EUROPEAN COMMISSION

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2011/0352 (COD)

**NEW LEGISLATIVE FRAMEWORK (NLF) ALIGNMENT PACKAGE**
**(Implementation of the Goods Package)**

Proposal for a

# DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**on the harmonisation of the laws of the Member States relating to making available on the market of non-automatic weighing instruments**

**(Recast)**
**(Text with EEA relevance)**

# EXPLANATORY MEMORANDUM

## 1. CONTEXT OF THE PROPOSAL

### General context, reasons for and objectives of this proposal

This proposal is presented in the framework of the **implementation of the "goods package"** adopted in 2008. It is part of a package of proposals aligning ten product directives to Decision No 768/2008/EC establishing a common framework for the marketing of products.

Union (EU) harmonisation legislation ensuring the free movement of products has contributed considerably to the completion and operation of the Single Market. It is based on a high level of protection and provides economic operators with the means to demonstrate conformity, thus ensuring free movement through trust in the products.

Directive 2009/23/EC is an example of that Union harmonisation legislation, ensuring the free movement of non-automatic weighing instruments. It sets out essential requirements that non-automatic weighing instruments must comply with in order to be made available on the EU market. Manufacturers must demonstrate that a non-automatic weighing instrument has been designed and manufactured in compliance with the essential requirements and affix the CE marking.

Experience with the implementation of Union harmonisation legislation has shown – on a cross-sector scale - certain weaknesses and inconsistencies in the implementation and enforcement of this legislation, leading to

– the presence of non-compliant or dangerous products on the market and consequently a certain lack of trust in CE marking

– competitive disadvantages for economic operators complying with the legislation as opposed to those circumventing the rules

– unequal treatment in the case of non-compliant products and distortion of competition amongst economic operators due to different enforcement practices

– differing practices in the designation of conformity assessment bodies by national authorities

– problems with the quality of certain notified bodies

Furthermore the regulatory environment has become more and more complex, as frequently several pieces of legislation apply simultaneously to one and the same product. Inconsistencies in these pieces of legislation make it increasingly difficult for economic operators and authorities to correctly interpret and apply that legislation.

To remedy these horizontal shortcomings in Union harmonisation legislation observed across several industrial sectors, the **"New Legislative Framework"** was adopted in 2008 as part of the **goods package**. Its objective is to strengthen and complete the existing rules and to improve practical aspects of their application and enforcement. The New Legislative Framework (NLF) consists of two complementary instruments, **Regulation (EC) No**

**765/2008 on accreditation and market surveillance** and **Decision No 768/2008/EC establishing a common framework for the marketing of products**.

The NLF Regulation has introduced rules on accreditation (a tool for the evaluation of competence of conformity assessment bodies) and requirements for the organisation and performance of market surveillance and controls of products from third countries. Since 1 January 2010 these rules apply directly in all Member States.

The NLF Decision sets out a common framework for EU product harmonisation legislation. This framework consists of the provisions which are commonly used in EU product legislation (e.g. definitions, obligations of economic operators, notified bodies, safeguard mechanisms, etc). These common provisions have been reinforced to ensure that the directives can be applied and enforced more effectively in practice. New elements, such as obligations on importers, have been introduced, which are crucial for improving the safety of products on the market.

The provisions of the NLF Decision and those of the NLF Regulation are complementary and closely interlinked. The NLF Decision contains the corresponding obligations for economic operators and notified bodies allowing market surveillance authorities and authorities responsible for notified bodies to properly perform the tasks imposed on them by the NLF Regulation and to ensure an effective and consistent enforcement of EU product legislation.

However, unlike the NLF Regulation, the provisions of the NLF Decision are not directly applicable. To ensure that all economic sectors subject to Union harmonisation legislation benefit from the improvements of the NLF, the provisions of the NLF Decision need to be integrated into the existing product legislation.

A survey after the adoption of the goods package in 2008 showed that a majority of Union harmonisation legislation on products was due to be revised within the following 3 years, not only to address the problems observed throughout all sectors but also for sector-specific reasons. Any such revision would automatically include an alignment of the legislation concerned to the NLF Decision since Parliament, Council and Commission have committed themselves to use its provisions as much as possible in future legislation on products in order to further the utmost coherence of the regulatory framework.

For a number of other Union harmonisation directives, including Directive 2009/23/EC no revision for sector-specific problems had been envisaged within this timeframe. To ensure that the problems in relation to non-compliance and notified bodies are nevertheless addressed in these sectors, and for the sake of consistency of the overall regulatory environment on products, it was decided to align these directives within a package to the provisions of the NLF Decision.

**Consistency with other policies and objectives of the Union**

This initiative is in line with the Single Market Act[1], which has stressed the need to restore consumer confidence in the quality of products on the market and the importance of reinforcing market surveillance.

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[1] Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, COM(2011) 206 final.

Furthermore it supports the Commission's policy on Better Regulation and simplification of the regulatory environment.

## 2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

### Consultation of interested parties

The alignment of Directive 2009/23/EC to the NLF Decision has been discussed with national experts responsible for the implementation of this Directive and with other interested stakeholders as well as in bilateral meetings with the European weighing instruments industry associations.

From June to October 2010 a public consultation was organised that comprised all the sectors involved in this initiative. It consisted of four targeted questionnaires for economic operators, authorities, notified bodies and users and the Commission services received 300 replies. The results are published at:

http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index_en.htm

In addition to the general consultation a specific SME consultation was carried out. 603 SMEs were consulted through the Enterprise Europe Network in May/June 2010. The results are available at http://ec.europa.eu/enterprise/policies/single-market-goods/files/new-legislative-framework/smes_statistics_en.pdf

The consultation process revealed widespread support for the initiative. There is unanimity on the need to improve market surveillance and the system for assessing and monitoring Notified Bodies. Authorities fully support the exercise because it will strengthen the existing system and improve cooperation at EU level. Industry expects a more level playing field resulting from more effective actions against products that do not comply with the legislation, as well as a simplification effect from the alignment of legislation. Certain concerns were expressed on some obligations which are, however, indispensable for increasing the efficiency of market surveillance. These measures will not entail significant costs for industry, and the benefits resulting from improved market surveillance should by far outweigh the costs.

### Collection and use of expertise

The impact assessment for this implementation package has largely built on the impact assessment carried out for the New Legislative Framework. In addition to the expertise collected and analysed in that context, further consultation of sector-specific experts and interest groups, as well as horizontal experts active in the area of technical harmonisation, conformity assessment, accreditation and market surveillance, has taken place.

### Impact assessment

Based on the information collected, the Commission carried out an impact assessment which examined and compared three options.

### Option 1 - No changes to the current situation

This option proposes no changes to the current directive and relies exclusively on certain improvements that can be expected from the NLF Regulation.

**Option 2 – Alignment to the NLF Decision by non-legislative measures**

Option 2 considers the possibility of encouraging a voluntary alignment to the provisions set out in the NLF Decision by, e.g., presenting them as best practices in guidance documents.

**Option 3 – Alignment to NLF Decision by legislative measures**

This option consists in integrating the provisions of the NLF Decision into the existing directives.

Option 3 was found to be the preferred option because

– it will improve the competitiveness of companies and notified bodies taking their obligations seriously, as opposed to those cheating on the system;

– it will improve the functioning of the internal market by ensuring equal treatment of all economic operators, notably importers and distributors, as well as notified bodies;

– it does not entail significant costs for economic operators and notified bodies; for those who are already acting responsibly, no extra costs or only negligible costs are expected;

– it is considered more effective than option 2: due to the lack of enforceability of option 2 it is questionable that the positive impacts would materialise under that option;

– options 1 and 2 do not provide answers to the problem of inconsistencies in the regulatory framework and therefore have no positive impact on the simplification of the regulatory environment.

## 3. MAIN ELEMENTS OF THE PROPOSAL

### 3.1. Horizontal definitions

The proposal introduces harmonised definitions of terms which are commonly used throughout Union harmonisation legislation and should therefore be given a consistent meaning throughout that legislation.

### 3.2. Obligations of economic operators and traceability requirements

The proposal clarifies the obligations of manufacturers and authorised representatives and introduces obligations for importers and distributors. Importers must verify that the manufacturer has carried out the applicable conformity assessment procedure and has drawn up a technical documentation. They must also make sure with the manufacturer that this technical documentation can be made available to authorities upon request. Furthermore importers must verify that the non-automatic weighing instruments are correctly marked and accompanied by instructions and information. They must keep a copy of the Declaration of conformity and indicate their name and address on the product, or where this is not possible on the packaging or the accompanying documentation. Distributors must verify that the non-automatic weighing instrument bears the CE marking, the name of the manufacturer and of

the importer, if relevant, and that it is accompanied by the required documentation and instructions.

Importers and distributors must cooperate with market surveillance authorities and take appropriate actions when they have supplied non-compliant non-automatic weighing instruments.

**Enhanced traceability obligations** are introduced for all economic operators. Non-automatic weighing instruments have to bear the manufacturer's name and address and a number allowing to identify and link the non-automatic weighing instrument to its technical documentation. When a non-automatic weighing instrument is imported the importer's name and address must also be on the non-automatic weighing instruments. Furthermore every economic operator must be able to identify towards authorities the economic operator who has supplied him with a non-automatic weighing instrument or to whom he has supplied a non-automatic weighing instrument.

### 3.3. Harmonised standards

Compliance with harmonised standards provides for a presumption of conformity with the essential requirements. On 1 June 2011 the Commission adopted a proposal for a Regulation on European Standardisation[2] that sets out a horizontal legal framework for European standardisation. The proposal for the Regulation contains inter alia provisions on standardisation requests from the Commission to the European Standardisation Organisations, on the procedure for objections to harmonised standards and on stakeholder participation in the standardisation process. Consequently the provisions of Directive 2009/23/EC which cover the same aspects have been deleted in this proposal for reasons of legal certainty. The provision conferring presumption of conformity to harmonised standards has been modified to clarify the extent of the presumption of conformity when standards only partially cover the essential requirements.

### 3.4. Conformity assessment and CE marking

Directive 2009/23/EC has selected the appropriate conformity assessment procedures which manufacturers have to apply in order to demonstrate that their non-automatic weighing instruments comply with the essential requirements. The proposal aligns these procedures to their updated versions set out in the NLF Decision. It keeps some sector specific elements already provided for in Directive 2009/23/EC as the intervention in certain cases of two notified bodies in the production control phase. Furthermore, the statistical verification provided for in Modules F and F1 of the NLF Decision has not been kept, as it is not relevant for the non-automatic weighing instruments sector.

General principles of the CE marking are set out in Article 30 of Regulation 765/2008, while the detailed provisions on the affixing of the CE marking and the M marking to non-automatic weighing instruments have been inserted in this proposal.

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[2] Proposal for a Regulation of the European Parliament and of the Council on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council. [COM(2011) 315 final]

### 3.5. Notified Bodies

The proposal reinforces the notification criteria for notified bodies. It clarifies that subsidiaries or subcontractors must also comply with the notification requirements. Specific requirements for notifying authorities are introduced, and the procedure for notification of notified bodies is revised. The competence of a notified body must be demonstrated by an accreditation certificate. Where accreditation has not been used to evaluate the competence of a notified body, the notification must comprise the documentation demonstrating how the competence of that body has been evaluated. Member States will have the possibility to object to a notification.

### 3.6. Market surveillance and the safeguard clause procedure

The proposal revises the existing safeguard clause procedure. It introduces a phase of information exchange between Member States, and specifies the steps to be taken by the authorities concerned, when a non-compliant non-automatic weighing instrument is found. A real safeguard clause procedure – leading to a Decision at Commission level on whether a measure is justified or not - is only launched when another Member State objects to a measure taken against a non-automatic weighing instrument. Where there is no disagreement on the restrictive measure taken, all Member States must take the appropriate action on their territory.

## 4. LEGAL ELEMENTS OF THE PROPOSAL

### Legal basis

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union.

### Subsidiarity principle

The internal market is a competence that is shared between the Union and the Member States. The subsidiarity principle arises in particular with regard to the newly added provisions aiming at the improvement of effective enforcement of Directive 2009/23/EC, namely, the importer and distributor obligations, the traceability provisions, the provisions on the assessment and notification of notified bodies, and the enhanced cooperation obligations in the context of the revised market surveillance and safeguard procedures.

Experience with the enforcement of the legislation has shown that measures taken at national level have led to divergent approaches and to a different treatment of economic operators inside the EU, which undermines the objective of this directive. If actions are taken at national level to address the problems, this risks creating obstacles to the free movement of goods. Furthermore action at national level is limited to the territorial competence of a Member State. In view of the increasing internationalisation of trade, the number of cross-border cases is constantly rising. Coordinated action at EU level can much better achieve the objectives set, and will in particular render market surveillance more effective. Hence it is more appropriate to take action at EU level.

As regards the problem of inconsistencies throughout the directives, this is a problem which can only be solved by the EU legislator.

### Proportionality

In accordance with the principle of proportionality, the proposed modifications do not go beyond what is necessary to achieve the objectives set.

The new or modified obligations do not impose unnecessary burdens and costs on industry - especially on small and medium sized enterprises - or administrations. Where modifications have been identified to have negative impacts, the analysis of the impacts of the option serves to provide the most proportionate response to the problems identified. A number of modifications concern the improvement of clarity of the existing Directive without introducing new requirements that entail added cost.

**Legislative technique used**

The alignment to the NLF Decision requires a number of substantive amendments to the provisions of Directive 2009/23/EC. To ensure the readability of the amended text the technique of recasting has been chosen in line with the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts[3].

The changes made to the provisions of Directive 2009/23/EC concern: the definitions, the obligations of economic operators, the presumption of conformity provided by harmonised standards, the declaration of conformity, CE marking, notified bodies, the safeguard clause procedure and the conformity assessment procedures.

The proposal does not change the scope of Directive 2009/23/EC and the essential requirements.

## 5. BUDGETARY IMPLICATIONS

This proposal does not have any implications for the EU budget.

## 6. ADDITIONAL INFORMATION

**Repeal of existing legislation**

The adoption of the proposal will lead to repeal of Directive 2009/23/EC.

**European Economic Area**

The proposal concerns the EEA and should therefore be extended to the European Economic Area.

[3] OJ C 77, 28.3.2002.

↓ 2009/23/EC (adapted)

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty ~~establishing the European Community~~ ⌦ on the Functioning of the European Union ⌫, and in particular Article ~~95~~ ⌦ 114 ⌫ thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[4],

Acting in accordance with the ordinary legislative procedure,

Whereas:

↓ 2009/23/EC recital 1 (adapted)

~~Council Directive 90/384/EEC of 20 June 1990 on the harmonisation of the laws of the Member States relating to non-automatic weighing instruments[5] has been substantially amended[6]. In the interests of clarity and rationality the said Directive should be codified.~~

4 OJ C […], […], p. […].

5 ~~OJ L 189, 20.7.1990, p. 1.~~

6 ~~See Annex VII, Part A.~~

⇩ new

(1) A number of substantive changes are to be made to Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments[7]. In the interests of clarity, that Directive should be recast.

(2) Regulation (EC) No 765/2008/EC of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93[8] lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC[9] lays down a common framework of general principles and reference provisions intended to apply across the legislation harmonising the conditions for the marketing of products in order to provide a coherent basis for revision or recasts of that legislation. Directive 2009/23/EC should therefore be adapted to that Decision.

⇩ 2009/23/EC recital 2

(4) Member States have the responsibility of protecting the public against incorrect results of weighing operations by means of non-automatic weighing instruments when used for certain categories of applications.

⇩ 2009/23/EC recital 3 (adapted)

~~In each Member State, mandatory provisions fix in particular the necessary performance requirements of non-automatic weighing instruments by specifying metrological and technical requirements, together with inspection procedures before and after going into service. These mandatory provisions do not necessarily lead to different levels of protection from one Member State to another but do, by their disparity, impede trade within the Community.~~

⇩ new

(5) Economic operators should be responsible for the compliance of non-automatic weighing instruments, in relation to their respective roles in the supply chain, so as to

[7] OJ L 122, 16.5.2009, p. 6.
[8] OJ L 218, 13.8.2008, p. 30.
[9] OJ L 218, 13.8.2008, p. 82.

ensure a high level of protection of public interests, as health and safety and the protection of users, and to guarantee fair competition on the Union market.

(6) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market non-automatic weighing instruments which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each operator in the supply and distribution process.

(7) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain the obligation of the manufacturer alone.

(8) It is necessary to ensure that non-automatic weighing instruments from third countries entering the Union market comply with the requirements of this Directive, and in particular that appropriate assessment procedures have been carried out by manufacturers with regard to those non-automatic weighing instruments. Provision should therefore be made for importers to make sure that the non-automatic weighing instruments they place on the market comply with the requirements of this Directive and that they do not place on the market non-automatic weighing instruments which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the supervisory authorities.

(9) The distributor makes a non-automatic weighing instrument available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the non-automatic weighing instrument does not adversely affect the compliance of the instrument.

(10) When placing a non-automatic weighing instrument on the market, every importer should indicate on the non-automatic weighing instrument his name and the address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the non-automatic weighing instrument does not allow it. This includes cases where the importer should have to open the packaging to put his name and address on the instrument.

(11) Any economic operator that either places a non-automatic weighing instrument on the market under his own name or trademark or modifies a non-automatic weighing instrument in such a way that compliance with the requirements of this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(12) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the non-automatic weighing instrument concerned.

(13) Ensuring traceability of a non-automatic weighing instrument throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing

economic operators who made non-compliant non-automatic weighing instruments available on the market.

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↓ 2009/23/EC recital 4 (adapted)
⇨ new

(14) This Directive should ~~set out~~ ⇨ be limited to the expression of ⇦ ~~mandatory and~~ the essential requirements as regards metrology and performance in relation to non-automatic weighing instruments. ⊠ In order ⊠ ~~T~~to facilitate ~~proof of~~ conformity ⊠ assessment ⊠ with ~~the essential~~ ⊠ those ⊠ requirements, it is necessary to ~~have~~ ⊠ provide for presumption of conformity for non-automatic weighing instruments which are in conformity with ⊠ harmonised standards ~~at European level,~~ ⇨ that are adopted in accordance with Regulation (EU) No [../..] of the European Parliament and of the Council of […..] on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council[10] for the purpose of expressing detailed technical specifications of those requirements, ⇦ in particular as to the metrological, design and construction characteristics~~, so that instruments complying with those harmonised standards may be assumed to conform to the essential requirements. These standards, harmonised at European level, are drawn up by private bodies and must remain non-mandatory texts. For that purpose the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (Cenelec) and the European Telecommunications Standards Institute (ETSI) are recognised as the competent bodies for the adoption of harmonised standards in accordance with the general guidelines[11] for cooperation between the Commission, the European Free Trade Association (EFTA) and those three bodies, signed on 28 March 2003~~.

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⇩ new

(15) Regulation (EU) No [../..] [European Standardisation] provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy requirements of this Directive.

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↓ 2009/23/EC recital 5 (adapted)

~~A series of Directives designed to remove technical barriers to trade in accordance with the principles established in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards[12] has been adopted; each of those Directives provides for the affixing of the 'CE' conformity marking. In its communication of 15 June 1989[13] on a global approach to certification and testing,~~

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10 OJ L […], […], p. […].
11 ~~OJ C 91, 16.4.2003, p. 7.~~
12 ~~OJ C 136, 4.6.1985, p. 1.~~
13 ~~OJ C 267, 19.10.1989, p. 3.~~

~~the Commission proposed that common rules be drawn up concerning a 'CE' conformity marking with a single design. In its Resolution of 21 December 1989 on a global approach to conformity assessment[14], the Council approved as a guiding principle the adoption of a consistent approach such as this with regard to the use of the 'CE' conformity marking. The two basic elements of the new approach which should be applied are the essential requirements and the conformity assessment procedures.~~

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↓ 2009/23/EC recital 6

(16) Assessment of conformity with the relevant metrological and technical provisions is necessary to provide effective protection for users and third parties. ~~The existing conformity assessment procedures differ from one Member State to another. To avoid multiple assessments of conformity, which are in effect barriers to the free movement of the instruments, arrangements should be made for the mutual recognition of conformity assessment procedures by the Member States. To facilitate the mutual recognition of conformity assessment procedures, Community procedures should be set up, together with criteria for the designation of the bodies responsible for carrying out tasks pertaining to the conformity assessment procedures.~~

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⇩ new

(17) In order to enable economic operators to demonstrate and the competent authorities to ensure that non-automatic weighing instruments made available on the market conform to the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.

(18) Manufacturers should draw up an EU declaration of conformity to provide detailed information on the conformity of the non-automatic weighing instrument with the requirements of this Directive and of other relevant Union harmonisation legislation.

(19) The CE marking, indicating the conformity of a non-automatic weighing instrument, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship to other markings are set out in Regulation (EC) No 765/2008. Together with the CE marking, the manufacturer should affix the sticker bearing the letter 'M'. Rules governing the affixing of the CE marking and the "M" sticker should be laid down in this Directive.

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[14] ~~OJ C 10, 16.1.1990, p. 1.~~

⇩ new

(20) The conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.

🡻 2009/23/EC recital 7

~~It is therefore essential to ensure that such designated bodies ensure a high level of quality throughout the Community.~~

⇩ new

(21) Experience has shown that the criteria set out in Directive 2009/23/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

(22) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

(23) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.

(24) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

(25) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(26) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard

the level of protection required for the non-automatic weighing instruments to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.

(27) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.

(28) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

(29) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.

(30) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to non-automatic weighing instruments covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.

(31) Directive 2009/23/EC already provides for a safeguard procedure allowing the Commission to examine the justification for a measure taken by a Member State against non-automatic weighing instruments it considers being non-compliant. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard clause procedure, with a view to making it more efficient and drawing on expertise available in Member States.

(32) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to non-automatic weighing instruments presenting a risk to the health and safety of persons or to other aspects of public interest protection. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such non-automatic weighing instruments.

(33) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

(34) Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

(35) It is necessary to provide for transitional arrangements that allow making available on the market and putting into service non-automatic weighing instruments that have already been placed on the market in accordance with Directive 2009/23/EC.

(36) Since the objective of this Directive, namely to ensure that non-automatic weighing instruments on the market fulfil the requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

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↓ 2009/23/EC recital 8

~~The presence on a non-automatic weighing instrument of the 'CE' conformity marking or of the sticker bearing the letter 'M' should indicate that there is a presumption that it satisfies the provisions of this Directive and therefore make it unnecessary to repeat the assessments of conformity already carried out.~~

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⇩ new

(37) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with Directive 2009/23/EC. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

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↓ 2009/23/EC recital 9

(38) This Directive should be without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and application of the Directives set out in ~~Annex VII,~~ Part B of Annex VII to Directive 2009/23/EC~~,~~,

↓ 2009/23/EC (adapted)

HAVE ADOPTED THIS DIRECTIVE:

# CHAPTER 1

# ~~*SCOPE, PLACING ON THE MARKET AND FREE MOVEMENT*~~

# ⌦ GENERAL PROVISIONS ⌫

*Article 1*

**⌦ Scope ⌫**

↓ 2009/23/EC (adapted)

1. This Directive shall apply to all non-automatic weighing instruments.

2. For the purposes of this Directive, the following categories of use of non-automatic weighing instruments shall be distinguished:

~~(a)~~

(a~~i~~) determination of mass for commercial transactions;

(b~~ii~~) determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;

(c~~iii~~) determination of mass for the application of laws or regulations or for an expert opinion given in court proceedings;

(d~~iv~~) determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;

(e~~v~~) determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories;

(f~~vi~~) determination of price on the basis of mass for the purposes of direct sales to the public and the making-up of prepackages;

(g~~b~~) all applications other than those listed in points (a) ⌦ to (f) ⌫ .

↓ 2009/23/EC (adapted)

*Article 2*

**⌦ Definitions ⌫**

For the purposes of this Directive, the following definitions ~~shall~~ apply:

(1~~.~~) ‘weighing instrument’~~:~~ ⌦ means ⌫ a measuring instrument serving to determine the mass of a body by using the action of gravity on that body~~. A weighing instrument may also~~ ⌦ or serving ⌫ ~~serve~~ to determine other mass-related magnitudes, quantities, parameters or characteristics;

(2~~.~~) ‘non-automatic weighing instrument’ or ‘instrument’~~:~~ ⌦ means ⌫ a weighing instrument requiring the intervention of an operator during weighing;

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↓ 2009/23/EC

~~3. ‘harmonised standard’: a technical specification (European standard or harmonised document) adopted by the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (Cenelec), or the European Telecommunications Standards Institute (ETSI), or by two or three of those bodies, upon a remit from the Commission in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations[15] and the general guidelines for cooperation between the Commission, the European Free Trade Association (EFTA) and those three bodies, signed on 28 March 2003.~~

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⇩ new

(3) ‘making available on the market’ means any supply of an instrument for distribution, or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(4) ‘placing on the market’ means the first making available of an instrument on the Union market;

(5) ‘manufacturer’ means any natural or legal person who manufactures an instrument or has an instrument designed or manufactured, and markets that instrument under his name or trademark;

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[15] ~~OJ L 204, 21.7.1998, p. 37.~~

(6) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(7) ‘importer’ means any natural or legal person established within the Union who places an instrument from a third country on the Union market;

(8) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an instrument available on the market;

(9) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;

(10) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by an instrument, process or service;

(11) ‘harmonised standard’ means harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No […] [European Standardisation];

(12) ‘accreditation’ means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;

(13) ‘national accreditation body’ means national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;

(14) ‘conformity assessment’ means the process demonstrating whether the requirements of this Directive relating to an instrument have been fulfilled;

(15) ‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(16) ‘recall’ means any measure aimed at achieving the return of an instrument that has already been made available to the end user;

(17) ‘withdrawal’ means any measure aimed at preventing an instrument in the supply chain from being made available on the market;

(18) ‘CE marking’ means a marking by which the manufacturer indicates that the instrument is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

(19) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products.

↓ 2009/23/EC (adapted)

*Article 3*

**⌦ Making available on the market and putting into service ⌫**

↓ 2009/23/EC
⇨ new

1. Member States shall take all steps to ensure that only instruments that meet the requirements of this Directive may be ~~placed~~ ⇨ made available ⇦ on the market.

↓ 2009/23/EC (adapted)

2. Member States shall take all steps to ensure that instruments may not be brought into service for the uses referred to in points (a) to (f) of Article 1(2) unless they meet the requirements of this Directive ~~and accordingly bear the 'CE' conformity marking provided for in Article 11~~.

~~*Article 14*~~

3. Member States shall take all steps to ensure that instruments ~~bearing the 'CE' conformity marking attesting conformity with the requirements of this Directive~~ continue to conform to ~~those~~ ⌦ the ⌫ requirements ⌦ of this Directive ⌫ .

*Article 4*

**⌦ Essential requirements ⌫**

↓ 2009/23/EC
⇨ new

Instruments used for the applications listed in points (a) to (f) of Article 1(2) must satisfy the essential requirements set out in Annex I ⇨ and bear the CE marking and the inscriptions provided for in point 1 of Annex III ⇦ .

↓ 2009/23/EC

In cases where the instrument includes, or is connected to, devices which are not used for the applications listed in points (a) to (f) of Article 1(2), such devices shall not be subject to those essential requirements.

↓ 2009/23/EC (adapted)

*Article 5*

**⌦ Free movement ⌫**

↓ 2009/23/EC
⇨ new

1. Member States shall not impede the ~~placing~~ ⇨ making available ⇦ on the market of instruments which meet the requirements of this Directive.

2. Member States shall not impede the putting into service, for the uses referred to in points (a) to (f) of Article 1(2), of instruments which meet the requirements of this Directive.

⇩ new

# CHAPTER 2

# OBLIGATIONS OF ECONOMIC OPERATORS

*Article 6 [Article R2 of Decision No 768/2008/EC]*

**Obligations of manufacturers**

1. When placing on the market their instruments used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I.

When placing on the market their instruments not used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall ensure that they bear the inscriptions provided for in point 2 of Annex III.

2. For the instruments used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall draw up the required technical documentation and carry out the relevant conformity assessment procedure referred to in Article 14 or have it carried out.

Where compliance of the instrument with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking and the inscriptions provided for in point 1 of Annex III.

For the instruments not used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall affix the inscriptions provided for in point 2 of Annex III.

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↓ 2009/23/EC (adapted)

Where an instrument which is used for any of the applications referred to in points (a) to (f) of Article 1(2) includes, or is connected to, devices that have not been subject to conformity assessment ~~as~~ referred to in Article ~~9~~13, each of those devices shall bear the symbol restricting its use as ~~defined~~ ⌦ provided for ⌫ in point 3 of ~~by~~ Annex ~~IV~~ III~~,~~ ~~point 3~~.

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⇩ new

3. For the instruments used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the instrument has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in instrument design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of an instrument is declared shall be adequately taken into account.

When deemed appropriate with regard to the performance presented by an instrument, manufacturers shall carry out sample testing of instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming instruments and instrument recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that their instruments bear a type, batch or serial number or other element allowing their identification, as set out in Annex III.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the instrument or, where that is not possible, on its packaging or in a document accompanying the instrument. The address must indicate a single point at which the manufacturer can be contacted.

7. Manufacturers shall ensure that the instrument is accompanied by instructions and information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

8. Manufacturers who consider or have reason to believe that an instrument which they have placed on the market is not in conformity with this Directive shall immediately take the

necessary corrective measures to bring that instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the instrument presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the instrument available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the instrument, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by instruments which they have placed on the market.

*Article 7 [Article R3 of Decision No 768/2008/EC]*

**Authorised representatives**

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 6(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authorities for 10 years after the instrument has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an instrument;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by instruments covered by the authorised representative’s mandate.

*Article 8 [Article R4 of Decision No 768/2008/EC]*

**Obligations of importers**

1. Importers shall place only compliant instruments on the Union market.

2. Before placing on the market an instrument used for the applications listed in points (a) to (f) of Article 1(2), importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the instrument bears the CE marking, the inscriptions provided for in point 1 of Annex III and is accompanied by the required

documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Where an importer considers or has reason to believe that an instrument used for the applications listed in points (a) to (f) of Article 1(2) is not in conformity with the essential requirements set out in Annex I, he shall not place the instrument on the market until it has been brought into conformity. Furthermore, where the instrument presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

Before placing on the market an instrument not used for the applications listed in points (a) to (f) of Article 1(2), importers shall ensure that the instrument bears the inscriptions provided for in point 2 of Annex III and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the instrument or, where that is not possible, on its packaging or in a document accompanying the instrument.

4. Importers shall ensure that the instrument is accompanied by instructions and information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while an instrument used for the applications listed in points (a) to (f) of Article 1(2) is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

6. When deemed appropriate with regard to the performance of an instrument, importers shall carry out sample testing of instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming instruments and instrument recalls, and shall keep distributors informed of such monitoring.

7. Importers who consider or have reason to believe that an instrument which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the instrument presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the instrument available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. For the instruments used for the applications listed in points (a) to (f) of Article 1(2), importers shall, for 10 years after the instrument has been placed on the market keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of an instrument in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by instruments which they have placed on the market.

*Article 9 [Article R5 of Decision No 768/2008/EC]*

**Obligations of distributors**

1. When making an instrument available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making an instrument used for the applications listed in points (a) to (f) of Article 1(2) available on the market, distributors shall verify that the instrument bears the CE marking, the inscriptions provided for in point 1 of Annex III, that it is accompanied by the required documents and by instructions and information in a language which can be easily understood by consumers and other end-users in the Member State in which the instrument is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3).

Where a distributor considers or has reason to believe that an instrument is not in conformity with the essential requirements set out in Annex I, he shall not make the instrument available on the market until it has been brought into conformity. Furthermore, where the instrument presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

Before making an instrument not used for the applications listed in points (a) to (f) of Article 1(2) available on the market, distributors shall verify that the instrument bears the inscriptions provided for in point 2 of Annex III and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3).

3. Distributors shall ensure that, while an instrument used for the applications listed in points (a) to (f) of Article 1(2) is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

4. Distributors who consider or have reason to believe that an instrument which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the instrument presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the instrument available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of an instrument. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by instruments which they have made available on the market.

*Article 10 [Article R6 of Decision No 768/2008/EC]*

**Cases in which obligations of manufacturers apply to importers and distributors**

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 6, where he places an instrument on the market under his name or trademark or modifies an instrument already placed on the market in such a way that compliance with the requirements of this Directive may be affected.

*Article 11 [Article R7 of Decision No 768/2008/EC]*

**Identification of economic operators**

Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with an instrument;

(b) any economic operator to whom they have supplied an instrument.

Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after they have been supplied with the instrument and for a period of 10 years after they have supplied the instrument.

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↓ 2009/23/EC (adapted)

# CHAPTER ~~2~~3

# CONFORMITY ~~ASSESSMENT~~ ⌦ OF INSTRUMENTS ⌫

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↓ 2009/23/EC

~~*Article 6*~~

~~1. Member States shall presume conformity with the essential requirements set out in Annex I in respect of instruments which comply with the relevant national standards implementing the harmonised standards that meet those requirements.~~

~~2. The Commission shall publish the references of the harmonised standards referred to in paragraph 1 in the *Official Journal of the European Union*.~~

~~Member States shall publish the references of the national standards referred to in paragraph 1.~~

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⇩ new

*Article 12 [Article R8 of Decision No 768/2008/EC]*

**Presumption of conformity**

Instruments which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential requirements covered by those standards or parts thereof, set out in Annex I.

[Where a harmonised standard satisfies the requirements which it covers and which are set out in Annex I or Article 23, the Commission shall publish the references of that standard in the *Official Journal of the European Union*.]

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↓ 2009/23/EC (adapted)

*Article ~~9~~13*

**⌦ Conformity assessment procedures ⌫**

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↓ 2009/23/EC

1. The conformity of instruments to the essential requirements set out in Annex I may be certified by either of the following procedures as selected by the applicant:

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↓ 2009/23/EC (adapted)

(a) ~~EC type examination~~ ⌦ Module B ⌫ as ~~referred to~~ ⌦ set out ⌫ in point 1 of Annex II, ~~point 1~~, followed either by ~~the EC declaration of type conformity (guarantee of production quality)~~ ⌦ Module D ⌫ as ~~referred to~~ ⌦ set out ⌫ in point 2 of Annex II, ~~point 2~~, or by ~~the EC verification~~ ⌦ Module F ⌫ as ~~referred to~~ ⌦ set out ⌫ in point 4 of Annex II~~,~~ ~~point 3~~.

However, ~~EC type examination~~ ⌦ Module B ⌫ shall not be compulsory for instruments which do not use electronic devices and the load-measuring device of which does not use a spring to balance the load ⌦ . For those instruments not submitted to Module B, Module D1

as set out in point 3 of Annex II or Module F1 as set out in point 5 of Annex II shall apply ⌫;

(b) ~~EC unit verification~~ ⌦ Module G ⌫ as ~~referred to~~ ⌦ set out ⌫ in point 6 of Annex II~~, point 4~~.

2. The documents and correspondence relating to the procedures referred to in paragraph 1 shall be drafted in ~~an~~ ⌦ one of the ⌫ official languages of the Member State where ~~the said~~ ⌦ those ⌫ procedures are carried out, or in a language accepted by the body notified in accordance with Article ~~10(1)~~18.

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↓ 2009/23/EC

~~3. Where the instruments are subject to other Directives covering other aspects and which also provide for the affixing of the 'CE' conformity marking, that marking shall indicate that the instruments in question are also presumed to conform to the provisions of those other Directives.~~

~~However, where one or more of the Directives which apply to the instruments allow the manufacturer, during a transitional period, to choose which arrangements to apply, the 'CE' conformity marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of publication in the *Official Journal of the European Union* of the Directives applied must be given in the documents, notices or instructions required by the Directives and accompanying such instruments.~~

~~*Article 7*~~

~~Where a Member State or the Commission considers that the harmonised standards referred to in Article 6(1) do not fully meet the essential requirements set out in Annex I, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Article 5 of Directive 98/34/EC, hereinafter referred to as 'the Committee', giving its reasons for doing so.~~

~~The Committee shall deliver an opinion without delay.~~

~~In the light of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the publications referred to in Article 6(2).~~

⇩ new

*Article 14 [Article R10 of Decision No 768/2008/EC]*

**EU declaration of conformity**

1. The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex III of Decision No 768/2008/EC, shall contain the elements specified in the relevant modules set out in Annex II to this Directive and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the instrument is placed or made available.

3. Where an instrument is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the acts concerned including the publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the instrument.

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🡻 2009/23/EC

~~*Article 8*~~

~~1. Where a Member State considers that instruments bearing the 'CE' conformity marking referred to in Annex II, points 2, 3 and 4, do not meet the requirements of this Directive when properly installed and used for the purposes for which they are intended, it shall take all appropriate measures to withdraw those instruments from the market or to prohibit or restrict their being put into service and/or placed on the market.~~

~~The Member State concerned shall immediately inform the Commission of any such measure, indicating the reasons for its decision, and in particular whether non-compliance is due to:~~

~~(a) failure to meet the essential requirements set out in Annex I, where instruments do not meet the harmonised standards referred to in Article 6(1);~~

~~(b) incorrect application of the harmonised standards referred to in Article 6(1);~~

~~(c) shortcomings in the harmonised standards referred to in Article 6(1) themselves.~~

~~2. The Commission shall enter into consultation with the parties concerned as soon as possible.~~

~~After such consultation the Commission shall immediately inform the Member State which took the action of the result. Should it find that the measure is justified it shall immediately inform the other Member States.~~

~~If the decision is attributed to shortcomings in the standards, the Commission, after consulting the parties concerned, shall bring the matter before the Committee within two months if the Member State which has taken the measures intends to maintain them, and shall subsequently initiate the procedures referred to in Article 7.~~

~~3. Where an instrument which does not comply bears the 'CE' conformity marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall inform the Commission and the other Member States thereof.~~

~~4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.~~

~~*Article 10*~~

~~1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 9 together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.~~

~~The Commission shall publish in the *Official Journal of the European Union* a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.~~

~~2. Member States shall apply the minimum criteria set out in Annex V for the designation of bodies. Bodies which satisfy the criteria fixed by the relevant harmonised standards shall be presumed to satisfy the criteria set out in that Annex.~~

~~3. A Member State which has designated a body shall cancel the designation if the body no longer meets the criteria for designation referred to in paragraph 2. It shall immediately inform the other Member States and the Commission thereof and withdraw the notification.~~

## ~~CHAPTER 3~~

## ~~'CE' CONFORMITY MARKING AND INSCRIPTIONS~~

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⇩ new

*Article 15 [Article R11 of Decision No 768/2008/EC]*

**General principles of the CE marking**

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

*Article 16 [Article R12 of Decision No 768/2008/EC]*

**Rules and conditions for affixing the CE marking and of the inscriptions**

1. The CE marking and the inscriptions provided for in point 1 of Annex III or the inscriptions provided for in point 2 of Annex III shall be affixed visibly, legibly and indelibly to the instrument or to its data plate.

2. The CE marking and/or the inscriptions shall be affixed before the instrument is placed on the market.

3. The CE marking shall be followed by the identification number of the notified body involved in the production control phase.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4. The CE marking and the identification number referred to in paragraph 3 may be followed by a pictogram or any other mark indicating a special risk or use.

5. The CE marking and the identification number referred to in paragraph 3 shall be followed by the sticker bearing the letter "M", provided for in point 1.1(b) of Annex III.

↓ 2009/23/EC

~~*Article 11*~~

~~1. The 'CE' conformity marking and the required supplementary data as described in Annex IV, point 1, shall be affixed in a clearly visible, easily legible and indelible form to instruments for which EC conformity has been established.~~

~~2. The inscriptions referred to in Annex IV, point 2 shall be affixed in a clearly visible, easily legible and indelible form to all other instruments.~~

~~3. The affixing on the instruments of markings which are likely to deceive third parties as to the meaning and form of the 'CE' conformity marking shall be prohibited. Any other marking may be affixed to the instruments provided that the visibility and legibility of the 'CE' conformity marking is not thereby reduced.~~

~~*Article 12*~~

~~Without prejudice to Article 8:~~

~~(a) where a Member State establishes that the 'CE' conformity marking has been affixed unduly, the manufacturer or his authorised representative established within the Community shall be obliged to make the instrument conform as regards the provisions concerning the 'CE' conformity marking and to end the infringement under the conditions imposed by the Member State;~~

~~(b) where non-conformity continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the instrument in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 8.~~

↓ 2009/23/EC (adapted)

*Article 17*

**⌦ Restrictive use symbol ⌫**

~~That~~ ⌦ The ⌫ symbol ⌦ referred to in the fourth subparagraph of Article 6(2) ⌫ shall be affixed to the devices in a clearly visible and indelible form.

⇩ new

# CHAPTER 4

# *NOTIFICATION OF CONFORMITY ASSESSMENT BODIES*

*Article 18 [Article R13 of Decision No 768/2008/EC]*

**Notification**

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

*Article 19 [Article R14 of Decision No 768/2008/EC]*

**Notifying authorities**

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 24.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 20(1) to (6). In addition it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

*Article 20 [Article R15 of Decision No 768/2008/EC]*

**Requirements relating to notifying authorities**

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

*Article 21 [Article R16 of Decision No 768/2008/EC]*

**Information obligation on notifying authorities**

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

*Article 22 [Article R17 of Decision No 768/2008/EC]*

**Requirements relating to notified bodies**

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under national law and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the instrument it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of instruments which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the instruments which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed instruments that are necessary for the operations of the conformity assessment body or the use of such instruments for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those instruments, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Article 13 and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of instruments in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the instrument technology in question and the mass or serial nature of the production process.

It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment activities shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 13 or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

*Article 23 [Article R18 of Decision No 768/2008/EC]*

**Presumption of conformity**

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 22 in so far as the applicable harmonised standards cover those requirements.

*Article 24 [Article R20 of Decision No 768/2008/EC]*

**Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the

subsidiary meets the requirements set out in Article 22 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 13.

*Article 25 [Article R22 of Decision No 768/2008/EC]*

**Application for notification**

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the instrument or instruments for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 22.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 22.

*Article 26 [Article R23 of Decision No 768/2008/EC]*

**Notification procedure**

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 22.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and instrument or instruments concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 25(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's

competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 22.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

*Article 27 [Article R24 of Decision No 768/2008/EC]*

**Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

.2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.

The Commission shall ensure that that list is kept up to date.

*Article 28 [Article R25 of Decision No 768/2008/EC]*

**Changes to notifications**

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 22, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

*Article 29 [Article R26 of Decision No 768/2008/EC]*

**Challenge of the competence of notified bodies**

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

*Article 30 [Article R27 of Decision No 768/2008/EC]*

**Operational obligations of notified bodies**

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex II.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the instrument technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the instrument with the provisions of this Directive.

3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that an instrument no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

*Article 31*

**Appeal against decisions of notified bodies**

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

*Article 32 [Article R28 of Decision No 768/2008/EC]*

**Information obligation on notified bodies**

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of and conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same instruments with relevant information on issues relating to negative and, on request, positive conformity assessment results.

*Article 33 [Article R29 of Decision No 768/2008/EC]*

**Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

*Article 34 [Article R30 of Decision No 768/2008/EC]*

**Coordination of notified bodies**

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral or cross sectoral group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that or those group or groups, directly or by means of designated representatives.

# CHAPTER 5

# UNION MARKET SURVEILLANCE, CONTROL OF INSTRUMENTS ENTERING THE UNION MARKET AND SAFEGUARD PROCEDURES

*Article 35*

**Union market surveillance, control of instruments entering the Union market**

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to instruments.

*Article 36 [Article R31 of Decision No 768/2008/EC]*

**Procedure for dealing with instruments presenting a risk at national level**

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that an instrument covered by this Directive presents a risk to the aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the instrument concerned covering all the requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

Where, in the course of that evaluation, the market surveillance authorities find that the instrument does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the instrument into compliance with those requirements, to withdraw the instrument from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the instruments concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the instrument's being made available on their national market, to withdraw the instrument from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant instrument, the origin of the instrument, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

(a) failure of the instrument to meet requirements relating to the aspects of public interest protection laid down in this Directive;

(b) shortcomings in the harmonised standards referred to in Article 12 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the instrument concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. Where, within two months of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures are taken in respect of the instrument concerned without delay.

*Article 37 [Article R32 of Decision No 768/2008/EC]*

**Union safeguard procedure**

1. Where, on completion of the procedure set out in Article 36(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant instrument is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

3. Where the national measure is considered justified and the non-compliance of the instrument is attributed to shortcomings in the harmonised standards referred to in Article 36(5)(b) of this Directive, the Commission shall apply the procedure provided for in Article 8 of Regulation (EU) No […] [on European Standardisation].

*Article 38 [Article R33 of Decision No 768/2008/EC]*

**Compliant instruments which present a risk**

1. Where, having performed an evaluation under Article 36(1), a Member State finds that although an instrument is in compliance with this Directive, it presents a risk to aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the instrument concerned, when placed on the market, no longer presents that risk, to withdraw the instrument from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the instruments concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the instrument concerned, the origin and the supply chain of the instrument, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not, and where necessary, propose appropriate measures.

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

*Article 39 [Article R34 of Decision No 768/2008/EC]*

**Formal non-compliance**

1. Without prejudice to Article 36, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking and/or the inscriptions provided for in Annex III have been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 16 of this Directive;

(b) the CE marking and/or the inscriptions provided for in Annex III have not been affixed;

(c) the EU declaration of conformity has not been drawn up;

(d) the EU declaration of conformity has not been drawn up correctly;

(e) technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the instrument being made available on the market or ensure that it is recalled or withdrawn from the market.

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↓ 2009/23/EC (adapted)

# CHAPTER ~~4~~6

# ⌦ TRANSITIONAL AND ⌫ FINAL PROVISIONS

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↓ 2009/23/EC

*~~Article 15~~*

~~Any decision taken pursuant to this Directive and resulting in restrictions on the putting into service of an instrument shall state the exact grounds on which it is based.~~

~~Such a decision shall be notified without delay to the party concerned, who shall at the same time be informed of the judicial remedies available to him under the laws in force in the Member State in question and of the time limits to which such remedies are subject.~~

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⇩ new

*Article 40*

**Penalties**

Member States shall lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced.

The penalties provided for shall be effective, proportionate and dissuasive.

Member States shall notify those provisions to the Commission by [the date set out in the second subparagraph of Article 42(1)] at the latest and shall notify to it without delay any subsequent amendment affecting them.

*Article 41*

**Transitional provisions**

Member States shall not impede the making available on the market and/or the putting into service of instruments covered by Directive 2009/23/EC which are in conformity with that Directive and which were placed on the market before [the date set out in the second subparagraph of Article 42(1)].

Certificates of conformity issued under Directive 2009/23/EC shall be valid under this Directive until [the date set out in the second subparagraph of Article 42(1)] unless they expire before that date.

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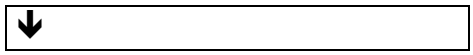

*Article 42*

**Transposition**

1. Member States shall adopt and publish by [insert date - 2 years after adoption] at the latest, the laws, regulations and administrative provisions necessary to comply with Articles 2(3) to (19), 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41 and Annex II. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from [day after the date set out in the first subparagraph].

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

↓ 2009/23/EC

~~*Article 16*~~

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

↓ 2009/23/EC (adapted)

*Article ~~17~~43*

**⌦ Repeal ⌫**

Directive ~~90/384/EEC~~ 2009/23/EC ~~as amended by the Directive listed in Annex VII, Part A,~~ is repealed ⌦ from the date set out in the second subparagraph of Article 42(1) ⌫, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and application of the Directives set out in ~~Annex VII,~~ Part B of Annex VII to Directive 2009/23/EC.

↓ 2009/23/EC

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex ~~VIII~~IV.

↓ 2009/23/EC (adapted)

*Article ~~18~~44*

**⌦ Entry into force ⌫**

This Directive shall enter into force on the twentieth day following ⌦ that of ⌫ its publication in the *Official Journal of the European Union*.

Articles 1, 2(1) and (2), 3, 4, 5, 17 and Annexes I and III shall apply from [the date set out in the second subparagraph of Article 42(1)].

↓ 2009/23/EC

*Article ~~19~~45*

This Directive is addressed to the Member States.

Done at […],

| | |
|---|---|
| *For the European Parliament* | *For the Council* |
| *The President* | *The President* |

↓ 2009/23/EC (adapted)

# ANNEX I

## *ESSENTIAL REQUIREMENTS*

The terminology used is that of the International Organisation of Legal Metrology.

### *Preliminary observation*

Where an instrument includes, or is connected to, more than one indicating or printing device used for the applications listed in points (a) to (f) of Article 1(2), those devices which repeat the results of the weighing operation and which cannot influence the correct functioning of the instrument shall not be subject to the essential requirements if the weighing results are printed or recorded correctly and indelibly by a part of the instrument which meets the essential requirements and the results are accessible to both parties concerned by the measurement. However, in the case of instruments used for direct sales to the public, display and printing devices for the vendor and the customer must fulfil the essential requirements.

## *METROLOGICAL REQUIREMENTS*

### 1. Units of mass

The units of mass used shall be the legal units within the meaning of Council Directive 80/181/EEC ~~of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement~~[16].

Subject to compliance with this condition, the following units are permitted:

(a) – SI units: kilogram, microgram, milligram, gram, tonne~~;~~,

(b) – imperial unit: troy ounce, if weighing precious metals~~;~~,

(c) – other non-SI unit: metric carat, if weighing precious stones.

For instruments that make use of the imperial unit of mass referred to above, the relevant essential requirements specified below shall be converted to that unit, using simple interpolation.

### 2. Accuracy classes

2.1. The following accuracy classes have been defined:

(a) I special

(b) II high

16 ~~OJ L 39, 15.2.1980, p. 40.~~

(c) III medium

(d) IIII ordinary

The specifications of these classes are given in Table 1.

*Table 1*

*Accuracy classes*

| Class | Verification scale interval (e) | | Minimum capacity (Min) | Number of verification scale intervals n = ((Max)/(e)) | |
|---|---|---|---|---|---|
| | | | minimum value | minimum value | maximum value |
| I | 0,001 | g ≤ e | 100 e | 50 000 | — |
| II | 0,001 | g ≤ e ≤ 0,05 g | 20 e | 100 | 100000 |
| | 0,1 | g ≤ e | 50 e | 5000 | 100000 |
| III | 0,1 | g ≤ e ≤ 2 g | 20 e | 100 | 10000 |
| | 5 | g ≤ e | 20 e | 500 | 10000 |
| IIII | 5 | g ≤ e | 10 e | 100 | 1000 |

The minimum capacity is reduced to 5 e for instruments in classes II and III for determining a conveying tariff.

*2.2. Scale intervals*

2.2.1. The actual scale interval (d) and the verification scale interval (e) shall be in the form:

$1 \times 10^k$, $2 \times 10^k$, or $5 \times 10^k$ mass units,

k being any integer or zero.

2.2.2. For all instruments other than those with auxiliary indicating devices:

d = e.

2.2.3. For instruments with auxiliary indicating devices the following conditions apply:

$e = 1 \times 10^k$ g;

$d < e \leq 10$ d.

~~except~~ ⌦ Those conditions do not apply ⌫ for instruments of class I with $d < 10^{-4}$ g, for which $e = 10^{-3}$ g.

**3. Classification**

*3.1. Instruments with one weighing range*

Instruments equipped with an auxiliary indicating device shall belong to class I or class II. For these instruments the minimum capacity lower limits for these two classes are obtained from Table 1 by replacement in column 3 of the verification scale interval (e) by the actual scale interval (d).

If $d < 10^{-4}$ g, the maximum capacity of class I may be less than 50000 e.

*3.2. Instruments with multiple weighing ranges*

Multiple weighing ranges are permitted, provided they are clearly indicated on the instrument. Each individual weighing range is classified according to point 3.1. If the weighing ranges fall into different accuracy classes the instrument shall comply with the severest of the requirements that apply for the accuracy classes in which the weighing ranges fall.

*3.3. Multi-interval instruments*

3.3.1. Instruments with one weighing range may have several partial weighing ranges (multi-interval instruments).

Multi-interval instruments shall not be equipped with an auxiliary indicating device.

3.3.2. Each partial weighing range i of multi-interval instruments is defined by:

| | |
|---|---|
| — its verification scale interval $e_i$ | with $e_{(i+1)} > e_i$ |
| — its maximum capacity $Max_i$ | with $Max_r = Max$ |
| — its minimum capacity $Min_i$ | with $Min_i = Max_{(i-1)}$<br>and $Min_1 = Min$ |

where:

| | | |
|---|---|---|
| i | = | 1, 2, … r, |
| i | = | partial weighing range number, |
| r | = | the total number of partial weighing ranges. |

All capacities are capacities of net load, irrespective of the value of any tare used.

3.3.3. The partial weighing ranges are classified according to Table 2. All partial weighing ranges shall fall into the same accuracy class, that class being the instrument's accuracy class.

| *Table 2* | | | | | |
|---|---|---|---|---|---|
| *Multi-interval instruments* | | | | | |
| i = 1, 2, … r<br>i = partial weighing range number<br>r = total number of partial weighing ranges | | | | | |
| Class | Verification scale interval (e) | | Minimum capacity (Min) | Number of verification scale intervals | |
| | | | Minimum value | Minimum value[17]<br>$n = ((Max_i)/(e_{(i+1)}))$ | Maximum value<br>$n = ((Max_i)/(e_i))$ |
| I | 0,001 | $g \leq e_i$ | 100 $e_1$ | 50000 | — |
| II | 0,001 | $g \leq e_i \leq 0{,}05$ g | 20 $e_1$ | 5000 | 100000 |
| | 0,1 | $g \leq e_i$ | 50 $e_1$ | 5000 | 100000 |
| III | 0,1 | $g \leq e_i$ | 20 $e_1$ | 500 | 10000 |
| IIII | 5 | $g \leq e_i$ | 10 $e_1$ | 50 | 1000 |

## 4. Accuracy

4.1. On implementation of the procedures laid down in Article ~~9~~13, the error of indication shall not exceed the maximum permissible error of indication as shown in Table 3. In case of digital indication the error of indication shall be corrected for the rounding error.

The maximum permissible errors apply to the net value and tare value for all possible loads, excluding preset tare values.

| *Table 3* | | | | |
|---|---|---|---|---|
| *Maximum permissible errors* | | | | |
| Load | | | | Maximum permissible error |
| Class I | Class II | Class III | Class IIII | |

[17] For i = r, the corresponding column of Table 1 applies, with e replaced by $e_r$.

| | | | | |
|---|---|---|---|---|
| 0 ≤ m ≤ 50000 e | 0 ≤ m ≤ 5000 e | 0 ≤ m ≤ 500 e | 0 ≤ m ≤ 50 e | ±0,5 e |
| 50000 e < m ≤ 200000 e | 5000 e < m ≤ 20000 e | 500 e < m ≤ 2000 e | 50 e < m ≤ 200 e | ±1,0 e |
| 200000 e < m | 20000 e < m ≤ 100000 e | 2000 e < m ≤ 10000 e | 200 e < m ≤ 1000 e | ±1,5 e |

4.2. The maximum permissible errors in service are twice the maximum permissible errors fixed in Section 4.1.

5. Weighing results of an instrument shall be repeatable, and shall be reproducible by the other indicating devices used and in accordance with other methods of balancing used.

The weighing results shall be sufficiently insensitive to changes in the position of the load on the load receptor.

6. The instrument shall react to small variations in the load.

**7. Influence quantities and time**

7.1. Instruments of classes II, III and IIII, liable to be used in a tilted position, shall be sufficiently insensitive to the degree of tilting that can occur in normal use.

7.2. The instruments shall meet the metrological requirements within the temperature range specified by the manufacturer. The value of this range shall be at least equal to:

(a) = 5 °C for an instrument in class $I_{=}$;

(b) = 15 °C for an instrument in class $II_{=}$;

(c) = 30 °C for an instrument in class III or IIII.

In the absence of a manufacturer's specification, the temperature range of – 10 °C to + 40 °C applies.

7.3. Instruments operated from a mains power supply shall meet the metrological requirements under conditions of power supply within the limits of normal fluctuation.

Instruments operated from battery power shall indicate whenever the voltage drops below the minimum required value and shall under those circumstances either continue to function correctly or be automatically put out of service.

7.4. Electronic instruments, except those in class I and in class II if e is less than 1 g, shall meet the metrological requirements under conditions of high relative humidity at the upper limit of their temperature range.

7.5. Loading an instrument in class II, III or IIII for a prolonged period of time shall have a negligible influence on the indication at load or on the zero indication immediately after removal of the load.

7.6. Under other conditions the instruments shall either continue to function correctly or be automatically put out of service.

***Design and construction***

*8. General requirements*

8.1. Design and construction of the instruments shall be such that the instruments will preserve their metrological qualities when properly used and installed and when used in an environment for which they are intended. The value of the mass must be indicated.

8.2. When exposed to disturbances, electronic instruments shall not display the effects of significant faults, or shall automatically detect and indicate them.

Upon automatic detection of a significant fault, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the fault disappears.

8.3. The requirements of points 8.1 and 8.2 shall be met on a lasting basis during a period of time that is normal in view of the intended use of such instruments.

Digital electronic devices shall always exercise adequate control of the correct operation of the measuring process, of the indicating device, and of all data storage and data transfer.

Upon automatic detection of a significant durability error, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the error disappears.

8.4. When external equipment is connected to an electronic instrument through an appropriate interface the metrological qualities of the instrument shall not be adversely influenced.

8.5. The instruments shall have no characteristics likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal. Components that may not be dismantled or adjusted by the user shall be secured against such actions.

8.6. Instruments shall be designed to permit ready execution of the statutory controls laid down by this Directive.

*9. Indication of weighing results and other weight values*

The indication of the weighing results and other weight values shall be accurate, unambiguous and non-misleading and the indicating device shall permit easy reading of the indication under normal conditions of use.

The names and symbols of the units referred to in point 1 of this Annex shall comply with the provisions of Directive 80/181/EEC with the addition of the symbol for the metric carat which shall be the symbol ‘ct’.

Indication shall be impossible above the maximum capacity (Max), increased by 9 e.

An auxiliary indicating device is permitted only to the right of the decimal mark. An extended indicating device may be used only temporarily, and printing shall be inhibited during its functioning.

Secondary indications may be shown, provided that they cannot be mistaken for primary indications.

*10. Printing of weighing results and other weight values*

Printed results shall be correct, suitably identified and unambiguous. The printing shall be clear, legible, non-erasable and durable.

*11. Levelling*

When appropriate, instruments shall be fitted with a levelling device and a level indicator, sufficiently sensitive to allow proper installation.

*12. Zeroing*

Instruments may be equipped with zeroing devices. The operation of these devices shall result in accurate zeroing and shall not cause incorrect measuring results.

*13. Tare devices and preset tare devices*

The instruments may have one or more tare devices and a preset tare device. The operation of the tare devices shall result in accurate zeroing and shall ensure correct net weighing. The operation of the preset tare device shall ensure correct determination of the calculated net value.

*14. Instruments for direct sales to the public, with a maximum capacity not greater than 100 kg: additional requirements*

Instruments for direct sale to the public shall show all essential information about the weighing operation and, in the case of price-indicating instruments, shall clearly show the customer the price calculation of the product to be purchased.

The price to pay, if indicated, shall be accurate.

Price-computing instruments shall display the essential indications long enough for the customer to read them properly.

Price-computing instruments may perform functions other than per-article weighing and price computation only if all indications related to all transactions are printed clearly and unambiguously and are conveniently arranged on a ticket or label for the customer.

Instruments shall bear no characteristics that can cause, directly or indirectly, indications the interpretation of which is not easy or straightforward.

Instruments shall safeguard customers against incorrect sales transactions due to their malfunctioning.

Auxiliary indicating devices and extended indicating devices are not permitted.

Supplementary devices are permitted only if they cannot lead to fraudulent use.

Instruments similar to those normally used for direct sales to the public which do not satisfy the requirements of this Section must carry near to the display the indelible marking 'Not to be used for direct sale to the public'.

*15. Price labelling instruments*

Price labelling instruments shall meet the requirements of price indicating instruments for direct sale to the public, as far as applicable to the instrument in question. The printing of a price label shall be impossible below a minimum capacity.

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↓ 2009/23/EC

## ANNEX II

## *CONFORMITY ASSESSMENT PROCEDURES*

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↓ 2009/23/EC (adapted)

### 1. ⌦ MODULE B : EU ⌫ ~~EC~~ type examination

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↓ 2009/23/EC

~~1.1. EC type-examination is the procedure whereby a notified body verifies and certifies that an instrument, representative of the production envisaged, meets the requirements of this Directive.~~

~~1.2. The application for EC type-examination shall be lodged with a single notified body by the manufacturer or his authorised representative established within the Community.~~

~~The application shall include:~~

~~– the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition,~~

~~– a written declaration that the application has not been lodged with any other notified body,~~

~~– the design documentation, as described in Annex III.~~

~~The applicant shall place at the disposal of the notified body an instrument, representative of the production envisaged, hereinafter the 'type'.~~

*1.3. The notified body shall:*

1.3.1. examine the design documentation and verify that the type has been manufactured in accordance with that documentation;

1.3.2. agree with the applicant on the location where the examinations and/or tests shall be carried out;

1.3.3. perform or have performed the appropriate examinations and/or tests to check whether the solutions adopted by the manufacturer meet the essential requirements where the harmonised standards referred to in Article 6(1) have not been applied;

1.3.4. perform or have performed the appropriate examinations and/or tests to check whether, where the manufacturer has chosen to apply the relevant standards, these standards have been applied effectively, thereby assuring conformity with the essential requirements.

1.4. Where the type complies with the provisions of this Directive, the notified body shall issue an EC type-approval certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions (if any) for its validity, the necessary data for identification of the approved instrument and, if relevant, a description of its functioning. All the relevant technical elements such as drawings and layouts shall be annexed to the EC type-approval certificate.

The certificate shall have a validity period of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.

In the event of fundamental changes to the design of the instrument, e.g. as a result of the application of new techniques, the validity of the certificate may be limited to two years and extended by three years.

1.5. Each notified body shall periodically make available to all Member States the list of:

– applications received for EC type-examination,

– EC type-approval certificates issued,

– applications for type-certificates refused,

– additions and amendments relating to documents already issued.

Each notified body shall moreover inform all the Member States forthwith of withdrawals of EC type-approval certificates.

Each Member State shall make this information available to the bodies which it has notified.

1.6. The other notified bodies may receive a copy of the certificates together with the annexes to them.

1.7. The applicant shall keep the notified body that has issued the EC type-approval certificate informed of any modification to the approved type.

~~Modifications to the approved type must receive additional approval from the notified body that issued the EC type-approval certificate where such changes influence conformity with the essential requirements of this Directive or the prescribed conditions for use of the instrument. This additional approval is given in the form of an addition to the original EC type-approval certificate.~~

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⇩ new

1.1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of this Directive that apply to it.

1.2. EU-type examination may be carried out in any of the following manners:

– examination of a specimen, representative of the production envisaged, of the complete instrument (production type);

– assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the instrument (combination of production type and design type);

– assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, without examination of a specimen (design type).

1.3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation. The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall contain, wherever applicable, at least the following elements:

(i) a general description of the instrument;

(ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(iv) a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out, etc.;

(vi) test reports;

(d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;

(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

1.4. The notified body shall:

For the instrument:

1.4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;

For the specimen(s):

1.4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of this Directive;

1.4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

1.5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

1.6. Where the type meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured instruments with the examined type to be evaluated and to allow for in-service control.

The certificate shall have a validity period of ten years from the date of its issue, and may be renewed for subsequent periods of ten years each. In the event of fundamental changes to the design of the instrument, e.g. as a result of the application of new techniques, the validity of the certificate may be limited to two years and extended by three years.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

1.7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

1.8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

1.9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

1.10. The manufacturer's authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.

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↓ 2009/23/EC (adapted)

**2. ~~EC declaration of type conformity (guarantee of production quality)~~ ⌦ MODULE D: Conformity to type based on quality assurance of the production process ⌫**

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↓ 2009/23/EC

~~2.1. The EC declaration of type conformity (guarantee of production quality) is the procedure whereby the manufacturer who satisfies the obligations of point 2.2 declares that the instruments concerned are, where applicable, in conformity with the type as described in the EC type-approval certificate and that they satisfy the requirements of this Directive.~~

~~The manufacturer or his authorised representative established within the Community shall affix the 'CE' conformity marking to each instrument and the inscriptions provided for in Annex IV and shall draw up a written declaration of conformity.~~

~~The 'CE' conformity marking shall be accompanied by the identification number of the notified body responsible for the EC surveillance referred to in point 2.4.~~

~~2.2. The manufacturer shall have adequately implemented a quality system as specified in point 2.3 and shall be subject to EC surveillance as specified in point 2.4.~~

~~*2.3. Quality system*~~

~~2.3.1. The manufacturer shall lodge an application for approval of his quality system with a notified body.~~

~~The application shall include:~~

~~– an undertaking to carry out the obligations arising from the approved quality system,~~

~~– an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness.~~

~~The manufacturer shall make available to the notified body all relevant information, in particular the quality system's documentation and the design documentation of the instrument.~~

~~2.3.2. The quality system shall ensure conformity of the instruments with the type as described in the EC type-approval certificate and with the requirement(s) of this Directive.~~

~~All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written rules, procedures and instructions. This quality system documentation shall ensure a proper understanding of the quality programmes, plans, manuals and records.~~

~~It shall contain in particular an adequate description of:~~

- ~~the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,~~
- ~~the manufacturing process, the quality control and assurance techniques and the systematic measures that will be used,~~
- ~~the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,~~
- ~~the means to monitor the achievement of the required product quality and the effective operation of the quality system.~~

~~2.3.3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in point 2.3.2. It shall presume conformity with these requirements in respect of quality systems that implement the corresponding harmonised standard.~~

~~It shall notify its decision to the manufacturer and inform the other notified bodies thereof. The notification to the manufacturer shall contain the conclusions of the examination and, in the event of refusal, the justification for the decision.~~

~~2.3.4. The manufacturer or his authorised representative shall keep the notified body that has approved the quality system informed of any updating of the quality assurance system in relation to changes brought about by, e.g. new technologies and new quality concepts.~~

~~2.3.5. Any notified body that withdraws approval of a quality system shall so inform the other notified bodies.~~

~~*2.4. EC surveillance*~~

~~2.4.1. The purpose of EC surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.~~

~~2.4.2. The manufacturer shall grant the notified body access for inspection purposes to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular:~~

- ~~the quality system documentation,~~
- ~~the design documentation,~~
- ~~the quality records, e.g. the inspection reports and tests and calibration data, reports on the qualifications of the personnel concerned, etc.~~

~~The notified body shall periodically carry out audits in order to ensure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report.~~

~~In addition, the notified body may carry out unscheduled visits to the manufacturer. During such visits, the notified body may carry out full or partial audits. It shall provide the manufacturer with a report on the visit, and, where appropriate, an audit report.~~

~~2.4.3. The notified body shall ensure that the manufacturer maintains and applies the approved quality system.~~

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⇩ new

2.1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2.2 and 2.5, and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2.2. Manufacturing

The manufacturer shall operate an approved quality system for production, final instrument inspection and testing of the instruments concerned as specified in point 2.3, and shall be subject to surveillance as specified in point 2.4.

2.3. Quality system

2.3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the instrument category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

2.3.2. The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to instrument quality;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;

(e) the means of monitoring the achievement of the required instrument quality and the effective operation of the quality system.

2.3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 2.3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2.3.1(e) to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

2.3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

2.3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 2.3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

2.4. Surveillance under the responsibility of the notified body

2.4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

2.4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

2.4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

2.4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

2.5. Conformity marking and declaration of conformity

2.5.1. The manufacturer shall affix the CE marking and the inscriptions provided for in point 1 of Annex III, and, under the responsibility of the notified body referred to in point 2.3.1, the latter's identification number to each individual instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

2.5.2. The manufacturer shall draw up a written declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

2.6. The manufacturer shall, for a period ending at least 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 2.3.1;

(b) the change referred to in point 2.3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 2.3.5, 2.4.3 and 2.4.4.

2.7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

2.8. Authorised representative

The manufacturer's obligations set out in points 2.3.1, 2.3.5, 2.5 and 2.6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

**3. MODULE D1: Quality assurance of the production process**

3.1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2, 3.4 and 3.7, and ensures and declares on his sole responsibility that the instruments concerned satisfy the requirements of this Directive that apply to them.

3.2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the instrument;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(d) a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

3.3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

3.4. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 3.5, and shall be subject to surveillance as specified in point 3.6.

3.5. Quality system

3.5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the instrument category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation referred to in point 3.2.

3.5.2. The quality system shall ensure compliance of the instruments with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to instrument quality;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;

(e) the means of monitoring the achievement of the required instrument quality and the effective operation of the quality system.

3.5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The

audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.5.2 or whether reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. Surveillance under the responsibility of the notified body

3.6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

3.6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the technical documentation referred to in point 3.2;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

3.6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

3.6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

3.7. Conformity marking and declaration of conformity

3.7.1. The manufacturer shall affix the CE marking and the inscriptions provided for in point 1 of Annex III, and, under the responsibility of the notified body referred to in point 3.5.1, the

latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

3.7.2. The manufacturer shall draw up a written declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

3.8. The manufacturer shall, for a period ending at least 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.5.1;

(b) the change referred to in point 3.5.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5.5, 3.6.3 and 3.6.4.

3.9. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

3.10. Authorised representative

The manufacturer's obligations set out in points 3.3, 3.5.1, 3.5.5, 3.7 and 3.8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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↓ 2009/23/EC (adapted)

**~~3~~4. ~~EC~~ ⌦ MODULE F: Conformity to type based on product ⌫ verification**

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↓ 2009/23/EC

~~3.1. EC verification is the procedure whereby the manufacturer or his authorised representative established within the Community ensures and declares that the instruments which have been checked in accordance with point 3.3 are, where applicable, in conformity with the type described in the EC type-examination certificate and that they satisfy the requirements of this Directive.~~

~~3.2. The manufacturer shall take all necessary measures in order that the manufacturing process ensures conformity of the instruments, where applicable, with the type as described in the EC type-examination certificate and with the requirements of this Directive which apply to them. The manufacturer or his authorised representative established within the Community shall affix the 'CE' conformity marking to each instrument and draw up a written declaration of conformity.~~

~~3.3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the product to the requirements of this Directive by examination and testing of every instrument, as specified in point 3.5.~~

~~3.4. For instruments not subject to EC type-approval, the documents relating to the design of the instrument, as set out in Annex III, must be accessible to the notified body should the latter so request.~~

~~*3.5. Verification by checking and testing of each instrument*~~

~~3.5.1. All instruments shall be individually examined and appropriate tests, as set out in the relevant harmonised standards referred to in Article 6(1), or equivalent tests, shall be carried out in order to verify their conformity, where applicable, with the type as described in the EC type-examination certificate and the requirements of this Directive.~~

~~3.5.2. The notified body shall affix, or cause to be affixed, its identification number on each instrument the conformity of which to requirements has been established, and shall draw up a written certificate of conformity relating to the tests carried out.~~

~~3.5.3. The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request.~~

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⇩ new

4.1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 4.2, 4.5.1 and 4.6, and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 4.3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

4.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instruments with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

4.3. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the instruments with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

The examinations and tests to check the conformity of the instruments with the appropriate requirements shall be carried out by examination and testing of every instrument as specified in point 4.4.

4.4. Verification of conformity by examination and testing of every instrument

4.4.1. All instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

4.4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the instrument has been placed on the market.

4.5. Conformity marking and declaration of conformity

4.5.1. The manufacturer shall affix the CE marking and the inscriptions provided for in point 1 of Annex III, and, under the responsibility of the notified body referred to in point 4.3, the latter's identification number to each individual instrument that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

4.5.2. The manufacturer shall draw up a written declaration of conformity for each instrument model and keep it at the disposal of the national authorities, for 10 years after the instrument has been placed on the market. The declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 4.3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the instruments.

4.6. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the instruments during the manufacturing process.

4.7. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 4.2 and 4.5.1.

**5. MODULE F1: Conformity based on product verification**

5.1. Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 5.2, 5.3, 5.6.1 and 5.7 and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 5.4, are in conformity with the requirements of this Directive that apply to them.

5.2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the instrument;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(d) a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

5.3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instruments with the applicable requirements of this Directive.

5.4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests to check the conformity of the instruments with the applicable requirements of this Directive.

The examinations and tests to check the conformity with those requirements shall be carried out by examination and testing of every instrument as specified in point 5.5.

5.5. Verification of conformity by examination and testing of every instrument

5.5.1. All instruments shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

5.5.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

5.6. Conformity marking and declaration of conformity

5.6.1. The manufacturer shall affix the CE marking and the inscriptions provided for in point 1 of Annex III, and, under the responsibility of the notified body referred to in point 5.4, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

5.6.2. The manufacturer shall draw up a written declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 5.5 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the instruments.

5.7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the instruments during the manufacturing process.

5.8. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 5.3 and 5.6.1.

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↓ 2009/23/EC (adapted)

**~~4~~6. ~~EC~~ ⌦ MODULE G: Conformity based on ⌫ unit verification**

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↓ 2009/23/EC

~~4.1. EC unit verification is the procedure whereby the manufacturer or his authorised representative established within the Community ensures and declares that the instrument, generally designed for a specific application, which has been issued with the certificate referred to in point 4.2 conforms to the requirements of this Directive that apply to it. The manufacturer or his authorised representative shall affix the 'CE' conformity marking to the instrument and shall draw up a written declaration of conformity.~~

~~4.2. The notified body shall examine the instrument and carry out the appropriate tests, as set out in the relevant harmonised standard(s) referred to in Article 6(1), or equivalent tests, in order to ensure its conformity with the relevant requirements of this Directive.~~

~~The notified body shall affix, or cause to be affixed, its identification number to the instrument the conformity of which to requirements has been established, and shall draw up a written certificate of conformity concerning the tests carried out.~~

~~4.3. The aim of the technical documentation relating to the design of the instrument, as referred to in Annex III, is to enable conformity with the requirements of this Directive to be assessed and the design, manufacture and operation of the instrument to be understood. It must be accessible to the notified body.~~

~~4.4. The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request.~~

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⇩ new

6.1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 6.2, 6.3 and 6.5, and ensures and declares on his sole responsibility that the instrument concerned, which has been subject to the provisions of point 6.4, is in conformity with the requirements of this Directive that apply to it.

6.2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 6.4. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the instrument;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(d) a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied

harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

6.3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instrument with the applicable requirements of this Directive.

6.4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, to check the conformity of the instrument with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved instrument, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

6.5. Conformity marking and declaration of conformity

6.5.1. The manufacturer shall affix the CE marking and the inscriptions provided for in point 1 of Annex III and, under the responsibility of the notified body referred to in point 6.4, the latter's identification number to each instrument that satisfies the applicable requirements of this Directive.

6.5.2. The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The declaration of conformity shall identify the instrument for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6.6. Authorised representative

The manufacturer's obligations set out in points 6.2 and 6.5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

↓ 2009/23/EC (adapted)

**~~5~~7. Common provisions**

~~5~~7.1. The ~~EC declaration of type conformity (guarantee of production quality), the EC verification, and the EC unit verification~~ ⌦ conformity assessment according to Module D, D1, F, F1 or G ⌫ may be carried out at the manufacturer's works or any other location if transport to the place of use does not require dismantling of the instrument, if the putting into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, ~~they~~ ⌦ it ⌫ shall be carried out at the place of use of the instrument.

↓ 2009/23/EC

~~5~~7.2. If the instrument's performance is sensitive to gravity variations the procedures referred to in point ~~5~~7.1 may be carried out in two stages, with the second stage comprising all examinations and tests of which the outcome is gravity-dependent, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument. If a Member State has established gravity zones on its territory the expression 'at the place of use of the instrument' may be read as 'in the gravity zone of use of the instrument'.

~~5~~7.2.1. Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in point ~~5~~7.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure shall bear the identification number of the notified body involved in that stage.

~~5~~7.2.2. The party which has carried out the first stage of the procedure shall issue for each of the instruments a certificate containing the data necessary for identification of the instrument and specifying the examinations and tests that have been carried out.

The party which carries out the second stage of the procedure shall carry out those examinations and tests that have not yet been carried out.

The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

↓ 2009/23/EC (adapted)

~~5~~7.2.3. A manufacturer who has opted for ~~the EC declaration of type conformity (guarantee of production quality)~~ ⌦ Module D or D1 ⌫ in the first stage may either use this same procedure in the second stage or decide to continue in the second stage with ~~EC verification~~ ⌦ Module F or F1 as appropriate ⌫ .

~~5~~7.2.4. The ~~'CE'~~ ⊠ CE ⊠ ~~conformity~~ marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the notified body which took part in the second stage.

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↓ 2009/23/EC

~~**ANNEX III**~~

~~***DESIGN TECHNICAL DOCUMENTATION***~~

~~The technical documentation must render the design, manufacture and operation of the product intelligible and enable an assessment to be made of its conformity with the requirements of this Directive.~~

~~The documentation shall include in so far as relevant for assessment:~~

~~– a general description of the type,~~

~~– conceptual designs and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.,~~

~~– descriptions and explanations necessary for the understanding of the above, including the operation of the instrument,~~

~~– a list of the harmonised standards referred to in Article 6(1), applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the harmonised standards referred to in Article 6(1) have not been applied,~~

~~– results of design calculations made and of examinations, etc.,~~

~~– test reports,~~

~~– the EC type-approval certificates and the results of relevant tests on instruments containing parts identical to those in the design.~~

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↓ 2009/23/EC (adapted)

**ANNEX ~~IV~~VIII**

***~~'CE'~~ ⊠ CE ⊠ ~~CONFORMITY~~ MARKING AND INSCRIPTIONS***

**1. Instruments subject to the ~~EC~~ ⊠ EU ⊠ conformity assessment procedure**

1.1. These instruments must bear:

(a) – the ~~'CE'~~ ⌦ CE ⌫ ~~conformity~~ marking ~~comprising the 'CE' symbol~~ as ~~described~~ ⌦ provided for ⌫ in Annex ~~VI~~III of Regulation (EC) No 765/2008, ⌦ followed by ⌫

– the identification number~~(s)~~ of the notified body~~/bodies that has/have carried out the EC surveillance or the EC verification~~ ⌦ involved in the production control phase ⌫;

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↓ 2009/23/EC

~~The abovementioned marking and inscriptions shall be affixed to the instrument and distinctly grouped together;~~

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↓ 2009/23/EC (adapted)

(b) a green sticker at least 12,5 mm × 12,5 mm square bearing a capital letter 'M' printed in black;

(c) the following inscriptions:

(i) – the number of the ~~EC type-approval~~ ⌦ EU-type examination ⌫ certificate, where appropriate~~;~~;

(ii) – the manufacturer's mark or name~~;~~;

(iii) – the accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles~~;~~;

(iv) – maximum capacity, in the form Max …~~;~~;

(v) – minimum capacity, in the form Min …~~;~~;

(vi) – verification scale interval, in the form *e* = …~~;~~;

(vii) – the last two digits of the year in which the ~~'CE'~~ ⌦ CE ⌫ ~~conformity~~ marking was affixed~~;~~;

~~plus,~~ ⌦ and ⌫ when applicable:

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↓ 2009/23/EC

(viii) – serial number~~;~~;

(ix) – for instruments consisting of separate but associated units: identification mark on each unit~~;~~;

(x) – scale interval if it is different from *e*, in the form *d* = …~~;~~;

(xi) = maximum additive tare effect, in the form $T = + \ldots$;

(xii) = maximum subtractive tare effect if it is different from Max, in the form $T = - \ldots$;

(xiii) = tare interval if it is different from *d*, in the form $d_T = \ldots$;

(xiv) = maximum safe load if it is different from Max, in the form Lim …;

(xv) = the special temperature limits, in the form … °C/… °C;

(xvi) = ratio between load receptor and load.

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↓ 2009/23/EC (adapted)

1.2. The instruments shall have adequate facilities for the affixing of the ~~'CE'~~ ⌦ CE ⌫ ~~conformity~~ marking and/or inscriptions. These shall be such that it shall be impossible to remove the marking and inscriptions without damaging them, and that the marking and inscriptions shall be visible when the instrument is in its regular operating position.

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↓ 2009/23/EC

1.3. Where a data plate is used it shall be possible to seal the plate unless it cannot be removed without being destroyed. If the data plate is sealable it shall be possible to apply a control mark to it.

1.4. The inscriptions Max, Min, *e*, and *d*, shall also be shown near the display of the result if they are not already located there.

1.5. Each load measuring device which is connected or can be connected to one or more load receptors shall bear the relevant inscriptions relating to the said load receptors.

**2. Other Instruments**

The other instruments must bear:

– the manufacturer's mark or name;

– maximum capacity, in the form Max ….

Those instruments may not bear the stickers provided for in point 1.1(b).

**3. Restrictive use symbol specified in Article ~~13~~17**

That symbol shall be constituted by a capital letter 'M' printed in black on a red background at least 25 mm × 25 mm square with two intersecting diagonals forming a cross.

↓ 2009/23/EC

**~~ANNEX V~~**

***~~THE MINIMUM CRITERIA TO BE APPLIED BY MEMBER STATES WHEN DESIGNATING BODIES FOR THE CARRYING-OUT OF TASKS PERTAINING TO THE PROCEDURES REFERRED TO IN ARTICLE 9~~***

~~1. The bodies shall have at their disposal the necessary personnel, means and equipment.~~

~~2. The personnel of the bodies shall have technical competence and professional integrity.~~

~~3. The bodies shall work independently of all circles, groups or persons having a direct or indirect interest in non-automatic weighing instruments as regards the carrying-out of the tests, the preparation of the reports, the issuing of the certificates and the surveillance required by this Directive.~~

~~4. The personnel of the bodies shall respect professional confidentiality.~~

~~5. The bodies shall take out a civil liability insurance if their civil liability is not covered by the State under national law.~~

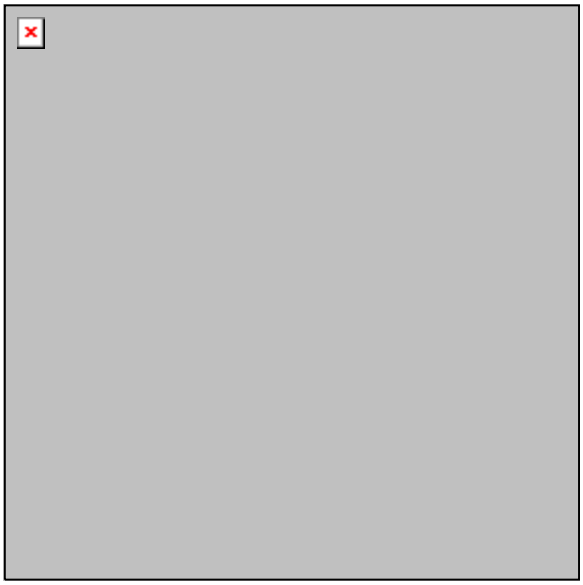
~~The fulfilment of the conditions under points 1 and 2 shall be periodically verified by the Member States.~~

↓ 2009/23/EC

**~~ANNEX VI~~**

***~~'CE' CONFORMITY MARKING~~***

~~– The 'CE' conformity marking shall consist of the initials 'CE' taking the following form:~~



~~— If the ‘CE’ conformity marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.~~

~~— The various components of the ‘CE’ conformity marking must have substantially the same vertical dimension, which may not be less than 5 mm.~~

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↓ 2009/23/EC (adapted)

## ~~ANNEX VII~~

***~~PART A~~***

| ~~*Repealed Directive with its amendment*~~ | |
|---|---|
| ~~(referred to in Article 17)~~ | |
| ~~Council Directive 90/384/EEC~~<br>~~(OJ L 189, 20.7.1990, p. 1)~~ | |
| ~~Council Directive 93/68/EEC~~<br>~~(OJ L 220, 30.8.1993, p. 1)~~ | ~~Article 1, point 7, and Article 8 only~~ |

***~~PART B~~***

| ~~*List of time limits for transposition into national law and application*~~ |
|---|
| ~~(referred to in Article 17)~~ |

| ~~Directive~~ | ~~Time limit for transposition~~ | ~~Date of application~~ |
|---|---|---|
| ~~90/384/EEC~~ | ~~30 June 1992~~ | ~~1 January 1993~~[18] |
| ~~93/68/EEC~~ | ~~30 June 1994~~ | ~~1 January 1995~~[19] |

↓ 2009/23/EC (adapted)

**ANNEX ~~VIII~~IV**

| *CORRELATION TABLE* | |
|---|---|
| Directive ~~90/384/EEC~~ ⌦ 2009/23/EC ⌫ | This Directive |
| ~~Recital 5, last sentence~~ | ~~Article 2, point (3)~~ |
| ~~Article 1(1), first subparagraph~~ | ~~Article 2, point (1)~~ |
| ~~Article 1(1), second subparagraph~~ | ~~Article 2, point (2)~~ |
| ~~Article 1(1), third subparagraph~~ | ~~Article 1(1)~~ |
| ~~Article 1(2), introductory wording~~ | ~~Article 1(2), introductory wording~~ |
| ~~Article 1(2), point (a)(1)~~ | ~~Article 1(2), point (a)(i)~~ |
| ~~Article 1(2), point (a)(2)~~ | ~~Article 1(2), point (a)(ii)~~ |
| ~~Article 1(2), point (a)(3)~~ | ~~Article 1(2), point (a)(iii)~~ |
| ~~Article 1(2), point (a)(4)~~ | ~~Article 1(2), point (a)(iv)~~ |
| ~~Article 1(2), point (a)(5)~~ | ~~Article 1(2), point (a)(v)~~ |
| ~~Article 1(2), point (a)(6)~~ | ~~Article 1(2), point (a)(vi)~~ |
| ~~Article 1(2), point (b)~~ | ~~Article 1(2), point (b)~~ |
| ~~Article 2~~ | ~~Article 3~~ |
| ~~Article 3~~ | ~~Article 4~~ |

[18] ~~In accordance with Article 15(3) of Directive 90/384/EEC Member States shall permit, during a period of 10 years from the date on which they apply the laws, regulations and administrative provisions adopted by the Member States in order to transpose that Directive into national law, the placing on the market and/or putting into service of instruments which conform to the rules in force before 1 January 1993.~~

[19] ~~In accordance with Article 14(2) of Directive 93/68/EEC: 'Until 1 January 1997, Member States shall allow the placing on the market and the bringing into service of products which comply with the marking arrangements in force before 1 January 1995'.~~

| | |
|---|---|
| ~~Article 4~~ | ~~Article 5~~ |
| ~~Article 5~~ | ~~Article 6~~ |
| ~~Article 6, first paragraph, first sentence~~ | ~~Article 7, first paragraph~~ |
| ~~Article 6, first paragraph, second sentence~~ | ~~Article 7, second paragraph~~ |
| ~~Article 6, second paragraph~~ | ~~Article 7, third paragraph~~ |
| ~~Article 7~~ | ~~Article 8~~ |
| ~~Article 8(1) and (2)~~ | ~~Article 9(1) and (2)~~ |
| ~~Article 8(3), point (a)~~ | ~~Article 9(3), first subparagraph~~ |
| ~~Article 8(3), point (b)~~ | ~~Article 9(3), second subparagraph~~ |
| ~~Article 9~~ | ~~Article 10~~ |
| ~~Article 10~~ | ~~Article 11~~ |
| ~~Article 11~~ | ~~Article 12~~ |
| ~~Article 12~~ | ~~Article 13~~ |
| ~~Article 13~~ | ~~Article 14~~ |
| ~~Article 14, first sentence~~ | ~~Article 15, first paragraph~~ |
| ~~Article 14, second sentence~~ | ~~Article 15, second paragraph~~ |
| ~~Article 15(1) to (3)~~ | ~~—~~ |
| ~~Article 15(4)~~ | ~~Article 16~~ |
| ~~Article 15(5)~~ | ~~—~~ |
| ~~—~~ | ~~Article 17~~ |
| ~~—~~ | ~~Article 18~~ |
| ~~Article 16~~ | ~~Article 19~~ |
| ~~Annexes I to VI~~ | ~~Annexes I to VI~~ |
| ~~—~~ | ~~Annex VII~~ |
| ~~—~~ | ~~Annex VIII~~ |
| ⌦ Article 1(1) ⌫ | ⌦ Article 1(1) ⌫ |

| | |
|---|---|
| ⌦ Article 1(2), introductory wording ⌫ | ⌦ Article 1(2), introductory wording ⌫ |
| ⌦ Article 1(2), point (a)(i) ⌫ | ⌦ Article 1(2), point (a) ⌫ |
| ⌦ Article 1(2), point (a)(ii) ⌫ | ⌦ Article 1(2), point (b) ⌫ |
| ⌦ Article 1(2), point (a)(iii) ⌫ | ⌦ Article 1(2), point (c) ⌫ |
| ⌦ Article 1(2), point (a)(iv) ⌫ | ⌦ Article 1(2), point (d) ⌫ |
| ⌦ Article 1(2), point (a)(v) ⌫ | ⌦ Article 1(2), point (e) ⌫ |
| ⌦ Article 1(2), point (a)(vi) ⌫ | ⌦ Article 1(2), point (f) ⌫ |
| ⌦ Article 1(2), point (b) ⌫ | ⌦ Article 1(2), point (g) ⌫ |
| ⌦ Article 2(1) ⌫ | ⌦ Article 2(1) ⌫ |
| ⌦ Article 2(2) ⌫ | ⌦ Article 2(2) ⌫ |
| ⌦ Article 2(3) ⌫ | ⌦ ____ ⌫ |
| ⌦ ____ ⌫ | ⌦ Article 2(3) to (19) ⌫ |
| ⌦ Article 3 ⌫ | ⌦ Article 3 ⌫ |
| ⌦ Article 4 ⌫ | ⌦ Article 4 ⌫ |
| ⌦ Article 5 ⌫ | ⌦ Article 5 ⌫ |
| ⌦ Article 6 ⌫ | ⌦ ____ ⌫ |
| ⌦ Article 7 ⌫ | ⌦ ____ ⌫ |
| ⌦ Article 8 ⌫ | ⌦ ____ ⌫ |
| ⌦ ____ ⌫ | ⌦ Article 6 ⌫ |
| ⌦ ____ ⌫ | ⌦ Article 7 ⌫ |
| ⌦ ____ ⌫ | ⌦ Article 8 ⌫ |
| ⌦ ____ ⌫ | ⌦ Article 9 ⌫ |
| ⌦ ____ ⌫ | ⌦ Article 10 ⌫ |
| ⌦ ____ ⌫ | ⌦ Article 11 ⌫ |
| ⌦ ____ ⌫ | ⌦ Article 12 ⌫ |
| ⌦ Article 9(1), introductory wording ⌫ | ⌦ Article 13(1), introductory |

| | |
|---|---|
| | wording ⌫ |
| ⌦ Article 9(1), point (a) ⌫ | ⌦ Article 13(1), point (a) ⌫ |
| ⌦ Article 9(1), point (b) ⌫ | ⌦ Article 13(1), point (b) ⌫ |
| ⌦ Article 9(2) ⌫ | ⌦ Article 13(2) ⌫ |
| ⌦ Article 9(3) ⌫ | ⌦ _____ ⌫ |
| ⌦ Article 10 ⌫ | ⌦ ____ ⌫ |
| ⌦ Article 11 ⌫ | ⌦ ___ ⌫ |
| ⌦ Article 12 ⌫ | ⌦ ____ ⌫ |
| ⌦ ____ ⌫ | ⌦ Article 14 ⌫ |
| ⌦ ____ ⌫ | ⌦ Article 15 ⌫ |
| ⌦ ____ ⌫ | ⌦ Article 16 (1) to (4) ⌫ |
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