Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (recast) (Text with EEA relevance)

CHAPTER 1

GENERAL PROVISIONS

Article 1

Scope

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 determination of mass for commercial transactions;

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

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

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

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

g all applications other than those listed in points (a) to (f).

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 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;

(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 trade mark;

(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;

(11) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

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

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

(14) 'conformity assessment' means the process demonstrating whether the essential 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) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;

(19) '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.

Article 3

Making available on the market and putting into service

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

2 Member States shall take all steps to ensure that instruments may not be put into service for the uses referred to in points (a) to (f) of Article 1(2) unless they meet the requirements of this Directive.

3 Member States shall take all steps to ensure that instruments put into service for the uses referred to in points (a) to (f) of Article 1(2) continue to conform to the applicable requirements of this Directive.

Article 4

Essential requirements

Instruments used or intended to be used for the applications listed in points (a) to (f) of Article 1(2) shall satisfy the essential requirements set out in Annex I.

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

Article 5

Free movement of instruments

1 Member States shall not impede the 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.