhaustive description of manufacturing processes. |
| (vii) description of the accessories, adaptors and other devices or equipment and other interfaces which are intended by the manufacturer to be used in combination with the device(s) | The technical documentation should include the description of other devices or equipment etc. which the device is intended to be used with; for example, where the manufacturer makes specific claims concerning compatibility. It should also include data on the verification and validation of the safety and performance of such combinations. |

In describing the requirements for safe and proper operation of the device(s) when used in combination with devices or equipment from other manufacturers, what is needed is a brief description sufficient to understand the important parameters or interfaces (for example, the connectors needed or the voltage, frequency and/or stability of the electricity supply required).

The technical documentation should also address known incompatibilities which may be

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

covered, for example, in the label or the instructions for use.

- (viii) classification of the device under the relevant Directive

The technical documentation should include the rule number(s) applied under the Directive, together with a brief rationale for this classification, and reasons why particular rules do not apply, if this is not self-evident.

In the case of IVDs, the classification of a particular device is self-evident from the lists given in Annex II of the IVDD or where the device is labelled as for “self-testing”.

3.3 Technical Requirements

Subject

- (i) Identification of technical requirements

Guidance

The manufacturer should make clear the Directive(s) which apply to the particular device(s) concerned, including Directives other than the medical devices Directives. Where not self-evident, the manufacturer should document the rationale for classifying as a medical device and deciding what other, if any, requirements apply.

In each case, those essential requirements (ERs) of the Directive(s) (e.g. MDD Annex I, AIMD Annex 1, IVDD Annex I) and other requirements of the Directives which apply should be identified. The manufacturer should define the technical requirements/specifications which must be satisfied in order to ensure that each of the applicable Directive requirements are met.

Where particular ERs are deemed not to apply to the device(s) concerned, a brief rationale should be given where this is not self-evident.

- (ii) Solutions adopted to fulfil the

The manufacturer is required by the Directives to

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

essential requirements

demonstrate how each of the applicable essential requirements and any derived technical requirements/specifications for the particular device(s) concerned has been met.

Compliance with published standards is voluntary.

Where “harmonized standards” are used to comply with relevant essential requirements, all that is needed is to demonstrate the device(s) concerned complies with the relevant clauses of the “harmonized standard(s)”.

Where other methods, including compliance with draft and in-house/industry standards, are used to comply with one of a range of relevant essential requirements, the manufacturer should justify that:

- a) the methods applied adequately address relevant essential requirement(s) and
- b) the device(s) concerned comply with the relevant provisions of these.

The evidence of device compliance with standards may take the form of, for example, test reports or records of application of Standard Operating Procedures (SOPs) intended to assure such compliance.

Note: The use of a checklist may facilitate demonstration of how the solutions adopted meet the relevant requirements (“Essential Requirements Checklist”). Such a checklist should:

- a) list the essential requirements, identifying those which are/are not applicable
- b) list the standards applied, and
- c) against each essential requirement, give the basis for claiming compliance. This will either directly make clear the solutions adopted to fulfil each requirement or refer to stand-alone specifications, reports and the like.

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

(iii) Standards applied

Where the manufacturer demonstrates conformity with particular essential requirements by claiming compliance with available published standards, the Directives require that these standards should be identified. The manufacturer should make clear where standards which are applied in full or in part are “harmonized standards” (including “common technical specifications” in the case of IVDs). Compliance with all or parts of such “harmonized standards” carries the presumption of conformity with relevant essential requirement(s) of the Directive(s).

Where device(s) do not comply with key relevant published standards, a rationale should be given.

Note: Draft standards may also be used as guidance, but here the manufacturer should have regard to how these may change prior to publication.

Note: Certain Pharmacopoeial Monographs have a status equivalent to that of “harmonized standards”.

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

3.4 Design

Subject

- (i) the results of the risk analysis

Guidance

The manufacturer is required by the Directives to present the documented results of the risk analysis.

The risk analysis should address all hazards known or reasonably foreseeable for the particular product types and technologies involved, together with the likelihood and consequences of occurrence and measures taken to reduce the resulting risks to acceptable levels. This should address all relevant risks. For example, in the case of devices incorporating e.g. a medicinal substance or materials of animal origin, or natural rubber latex, the risk analysis should include the additional risks and benefits associated with incorporation of such substances.

In the case of devices intended and labelled for “single use”, the risk analysis should address the hazards associated with reuse as an example of foreseeable misuse.

The results must demonstrate that an appropriate risk analysis has been performed and provide a conclusion, with appropriate evidence, that the remaining risks are acceptable when weighed against the intended benefits to the patient. The results of the risk analysis should be reviewed and approved by the manufacturer.

Note: There are a number of published techniques for performing a risk analysis. It is recommended that the risk analysis performed in connection with Directive conformity assessment should follow EN 1441.

- (ii) specification of materials, and The technical documentation should specify the

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

manufacturing/special
processing

materials used in the construction of the device, together with the biological safety and biocompatibility of materials intended to come into contact with the body. Particular attention should be paid where materials are invasive with respect to the body and/or will have prolonged contact with the body.

This may include special processes (e.g. moulding, sterilization) and environmental conditions to be used for production (e.g. prevention of particulate contamination or electrostatic discharge). In the case of medical devices covered by the IVDD, this should cover characterisation of starting materials.

A general description of the method of manufacture of the device(s) concerned forms part of the "Product Description" detailed in 4. This is provided solely to allow a basic understanding necessary for conformity assessment procedures.

The majority of procedures, work instructions etc. and the training associated with the proper performing of these tasks forms part of the manufacturer's quality system.

The technical documentation should specify any 'special processes', for example sterilization, the results of which may affect the safety and performance of the finished device(s). (See 3.2 (vi)).

- (iii) specifications, drawings and circuit diagrams for components, sub-assemblies and the complete product including packaging, where appropriate.

The manufacturer should determine what specifications, drawings, diagrams etc. are appropriate and sufficient to enable proper manufacture, installation, maintenance and servicing etc. of the product(s) involved in order to assure the intended characteristics and performances are achieved and maintained.

In some cases, the manufacturer will need de-

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

tailed engineering scale drawings for their product(s). Whereas such drawings may be necessary, for example, for electro-medical devices, it is often sufficient to produce a schematic diagram of, for example, product configuration or kit contents with dimensions and other characteristics indicated as appropriate.

Equally, it may be necessary to have drawings for certain components or sub-assemblies but not for others.

- (iv) the specifications of the checks, tests and trials that are intended to be carried out as part of routine production

The procedures, work instructions etc. relating to the conduct of such checks, tests and trials form part of the manufacturer's quality system.

- (v) the performances and compatibilities intended by the manufacturer

The manufacturer is required by the directives to identify the characteristics, performances and compatibilities needed to assure the safe and correct operation of the device. A relevant characteristic might be, for example, sterility assurance of a catheter. A relevant performance might be, for example, the ability of the protective packaging to maintain sterility of that catheter when subject to the stresses associated with transport and storage.

In the case of IVDs, the indication of performances should include those required in connection with analytical performance, for example, to do with sensitivity, specificity, limit of detection, and ratio of false to true results, where relevant.

- (vi) labelling, including any instructions for use

The manufacturer is required by the Directives to include in the technical documentation the label, and where appropriate, the instructions for use, together with any changes to these during the lifetime of the product. This should include the information to be given, both by text and the use of symbols, in the final version of the labelling.

The labelling documentation should make clear

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

where particular information will be provided, for example on the device itself or its component parts, on the packaging for each unit, on the sales packaging, or on the leaflet or user manual supplied with one or more devices.

Information may be provided, for example, by means of electronic display screens or synthesised voice messages.

Note: Several European standards provide useful guidance for devices covered by the MDD, AIMD and IVDD on the circumstances in which particular information is required, and the type of information needed. Additional information may be required by applicable regulations (for example, the dangerous substances Directive), or product-specific standards, or to indicate the presence of natural latex, materials of animal origin etc.

Note: See also NB-MED Recommendation NB-MED/2.5.2/Rec3 “Translation procedure”

- (vii) identification of ‘shelf-life’ reflected by any ‘use by’ date, or other ‘lifetime’ of the device(s)

In certain cases, such restrictions on use will reflect a time-related deterioration in characteristics that are important to product safety and performance. In other cases, however, the restrictions will be based on other considerations. The ‘lifetime’ of an active device, for example, may be determined by the period for which the manufacturer will support the device by way of availability of spare parts, manuals, training, service/repairs etc.

Note: See also the NB-MED Recommendation NB-MED/2.2/Rec3 “ ‘Use-by’ date for medical devices”. Guidance on the verification of the stability of IVDs is provided in a European standard (in draft).

- (viii) Results of Bench Testing

Bench testing includes *in-vitro*/animal studies, simulated use testing and validation of software

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

and the results of special processes (e.g. sterilization validation report(s)).

Note: Testing should follow a pre-defined protocol, which should include the parameters to be measured, measuring and test equipment to be used including calibration arrangements, statistical treatment of results and acceptance criteria, together with necessary formal approval of the report

(ix) Clinical data

Clinical data includes data from market experience of the same or similar devices (particularly relevant to 'well established' devices), prospective clinical investigations and information from the scientific literature.

The scientific literature will often relate to medical devices other than those being assessed. The manufacturer must therefore establish the extent to which the scientific literature is relevant to his device(s). The results from bench testing may be used to establish the extent to which the characteristics of the device(s) being assessed are similar to those of the device(s) covered by the scientific literature, and therefore the relevance of that scientific literature.

The manufacturer should make clear where clinical data is being used to demonstrate conformity with each of the applicable essential requirements for the particular device(s) concerned.

Note: Guidance on the "Evaluation of Clinical Data" is provided in the NB-MED Recommendation, NB-MED/2.7/Rec3.

Note: In the case of IVDs, investigations in a clinical environment are described as "performance evaluation studies".

(x) Documentation and reporting

The technical documentation should include re-

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

of Design Changes

records of each design change and the reasons for these, together with any associated verification/validation data. The documentation should include evidence for believing that the change achieves the desired effect, and that the device continues to comply with the requirements of the Directive.

Where the technical documentation or part thereof has been submitted to the Notified Body in connection with conformity assessment involving design - or type - examination, the manufacturer is required to inform the Notified Body of substantial changes and obtain further approval.

Note: Guidance on the “Reporting of design changes and changes of the quality system” is provided in the NB-MED Recommendation, NB-MED/2.5.2/Rec2. This Recommendation describes the system to be applied by the manufacturer for classifying changes as ‘substantial’ and so must be approved by the Notified Body, and what must be included as a supplement to the technical documentation already submitted.

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

3.5 Administrative Details

Subject

- (i) Declaration of Conformity

Guidance

Upon completion of all other steps required for conformity assessment, the manufacturer is expected to provide a written declaration that the device(s) concerned meet the provisions of the Directive which apply to them, regardless of whether or not a Notified Body is involved in the conformity assessment.

Note: The declaration must be the final step in the relevant conformity assessment procedure. It would not be possible for example, for the manufacturer to issue a **final** declaration under MDD Annex II until the Notified Body had approved the quality system, and additionally for class III devices approved the design. It may be helpful however for the manufacturer to prepare a **draft** declaration of conformity for Notified Body review.

The declaration should make clear under what Directive(s) and Annex(es) it is made, and the product(s) to which it relates. It should also present the name and address of the manufacturer, and in the case of devices for which the manufacturer is not resident in the Community, additionally the name and address of the authorised representative of the manufacturer established within the Community.

Note: See also NB-MED Consensus Statement S/01/99 on “Declaration of conformity”

- (ii) Application for Conformity Assessment

Where the manufacturer lodges an application for approval of the device type it should include the information referred to in 4.1 (i), (ii), (iii), (v), (vi) and (vii), together with the relevant parts of the technical documentation.

Note: Particular Notified Bodies may have de-

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

veloped standard forms to be used for application for conformity assessment. Where available, these should be used.

(iii) Declaration that no other Notified Body is used in Conformity Assessment

Where conformity assessment involves a Notified Body within the application for conformity assessment, the manufacturer is expected to provide a written declaration that no application has been lodged with any other Notified Body for the same product type and conformity assessment route.

(iv) Notified Body Decisions and Reports

The manufacturer is required by the Directive to keep the Notified Body decisions and reports at the disposal of the national authorities for a period at least five years after last product to which they relate has been manufactured. These decisions and reports include the Notified Body certificates of approval of the quality system and the device design/type, together with any supplemental approvals of 'substantial' changes to the quality system and device design/type.

Note: For guidance on the classification of changes as 'substantial' and their reporting to the Notified Body see NB-MED Recommendation NB-MED/2.5.2/Rec2.

(v) Manufacturer's undertaking on procedure to review post-production experience

The manufacturer is required by the Directives to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action and to notify the Competent authorities of relevant incidents.

Note: See MedDev 2.12/1 "Guidelines on a medical device vigilance system".

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

4 Recommended structure of the technical documentation

To enable effective management of the technical documentation for placing on the market or market surveillance purposes, excessive paperwork should be avoided. To achieve this and to facilitate the task of manufacturers, Notified Bodies and Competent Authorities, it is proposed that the technical documentation is subdivided into two parts.

4.1 Part A of the technical documentation

The first **part (A)** would consist of a summary of the essential technical data relevant to the conformity assessment procedures, including in particular the data listed below.

Note: Such a 'Summary' would contain details of compliance with regulations, standards etc. and act as an overview and 'road map' to the relevant parts of the manufacturer's technical documentation and their status and location. It may also include or refer to appropriate certifications, quality system procedures, reports, declarations etc.

Note: Where the 'technical documentation' is to be submitted to the Notified Body to enable assessment of conformity of the device(s) with the requirements of the relevant Directive, all that is needed is a statement of the manufacturer's Quality Policy and an overview of the quality system (e.g. quality manual). Clearly, it is neither appropriate nor feasible to include copies of all the various Standard Operating Procedures which may apply to the company's manufacturing and quality assurance arrangements, since these documents are constantly being revised and may be extensive.

The 'part A' of the technical documentation may serve as the basis for submission to Competent Authorities and for class I enforcement etc., and also as the starting point for answering enquiries where there are problems etc.

Subject

Guidance

- | | |
|--|--|
| (i) the name and address of the 'manufacturer' within the meaning of the Directive(s). | Where the manufacturer is not resident in the Community, additionally the name and address of the authorised representative of the manufacturer established within the Community |
| (ii) identification of the device(s) | This should include the trade or proprietary |

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

covered by the 'summary documentation'

name(s) if applicable, the common or usual name(s), the device classification(s) and rule(s) assigned by the manufacturer in accordance with the relevant Directive Annex.

(iii) the name(s) and address(es) of the facilities

This should include all the facilities involved in the design and manufacture of the particular device(s) covered by the 'Summary Statement'

(iv) the name and address of any Notified Body involved

(v) a statement of the conformity assessment procedure being followed

(vi) the declaration of conformity

This would include the manufacturer's Declaration of Conformity with the essential requirements of the medical devices Directives

Note: Where a Notified Body has been involved in the conformity assessment procedure, the Notified Body's certificate(s) relating to the product design/type and/or the manufacturer's quality system should be included

(vii) a brief description of the device(s)

The description should include the intended purpose(s) and indications for use, together with a listing of any accessories

(viii) label and instructions of use

(ix) a statement of relevant regulations

This should make clear the regulations which the products comply with, together with reference to any third party certifications and approvals

(x) identification of technical standards with which compliance is claimed

This should include reference to any third party certifications

(xi) a brief statement of the bench testing performed and clinical

This should make clear how the results of bench testing and clinical data are used to demonstrate

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

data obtained

compliance with the Directive(s), and make reference to relevant part(s) of the manufacturer's technical documentation

4.2 Part B of the technical documentation

The second **part (B)** would consist of remaining technical documentation detailing the risk analysis, the test reports, information concerning the quality manual, plans, descriptions of the products and processes, standards applied, etc. as detailed in the previous section.

If the manufacturer does not follow this recommended two-part structure of the technical documentation and unless the details given in the declaration of conformity or in the certificate of conformity appear sufficient, the authorities could request submission of the complete technical documentation or part thereof according to the requirements for relevant purposes.

The manufacturer should be able to demonstrate where and how the various parts of the technical documentation are held and maintained. The technical documentation may be held as decentralised separate documents or together in a single location. Equally, it may be maintained in electronic or hardcopy form.

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

5 Availability of the technical documentation

The technical documentation should be kept at the disposal of the Competent Authorities for inspection and control purposes.

This obligation is incumbent upon the “manufacturer” within the meaning of the medical devices Directives who places the product on the market under his own name.

Any person responsible for placing a product on the market but not in possession of the technical documentation should be capable of:

- stating where the technical documentation is situated;
- presenting the technical documentation as soon as possible on request from the Competent Authorities.

However, the name and address of the person in possession of the technical documentation need not be expressly mentioned on the product or on its packaging.

The technical documentation should not be requested systematically by the Notified Body or Competent Authority. In general, it should be requested only during checks made for placing on the market or market surveillance purposes by the Competent Authorities.

To facilitate these tasks part A of the technical documentation should be capable of ready transmission to the relevant authorities. This will eliminate or reduce the need to refer to the remaining documentation identified in part B.

The complete technical documentation has to be able to be collated but this action should only required where total assessment of conformity of the device with the Directives is necessary.

If the Competent Authorities request the technical documentation, the first part of the technical documentation should be submitted immediately, allowing a reasonable time for transmission. Additional time will be required for the submission of the relevant sections of the second part of the documentation, taking into account its volume and form (written, computerized, ...) and location.

This organisation of the technical documentation should enable avoidance of repeated submission of the same technical documentation by the same manufacturer to different authorities.

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Recommendation NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

The technical documentation should be kept for at least five years from the last date of manufacture of the product. The manufacturer should, however, also consider product liability issues when determining the time and content of technical documentation maintained for obsolete devices.

6 Language of the technical documentation

The technical documentation should be maintained in the language selected by the manufacturer either by himself or in agreement with a Notified Body where applicable. The Competent Authority may request presentation of the first part of the technical documentation in the official language of the Competent Authority but should not do so if the authority can understand the documentation or its contents in another language. Where a translation is required, the person in possession of the documentation should be allowed extra time to submit the first part of the documentation to the authorities. Part B of the technical documentation should be accepted in the language established by the manufacturer.

Note: See also NB-MED Recommendation NB-MED/2.5.2/Rec3 “Translation procedure”

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	<u>Rationale and history sheet</u> to NB-MED/2.5.1/Rec5
Title:	Technical Documentation	

Rev 1: Meeting of NB-MED task force "Technical Documentation", Lübeck, September 1 & 2, 1998:

First concrete discussion was made within this meeting of the task force on "What are the requirements for the technical documentation laid down in the various Annexes of the medical devices Directives?".

A document for presenting to the next NBRG meeting in Brussels on 04./05.11.99 was elaborated.

Revision no: 1

Confirmed to be at Stage: 1

Rev 2: Meeting of NBR Group, Brussels, November 5 & 6, 1998:

The draft Recommendation for technical documentation NB-MED/2.5.1/Rec5 (NBRG/57/99) was discussed and revised, also in line with the relevant draft document of the GHTF/Study Group 1 on "Summary technical file" and the current issue of the Commission's "Guide to the implementation of directives based on New Approach and Global Approach". Before presentation to the NB-MED plenary this document needs further consideration within the task force and NBRG.

The new revision 2 document was provided by the Technical Secretariat to the members of the task force but not NBRG and NB-MED.

Revision no: 1

Confirmed to be at Stage: 1

Rev 3: Meeting of NBR Group, Nuremberg, September 27 & 28, 1999:

In the meanwhile the task force has met frequently; a new draft Recommendation (without revision number) was distributed (as document NBRG/144/99) to NBRG for discussion of their meeting on 27./28.09.99

The draft NB-MED Recommendation was finalised. The main changes were to do with

- (a) listing the relevant requirements for technical documentation given in the medical devices Directives, with guidance against each on what is meant, the type and level of information needed for particular circumstances and giving references to other guidance, for example, other Recommendations, MedDevs, standards etc. Also, making clear, that what is needed will depend of the type of product and be proportional to the risks involved
- (b) improving the format of the document to make it clear how the guidance addresses each of the directive requirements for technical documentation
- (c) including provision for the two part structure for the technical documentation envisaged by the Commission's guidance in relation to all 'New approach' Directives

Due regard was paid to the work of the GHTF/SG 1, and a copy of the revised Notified Body Recommendation will be provided for circulation to SG 1

Rev.-Nr.	Rev. date	accepted	amended	withdrawn
	29.02.2000			

Page
1/3

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	<u>Rationale and history sheet</u> to NB-MED/2.5.1/Rec5
---	--	---

NBRG agreed to send the revised document, with its "Rationale and history" sheet to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in November 1999.

Revision no: 3

Confirmed to be at Stage: 2

Meeting of NB-MED, Brussels, November 2 & 3, 1999:

The results of the meeting of the NBRG on 27./28.09.99 (NBM/129/99) were presented. The earlier concept to write a document on "Technical file" was got away; not a *technical file* but a *system/organisation of technical documentation* is required. Further it will be recommended that the technical documentation is built up in a kind of a two layer system ("Summary" (so called part A in the Recommendation) and part B, the entire "Technical documentation"); this shows the older concept of the Commission's "blue guide" but the whole draft Recommendation is also in line with the revised "blue guide" and the GHTF document on "technical file". This Recommendation could be applied from the user as a check-list explained by each point on the right hand side.

Discussion within NB-MED: It should be considered that the work within the NB-MED and NBRG is geared particularly to the (European) directives but the tabled document should also fit in the global framework. It was once again encouraged sharply, that both documents should be identically or compatible with regard to part A of NB-MED Recommendation and the Summary Technical File document of GHTF. Also it was mentioned that the 2nd note under chapter 4.1 (page 17) seems to be misplaced. Mr. S.-A. asked whether his comments – brought in written format before the last NBRG meeting on 27./28.09.99 – were considered and explained some of these. The members of NB-MED were asked to use this stage 2 draft document as much as possible. Due to the very importance of this document the members of NB-MED and especially the representatives of the Commission were asked to submit their comments until end of November '99 the latest. The NB-MED representatives of relevant GHTF groups were asked to provide the document also for commenting within these groups (SG1 and SG3).

Meeting of NBR Group, Brussels, November 3, 1999:

NBRG proposed to add some references to the document (references to NB-MED Recommendation NB-MED/2.5.2/Rec3 "Translation procedure" and to NB-MED Consensus Statement S/01/99 on "Declaration of conformity"). Further it was agreed to consider also the submitted comments (deadline: end of November '99) within the next meeting of NBRG.

Rev 4: Meeting of NBR Group, Cologne, February 3, 2000:

No further comment have reached NBRG as asked NB-MED on its plenary meeting in November. NBRG agreed to send the revised document (only two new references were added) with its "Rationale and history" sheet to all member of NB-MED for commenting before presenting it for approval in the Plenary meeting in February/March 2000.

Revision no: 4

Confirmed to be at Stage: 2

	Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC	<u>Rationale and history sheet</u> to NB-MED/2.5.1/Rec5
---	--	---

Meeting of NB-MED, Brussels, February 29 & March 1, 2000:
The NB-MED adopted the revised document with the above mentioned changes.
The document will be incorporated in the booklet of NB-MED Recommendations
and shall be presented also to the Medical Devices Experts Group.
Revision no: 4
Confirmed at stage 3



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
---	--	--	--	---