	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/2.13/Rec2**

Title:	**CE-Marking of established IVD devices**
Chapter:	**2.13 Transitional provisions**

Text:	**"...take account of any relevant information regarding the characteristics and performance of such devices, including in particular the results of any relevant tests and verification already carried out under pre-existing national law, regulations or administrative provisions in respect of such devices" (IVD Article 22.4)**
Key words:	**pre-existing national law, pre-existing national regulations, pre-existing national administrative provisions, implementation, transitional provisions**

1 Introduction

This document applies to medical devices which are placed on the market under the provisions of the '*In Vitro* Diagnostic Medical Device Directive' (IVD) but which were designed and manufactured in compliance with pre-existing national law or regulations in the Member States before the IVD-Directive came into force. Such "established devices" were based on design/manufacturing and approval requirements which existed before the IVD-Directive.

Manufacturers frequently request clarification on how existing data could be used for CE-marking of "established devices". The purpose of this document is to provide guidance to Notified Bodies and manufacturers on how to assess the documentary evidence for established devices in respect of the requirements of the IVD-Directive.

Note: Manufacturers may follow the same approach for procedures where a Notified Body is not involved.

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

Reference to Directives:	**Article/ Annex:**	**Reference to standards:**
AIMD		
MDD		
IVDD	Article 22.4, Annexes I, III-6, IV, V, VI	

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2 Requirements of the Directive

The placing of the CE marking on a device requires conformity to the essential requirements of the applicable Directive. The IVD-Directive requires by Article 22.4, that "the notified bodies which are responsible pursuant to Article 9 for conformity assessment take account of any relevant information regarding the characteristics and performance of such devices, including in particular the results of any relevant test and verification already carried out under pre-existing national law, regulations or administrative provisions in respect of such devices."

The following clauses present a general interpretation on how to apply the 'transitional provisions' of the IVD-Directive in respect of established devices. The aim is in particular to reach a level of harmonisation, on the approach taken by Notified Bodies and manufacturers, which will be acceptable to Member States and may avoid problems in market access. Of special importance for IVD devices included in Annex II will be the compliance with the 'Common Technical Specifications' (CTS). The guidance related to the CTS will be presented in an associated NB-MED document.

3 Pre-existing regulations and provisions

According to the IVD-Directive, the Notified Body which is responsible pursuant to Article 9 for conformity assessment shall take account of **any relevant information** regarding the characteristics and performance of a device based on pre-existing national law, regulations or administrative provisions. This will include pre-existing device market authorisations by the Member States and quality system certification held by a manufacturer prior to the IVD-Directive.

The manufacturer will need to have technical documentation regarding the design and manufacturing of a device. This documentation should contain a description of the device and all the information used to demonstrate compliance with the pre-existing national law, regulations or administrative provisions. It should also document any changes and modifications made to the design and manufacturing of the device. (Examples for such regulations and provisions are special national drug and device laws, GMP/PIC rules and relevant EN/ISO 9000/EN 46000 certificates).

The manufacturer should assess his documentation and decide if the design of the device and the manufacturing process meet the requirements of the IVD-Directive. Documentation previously required by the health authorities under pre-existing national law in Member States may serve as a basis for a comparison analysis as regards to the requirements of the IVD Directive. The differences between the

existing documented evidence and the requirements of the Directive need to be addressed by the manufacturer.

4 CE-marking of conformity

The manufacturer shall demonstrate and document compliance to the Essential Requirements. This compliance may be supported by the data related to pre-existing national law, regulations or administrative provisions as stated before. The data may be recorded through the use of "ER-checklists" by cross-referencing the relevant information. This information may be contained in the device design documentation, quality-system documentation, specific publications, reports, dossiers and any other relevant information regarding the characteristics and performance of a device. Compliance may be supported by information gained in the field (through Post-Marketing Surveillance, complaint handling and corrective action) or on similar devices. Such information shall include an evaluation of the data together with a justification as to how the manufacturer feels the data demonstrates compliance with the essential requirements of the IVD-Directive. The device design documentation, as mentioned above, may be a compilation of documents or a file referring to the location of such information. (Appendix 1 describes a possible process of demonstrating compliance to the essential requirements).

If compliance with a certain essential requirement can not be demonstrated by the above-mentioned documentation, evidence shall be provided by collecting additional data and information to complete the technical documentation. This may include additional tests and/or verification activities.

4.1 Risk Analysis

The results of the risk analysis of a device shall be part of the technical documentation, as required by the IVD-Directive. For 'established devices' the experience gained in the post-production phase (market experience) could be important to the subject of risk analysis if properly documented and transferable to objective evidence.

Using the pertaining EN document for risk analysis as a guide, the manufacturer should identify any potential risk that may be associated with the use of the device. The manufacturer should demonstrate how that risk has been eliminated or reduced as far as possible. Market experience (see also NB-MED/2.12/Rec1 *Post-Marketing Surveillance (PMS) post market/production*) may be used as supported evidence, where applicable, to demonstrate that a device is safe or a specific risk has been

adequately addressed. In such a case, the manufacturer should indicate how long the device has been in use and the number of units sold. Market experience include complaint handling and the manufacturer should demonstrate how complaints, relevant to the subject, are addressed. Where relevant, a critical appraisal of scientific literature may be used in the same approach as market experience.

Market experience is an important contribution to risk assessment; nevertheless, a successful history on the market by itself may not be sufficient. The outcome of the risk analysis should enable the manufacturer to state that any risks which may be associated with the use of the device is acceptable when weighed against the benefits to the patient and compatible with a high level of protection of health and safety.

4.2 Performance evaluation

Any performances stated by the manufacturer must be supported by either external performance evaluation data generated at the time of the design of the device, data established in the manufacturer's own premises during the R&D phase or by data taken from literature.

Data based on experience gained in the post-production phase may be used to support the claims made by the manufacturer.

4.3 Generic approach

The technical documentation must allow assessment of the conformity of the product with the requirements of the IVD-Directive.

The documentation may be structured for individual or particular products or where applicable across various products - a „generic approach".

The intent of a „generic approach" is to reduce the workload in building up the technical documentation by using information sources as efficiently as possible.

This approach may be valid e. g. for the following situations
- where one component of a device is used as a component in different products/configurations
- where the same Essential Requirements apply to a family of products

- where a quality system element can be used across a variety of products and demonstration of conformity with that system element will contribute to demonstration of compliance with a particular Essential Requirement

In taking a „generic approach“ the manufacturer shall demonstrate that the approach is valid for the products concerned and shall document his justification for that validity.

It is considered that a „generic Approach“ may not be applicable to all devices or to all particular requirements.

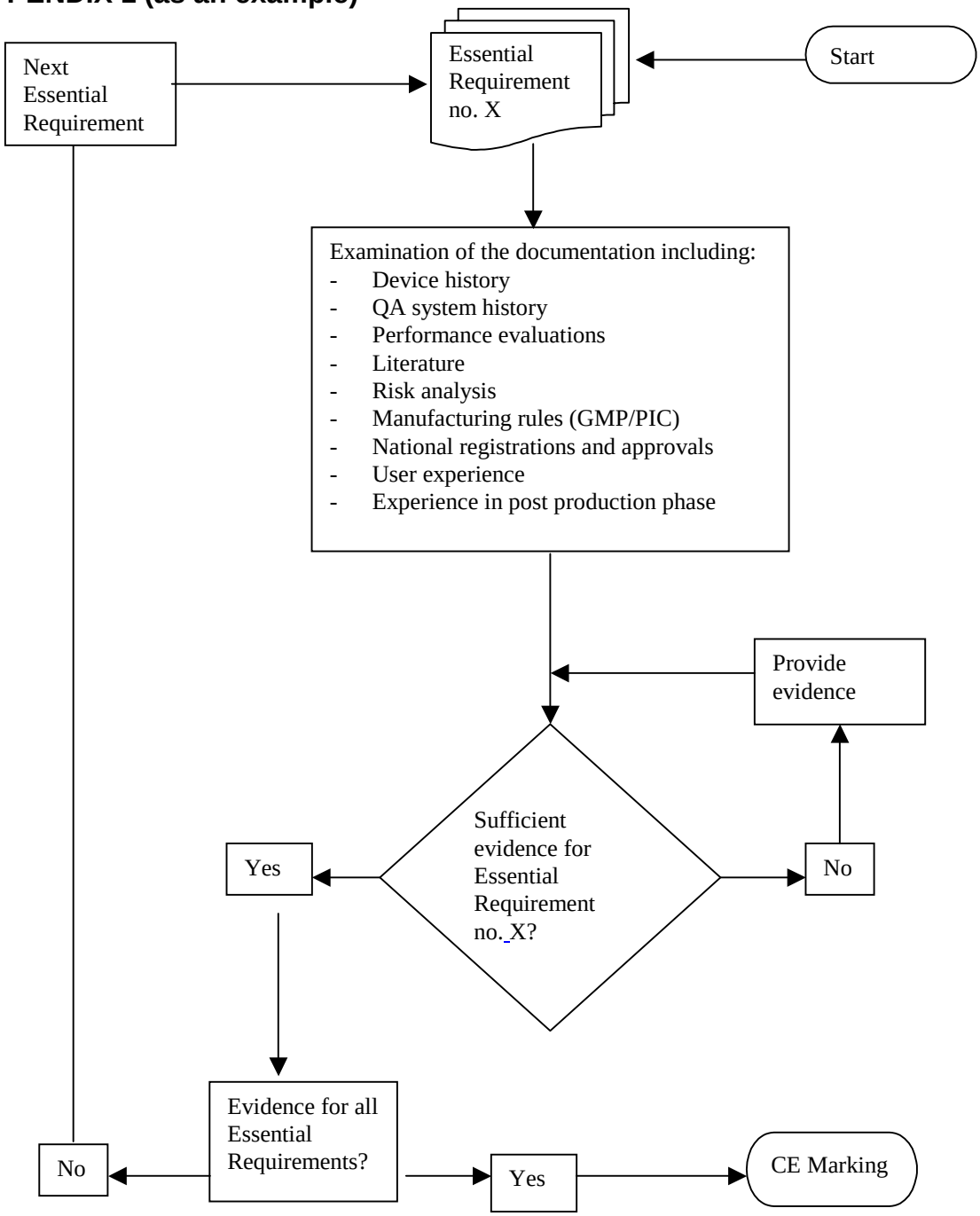
4.4 Devices listed in Annex II of the IVD-Directive

The IVD-Directive requires for devices listed in 'Annex II' that; manufacturers shall as a general rule be required to comply with the common technical specifications; if for duly justified reasons manufacturers do not comply with those specifications they must adopt solutions of a level at least equivalent thereto (Article 5.3).

These Common Technical Specifications (CTS) will be prepared and adopted according to the procedures of the Directive. For the moment the CTS under preparation includes provisions relating to 'Annex II List A' devices. It is anticipated that future editions of the CTS will be prepared if considered necessary.

The compliance with the CTS will be of special importance. Guidance for conformity assessment of devices designed and evaluated before the advent of the CTS will be presented in an associated NB-MED Recommendation.

APPENDIX 1 (as an example)



EUROPEAN CO-ORDINATION NB-MED NOTIFIED BODIES	**Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC**	**Rationale and history sheet to NB-MED/2.13/Rec2**
Title:	**CE-Marking of established IVD devices**	

Rev. 3: Notified Body Meeting, Brussels, November, 2 & 3, 1999:
The NBRG was asked to elaborate new NB-MED Recommendations in light of the IVD-directive if needed.

A small task force on NBRG-IVDD was established and met several times (on 03.12.99 at PEI and on 24.01.2000 at LRQA). First draft documents were elaborated (see also minutes NBRG/166/00 and NBRG/167/00).

Meeting of NBR Group, Brussels, March 2, 2000:
The work results of the small task force (elaborate new NB-MED Recommendations in light of IVDD) were presented to that NBRG-meeting.
The tabled revised working document (without revision no.) on "CE-Marking of established devices" was discussed and some comments for improvement were made. It was agreed that further development will be made by the task force group.

Meeting of NBR Group, Brussels, April 10 &11, 2000:
A new draft document was presented as NBRG/186/00 to that meeting (rev 2). NBRG reworked the document within an intensive discussion. It was decided to fit the document in the *recommendations nomenclature system* under chapter 2.13 *Transitional provisions*. Therefore the recommendation gets the number **NB-MED/2.13/Rec2**.
NBRG agreed that the document, as discussed and - during the meeting - revised, should be presented for formal adoption at the June NB-MED Plenary meeting **but could find application/knowledge in the meanwhile**.
Revision no: 3
stage 2

Notified Body Meeting, Brussels, June 6 & 7, 2000:
The document (NBM/56/00) was approved by the NB-MED plenary.
Confirmed at stage 3.
Revision no: 3

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