# STATUTORY INSTRUMENTS

# 2016 No. 1152

# The Non-automatic Weighing Instruments Regulations 2016

# PART 2

# REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS – OBLIGATIONS OF ECONOMIC OPERATORS

# CHAPTER 1

# OBLIGATIONS OF MANUFACTURERS AND PERSONS TO BE TREATED AS MANUFACTURERS

## Introductory

**5.**—(1) This Chapter applies in relation to the placing on the market of a regulated non-automatic weighing instrument by a manufacturer.

(2) The obligations in this Chapter also apply to an importer or distributor who-

- (a) places a regulated non-automatic weighing instrument on the market under the name or trade mark of that importer or distributor; or
- (b) modifies a regulated non-automatic weighing instrument already placed on the market in such a way that compliance with these Regulations may be affected,

and the expression "manufacturer" is to be construed accordingly.

# Manufacturers' responsibilities – design, conformity assessment and marking of regulated non-automatic weighing instruments

**6.** A manufacturer must not place on the market a regulated non-automatic weighing instrument unless the manufacturer has—

- (a) designed and manufactured the instrument in accordance with the essential requirements;
- (b) drawn up technical documentation in relation to the instrument;
- (c) carried out (or procured the carrying out of) the relevant conformity assessment procedure which has demonstrated compliance of the instrument with the applicable requirements;
- (d) drawn up an EU declaration of conformity; and
- (e) affixed to the instrument—
  - (i) the CE marking; and
  - (ii) the M marking.

# Manufacturers' obligations in respect of records

7. A manufacturer must keep the technical documentation and the EU declaration of conformity for a period of 10 years beginning with the day after the day on which the regulated non-automatic weighing instrument to which it relates has been placed on the market.

#### Manufacturers' obligations to ensure continuing conformity with the essential requirements

**8.**—(1) Manufacturers must have procedures in place for series production of regulated nonautomatic weighing instruments by them to ensure that instruments so manufactured continue to meet the essential requirements.

(2) These procedures must adequately take into account changes in-

- (a) regulated non-automatic weighing instrument design or characteristics; and
- (b) changes in the harmonised standards or in other technical specifications by reference to which the conformity of the regulated non-automatic weighing instrument is declared.

(3) When deemed appropriate with regard to the risks presented by the use of a regulated nonautomatic weighing instrument, a manufacturer must—

- (a) carry out sample testing of regulated non-automatic weighing instruments made available by the manufacturer on the market;
- (b) investigate complaints about regulated non-automatic weighing instruments made available by the manufacturer on the market;
- (c) if necessary, keep a register of-
  - (i) such complaints;
  - (ii) non-conforming regulated non-automatic weighing instruments; and
  - (iii) regulated non-automatic weighing instrument recalls; and
- (d) keep distributors informed of any monitoring action the manufacturer has undertaken.

# Manufacturers' obligations in relation to the marking of regulated non-automatic weighing instruments with serial numbers etc.

**9.**—(1) A manufacturer must ensure that a regulated non-automatic weighing instrument, which that manufacturer has placed on the market, bears a type, batch, serial number or other element allowing identification of the instrument.

(2) A manufacturer must ensure that a regulated non-automatic weighing instrument is marked with the information specified in Schedule 1 (information to be marked on regulated non-automatic weighing instruments) and in the manner required by that Schedule.

(3) Where a regulated non-automatic measuring instruments includes or is attached to devices which are not used or intended to be used for any of the purposes listed in regulation 3(2), the manufacturer must affix to those devices a symbol constituted by a capital letter (M) printed in black on a red background at least 25mm x 25mm square with two intersecting diagonals forming a cross.

(4) The symbol referred to in paragraph (3) must be affixed in a clearly visible and indelible form.

### Manufacturers to mark contact details on regulated non-automatic weighing instruments

**10.**—(1) A manufacturer must indicate on every regulated non-automatic weighing instruments manufactured by that manufacturer, the manufacturer's name, registered trade name or registered trade mark and the postal address at which the manufacturer can be contacted.

(2) The address required by these Regulations must indicate a single point at which the manufacturer can be contacted.

(3) The contact details required by this regulation must be in a language that is easily understood by end-users and market surveillance authorities and in the case of regulated non-automatic weighing instruments made available in the United Kingdom, they must be in English.

#### Documentation to accompany regulated non-automatic weighing instruments

11.—(1) A manufacturer must ensure that regulated non-automatic weighing instruments manufactured by that manufacturer are accompanied by instructions and information easily understood by end-users.

(2) Where end-users are in the United Kingdom, those instructions and information must be in English.

(3) Such instructions and information and any labelling relating to a regulated non-automatic weighing instrument must be clear, understandable and intelligible.

# Action to be taken where regulated non-automatic weighing instruments placed on the market are not in conformity with the essential requirements

**12.**—(1) This regulation applies where a manufacturer considers or has reason to believe that a regulated non-automatic weighing instrument placed on the market by that manufacturer is not in conformity with the requirements of these Regulations.

(2) The manufacturer must immediately take the corrective measures necessary to bring the regulated non-automatic weighing instrument into conformity, or withdraw or recall it, if appropriate.

(3) Where the regulated non-automatic weighing instrument presents a risk, the manufacturer must immediately inform the competent national authorities of the EEA states in which the instrument has been made available on the market to that effect giving details, in particular, of the non-compliance and of any corrective measures taken.

#### Provision of information to the competent authority

**13.**—(1) A manufacturer must, further to a reasoned request from a competent authority, provide that authority, with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a regulated non-automatic weighing instrument manufactured by that manufacturer with the requirements of these Regulations.

(2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.

(3) A manufacturer must co-operate with a competent authority, at the request of that authority, on any action to eliminate the risks posed by regulated non-automatic weighing instruments that the manufacturer has placed on the market.

### Use of authorised representatives by manufacturers

14.—(1) A manufacturer may, by written mandate, appoint an authorised representative to discharge the responsibilities of that manufacturer under these Regulations in relation to the placing on the market of a regulated non-automatic weighing instrument.

(2) The authorised representative does not have the power to discharge the manufacturer's obligations under regulations 6(a) and 6(b).

- (3) The authorised representative must be treated as authorised to—
  - (a) keep the EU declaration of conformity and the technical documentation at the disposal of the market surveillance authority for 10 years beginning with the day after the day on which a regulated non-automatic weighing instrument has been placed on the market;
  - (b) provide a competent authority further to a reasoned request from that authority with all the information and documentation necessary to demonstrate the conformity of a regulated non-automatic weighing instrument; and

(c) co-operate with a competent authority, at its request, on any action taken to eliminate the risks posed by regulated non-automatic weighing instruments covered by its mandate.

# CHAPTER 2

# OBLIGATIONS OF IMPORTERS

### Introductory

**15.** This Chapter applies to the placing on the market of a regulated non-automatic weighing instrument that is imported into the United Kingdom from a country outside the European Economic Area.

#### Ensuring compliance of regulated non-automatic weighing instruments

**16.**—(1) An importer must only place compliant regulated non-automatic weighing instruments on the market.

- (2) An importer must ensure that—
  - (a) the appropriate conformity assessment procedure has been carried out by the manufacturer of the regulated non-automatic weighing instrument (or by the importer where the importer is to be regarded as the manufacturer by virtue of regulation 5(2);
  - (b) the manufacturer has drawn up the technical documentation (or that the importer has done so where the importer is treated as the manufacturer by virtue of regulation 5(2);
  - (c) the regulated non-automatic weighing instrument bears the CE marking and the M marking;
  - (d) the manufacturer (or the importer where he is treated as the manufacturer under regulation 5(2)) has complied with the requirements of regulations 9 (manufacturers' obligations in relation to the marking of regulated non-automatic weighing instruments with serial numbers etc.) and 10 (manufacturers to mark contact details on regulated nonautomatic weighing instruments).

# Importers duty to notify manufacturer and market surveillance authorities of non-compliant regulated non-automatic weighing instruments that present a risk

17. Where an importer considers, or has reason to believe, that the regulated non-automatic weighing instrument is not in conformity with the essential requirements and presents a risk, the importer must inform the manufacturer and the market surveillance authority.

### Requirements to mark importers' details on regulated non-automatic weighing instruments

**18.**—(1) An importer must indicate on any regulated non-automatic weighing instrument imported by that importer, the importer's name, registered trade name or trademark, and the postal address at which the importer can be contacted.

(2) Where this would require the packaging to be opened, those indications may be given on the packaging and in a document accompanying the instrument.

(3) The contact details required by this regulation must be in a language that is easily understood by end-users and market surveillance authorities, and in the case of regulated non-automatic weighing instruments made available in the United Kingdom, they must be in English.

# Importers' duty to ensure that regulated non-automatic weighing instruments are accompanied by relevant documentation.

**19.**—(1) An importer must ensure that regulated non-automatic weighing instruments imported by the importer are accompanied by instructions and information in a language easily understood by end users

(2) Where end users are in the United Kingdom, the instructions and information referred to in paragraph (1) must be in English.

## Duty of importers to ensure proper conditions of storage and transport

**20.** An importer must, in respect of regulated non-automatic weighing instruments under the importer's responsibility, ensure that the conditions of their storage or transport are not such as to jeopardise their continuing compliance with the essential requirements.

## Duties of importers with regard to monitoring etc.

**21.**—(1) When deemed appropriate with regard to the performance of a regulated non-automatic weighing instrument imported by an importer, the importer must—

- (a) carry out a sample testing of regulated non-automatic weighing instruments made available on the market by the importer;
- (b) investigate complaints about regulated non-automatic weighing instruments imported by them; and
- (c) if necessary, keep a register of-
  - (i) such complaints;
  - (ii) non-conforming regulated non-automatic weighing instruments;
  - (iii) regulated non-automatic weighing instrument recalls; and
- (d) where the importer is not also the distributor of the regulated non-automatic weighing instrument, keep distributors, to whom he has supplied an instrument, informed of any monitoring undertaken by that importer.

# Action to be taken by importers where regulated non-automatic weighing instruments placed on the market by them are not in conformity with essential requirements

**22.**—(1) This regulation applies where an importer considers, or has reason to believe, that a regulated non-automatic weighing instrument placed on the market by the importer is not in conformity with the requirements of these Regulations.

(2) Where this regulation applies, the importer must immediately take the corrective measures necessary to bring the regulated non-automatic weighing instrument into conformity, or withdraw or recall it, if appropriate.

(3) Where the non-automatic weighing instrument presents a risk, the importer must immediately inform the competent authority to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that importer.

### Requirement for importer to keep copy of EU declaration of conformity

**23.** The importer must, for a period of 10 years beginning with the day after the day on which the regulated non-automatic weighing instrument is 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.

#### Provision of information to a competent authority

**24.**—(1) The importer must, further to a reasoned request from a competent authority, provide the competent authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the regulated non-automatic weighing instrument with the requirements of these Regulations.

(2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.

(3) An importer must co-operate with a competent authority, at its request, as regards any action to eliminate the risks posed by any regulated non-automatic weighing instrument that the importer has placed on the market.

## CHAPTER 3

### **OBLIGATIONS OF DISTRIBUTORS**

### Introductory

**25.** This Chapter applies in relation to the making available on the market of a regulated non-automatic weighing instrument by a distributor.

## Distributors - duty to act with due care

26. Before making the regulated non-automatic instrument available on the market, the distributor must act with due care in relation to the requirements of these Regulations.

#### **Distributors – verification obligations**

**27.**—(1) The distributor must verify that the regulated non-automatic weighing instrument bears the CE marking and the M marking.

(2) The distributor must verify that the regulated non-automatic weighing instrument, it is accompanied by instructions and information easily understood by end users.

(3) Instructions and information supplied in accordance with this regulation must be in a language that is easily understood by end users and where those users are in the United Kingdom must be in English.

(4) The distributor must verify that the manufacturer and the importer have complied with the requirements set out in regulation 9 (manufacturers' obligations in relation to the marking of regulated non-automatic weighing instruments with serial numbers etc.), regulation 10 (manufacturers to mark contact details on regulated non-automatic weighing instruments) and regulation 18 (requirements to mark importers' details on regulated non-automatic weighing instruments).

# Distributors not to make non-conforming non-automatic weighing instruments available on the market etc.

**28.**—(1) This regulation applies where a distributor considers, or has reason to believe, that a regulated non-automatic weighing instrument is not in conformity with the essential requirements.

(2) Where this regulation applies, the distributor must not make the regulated non-automatic weighing instrument available on the market until it has been brought into conformity.

(3) Where the regulated non-automatic weighing instrument presents a risk, the distributor must immediately inform—

(a) the manufacturer;

- (b) the importer (where the distributor is not also the manufacturer or importer); and
- (c) the market surveillance authority,

to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that distributor.

#### Duty of distributors to ensure proper conditions of storage and transport

**29.** A distributor must, in respect of regulated non-automatic weighing instruments under that distributor's responsibility, ensure that the conditions of their storage or transport are not such as to jeopardise their continuing compliance with the essential requirements.

# Action to be taken by distributors where regulated non-automatic weighing instruments placed on the market by them are not in conformity with essential requirements

**30.**—(1) This regulation applies where a distributor considers, or has reason to believe, that a regulated non-automatic weighing instrument placed on the market by that distributor is not in conformity with the requirements of these Regulations.

(2) Where this regulation applies, the distributor must immediately take the corrective measures necessary to bring the regulated non-automatic weighing instrument into conformity, or withdraw or recall it, if appropriate.

(3) Where the regulated non-automatic weighing instrument presents a risk, the distributor must immediately inform the competent authority to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that distributor.

#### Provision of information to the competent authority

**31.**—(1) The distributor must, further to a reasoned request from a competent authority, provide that authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the regulated non-automatic weighing instrument with the requirements of these Regulations.

(2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.

(3) A distributor must co-operate with a competent authority, at its request, as regards any action to eliminate the risks posed by any regulated non-automatic weighing instrument that the distributor has placed on the market.

### **CHAPTER 4**

# IDENTIFICATION OF ECONOMIC OPERATORS

**32.**—(1) Economic operators must, on request, identify to the market surveillance authorities—

- (a) any economic operator who has supplied them with a regulated non-automatic weighing instrument; and
- (b) any economic operator to whom they have supplied a regulated non-automatic weighing instrument.

(2) Economic operators must be able to present the information referred to in paragraph (1) for 10 years beginning with the day on which they have been supplied with the regulated non-automatic weighing instrument and for 10 years beginning with the day after the day on which they have supplied the instrument.

(3) The Secretary of State may impose a monetary penalty on an economic operator who fails to comply with an obligation imposed by this regulation.

(4) Schedule 5 has effect in relation to the imposition of a monetary penalty under paragraph (3).