Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments (Codified version) (Text with EEA relevance) (repealed)

CHAPTER 1

SCOPE, PLACING ON THE MARKET AND FREE MOVEMENT

Article 1

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 (i) determination of mass for commercial transactions;

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

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

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

(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;

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

b all applications other than those listed in point (a).

Article 2

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

1. ‘weighing instrument’	:	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 serve to determine other mass-related magnitudes, quantities, parameters or characteristics;
2. ‘non-automatic weighing instrument’ or ‘instrument’	:	a weighing instrument requiring the intervention of an operator during weighing;
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[(1)] and the general guidelines for cooperation between the Commission, the

European Free Trade Association (EFTA) and those three bodies, signed on 28 March 2003.

Article 3

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

2 Member States shall take all steps to ensure that instruments may not be brought into service for the uses referred to in point (a) 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 4

Instruments used for the applications listed in point (a) of Article 1(2) must satisfy the essential requirements set out in Annex I.

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

Article 5

1 Member States shall not impede the placing 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 point (a) of Article 1(2), of instruments which meet the requirements of this Directive.

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.

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).

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.

CHAPTER 2

CONFORMITY ASSESSMENT

Article 9

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:

a EC type examination as referred to in Annex II, point 1, followed either by the EC declaration of type conformity (guarantee of production quality) as referred to in Annex II, point 2, or by the EC verification as referred to in Annex II, point 3.

However, EC type examination 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;

b EC unit verification as referred to in Annex II, point 4.

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

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 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

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.

Article 13

Where an instrument which is used for any of the applications referred to in point (a) of Article 1(2) includes, or is connected to, devices that have not been subject to conformity assessment as referred to in Article 9, each of those devices shall bear the symbol restricting its use as defined by Annex IV, point 3. That symbol shall be affixed to the devices in a clearly visible and indelible form.

CHAPTER 4

FINAL PROVISIONS

Article 14

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 requirements.

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.

Article 16

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

Article 17

Directive 90/384/EEC, as amended by the Directive listed in Annex VII, Part A, is repealed, 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.

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.

Article 18

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

Article 19

This Directive is addressed to the Member States.

Done at Strasbourg, 23 April 2009.

For the European Parliament

The President

H.-G. PÖTTERING

For the Council

The President

P. NEČAS

(**1**) OJ L 204, 21.7.1998, p. 37.