	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/2.2/Rec4
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Title:	Software and Medical Devices
Chapter:	2.2 Essential Requirements

Text:	„....“
Key words:	Software, accessories, conformity assessment, combination of medical devices

1. INTRODUCTION

The purpose of this document is to provide guidance to Notified Bodies and manufacturers on the application of all the provisions which apply to software within the scope of the Medical Device Directives.¹

Where guidance relating to a particular issue already exists in a MEDDEV document and/or in a harmonized standard, this recommendation specifically refers to it.

2. GENERAL

In general of the guidance on software given in this recommendation applies equally to all Medical Device Directives. In most of the cases, there is no reason to differentiate between particular directives. Reference to a particular directive is only mentioned by way of examples and for some aspects, which are specifically addressed in a particular directive.

For the purposes of this document, the meaning of the term “Software” is as defined in section 3.4.

¹ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD), Council Directive 90/385/EEC of 20 June 1990 concerning active implantable medical devices (AIMD) and Council Directive 98/79/EC of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD).

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

Reference to Directives:	Article/ Annex:	Reference to standards:
AIMD	Annex 1	
MDD	Annex IX (II)	
IVDD	Annex I, Annex II	

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			1/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

3. APPLICATION

3.1 Decision on whether particular software must be CE marked under the Medical Devices Directives

The manufacturer must decide whether particular software needs to be “CE” marked, and should be able to justify that decision.

Depending on the use intended by the manufacturer and the manner in which the product is placed on the market, the software can be

- a) a medical device or an accessory to a medical device, which must be CE-Marked, or
- b) a component and integral part of a medical device, which cannot be CE marked in its own right, but which is covered by the conformity assessment of the medical device of which it forms a part or
- c) none of the above and therefore not covered by the Medical Devices Directives.

Sections 3.1.1, 3.1.2 and 3.1.3 below give guidance on the particular application, basic decisions to be taken when considering CE-marking of software and give examples.

3.1.1. Software which is a medical device or an accessory to a medical device

- (i) Software as medical device.

Where software is regarded as a medical device or an accessory to a medical device in its own right, it falls within the definition of “active medical device” given in the Medical Devices Directive and Active Implantable Medical Device Directive. This is because operation of software depends on electrical energy and software acts by converting this energy by means of interfaces and/or actuators, which are parts of the [same] programmable electrical medical system.

- (ii) Classification of software.

Software, which is intended to control a device or influence the functions of a device falls automatically in the same class. Software intended as an accessory to a medical device under the Medical Device Directives should be classified separately from the device with which it is used.

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			2/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

(iii) Circumstances under which software is regarded as a medical device.

Software is regarded as a medical device when one or more of the circumstances given at (a) to (d) apply:

(a) The software is for a purpose explicitly mentioned in a Medical Device Directive.

Example 1: software designated specifically within the In Vitro Diagnostic Medical Device Directive for evaluating the risk of trisomy 21².

Example 2: Software used for the proper functioning of the programming and control of active implantable medical devices as specified in directive 90/385/EEC, Annex 1, Essential Requirement 9 (7th dash). This includes the software embedded in the implanted pulse generator and the software used by external devices such as programmers to support the operation of the implanted device.

(b) The software is intended to control or influence the functioning of a medical device

Example 3: software for dose₃ planning with a view to control the setting of oncology treatment devices³.

(c) The software is intended for the analysis of patient data generated by a medical device with a view to diagnosis and monitoring⁴.

Example 4: for analysis of stored long duration cardiac signal from a Holter ECG.

Example 5: for diagnostic image processing.

Example 6: for correlating or physical measurements or signals to clinical or analytical results such as for IVD instruments.

Example 7: for calculating, estimating, modelling or predicting surgical placements or dosimetry regimes.

Example 8: long term comparative monitoring of stored images for oncological diagnosis.

Example 9: software for the measurement/calculation of anatomical sites of the body with a view of an irradiation or surgical intervention.

(d) The software is intended for use for/by patients to diagnose or treat a physical or mental condition or disease

Example 10: diagnostic test equipment intended for Alzheimer syndrome determination or,
Example 11: diagnostic equipment intended for diagnosis of paediatric Attention Deficit Hyperactivity Disorder (ADHD)

² Article 1 section 2 (b) and IVDD directive Annex II list B products

³ Article 1 section 2 (a) & Annex IX rule #9 and #10 in the MDD

⁴ Article 1 section 2 (a) 1. Indent & 2. Indent

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			3/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

3.1.2. Software which is a component and integral⁵ part of a medical device

Software, which is a component and integral part, is not regarded as a medical device in its own right and therefore cannot be CE-marked.

Example 12: software built into and controlling the functions of a medical device such as a ventilator, patient cardiac monitor, infusion pump, blood pressure measuring device, transcutaneous blood gas monitor etc.

The conformity assessment procedure of the medical device of which it forms a part includes the software just as it should include all the other components of the medical device.

3.1.3. Software which is not covered by the Medical Devices Directives

In some cases, software does not fall within the definitions of a medical device or an accessory given in Article 1 of the Directives. It also does not form a component and integral part of a medical device. The Medical Device Directives do therefore, not cover it.

Example 13: Software to be used for the administrative handling of patients. Related data such as laboratory information system.

Example 14: Software to be used for the education of medical doctors (ex. continuing education software on CDs containing state of the art medical information)

Example 15: Software used for or assisting in general maintenance of medical devices or components of medical devices (e.g. parts lists, service diagrams, expert servicing systems)

Example 16: Software used as a tool within the overall design and manufacturing processes of the medical device. (e.g. compilers, CM systems, MRP, production control, inventory control, SPC etc.)

Example 17: A proprietary 'Operating System', support or system software would not normally be considered a medical device. Rather, it would simply be specified within the instructions for use of a medical device as one of the requirements for the intended use of the device, and the validation of the medical device should cover the necessary compatibility

⁵ MDD Article 1 section 2 (b) and IVDD directive Annex II list B products

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			4/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

3.2. Use of conformity assessment procedures

3.2.1. Special considerations⁶

The use of software as a medical device, as an accessory to a medical device or as a part of a medical device introduces a level of complexity, which means that systematic failures can escape practical accepted limits of testing.

Accordingly, traditional testing and assessment of the finished medical device is not, by itself, adequate to address the safety of a medical device based on software in full or in part.

Rather, the assessment requires that a process based on risk management and the use of a development methodology which includes the concept of software life-cycle is followed for the design of the software and that records of that process are established to support the safety of the medical device.

Therefore, a pure product related evaluation without consideration of the design process is not considered adequate.

Consequently, the use of some of the Conformity Assessment Procedures (CAP), as defined by the directives may be unsuitable for software.

3.2.2. Objectives

The manufacturer must ensure and declare that the product concerned meets the provisions of the directives, which apply to it.

The CAP selected by the manufacturer is a combination of annexes which should ensure that the following is achieved,

- that a development methodology based on the concept of development life-cycle for the product has been established involving all aspects of the requirements including planning, risk management, verification and validation.
- that procedures for document control and configuration management have been established.

⁶ See standards:
EN 60601-1-4: 1996 MEDICAL ELECTRICAL EQUIPMENT - Part 1: General requirements for safety - 4. Collateral Standard: Programmable electrical medical Systems and
EN 60601-1-4: 1999 Am1 MEDICAL ELECTRICAL EN ISO 14971 (It should be noted that the standard EN 60601-1-4 is only harmonized to the AIMD and the MDD directives) and
ISO/IEC 12119:1994 "Information technology – Software packages – Quality requirements and testing".

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			5/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

- that management responsibility, identification of software development personnel authority and resources for the design, risk management, verification and validation have been defined.
- control of combination between software versions and the intended hardware.

In the case of well-established products, introduced prior to the implementation of the Medical Devices Directives, certain documentation may not exist. See NB-MED Recommendations for CE marking of pre-MDD devices/established IVD-Devices⁷.

3.2.3. Use of Full Quality Assurance

The objective of Full Quality Assurance is to ensure that the products concerned meet the provisions of the directive, which applies to them. This may include, in addition to procedures for design control etc., design examination of the product by the notified body in cases of higher risk devices.

3.2.3.1. Quality system

Whether software is regarded as a component and integral part of a medical device or is a medical device or accessory in its own right the same principles apply with regard to ensuring compliance to the Essential Requirements by using a quality system.

This can be achieved by adapting⁸ the full quality assurance system to the requirements for the development life-cycle of the software⁹.

This may involve special considerations for:

- **design control**
Development life cycle for the product should be defined based on a development methodology involving all aspects of the requirements including planning, risk management, verification and validation.
- **document control and quality records**
Procedures for document control and configuration management should be identified.
- **management responsibility**

⁷ NB-MED Recommendations NB-MED/2.13/Rec1 "CE Marking of pre-MDD Devices" and NB-MED/2.13/Rec2 "CE Marking of established IVD-Devices"

⁸ One way to achieve control of design and maintenance of software is to map the requirements from EN 60601-1-4 into the requirements of EN 46001.

⁹ Use of ISO 9000-3.

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			6/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

Identification of software development personnel authority and resources for the design, risk management, verification and validation should be defined.

- **control of combinations**

If the software is intended to be used in combination with other devices all aspects of the whole combination should be identification with a view to safety and intended purpose of the software.

3.2.3.2. Design examination

The design examination should include review of the quality records¹⁰ and documents produced by the manufacturer during the development life-cycle of the software. The review should ensure that all requirements have been achieved with respect to repeatability, reliability and performance of the software.

3.2.4. Use of EC type-examination

Type-examination should involve both review of records produced during the development life cycle (see above) and appropriate inspection and testing including but not limited to verification of the software configuration management system, the cyclic redundancy check code for the program or the program checksum. The review should ensure that all requirements have been achieved with respect to repeatability, reliability and performance of the software.

3.2.5. Use of Production Quality Assurance

The objective of the Production Quality Assurance is to ensure that the products manufactured are in conformity with the type described in the EC type-examination certificate¹¹ or the technical documentation¹² of the product.

To reach this objective *“the manufacturer must ensure application of the quality system approved for the manufacture of the products concerned and carry out the final inspection,...”*

As mentioned in paragraph 3.2.1 of the present recommendation, the final inspection of the product by it self is not adequate to ensure conformity to the type but the application of the quality system for the manufacture may be adequate under the conditions specified below.

¹⁰ It is recommended to take advice from the harmonized standard EN 60601-1-4 and/or EN ISO 14971 Medical devices - Application of risk management to medical devices.

¹¹ Section 2 Annex III (MDD); Annex V (IVDD)

¹² Section 6 Annex VII (MDD), Annex III, excluding section 6 (IVDD)

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			7/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

3.2.5.1. Conformity with the technical documentation¹³

In cases where the quality system ensures conformity with the technical documentation, this combination seems less suitable unless adequate records from the design process according to the development life cycle approach can be made available for review.

This review may document:

- whether, during design control a development methodology including the concept of development life-cycle for the product has been defined involving to all aspects of the requirements including planning, risk management, verification and validation.
- whether, procedures for document control and configuration management have been applied during the design.
- whether identification of software development personnel authority and resources for the design have been identified by the management
- whether proprietary system and support software has been validated for the particular medical device application

However, if the manufacturer cannot make available the relevant documents for performing this review, the use of this CAP is not recommended.

3.2.5.2. Conformity with the EC type-examination certificate

In cases where the quality system ensures conformity with EC type-examination certificate, information from the product documentation for the approved software, e.g. methods of manufacture envisaged, can be used for the development of the quality system.

In these cases this CAP seems suitable and is therefore recommended for use.

¹³ For guidance on Technical Documentation see NB-MED Recommendation NB-MED/2.5.1/Rec 5 "Technical Documentation »

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			8/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

3.2.6. Use of Product Quality Assurance

The objective of the Product Quality Assurance is to ensure that the product manufactured conforms to the type described in the EC type examination certificate or the technical documentation of the product.

To reach this objective *“the manufacturer must ensure application of the quality system approved for the final inspection and testing of the product, as specified ...”*

As mentioned in paragraph 3.2.1 of the present recommendation, the final inspection and testing of the product is not adequate to ensure conformity to the type, as far as software are concerned.

Consequently, for software and with regard to the generally acknowledge state of the art, any CAP which is only based on the use of Product Quality Assurance is inadequate to reach the assigned objective and therefore not recommended.

3.2.7. Use of EC Verification

The objective of EC verification is to ensure that a product, which has been subject to the examination and test by the notified body, is in conformity with the type described in the EC type examination certificate or the technical documentation¹⁴ of the product.

To reach this objective, *“the notified body must carry out appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Directive, either by examining and testing every product as stated in section ... or by examining and testing products on a statistical basis as specified in section ..., as the manufacturer decides”*

As mentioned in paragraph 3.2.1 of the present recommendation, the testing of the product is not adequate to ensure conformity to the type, as far as software is concerned. In addition, acting on a statistical basis is not adequate for identifying out systematic failures, which are specific to software.

Consequently, for software and with regard to the generally acknowledge state of the art, any CAP which is only based on the use of EC Verification is inadequate to reach the assigned objective and therefore not recommended.

¹⁴ Section 6 Annex VII (MDD), Section 3 Annex III (IVDD)

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			9/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

3.3. Practical Issues

3.3.1. Proprietary, support and system software

Where proprietary, support and system software is used, the development life cycle documentation is not usually available to the manufacturer. The validation performed by the manufacturer is therefore limited to his particular application of that software.

3.3.2. Control of software subcontractor

If the manufacturer chooses to subcontract the software development process, he should demonstrate control over the process within the software life cycle.

Requiring the subcontractor to comply with the harmonized standards or any other appropriate standards and periodically assessing the compliance with the requirements imposed on the subcontractor may be one way of ensuring that the manufacturer has the necessary control.

If design changes include software then the issues of reporting design changes¹⁵ and updating certificate¹⁶ may apply.

3.3.3. Changes to software¹⁷

If the software is changed compared to an earlier version, or if the intended use of the software is changed or if the platform where the software is intended to run is changed, or all, then the manufacturer should ensure that:

- the product after the changes is still in compliance with the Essential Requirements
- the changes have been documented¹⁸ by means of the configuration management system
- the changes have been validated and approved
- if compatibility with (new) hardware, or existing software, or both are an issue it should be ensured that compliance has been achieved.
- reporting takes place with respect to the requirements for reporting substantial changes to the Notified Body if involved or if applicable to the Competent Authorities.

¹⁵ See Ref. 7 (NB-MED Recommendation NB-MED/2.5.2/Rec2 "Reporting of design changes and changes of the quality system")

¹⁶ See Ref. 6 (NB-MED Recommendation NB-MED/2.5.1/Rec4 "Content of mandatory certificates")

¹⁷ See NB-MED Recommendation NB-MED/2.5.2/Rec1 "Subcontracting – QS related"

¹⁸ Consultation with the harmonized standard EN 60601-1-4 is recommended.

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			10/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

- the conformity assessment procedure is still applicable if the software change changes the risk class of the product.
- the configuration management is resulting in clear identification and control of software versions¹⁹.

Further guidance can be obtained from the NB-MED Recommendation NB-MED/2.5.2/Rec2 "Reporting of design changes".

3.3.4. Combinations of CE marked and non CE marked devices.

The NB-MED Recommendation NB-MED/2.5.5/Rec2 "Combination of CE marked and non CE marked devices" applies as it is.

3.3.5. Affixing the CE marking

Where the identification of the software is displayed on a monitor screen, a good means to comply with the directives²⁰ is to display the CE mark close to this identification.

Where software is submitted on a media it should be properly CE marked.

In addition the CE marking must appear on the appropriate accompanying documents.

¹⁹ Software versions may form part of the content of the certificate. Further guidance can be obtained from: NB-MED Recommendation NB-MED/2.5.1/Rec4 "Content of mandatory certificates" as regards the identification of software.

²⁰ Medical Device Directive article 17.2, or Active Implantable Medical Device Directive article 12.1, or In Vitro Diagnostic Medical Device Directive article 16.2,

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			11/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

3.4. Explanation of terms

Term	Explanation
CAP	Conformity Assessment Procedure (CAP)
configuration management	The systematic procedures adopted to identify software items and control all software changes in a product with respect to development, support, upgrading, updating, revision and enhancement to the said software. It is analogous to, and may be often related to, a hardware 'engineering control system'.
cyclic redundancy [check] code (CRC)	A technique for error detection in data communications used to assure a program or data file has been accurately transferred. The CRC is the result of a calculation on the set of transmitted bits by the transmitter which is appended to the data. At the receiver the calculation is repeated and the results compared to the encoded value. The calculations are chosen to optimise error detection. Contrast with check summation, parity check. By incorporating the CRC code in the same software the method can also be used as means for verifying the integrity of the software code when transferred between electronic medias such as CD-ROM, Floppy Disks etc.
Manufacturer	For the explicit definition of this term see the text of the directives. See Ref.1 Article 1,(f) ; Ref.2.Article1,(l) and ; Ref.3, Article 1, (f)
Software	(1) A set of instructions processed by a state machine, which affect the intended behaviour of a system. (2) (ANSI) Programs, procedures, rules, and any associated documentation pertaining to the operation of a system. Contrast with hardware.
software platform	The environment in which the instructions of the software is executed. The platform may include both the central processing hardware, the operation system, firmware, BIOS (Basic input/output system) and the peripheral equipment.
software development life cycle	Period of time beginning when a software product is conceived and ending when the product ready for production. The software development life cycle is typically broken into phases denoting activities such as requirements, design, programming, testing, installation
software development methodology	(ANSI) A systematic approach to software creation that defines development phases and specifies the activities, products, verification procedures, and completion criteria for each phase.

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			12/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

Term	Explanation
software development process	(IEEE) The process by which user needs are translated into a software product. The process involves translating user needs into software requirements, transforming the software requirements into design, implementing the design in code, testing the code, and sometimes installing and checking out the software for operational activities. Note: these activities may overlap or be performed iteratively.
software life cycle	(NIST), Period of time beginning when a software product is conceived and ending when the product is no longer available for use. The software life cycle is typically broken into phases denoting activities such as requirements, design, programming, testing, installation and operation and maintenance.
support software	(IEEE) Software that aids in the development and maintenance of other software; e.g., compilers, loaders, and other utilities
system software	(1) (ISO) Application- independent software that supports the running of application software. (2) (IEEE) Software designed to facilitate the operation and maintenance of a computer system and its associated programs; e.g., operating systems, assemblers, utilities. Contrast with application software. See: support software.
Updating	Refreshing the list of intended features in a software offering. This may include additions to intended use, reductions in intended use, applicability to new hardware platforms, addition of communications functions, networking. All these type of changes should require co-ordination with the Notified body.
Upgrading	Synonymous with updating

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
3	ad hoc group/NBRG	5	06.11.2001	06.11.2001			13/13

	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/2.2/Rec4
Title:	Software and Medical Devices	

Rev. 1.0 Notified Body Recommendation Meeting, Berlin, 4 to 5 September 2000

- First draft presented by Robert Virefléau
- Work group defined. Poul Schmidt-Andersen elected convener

Rev. 2.0 Notified Body Meeting, Brussels, 8 November 2000

- Updated draft submitted (e-mail) to working group (WG) end of October 2000
- Updated draft reviewed at meeting 8 November 2000. Discussion about "embedded" and stand alone "software".
- Agreed changes to document from the meeting picked-up by David Barrows

Rev. 2.1 Copenhagen 11 November 2000

- Document partly updated by convener.
- E-mailed to David Barrow, UK for incorporation of notes from WG meeting.

Rev. 2.2 Copenhagen 23 November 2000

- Document received, updated by David Barrow.
- Document disseminated to WG members.

Notified Body Recommendation Meeting, Brussels 1 December 2000

- Document rev 2.2 reviewed by taskforce

Rev. 2.3 Copenhagen 8 January 2001

- Document updated by convener based on input from Brussels meeting 1 December 2000. This has among other things resulted in:
 - Deleting of the paragraph: "Issues addressed in the present recommendation"
 - Emplaning that the use of harmonized standards is voluntary
 - Written input from CIBEC and AMTAC has been taken into consideration, but not always followed.
 - The use of Product Quality Assurance (e.g. MDD, Annex VI) suggested not to be recommended as a viable conformity assessment procedure.
- Document disseminated to WG members.

Notified Body Recommendation Meeting, Brussels 10 January 2001

- Document rev 2.3 reviewed by taskforce
 - Major revision of section "Use of assessment procedure" suggested.

Rev.-Nr.	Rev. date	accepted	amended	withdrawn
5	06.11.2001	06.11.2001		

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/2.4/Rec4
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Rev. 2.4 Copenhagen 6 February 2001

- Document updated by convener based on input from Brussels meeting 10 January 2001
- Document disseminated to WG members.

Notified Body Recommendation Meeting, Brussels 7 February 2001

- Document rev 2.4 reviewed by taskforce
 - Major revision of section "Use of assessment procedure" accepted by task force.
- Document revised during meeting to become 2.5 by fine tuning the language. New draft disseminated to members during meeting

Rev. 2.5 Copenhagen 12 February 2001

- Document updated by convener based on further inputs from Brussels meeting 7 February 2001
 - "Table of Content" removed.
 - All footnotes revised
 - Update of explanation of terms
- Document disseminated to WG members and NB-MED secretariat

Rev. 3.0 Brussels 7 March 2001

- Rev. 2.5 not accepted at NBRG meeting 5 March in Brussels because of lack of rationale for the examples and reservations with respect to the stated cooperation between manufacturer and notified body and control of subcontractor. Document partly updated based on these inputs after the plenary NB-MED meeting. Then submitted to industry representative David Barrow (EUCOMED) to be updated with respect to his notes taken during the meetings.

Rev. 3.1 Copenhagen 20 April 2001

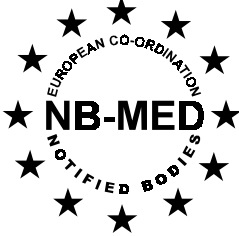
- Document updated by convener based on received inputs since Brussels meeting 7 March 2001
 - "Explanation of terms" extended
 - Introduction of the concepts of configuration management, development methodology and software platform
- Document disseminated to WG members and NB-MED secretariat

Rev. 3.2 Copenhagen 23 May 2001

- Document updated by convener based on received inputs since Brussels meeting 3 May 2001. This meeting did not review the document to its end. Section 3.3 and onward was not discussed. Consequently a new meeting end of May was agreed.
- Document disseminated to WG members and NB-MED secretariat

Rev.-Nr.	Rev. date	accepted	amended	withdrawn
5	06.11.2001	06.11.2001		

Page
2/3

	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/2.4/Rec4
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Rev. 3.30 Brussels 30 May 2001

- Document updated by convener during meeting.

Rev. 3.31 Brussels 30 May 2001

- Document updated by convener after meeting.

Rev. 4.0 Copenhagen 5 June 2001

- Document further updated by convener after meeting 30 May 2001.

Rev. 4.1 Copenhagen 12 July 2001

- Document editorial updated by convener based on incoming comments.
- Submitted to NB-MED Technical Secretariat att.: Jörg Höppner for update of format and dissemination to recommendation working group.

Rev. 5 Notified Body Meeting, Brussels, November 6 & 7, 2001:

The document – presented to NB-MED as document NBM/021/01 – was approved by the NB-MED plenary without any changes. But concession: Comments which have received the Technical Secretariat (tabled as document NBM/067/01) were referred to the task force with request to consider those in the next step a.s.a.p.

The Technical Secretariat has only made addendums to “Key words” and “Reference to Directives” (therefore new revision).

Confirmed at stage 3.

Revision no: 5

Rev.-Nr.	Rev
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Page
3/3