

WELMEC 4.1
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WELMEC

European cooperation in legal metrology

**Guide for the assessing and operation
of Notified Bodies performing conformity
assessment according to the Directive
90/384/EEC**



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WELMEC is a cooperation between the legal metrology authorities of the Member States of the European Union and EFTA. This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to notified bodies responsible for conformity assessment of their products. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC Directives. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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1. FOREWARD / SCOPE

This guide is developed for the assessment and operation of notified bodies performing conformity assessment according to directive 90/384 as amended 93/68 and with reference to the "Guide to the implementation of community harmonisation directives based on the new approach and the global approach" (first version 1994). – referred to hereafter as the "blue book".

Bodies are notified by the competent authority in the Member State (EEA). The Member State is responsible for the assessment of the notified body.

The Member State may take advantage of the competence of the accreditation bodies for the assessment of a notified body.

This guide gives advice on the use of particular quality standards within the EN-45000 series for each conformity assessment module. The overall aim is that all valid combinations of the quality standards and modules featured here shall give the same confidence in the work performed by the notified body. Annex 1 to this guide is a flow diagram which illustrates the conformity assessment options allowed by 90/384, together with the supporting structure of operational bodies and standards.

The conformity assessment procedures may consist of different elements:

- product testing
- product assessment decision
- assessment and approval of quality systems

2. GENERAL GUIDELINES FOR THE ASSESSMENT OF A NOTIFIED BODY

Assessment of notified bodies for 90/384: An expert on legal metrology shall always be a part of the assessment team. A legal metrology expert must have the competence with regard to the functioning and use of measuring instruments within the relevant field of application and must also have the knowledge of the legal requirements which are laid down for the instruments according to the directive.

Notified bodies must meet the minimum criteria of Annex V in directive 90/384. Some further general requirements will ensure that all parties can have confidence in the decisions of the notified bodies. These requirements are basically the same as given in EN 45504:1995, § 3 and 4 for the requirements on impartiality, integrity etc.; the requirements listed below are considered to fulfil the following Sections:

- EN 45011:1998, §4.2
- EN 45012:1998, §2.1.1 and 2.1.2
- EN 45004:1995, §3 and 4 (where EN 45004 is applied, it shall be the "type A-body".)

- a. The notified body shall be legally identifiable.
- b. The notified body shall provide documentation which describes its functions and the technical scope of activity for which it is competent in addition to operational procedures.

- c. The notified body and its personnel shall be free from any commercial, financial and other pressure which might affect their judgement. Procedures shall be implemented to ensure that persons or organisations external to the notified body, cannot influence the results of activities performed by the body.
- d. All interested parties shall have access to the services of the notified body. There shall not be undue financial or other conditions. The procedures under which the body operates shall be non-discriminatory.

A notified body may be notified for more than one of the conformity assessment procedures mentioned in the directive, but can on the other hand only be notified for a whole conformity assessment procedure. If a body is doing product testing and a notified body makes use of the test results from this testing in its assessment, the first body will be considered as a sub-contractor to the notified body.

In all cases where sub-contractors are used, the guidelines given in the “blue book”, pages 63 – 66 on notified bodies and sub-contracting, shall be followed. In particular it should be noted that subcontractors must be identifiable, technically competent and display independence and objectivity. Notified bodies retain responsibility for the work and cannot subcontract assessment and appraisal activities. Only technical tasks to pre-established specifications may be subcontracted.

3. GENERAL GUIDANCE FOR PRODUCT TESTING

A body fulfilling the EN 45001:1989 standard (reference may also be given to ISO/IEC Guide 25, draft version, 4th edition 1997) for the applicable methods, will give the necessary confidence in the test results for the conformity assessment decision.

The uncertainty in the test results has to be handled in a uniform way. In accord with the general view and tradition in Legal Metrology, the “shared risk concept” will generally be applied. This means that provided that the uncertainty of the test system is small compared to limits of error for instruments under test, uncertainty is not considered when using the test result for the conformity assessment procedure. In this way there will be an equally shared risk that a test result for an instrument on the borderline of the tolerances will be inside or outside these limits. Further explanation on how to handle uncertainty is given for each conformity assessment procedure.

In all cases the following requirements should be fulfilled:

- The traceability on the instruments and standards that are used in all tests shall be documented.
- The overall uncertainty of the test system shall not exceed one third of the tolerances for the instrument on test
- On request, the uncertainty in the test results shall be documents according to accepted methods (Guide to the expression of uncertainty in measurements, I 993/EAL-R2).

Generally the uncertainty in the test results is not required to be stated as a part of the conformity assessment.

4. USE OF HARMONISED STANDARD AND OTHER WELMEC GUIDES

In accordance with the “new approach”, use of the harmonised standard, EN 45501, is one way to produce a product that fulfils the requirements in the directive. It is, however, possible to achieve that result without the use of this standard.

The following WELMEC guides, of an advisory nature, are of particular relevance to the notified body:

- WELMEC 2, directive 90/384/EEC: Common application
- WELMEC 2.1 Guide for testing indicators
- WELMEC 2.2 Guide for testing point of sale devices
- WELMEC 2.3 Guide for examining software (including Amendment to WELMEC 2.3)
- WELMEC 2.5 Guide for Modular Approach and Testing of PCs and other Digital Peripheral Devices
- WELMEC 3.1, directive 90/384/EEC: Explanation and Interpretation

5. EC TYPE EXAMINATION (MODULE B)

The notified body shall work according to EN 45011 or 45004. The requirements on impartiality etc. and the use of sub-contractors shall be those given in Section 2 of this guide.

Records of approved instruments and technical files which include test results and reports shall be kept for as long as the instruments are likely to be in use.

In view of the importance of test results at the type examination stage the uncertainty of the system used in EC-type examination shall not be greater than 1/5 of the maximum permissible error. In this case, the shared-risk concept can still be applied for this module.

Personnel shall have adequate knowledge of the technology and applications of the instruments that are to be examined and also of the subsequent verification process. The competence of each person shall be documented.

6. EC PRODUCT VERIFICATION (MODULE F)

The necessary confidence in EC verification will be provided by a notified body operating in accordance with EN 45004. In the case where the notified body is part of a national or local government body operating legally established and accepted procedures, detailed requirements of EN 45004 for control and documentation of quality systems, test records and contract conditions may be inappropriate. However, the notified body shall be subject to independent quality audits to ensure that it meets the requirements of Annex V of the directive and section 2 of this guide.

The personnel shall have the necessary competence in the functioning and operation of the instrument to be verified and in the legal requirements for marking etc. as stated in directive 90/384, amended 93/68.

Subject to the requirements for the test system specified in Section 3, the uncertainty of the test results shall not be taken into account in the decision of conformity. (Shared risk.)

Where appropriate the notified body shall issue a certificate of conformity and ensure that the instrument is marked correctly according to the requirements in 90/384, amended by 93/68. (An example of the content of such a certificate of conformity is in WELMEC 2 (Issue 2, July 96)).

The certificate shall be kept by the manufacturer, or by agreement with the manufacturer, by the notified body,

The notified body shall keep a record of certificates that are issued.

If the notified body considers that an instrument does not fulfil the requirements, the reasons for this shall be given to the manufacturer and may be accompanied by test results.

7. EC UNIT VERIFICATION (MODULE G)

The body shall work according to EN 45011 or 45004. The requirements on impartiality etc. and the use of the sub-contractors shall be those given in Section 2 of this guide.

Records of approved instruments and technical files which include test results and reports shall be kept for as long as the instruments are likely to be in use.

Subject to the requirements for the test system specified in Section 3, the uncertainty of the test results shall not be taken into account in the decision of conformity. (Shared risk.)

Personnel shall have adequate knowledge of the technology and application of the instrument to be verified. The competence of each person shall be documented.

8. PRODUCTION QUALITY ASSURANCE (MODULE D)

8.1 Guidance on the operation of the notified body

The notified body shall work according to EN 45012. The requirement on impartiality etc. shall be given the interpretation of Section 2 of this guide. An expert in legal metrology shall be part of the assessment team.

8.2 Assessment of the manufacturer

The notified body shall generally assess the manufacturer according to ISO 9002, including all aspects that are relevant to the declaration of conformity of the products concerned.

The manufacturer shall have documented traceability for all instruments and standards used for testing. All test results shall be recorded and available for the notified body responsible for the assessment.

Subject to the requirements of Section 3 of this guide the manufacturer may apply the shared risk concept on uncertainty of final test results. The uncertainty of the test system shall not be more than 1/3 of the maximum permissible errors.

The manufacturer shall have the necessary competence in order to apply the end testing in a correct way for the conformity assessment.

The manufacturer shall keep the test results that are appropriate for the assessment of the product for a period of at least 3 years.

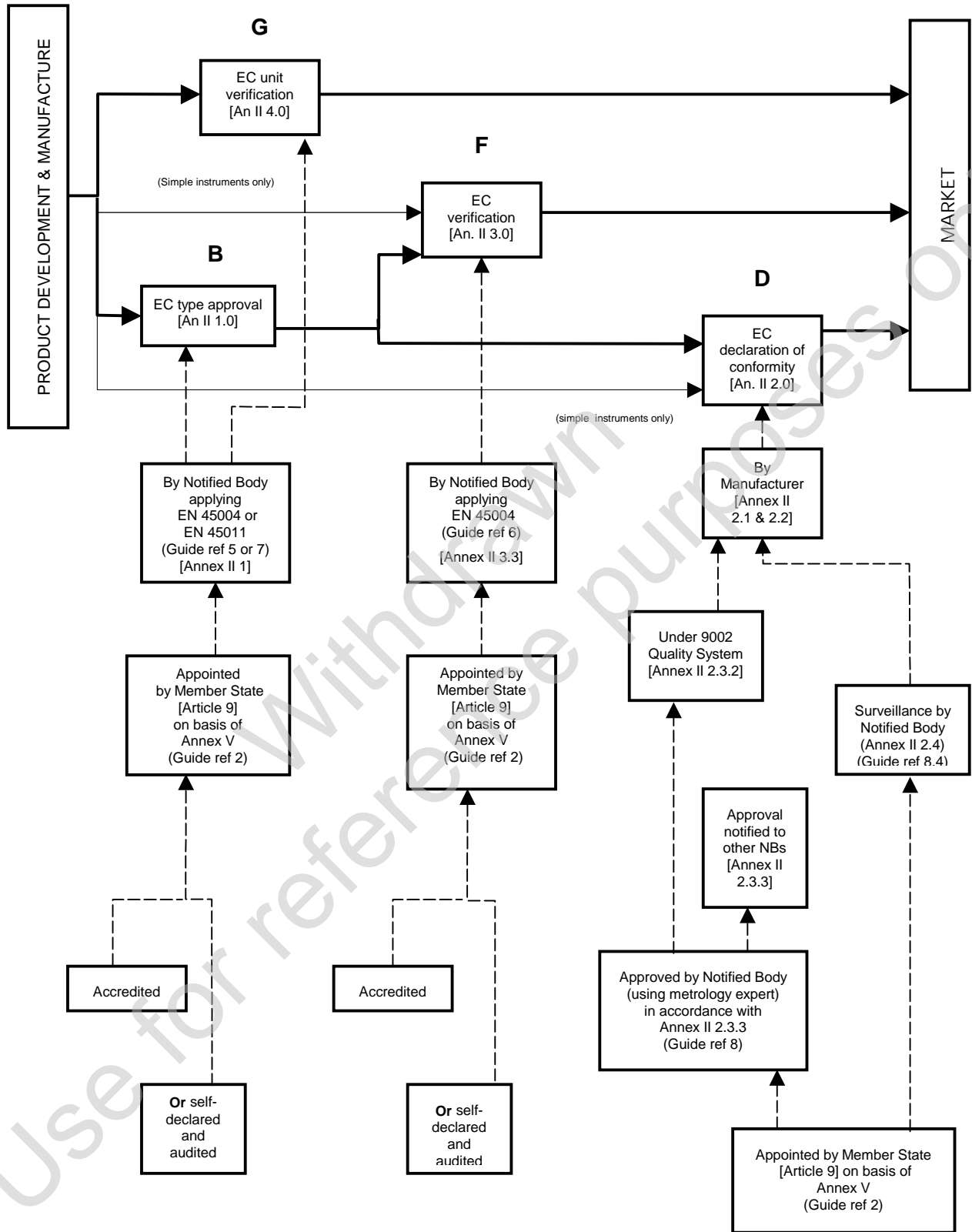
8.3 Manufacturer certified according to ISO 9001/9002

If the manufacturer already has a quality system approved in accordance with ISO 9001 or 9002 then the notified body may take this into account in assessing compliance with the requirements for declaration of conformity of products to 90/384. However the notified body must assess the quality system to ensure that it covers all aspects of the production and quality control that are relevant to the declaration of conformity for the products concerned, and these aspects must be assessed by a team which includes an expert on legal metrology.

8.4 EC – surveillance

Surveillance shall be performed by the notified body on a periodic basis. The first period shall not be more than one year, further evaluation shall be within a period of 3 years.

Conformity Control Options



An explanation of the term “shared risk” as given in a draft document from ILAC

“Draft second version of November 1995) of Committee 3, WG 5
ILAC Guide to assessment and reporting of compliance with specification”

Often, the specification requires a compliance statement in the certificate or report but makes no reference to taking into account the effect of uncertainty on the assessment of compliance. In such cases it may be appropriate for the user to make a judgement of compliance, based on whether the result is within the specified limits with no account taken of the uncertainty. This is often referred to as “shared risk” since the end-user takes some of the risk that the product may not meet the specification after being tested with an agreed measurement method. In this case there is an implicit assumption that the magnitude of the uncertainty is acceptable and it is important that it can be evaluated when necessary. The laboratory should be in a position to be able to determine the magnitude of the uncertainty if requested to do so by the client.