

## SCHEDULE 26

Regulation 29

### Amendment of the Non-automatic Weighing Instruments Regulations 2016

#### Introduction

1. The Non-automatic Weighing Instruments Regulations 2016 are amended in accordance with paragraphs 2 to 45.

#### Amendment to regulation 2

2.—(1) Regulation 2 (interpretation) is amended as follows.

(2) In paragraph (1)—

- (a) omit the definition of “accreditation”;
- (b) omit the definition of “accreditation certificate”;
- (c) before the definition of “authorised representative” insert—  
““approved body” has the meaning given to it in regulation 47 (approved bodies);”;
- (d) for the definition of “authorised representative” substitute—  
““authorised representative” means—
  - (a) a person who—
    - (i) immediately before exit day was established in the United Kingdom or an EEA state and was appointed by a manufacturer by written mandate to perform specified tasks for that manufacturer, in accordance with regulation 14, as it had effect immediately before exit day; and
    - (ii) on or after exit day continues to be so established and appointed by the manufacturer to perform those tasks; or
  - (b) a person who, on or after exit day, is established in the United Kingdom and is appointed in accordance with regulation 14;”;
- (e) omit the definition of “CE marking”;
- (f) omit the definition of “Commission”;
- (g) after the definition of “conformity assessment body” insert—  
““conformity assessment procedure” means a procedure referred to in regulation 36;”;  
“declaration of conformity” means a declaration of conformity required to be drawn up in accordance with Chapter 2 of Part 3;”;  
“designated standard” has the meaning given to it in regulation 2A;”;
- (h) in the definition of “the Directive” for “as from time to time amended;” substitute “(as it has effect immediately before exit day)”;
- (i) in the definition of “essential requirements” for “Annex I to the Directive” substitute Schedule 6;
- (j) omit the definition of “EU declaration of conformity”;
- (k) in the definition of “EU-type examination certificate”—
  - (i) for “EU-type” substitute “type”;
  - (ii) for “a notified” substitute “an approved”;
  - (iii) for “Annex II to the Directive” substitute “Schedule 7”;

- (l) omit the definition of “harmonised standard”;
  - (m) for the definition of “importer” substitute—
    - ““importer” means a person who—
    - (a) is established in the United Kingdom; and
    - (b) places a non-automatic weighing instrument from a country outside of the United Kingdom on the market;”;
  - (n) in the definition of “M marking” for “CE” substitute “UK”;
  - (o) in the definition of “make available on the market” for “European Economic Area” substitute “United Kingdom”;
  - (p) omit the definition of “national accreditation body”;
  - (q) omit the definition of “notified body requirements”;
  - (r) omit the definition of “notifying authority”;
  - (s) in the definition of “place on the market” for “European Economic Area” substitute “United Kingdom”;
  - (t) in the definition of “technical documentation” for “Annex II to the Directive” substitute Schedule 7;
  - (u) after the definition of “technical specification” insert—
    - ““UK marking” means the marking in the form published in accordance with 30(1) of RAMS;
    - “UK national accreditation body” means the body appointed by the Secretary of State in accordance with Article 4 of RAMS;”;
  - (v) omit the definition of “Union harmonisation legislation”.
- (3) After paragraph (1) insert—
- “(1A) Schedules 6 to 8 reproduce the provisions of Annexes I to III to the Directive (respectively) with amendments to correct deficiencies in retained EU law.
  - (1B) A reference to any provision of Schedules 6 to 8 is a reference to the equivalent provision of the relevant Annex to the Directive as set out in the relevant Schedule.”.
- (4) Omit paragraph (2).

## **Insertion of regulation 2A**

### **3. After regulation 2 insert—**

#### **“Designated standard**

**2A.—**(1) Subject to paragraphs (6) and (7), in these Regulations a “designated standard” means a technical specification which is—

- (a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and
- (b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

(2) For the purposes of paragraph (1), a “technical specification” means a document that prescribes technical requirements to be fulfilled by a non-automatic weighing instrument, process, service or system and which lays down one or more of the following—

- (a) the characteristics required of a non-automatic weighing instrument, including—
    - (i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and
    - (ii) the requirements applicable to the non-automatic weighing instrument as regards the name under which the measuring instrument is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and
  - (b) production methods and processes relating to the non-automatic weighing instrument, where these have an effect on the characteristics of the non-automatic weighing instrument.
- (3) For the purposes of this regulation a “recognised standardisation body” means any one of the following organisations—
- (a) the European Committee for Standardisation (CEN);
  - (b) the European Committee for Electrotechnical Standardisation (Cenelec);
  - (c) the European Telecommunications Standards Institute (ETSI);
  - (d) the British Standards Institution (BSI).
- (4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any persons who may have an interest in the standard.
- (5) Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation bodies.
- (6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).
- (7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.
- (8) The Secretary of State may by regulations amend paragraph (3) to reflect any changes in the name or structure of the recognised standardisation bodies.
- (9) Regulations made under paragraph (8) are to be made by statutory instrument.
- (10) A statutory instrument containing regulations made under paragraph (8) is subject to annulment in pursuance of a resolution of either House of Parliament.”.

#### **Amendment to regulation 4**

**4.** Regulation 4 (revocations and transitional and consequential provisions) is amended as follows—

- (a) in paragraph (2) after “in paragraph (1)” insert “subject to the modifications made in paragraph (3A)”;
- (b) after paragraph (3) insert—
  - “**3A.** The modifications referred to in paragraph (2) are as follows—
    - (a) in the Non-automatic Weighing Instruments Regulations 2000 and the Non-automatic Weighing Instruments (Amendment) Regulations 2008—
      - (i) any reference to “the Community” is to be read as including the United Kingdom;

**Draft Legislation:** This is a draft item of legislation and has not yet been made as a UK Statutory Instrument. This draft has been replaced by a new draft, *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019* ISBN 978-0-11-118040-2

- (ii) references to “member State” is to be read as including the United Kingdom;
- (b) in the Non-automatic Weighing Instruments Regulations 2000—
  - (i) omit regulation 10(14);
  - (ii) in regulations 25(6)(a)(i) and 25(7)(a) for “; and” substitute “.”; and
  - (iii) omit regulations 25(6)(a)(ii), 25(6)(b) and 25(7)(b).”.

## **Transitional provision in relation to EU Exit**

### **5. After regulation 4 insert—**

#### **“Transitional provision in relation to EU Exit**

##### **4A.—(1) In this regulation—**

“pre-exit period” means the period beginning with the commencement date and ending immediately before exit day.

(2) Subject to paragraph (3), where a non-automatic weighing instrument was made available on the market during the pre-exit period, despite the amendments made by Schedule 26 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019<sup>(1)</sup>, any obligation to which a person was subject under these Regulations as they had effect immediately before exit day, continues to have effect as it did immediately before exit day, in relation to that non-automatic weighing instrument.

##### **(3) Paragraph (2) does not apply to—**

- (a) any obligation of any competent authority to inform the European Commission or Member States of any matter; or
- (b) any obligation to take action outside of the United Kingdom in respect of that non-automatic weighing instrument.

##### **(4) Where during the pre-exit period—**

- (a) a non-automatic weighing instrument has not been placed on the market; and
- (b) a manufacturer has taken any action under regulation 36 as it had effect immediately before exit day in relation to that non-automatic weighing instrument,

that action has effect as if it had been done under regulation 36 as it had effect on and after exit day.”.

## **Amendment to regulation 6**

**6.** In regulation 6 (manufacturers’ responsibilities - design, conformity assessment and marking of regulated non-automatic weighing instruments)—

- (a) in paragraph (d) for “an EU” substitute “a”; and
- (b) in paragraph (e)(i) for “CE” substitute “UK”.

## **Amendment to regulation 7**

**7.** In regulation 7 (manufacturers’ obligations in respect of records) omit “EU”.

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### **Amendment to regulation 8**

8. In regulation 8 (manufacturers' obligations to ensure continuing conformity with essential requirements) in paragraph (2)(b) for "harmonised" substitute "designated".

### **Amendment to regulation 10**

9. In regulation 10 (manufacturers to mark contact details on regulated non-automatic weighing instruments) in paragraph (3) for "in a language" to "be in", substitute "clear, legible and in easily understandable".

### **Amendment to regulation 11**

10. In regulation 11 (documentation to accompany regulated non-automatic weighing instruments)—

- (a) omit paragraph (2);
- (b) in paragraph (3) for "clear, understandable and intelligible" substitute "clear, legible and in easily understandable English".

### **Amendment to regulation 12**

11. In regulation 12 (action to be taken where regulated non-automatic weighing instruments placed on the market are not in conformity with the essential requirements) in paragraph (3) for "national" to "market" substitute "authority".

### **Amendment to regulation 14**

12. In regulation 14 (use of authorised representatives by manufacturers) in paragraph (3)(a) omit "EU".

### **Amendment to regulation 15**

13. In regulation 15 (introductory)—

- (a) omit "that is imported into the United Kingdom"; and
- (b) for "European Economic Area" substitute "United Kingdom".

### **Amendment to regulation 16**

14. In regulation 16 (ensuring compliance of regulated non-automatic weighing instruments) in paragraph (2)(c) for "CE" substitute "UK".

### **Amendment to regulation 18**

15. In regulation 18 (requirements to mark importers' details on regulated non-automatic weighing instruments) —

- (a) for paragraph (2) substitute—
  - "(2) Paragraph (1) does not apply where—
  - (a) either—
    - (i) the importer would have to open the packaging in order to indicate the information on the instrument; or

- (ii) the importer has imported the instrument from an EEA state and places it on the market within the period of 18 months beginning with exit day, and
- (b) before placing the instrument on the market, the importer sets out the information referred to in paragraph (1)—
  - (i) where sub-paragraph (a)(i) applies, on the packaging and in a document accompanying the instrument;
  - (ii) where sub-paragraph (a)(ii) applies, in a document accompanying the instrument.”;
- (b) in paragraph (3) for “in a language” to “be in” substitute “clear, legible and in easily understandable”.

#### **Amendment to regulation 19**

**16.** In regulation 19 (importers’ duty to ensure that regulated non-automatic weighing instruments are accompanied by relevant documentation)—

- (a) in paragraph (1) for “in a language easily understood by end users” substitute “clear, legible and in easily understandable English”; and
- (b) omit paragraph (2).

#### **Amendment to regulation 23**

**17.** In regulation 23 (requirement for importer to keep copy of EU declaration of conformity) and in the heading to that regulation, omit “EU”.

#### **Amendment to regulation 27**

**18.** Regulation 27 (distributors-verification obligations) is amended as follows—

- (a) in paragraph (1) for “CE” substitute “UK”;
- (b) in paragraph (2) for “easily understood by end users” substitute “which is clear, legible and in easily understandable English”; and
- (c) omit paragraph (3).

#### **Insertion of regulation 32A**

**19.** After regulation 32 insert—

##### **“Obligations which are met by complying with obligations in the Directive**

**32A.—**(1) In this regulation—

- (a) any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive;
- (b) “CE marking” has the meaning given to it in Article 2(19);
- (c) “Module B” means the conformity assessment procedure set out in point 1 of Annex II;
- (d) “EU-type examination certificate” means an EU-type examination certificate issued in accordance with Module B;
- (e) “harmonised standard” has the meaning given to it in Article 2(11).

(2) Paragraph (3) applies where, before placing a non-automatic weighing instrument on the market, the manufacturer—

- (a) ensures that the non-automatic weighing instrument has been designed and manufactured in accordance with the essential requirements set out in Annex I;
- (b) ensures that the relevant conformity assessment procedures that apply to that non-automatic weighing instrument in accordance with Article 13 have been carried out;
- (c) draws up the technical documentation referred to in Annex II;
- (d) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;
- (e) affixes the CE marking and the supplementary metrology marking, in accordance with Articles 16 and 17(1) to (5);
- (f) affixes the inscriptions provided for in points 1 or 2 of Annex III in accordance with Article 6(5);
- (g) affixes where required in accordance with Article 6(5) the restrictive use symbol as provided for in Article 18 and in point 3 of Annex III;
- (h) draws up an EU declaration of conformity, in accordance with Article 14; and
- (i) ensures that the EU declaration of conformity is prepared in or translated into English.

(3) Where this paragraph applies—

- (a) the requirements of regulations 6, 9(3) and (4), 41 and 45(2) are to be treated as being satisfied;
- (b) regulations 7, 8(2), 44, 63(1)(a) to (e), 67, 68 and 71 apply subject to the modifications in paragraph (8); and
- (c) Regulations 34 to 36 do not apply.

(4) Paragraph (5) applies where, before placing a regulated non-automatic weighing instrument on the market, the importer ensures that—

- (a) the relevant conformity assessment procedure referred to in Article 13 has been carried out;
- (b) the manufacturer has drawn up the technical documentation referred to in Annex II; and
- (c) the non-automatic weighing instrument bears the CE marking and supplementary metrology marking in accordance with Articles 16 and 17(1) to (5).

(5) Where this paragraph applies—

- (a) the requirements of regulation 16(2)(a) to (c) are to be treated as being satisfied; and
- (b) regulations 23, 63(1)(a) to (e), 67 and 68 apply subject to the modifications in paragraph (8).

(6) Paragraph (7) applies where, before making a regulated non-automatic weighing instrument available on the market, a distributor ensures that the non-automatic weighing instrument bears the CE marking and the inscriptions referred to in point 1 of Annex III.

(7) Where this paragraph applies—

- (a) regulation 27(1) is to be treated as being satisfied; and

- (b) regulations 28(1), 28(2), 29, 63(1)(a), 63(1)(b), 67, 68 and 71 apply subject to the modifications in paragraph (8).
- (8) The modifications referred to in sub-paragraphs (3)(b), (5)(b) and (7)(b) are that—
  - (a) any reference to “declaration of conformity” is to be read as a reference to the EU declaration of conformity;
  - (b) any reference to “UK marking” is to be read as a reference to the CE marking;
  - (c) any reference to “designated standard” is to be read as a reference to a harmonised standard;
  - (d) any reference to “relevant conformity assessment procedure” is to be read as a reference to the relevant conformity assessment procedures referred to in Article 13;
  - (e) any reference to “technical documentation” is to be read as a reference to the technical documentation referred to in Annex II;
  - (f) any reference to “type examination certificate” is to be read as a reference to an EU-type examination certificate;
  - (g) any reference to “M marking” is to be read as a reference to the supplementary metrology marking;
  - (h) any reference to “approved body” is to be read as a reference to the body that undertook any conformity assessment procedure in accordance with Article 13;
  - (i) any reference to “authorised mark” includes the CE marking and the supplementary metrology marking.

#### **Conformity assessment procedure obligations that are met by complying with the Directive**

##### **32B.—(1) In this regulation—**

- (a) any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive;
- (b) “EU-type examination certificate” means an EU-type examination certificate issued in accordance with the conformity assessment procedure set out in point 1 of Annex II (Module B);
- (c) any reference to “the first stage of the conformity assessment procedure” is a reference to one or both of the following—
  - (i) all examinations and tests which are not gravity dependent and which are included in the conformity assessment procedures set out in points 2 to 5 of Annex II;
  - (ii) the examinations and tests included in the conformity assessment procedures set out in points 2 to 5 of Annex II that may be carried out at the manufacturer’s works or any other location where—
    - (aa) the transport of the instrument to its place of use requires dismantling of the instrument; or
    - (bb) the putting into service of the instrument in its place of use requires assembly of the instrument or other technical installation work that is likely to affect the instrument’s performance.

(2) Paragraph (3) applies where, prior to the manufacture of a non-automatic weighing instrument the manufacturer has ensured that the conformity assessment procedure as set out in point 1 of Annex II (Module B) has been carried out.

- (3) Where this paragraph applies—
  - (a) the reference in regulation 36(a) to “Module B as set out in point 1 of Schedule 7” is to be read as a reference to the conformity assessment procedure as set out in point 1 of Annex II (Module B); and
  - (b) regulations 6(b) and (c), 7, 16(2)(a) and (b), 63(1)(e), 67(2)(b), 68(4)(b) and paragraph 1 of Schedule 1 apply subject to the modifications in paragraph (6).
- (4) Paragraph (5) applies where—
  - (a) in accordance with point 7.1 of Annex II, the procedures set out in points 2 to 5 of that Annex may be carried out in two stages; and
  - (b) the first stage of the conformity assessment procedure is carried out in accordance with any of the following points of Annex II—
    - (i) point 2 (Module D);
    - (ii) point 3 (Module D1);
    - (iii) point 4 (Module F); or
    - (iv) point 5 (Module F1).
- (5) Where this paragraph applies—
  - (a) the reference in regulation 36(1)(a)(i) to “Module D as set out in point of Schedule 7” is to be read as including the first stage of the conformity assessment procedure as set out in point 2 of Annex II (Module D);
  - (b) the reference in regulation 36(1)(a)(ii) to “Module F as set out in point 4 of Schedule 7” is to be read as including the first stage of the conformity assessment procedure as set out in point 4 of Annex II (Module F);
  - (c) the reference in regulation 36(3)(a) to “Module D1 as set out in point 3 of Schedule 7” is to be read as including the first stage of the conformity assessment procedure as set out in point 3 of Annex II (Module D1);
  - (d) the reference in regulation 36(3)(b) to “Module F1 as set out in point 5 of Schedule 7” is to be read as including the first stage of the conformity assessment procedure as set out in point 5 of Annex II (Module F1);
  - (e) regulations 6(b) and (c), 7, 16(2)(a) and (b), 45(6) and (7), 63(1)(c) and (e) and 67(1)(c) apply subject to the modifications in paragraph (6).
- (6) The modifications referred to in paragraphs (3)(b) and (5)(e) are that—
  - (a) any reference to “relevant conformity assessment procedure” is to be read as including—
    - (i) where paragraph (3) applies, the conformity assessment procedure set out in point 1 of Annex II;
    - (ii) where paragraph (5) applies, the relevant first stage conformity assessment procedure;
  - (b) any reference to “type examination” is to be read as a reference to the EU-Type examination certificate;
  - (c) any reference to “technical documentation” is to be read as including the technical documentation required by points 1 to 5 of Annex II (as applicable);
  - (d) any reference to “approved body” is to be read as including the body which undertook the first stage conformity assessment procedure.”.

#### **Amendment to regulation 34**

20. In regulation 34 (methods of establishing conformity with the essential requirements)—
- (a) in sub-paragraph (a) for “harmonised” the first time it appears, substitute “designated”; and
  - (b) omit from “where” to “European Union”.

#### **Amendment to regulation 35**

21. In regulation 35 (presumptions of conformity of regulated non-automatic weighing instruments) for “harmonised” substitute “designated”.

#### **Amendment to regulation 36**

22. In regulation 36 (conformity assessment procedures)—
- (a) in paragraphs (1)(a) and (6) for “Annex II to the Directive” substitute “Schedule 7”;
  - (b) in paragraphs (1)(a)(i), (1)(a)(ii), (1)(b), (3)(a) and (3)(b) for “Annex II” substitute “Schedule 7”;
  - (c) in paragraph (4), for “A notified” substitute “An approved”.

#### **Amendment to regulation 37**

23. Omit regulation 37 (subsidiaries and contractors).

#### **Amendment to regulation 38**

24. In regulation 38 (fees)—
- (a) for “a United Kingdom notified”, substitute “an approved” in both places in which it occurs;
  - (b) In sub-paragraph (2)(a), for “United Kingdom notified” substitute “approved”.

#### **Amendment to regulation 39**

25. In regulation 39 (application of Chapter) and in the heading to Chapter 2 omit “EU” in both places in which it occurs.

#### **Amendment to regulation 40**

26. In regulation 40 (form and contents of EU declaration of conformity etc.)—
- (a) in paragraph (1) and in the heading omit “EU”;
  - (b) in paragraph (1)(b) for “Annex IV to the Directive” substitute Schedule 9;
  - (c) in paragraph (1)(c) for “Annex II to the Directive” substitute Schedule 7; and
  - (d) in paragraph (2) omit “EU”.

#### **Amendment to regulation 41**

27. For regulation 41 (regulated instruments that require more than one declaration of conformity) substitute—

“41. Where a non-automatic weighing instrument is subject to more than one enactment requiring the drawing up of a declaration of conformity, the manufacturer must draw up a single declaration of conformity which identifies each enactment by its title.”.

#### **Amendment to regulation 42**

**28.** In regulation 42 (responsibility of manufacturer that draws up declaration of conformity) for “an EU” substitute “a”.

#### **Amendment to regulation 43**

**29.** In regulation 43 (conformity with Directive requirements to be indicated by the CE marking)

- (a) in the heading omit “Directive”; and
- (b) in the regulation and in the heading for “CE” substitute “UK”.

#### **Amendment to regulation 44**

**30.** For regulation 44 (general principles relating to the M marking) substitute—

**“Prohibition on improper use of UK marking and the M marking**

**44.—**(1) An economic operator must not affix the UK marking or the M marking to a regulated non-automatic weighing instrument unless—

- (a) that economic operator is the manufacturer of the non-automatic weighing instrument; and
- (b) the conformity of the non-automatic weighing instrument with the essential requirements has been demonstrated by a conformity assessment procedure.

(2) An economic operator must not affix a marking to a regulated non-automatic weighing instrument which is not the UK marking or the M marking but which purports to attest that the non-automatic weighing instrument satisfies the essential requirements.

(3) An economic operator must not affix to a regulated non-automatic weighing instrument a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the marking.

(4) An economic operator must not affix to a regulated non-automatic weighing instrument any other marking if the visibility, legibility and meaning of the UK marking or the M marking would be impaired as a result.”.

#### **Amendment to regulation 45**

**31.** Regulation 45 (rules and conditions for affixing the CE marking and the M marking etc.) is amended as follows—

- (a) in paragraphs (1) and (4) and in the heading for “CE” substitute “UK”;
- (b) in paragraph (5) for “Annex II to the Directive” substitute “Schedule 7”; and
- (c) in paragraphs (5), (6) and (7) for “notified” substitute “approved” in each place in which it occurs.

#### **Amendment to Part 5**

**32.** For Part 5, substitute—

## “PART 5

### APPROVAL OF CONFORMITY ASSESSMENT BODIES

#### Approved bodies

- 47.—**(1) An approved body is a conformity assessment body which—
- (a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 48 (approval of conformity assessment bodies); or
  - (b) immediately before exit day was a notified body in respect of which the Secretary of State had taken no action under regulation 54(1) or (2) as they had effect immediately before exit day to suspend or withdraw the body’s status as a notified body.
- (2) Paragraph (1) has effect subject to regulation 51 (restriction, suspension or withdrawal of approval).
- (3) In this Part—
- “notified body” means a body—
- (a) which the Secretary of State had before exit day notified to the European Commission and the member State of the European Union, in accordance with Article 27 of the Directive; and
  - (b) in respect of which no objections had been raised, as referred to in regulation 47(2)(b), as it had effect immediately before exit day;
- “approved body requirements” means the requirements set out in Schedule 3.

#### Approval of conformity assessment bodies

- 48.—**(1) The Secretary of State may approve only those conformity assessment bodies that qualify for approval.
- (2) A conformity assessment body qualifies for approval if the first and second conditions below are met.
- (3) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—
- (a) a description of—
    - (i) the conformity assessment activities that the conformity assessment body intends to carry out;
    - (ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;
    - (iii) the class of regulated non-automatic weighing instruments in respect of which the conformity assessment body claims to be competent; and
  - (b) either—
    - (i) an accreditation certificate; or
    - (ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body’s compliance with the approved body requirements.
- (4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (3)(b)(i), as sufficient evidence that the conformity assessment body meets the approved body requirements.

(6) When deciding whether to approve a conformity assessment body that qualifies for approval, the Secretary of State may—

- (a) have regard to any other matter which appears to the Secretary of State to be relevant; and
- (b) set conditions that the conformity assessment body must meet.

(7) For the purposes of this regulation “accreditation certificate” means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.

### **Presumption of conformity of approved bodies**

**49.**—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such standard), the Secretary of State is to presume that the conformity assessment body meets the approved body requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

### **Monitoring**

**50.** The Secretary of State must monitor each approved body with a view to verifying that the body—

- (a) continues to meet the approved body requirements;
- (b) meets any conditions set—
  - (i) in accordance with regulation 48(6)(b); or
  - (ii) in the case of an approved body which was a notified body immediately before exit day, in accordance with regulation 48(6)(b), as it applied immediately before exit day; and
- (c) carries out its functions in accordance with these Regulations.

### **Restriction, suspension or withdrawal of approval**

**51.**—(1) Where the Secretary of State determines that an approved body—

- (a) no longer meets an approved body requirement, or
- (b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 48(6)(b),

the Secretary of State must restrict, suspend or withdraw the body’s status as an approved body under regulation 48 (approval of conformity assessment bodies).

(2) With the consent of an approved body, or where the Secretary of State determines that an approved body no longer meets a condition in accordance with regulation 48(6)(b), the Secretary of State may restrict, suspend or withdraw the body’s status as an approved body under regulation 48 (approval of conformity assessment bodies).

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the failure.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

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- (a) give notice in writing to the approved body of the proposed action and the reasons for it;
  - (b) give the approved body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of that notice; and
  - (c) consider any such representations made by the approved body.
- (5) Where the Secretary of State has taken action in respect of an approved body under paragraph (1) or (2), or where an approved body has ceased its activity, the approved body must—
- (a) on the request of the Secretary of State, transfer its files to another approved body or to the Secretary of State; or
  - (b) in the absence of a request under sub-paragraph (a), ensure that its files relating to the activities it has undertaken as an approved body are kept available for the Secretary of State and competent authorities for a period of 10 years from the date they were created.
- (6) The activities undertaken as an approved body referred to in paragraph (5) include any activities that the body has undertaken as a notified body.
- (7) The Secretary of State may impose a monetary penalty on an approved body that fails to comply with any requirement imposed by or under paragraph (5).
- (8) Schedule 5 has effect in relation to monetary penalties imposed under paragraph (7).

### **Subsidiaries and contractors**

**52.—**(1) An approved body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

- (a) the body is satisfied that the subcontractor or subsidiary meets the approved body requirements;
  - (b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meets those requirements; and
  - (c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.
- (2) The approved body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).
- (3) Where an approved body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the approved body must, for a period of 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documentation concerning—
- (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
  - (b) the conformity assessment activity carried out by the subcontractor or subsidiary.
- (4) In this regulation “subsidiary” has the meaning given to it in section 1159 of the Companies Act 2006(2).

### **Register of approved bodies**

**53.—**(1) The Secretary of State must—

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(2) 2006 c.46.

- (a) assign an approved body identification number to each approved body; and
- (b) compile and maintain a register of—
  - (i) approved bodies;
  - (ii) their approved body identification numbers;
  - (iii) the activities for which they have been approved; and
  - (iv) any restrictions on those activities.
- (2) The register referred to in paragraph (1) must be made publicly available.

#### **UK national accreditation body**

**54.**—(1) The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

- (a) assessing whether a conformity assessment body meets the approved body requirements; and
- (b) monitoring approved bodies in accordance with regulation 50.

(2) Where the Secretary of State authorises the UK national accreditation body pursuant to paragraph (1), the Secretary of State remains fully responsible for anything done pursuant to that authorisation.”.

#### **Amendment to regulation 58**

**33.** Regulation 58 (regulated non-automatic weighing instruments presenting a risk) is amended as follows—

- (a) in paragraph (5), for “notified” substitute “approved”;
- (b) omit paragraph (6);
- (c) in paragraph (7) for “on the market throughout the European Economic Area” substitute “in the United Kingdom”;
- (d) in paragraph (9) for “Commission and the other EEA States” substitute “Secretary of State”; and
- (e) in paragraph (10)(f)(ii) for “harmonised” substitute “designated”.

#### **Amendment to regulation 59**

**34.** Omit regulation 59 (EU safeguard procedure).

#### **Amendment to regulation 60**

**35.** In regulation 60 (compliant regulated non-automatic weighing instruments which present a risk) in paragraph (3), for “Commission and the other EEA states” substitute “Secretary of State”.

#### **Amendment to regulation 63**

**36.** In regulation 63 (compliance notice procedure) in paragraph (1)—

- (a) in sub-paragraphs (a) and (b), for “CE” substitute “UK” in both places in which it occurs;
- (b) in sub-paragraph (a) for “Article 30 of the RAMS Regulation or the requirements of these Regulations” substitute “regulation 44 or regulation 45”;
- (c) in sub-paragraph (c) for “notified” substitute “approved”; and
- (d) in sub-paragraph (d) omit “EU”.

#### **Amendment to regulation 64**

- 37.** In regulation 64 (enforcement notice procedure)—
- (a) in paragraph (5)—
    - (i) for “a United Kingdom notified” substitute “an approved”;
    - (ii) for “that notified” substitute “that approved”; and
  - (b) omit paragraph (6).

#### **Amendment to regulation 67**

- 38.** In regulation 67 (disqualification)—
- (a) in paragraph (1)—
    - (i) in sub-paragraph (a) for “CE” substitute “UK”;
    - (ii) in sub-paragraph (c) for “notified” substitute “approved”; and
  - (b) in paragraph 2(b) omit “EU-”.

#### **Amendment to regulation 68**

- 39.** In regulation 68 (requalification)—
- (a) in paragraph (3)(c)—
    - (i) omit “notified”; and
    - (ii) for “Annex II to the Directive” substitute “Schedule 7”;
  - (b) in paragraph (3)(d)—
    - (i) for “notified” substitute “approved”; and
    - (ii) for “Annex II to the Directive” substitute Schedule 7;
  - (c) in paragraph (4)(b) omit “EU-”.

#### **Amendment to regulation 71**

- 40.** In regulation 71 (unauthorised application of authorised marks) in paragraph (5)—
- (a) in sub-paragraph (a) for “CE” substitute “UK”; and
  - (b) in sub-paragraph (c) for “notified” substitute “approved”.

#### **Amendment to Schedule 1**

- 41.** In Schedule 1 (information to be marked on regulated non-automatic weighing instruments)—
- (a) in paragraph 1 omit “EU-”; and
  - (b) in paragraph 9 for “the Annex III to the Directive” substitute “Schedule 8”.

#### **Amendment to Schedule 2**

- 42.** In Schedule 2 (operational obligations of notified bodies)—
- (a) in paragraphs 3, 4 and 6 for “a notified” substitute “an approved”;
  - (b) in all places in which it occurs (other than the paragraphs referred to in sub-paragraph (a)), including in the heading, for “notified” substitute “approved”;
  - (c) in paragraph 7 for “notifying authority” substitute “Secretary of State”;

- (d) in paragraph 7(b) for “notification” substitute “approval”;
- (e) in paragraph 8 for “this Directive” substitute “these Regulations”; and
- (f) omit paragraph 9.

### Amendments to Schedule 3

**43.** In Schedule 3 (requirements related to notified bodies)—

- (a) for the heading, substitute—  
“SCHEDULE 3

*Approved Body requirements”;*

- (b) in paragraph 1 for “under the national law of an EEA state” substitute “in the United Kingdom”;
- (c) in paragraph 8 for “Annex II to the Directive” substitute “Schedule 7”;
- (d) in paragraph 9(c) for “a notified” substitute “an approved”;
- (e) in all places in which it occurs (other than the paragraph referred to in sub-paragraph (d)), including in the heading, for “notified” substitute “approved”;
- (f) in paragraph 11(c)—
  - (i) for “Annex I to the Directive” substitute “Schedule 6”;
  - (ii) for “harmonised” substitute “designated”; and
  - (iii) for “European harmonisation legislation and of national legislation” substitute “these Regulations”;
- (g) in paragraph 16 for “under the European Union harmonisation legislation” substitute “by the Secretary of State”.

### Amendments to Schedule 4

**44.** In Schedule 4 (use for trade of regulated non-automatic weighing instruments in Great Britain) in paragraphs 1(3) and 1(5) for “Annex I to the Directive” substitute “Schedule 6”.

### Insertion of Schedule 6

**45.** After Schedule 5 (monetary penalties) insert—

“SCHEDULE 6

Regulation 2

(Annex I to the Directive)

#### *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 sub-paragraphs (a) to (f) of regulation 3(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 the Weights and Measures Act 1985 relating to units of measurement<sup>(3)</sup>.

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
- (c) III medium
- (d) IIII ordinary

The specifications of these classes are given in Table 1.

**Table 1**

<i>Accuracy classes</i>				
<i>Class</i>	<i>Verification scale interval (e)</i>	<i>Minimum capacity (Min)</i>	Number of verification scale intervals $n = ((\text{Max})/(\text{e}))$	
		minimum value	minimum value	maximum value
I	$0,001 \text{ g} \leq e$	100 e	50 000	—
II	$0,001 \text{ g} \leq e \leq 0,05 \text{ g}$	20 e	100	100 000
	$0,1 \text{ g} \leq e$	50 e	5 000	100 000
III	$0,1 \text{ g} \leq e \leq 2 \text{ g}$	20 e	100	10 000
	$5 \text{ g} \leq e$	20 e	500	10 000
IIII	$5 \text{ g} \leq e$	10 e	100	1 000

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—

(3) 1985 c.72.

$1 \times 10^k$ ,  $2 \times 10^k$ , 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—

$e = 1 \times 10^k \text{ g}$ ;

$d < e \leq 10 d$ .

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

### 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  $d < 10^{-4} \text{ g}$ , the maximum capacity of class I may be less than 50 000 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 $\text{Max}_i$	with $\text{Max}_r = \text{Max}$
— its minimum capacity $\text{Min}_i$	with $\text{Min}_i = \text{Max}_{(i-1)}$ and $\text{Min}_1 = \text{Min}$

Where:

$i = 1, 2, \dots, r$ ,

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**

<b>Multi-level instruments</b>				
$i = 1, 2, \dots, r$ , $i$ = partial weighing range number, $r$ = the total number of partial weighing ranges				
Class	Verification scale interval (e)	Minimum capacity (Min)	Number of verification scale intervals	
		Minimum value	Minimum value(4) $n = ((\text{Max}_i) / (e_{(i+1)}))$	Maximum value $n = ((\text{Max}_i) / (e_i))$
I	$0,001 \text{ g} \leq e_i$	$100 \text{ e1}$	50 000	—
II	$0,001 \text{ g} \leq e_i \leq 0,05 \text{ g}$	$20 \text{ e1}$	5 000	100 000
	$0,1 \text{ g} \leq e_i$	$50 \text{ e1}$	5 000	100 000
III	$0,1 \text{ g} \leq e_i$	$20 \text{ e1}$	500	10 000
IIII	$5 \text{ g} \leq e_i$	$10 \text{ e1}$	50	1 000

#### 4. Accuracy

**4.1.** On implementation of the procedures laid down in regulation 36, the error of indication shall not exceed the maximum permissible error of indication as shown in Table 3. In the 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**

<b>Maximum permissible errors</b>				
Load				Maximum permissible error
Class I	Class II	Class III	Class IIII	
$0 \leq m \leq 50\,000 \text{ e}$	$0 \leq m \leq 5\,000 \text{ e}$	$0 \leq m \leq 500 \text{ e}$	$0 \leq m \leq 50 \text{ e}$	$\pm 0,5 \text{ e}$
$50\,000 \text{ e} < m \leq 200\,000 \text{ e}$	$5\,000 \text{ e} < m \leq 20\,000 \text{ e}$	$500 \text{ e} < m \leq 2\,000 \text{ e}$	$50 \text{ e} < m \leq 200 \text{ e}$	$\pm 1,0 \text{ e}$
$200\,000 \text{ e} < m$	$20\,000 \text{ e} < m \leq 100\,000 \text{ e}$	$2\,000 \text{ e} < m \leq 10\,000 \text{ e}$	$200 \text{ e} < m \leq 1\,000 \text{ e}$	$\pm 1,5 \text{ e}$

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

(4) For I = r, the corresponding column of Table 1 applies, with e replaced by  $e_r$ .

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 these Regulations.

**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 Schedule shall comply with the provisions of the Weights and Measures Act 1985 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.

### SCHEDULE 7

Regulations 2, 36(1), (3) and (6),  
40(1)(c), 45(5), 68(3)(c) and (d)

(Annex II to the Directive)

### CONFORMITY ASSESSMENT PROCEDURES

#### 1. Module B: type examination

**1.1.** type examination is the part of a conformity assessment procedure in which an approved body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of these Regulations that apply to it.

**1.2.** 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 type examination with a single approved 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 approved body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of these Regulations 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 designated standards applied in full or in part, and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated 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 approved 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 designated standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.

**1.4. The approved 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 designated standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

**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 designated standards, 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 designated standards have not been applied, the

solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of these Regulations;

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

1.5. The approved 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 Secretary of State, the approved 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 these Regulations, that apply to the instrument concerned, the approved body shall issue a type examination certificate to the manufacturer. That 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 type examination certificate may have one or more annexes attached.

The type examination 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 type examination 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 type examination certificate may be limited to two years and extended by three years.

Where the type does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

1.7. The approved 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 these Regulations, and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly. The manufacturer shall inform the approved body that holds the technical documentation relating to the type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of these Regulations or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original type examination certificate.

1.8. Each approved body shall inform the Secretary of State concerning the type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each approved body shall inform the other approved bodies concerning the type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The other approved bodies and the Secretary of State may, on request, obtain a copy of the type examination certificates and/or additions thereto. On request, the Secretary of State may obtain a copy of the technical documentation and the results of the examinations carried out by the approved body. The approved body shall keep a copy of the 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 that certificate.

**1.9.** The manufacturer shall keep a copy of the type examination certificate, its annexes and additions together with the technical documentation at the disposal of the market surveillance 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.

## **2. Module D: Conformity to type based on quality assurance of the production process**

**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 type examination certificate and satisfy the requirements of these Regulations that apply to them.

### **2.2. Manufacturing**

The manufacturer shall operate an approved quality system for production, final product 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 approved 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 approved body;
- (c) all relevant information for the instrument category envisaged;
- (d) the documentation concerning the quality system; and
- (e) the technical documentation of the approved type and a copy of the type examination certificate.

**2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the type examination certificate and comply with the requirements of these Regulations 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 product 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 product quality and the effective operation of the quality system.

**2.3.3.** The approved 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 relevant designated standard.

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 these Regulations. 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 these Regulations 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 approved body that has approved the quality system informed of any intended change to the quality system.

The approved 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 approved 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 approved 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 approved 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 approved body may pay unexpected visits to the manufacturer. During such visits the approved 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 approved 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 UK marking and the M metrology marking set out in these Regulations, and, under the responsibility of the approved 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 type examination certificate and satisfies the applicable requirements of these Regulations.

**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 market surveillance 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 10 years after the instrument has been placed on the market, keep at the disposal of the market surveillance authorities—

- (a) the documentation referred to in point 2.3.1;
- (b) the information relating to the change referred to in point 2.3.5, as approved;
- (c) the decisions and reports of the approved body referred to in points 2.3.5, 2.4.3 and 2.4.4.

**2.7.** Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State 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 these Regulations 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 designated standards applied in full or in part, and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated 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 approved 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 approved 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 these Regulations 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 product 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 product quality and the effective operation of the quality system.

**3.5.3.** The approved 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 relevant designated standard.

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 these Regulations. 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 these Regulations 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 approved body that has approved the quality system informed of any intended change to the quality system.

The approved 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 approved 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 approved 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 approved 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 approved body may pay unexpected visits to the manufacturer. During such visits the approved 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 approved 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 UK marking and the M metrology marking, set out in these Regulations, and, under the responsibility of the approved body referred to in point 3.5.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of these Regulations.

**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 market surveillance 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 market surveillance authorities upon request.

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

- (a) the documentation referred to in point 3.5.1;
- (b) the information relating to the change referred to in point 3.5.5, as approved;
- (c) the decisions and reports of the approved body referred to in points 3.5.5, 3.6.3 and 3.6.4.

**3.9.** Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State 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.

**4. Module F: Conformity to type based on product verification**

**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 and 4.5 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 type examination certificate and satisfy the requirements of these Regulations 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 type examination certificate and with the requirements of these Regulations that apply to them.

**4.3. Verification**

An approved 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 type examination certificate and with the appropriate requirements of these Regulations.

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 designated standard(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the type examination certificate and with the appropriate requirements of these Regulations.

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

**4.4.2.** The approved 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 market surveillance 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 UK marking and the M metrology marking, set out in these Regulations, and, under the responsibility of the approved 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 type examination certificate and satisfies the applicable requirements of these Regulations.

**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 market surveillance 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 market surveillance authorities upon request.

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

**4.6.** If the approved body agrees and under its responsibility, the manufacturer may affix the approved 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 point 4.2.

### **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 and 5.6 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 these Regulations that apply to them.

#### **5.2. Technical documentation**

**5.2.1.** 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 designated standards applied in full or in part, and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated 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.

**5.2.2.** The manufacturer shall keep the technical documentation at the disposal of the market surveillance 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 these Regulations.

#### 5.4. Verification

An approved body chosen by the manufacturer shall carry out appropriate examinations and tests to check the conformity of the instruments with the applicable requirements of these Regulations.

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 designated standards and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a designated standard the approved body concerned shall decide on the appropriate tests to be carried out.

**5.5.2.** The approved 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 market surveillance 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 UK marking and the M metrology marking, set out in these Regulations, and, under the responsibility of the approved body referred to in point 5.4, the latter's identification number to each individual instrument that satisfies the applicable requirements of these Regulations.

**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 market surveillance 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 approved body referred to in point 5.5 agrees and under its responsibility, the manufacturer may also affix the approved body's identification number to the instruments.

**5.7.** If the approved body agrees and under its responsibility, the manufacturer may affix the approved 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 5.2.1 and 5.3.

### 6. Module G: Conformity based on unit verification

**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 these Regulations that apply to it.

#### 6.2. Technical documentation

**6.2.1.** The manufacturer shall establish the technical documentation and make it available to the approved 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 designated standards applied in full or in part, and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated 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.

**6.2.2.** The manufacturer shall keep the technical documentation at the disposal of the relevant market surveillance 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 these Regulations.

### **6.4. Verification**

An approved body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant designated standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the instrument with the applicable requirements of these Regulations, or have them carried out. In the absence of such a designated standard the approved body concerned shall decide on the appropriate tests to be carried out.

The approved 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 market surveillance 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 UK marking and the M metrology marking, set out in these Regulations, and, under the responsibility of the approved body referred to in point 6.4, the latter's identification number to each instrument that satisfies the applicable requirements of these Regulations.

**6.5.2.** The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the market surveillance 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 market surveillance authorities upon request.

### **6.6. Authorised representative**

The manufacturer's obligations set out in points 6.2.2 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.

## 7. Common provisions

**7.1.** The 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, it shall be carried out at the place of use of the instrument.

**7.2.** If the instrument's performance is sensitive to gravity variations the procedures referred to in point 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.

**7.2.1.** Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in point 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 approved body involved in that stage.

**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 approved body's certificates of conformity on request.

**7.2.3.** A manufacturer who has opted for 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 Module F or F1 as appropriate.

**7.2.4.** The UK marking and the M metrology marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the approved body which took part in the second stage.

## SCHEDULE 8

Regulations 2, 44 and 72

(Annex III to the Directive)

### INSCRIPTIONS

**1.** Instruments intended to be used for the applications listed in sub-paragraphs (a) to (f) of regulation 3(2).

**1.1.** Those instruments shall bear visibly, legibly and indelibly the following inscriptions—

- (i) the number of the type examination certificate, where appropriate;
- (ii) the manufacturer's name, registered trade name or registered trade mark;

- (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  $e = \dots$ ;
- (vii) type, batch or serial number and when applicable;
- (viii) for instruments consisting of separate but associated units: identification mark on each unit;
- (ix) scale interval if it is different from  $e$ , in the form  $d = \dots$ ;
- (x) maximum additive tare effect, in the form  $T = + \dots$ ;
- (xi) maximum subtractive tare effect if it is different from Max, in the form  $T = - \dots$ ;
- (xii) tare interval if it is different from  $d$ , in the form  $dT = \dots$ ;
- (xiii) maximum safe load if it is different from Max, in the form Lim ...;
- (xiv) the special temperature limits, in the form  $\dots^\circ\text{C}/\dots^\circ\text{C}$ ;
- (xv) ratio between load receptor and load.

**1.2.** Those instruments shall have adequate facilities for the affixing of the conformity marking and inscriptions. These shall be such that it shall be impossible to remove the conformity marking and inscriptions without damaging them, and that the conformity marking and inscriptions shall be visible when the instrument is in its regular operating position.

**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.** Instruments not intended to be used for the applications listed in points (a) to (f) of regulation 3(2) shall bear visibly, legibly and indelibly—

- the manufacturer's name, registered trade name or registered trade mark;
- maximum capacity, in the form Max ....

Those instruments shall not bear the conformity marking as set out in these Regulations.

**3.** Restrictive use symbol referred to in regulation 9(3).

The restrictive use 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.

## SCHEDULE 9

Regulations 2 and 40(1)(b)

### DECLARATION OF CONFORMITY (No XXXX)(5)

**1.** Instrument model/Instrument (product, type, batch or serial number):

(5) It is optional for the manufacturer to assign a number to the declaration of conformity.

2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of instrument allowing traceability; it may, where necessary for the identification of the instrument, include an image):
5. The object of the declaration described above is in conformity with the relevant UK legislation:
6. References to the relevant designated standards used or references to the other technical specifications in relation to which conformity is declared:
7. The approved body ... (name, number) performed ... (description of intervention) and issued the certificate:
8. Additional information:
  - Signed for and on behalf of:
  - (place and date of issue):
  - (name, function) (signature):”.