
STATUTORY INSTRUMENTS

2016 No. 1152

The Non-automatic Weighing Instruments Regulations 2016

PART 3

**CONFORMITY OF REGULATED NON-
AUTOMATIC WEIGHING INSTRUMENTS**

CHAPTER 1

ESTABLISHING COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

Introductory

33. This Chapter applies for the purposes of establishing whether a regulated non-automatic weighing instrument complies with the essential requirements.

Methods of establishing conformity with the essential requirements

34. Conformity with the essential requirements may be established in relation to a regulated non-automatic weighing instrument—

- (a) through conformity with harmonised standards (or parts of those standards) covering the essential requirements where the harmonised standards have been published in the Official Journal of the European Union; or
- (b) through the use by the manufacturer of any other technical solution that complies with the essential requirements.

Presumptions of conformity of regulated non-automatic weighing instruments

35. Regulated non-automatic weighing instruments which are in conformity with harmonised standards (or parts of those standards) shall be presumed to be in conformity with the essential requirements covered by those standards (or parts of those standards).

Conformity assessment procedures

36.—(1) The conformity of regulated non-automatic weighing instruments to the essential requirements may, subject to paragraph (2), be established by either of the following conformity assessment procedures as selected by the manufacturer—

- (a) Module B as set out in point 1 of Annex II to the Directive followed by either—
 - (i) Module D as set out in point 2 of Annex II; or
 - (ii) Module F as set out in point 4 of Annex II; or
 - (b) Module G as set out in point 6 of Annex II.
- (2) Module B is compulsory for instruments—
- (a) which use electronic devices; and

- (b) the load measuring device of which uses a spring to balance the load.
- (3) Where an instrument is not submitted to Module B, either of the following modules must be applied—
 - (a) Module D1 as set out in point 3 of Annex II; or
 - (b) Module F1 as set out in point 5 of Annex II.
- (4) A notified body must carry out the conformity assessment procedure selected by the manufacturer in accordance with the requirements of Schedule 2.
- (5) The documents and correspondence relating to the conformity assessment procedures referred to in this regulation, and which are carried out in the United Kingdom, must be drawn up in English.
- (6) In this regulation a reference to a module other than Module B includes the common provisions as set out in point 7 of Annex II to the Directive.

Subsidiaries and contractors

- 37.**—(1) This regulation applies where—
- (a) a notified body subcontracts specific conformity assessment activities, or
 - (b) has such activities carried out by a subsidiary.
- (2) The activities are only to be treated as having been carried out by a notified body for the purposes of regulation 36 (conformity assessment procedures) where the conditions in paragraphs (3) and (4) are met.
- (3) The notified body must—
- (a) ensure that the subcontractor or subsidiary meets the notified body requirements; and
 - (b) inform the Secretary of State accordingly.
- (4) The notified body must have obtained the agreement of the client to the use of a subcontractor or subsidiary.
- (5) Where a notified body subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the notified body must for a period of at least 10 years beginning on the day after the activities are carried out, keep at the disposal of the Secretary of State the documentation concerning—
- (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
 - (b) the conformity assessment activities carried out by the subcontractor or subsidiary.
- (6) When monitoring a notified body in accordance with regulation 52 (monitoring), the Secretary of State must treat the notified body as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.

Fees

- 38.**—(1) A United Kingdom notified body may charge fees in connection with, or incidental to, the carrying out of conformity assessment procedures or specific tasks as it may determine.
- (2) The fees referred to in paragraph (1) must not exceed the following—
- (a) the costs incurred or to be incurred by the United Kingdom notified body in performing the relevant function; and
 - (b) an amount on account of profit which is reasonable in the circumstances having regard to—
 - (i) the character and extent of the work done or to be done by that notified body on behalf of the applicant; and

(ii) the commercial rate normally charged on account of profit for that work or similar work.

(3) The power in paragraph (1) includes the power to require payment of fees or a reasonable estimate of such fees in advance of carrying out the work requested by the applicant.

(4) Where any fees payable to a United Kingdom notified body pursuant to this regulation remain unpaid 28 days after either the work has been requested or payment of the fees has been requested in writing, whichever is the later, the notified body may by 14 days' notice in writing provide that, unless the fees are paid before the expiry of the notice, the certificate or notification appropriate to the relevant conformity assessment procedure may be suspended until payment of the fees has been received.

(5) This regulation does not apply to the Secretary of State.

CHAPTER 2

REQUIREMENTS RELATING TO EU DECLARATIONS OF CONFORMITY

Application of Chapter

39. This Chapter applies in relation to EU declarations of conformity made in relation to a regulated non-automatic weighing instrument for the purposes of these Regulations.

Form and contents of EU declaration of conformity etc.

40.—(1) The EU declaration of conformity must—

- (a) state that the fulfilment of the essential requirements has been demonstrated in relation to the regulated non-automatic weighing instrument;
- (b) have the model structure set out in Annex IV to the Directive; and
- (c) contain the elements specified in the relevant modules set out in Annex II to the Directive and must be updated when appropriate.

(2) Where a regulated non-automatic weighing instrument is placed or made available on the market in the United Kingdom, the EU declaration of conformity in relation to the instrument must be in English.

Regulated instruments that require more than one declaration of conformity

41.—(1) This regulation applies where a regulated non-automatic weighing instrument is subject to a requirement of European Union legislation for an EU declaration of conformity otherwise than by virtue of these Regulations.

(2) Where this regulation applies, a single EU declaration of conformity must be drawn up covering all applicable requirements which identifies the Union acts concerned including their publication references.

Responsibility of manufacturer that draws up declaration of conformity

42. A manufacturer, who draws up an EU declaration of conformity in relation to a regulated non-automatic weighing instrument, is responsible for compliance of that instrument with the requirements of these Regulations.

CHAPTER 3 CONFORMITY MARKING

Conformity with Directive requirements to be indicated by the CE marking

43. The conformity of a regulated non-automatic weighing instrument with the requirements of these Regulations must be indicated by the presence on it of the CE marking and the M marking.

General principles relating to the M marking

44. The general principles set out in article 30 of RAMS apply to the M marking with such modifications as are necessary in the circumstances.

Rules and conditions for affixing the CE marking and the M marking etc.

45.—(1) The CE marking and M marking (“the markings”) must be affixed to a regulated non-automatic weighing instrument in accordance with the provisions of this regulation.

(2) The markings must be affixed visibly, legibly and indelibly to the regulated non-automatic weighing instrument or its data plate.

(3) The markings must be affixed before the regulated non-automatic weighing instrument is placed on the market.

(4) The M marking must immediately follow the CE marking.

(5) The markings must immediately be followed by the identification of the notified body where that body is involved in the production control phase as set out in Annex II to the Directive.

(6) The identification number of the notified body which carried out the conformity assessment procedure must be affixed by the body itself, or under its instructions by the manufacturer or the manufacturer’s authorised representative.

(7) The markings and the identification number of the notified body may be followed by any other mark indicating a special risk or use.