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STATUTORY INSTRUMENTS

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**2000 No. 3236**

**The Non-automatic Weighing Instruments Regulations 2000**

**PART II**

**APPROVAL AND CERTIFICATION OF NON-AUTOMATIC WEIGHING INSTRUMENTS**

**Examination and Supervision**

**EC type-examination**

**10.**—(1) An application for EC type-examination shall be made in writing by the manufacturer or by his authorised representative to the Secretary of State or to an approved body designated by another member State for the purpose of EC type-examination.

(2) An application made to the Secretary of State shall include—

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;
- (b) a declaration that no other application for EC type-examination in respect of the instrument has been made to the Secretary of State or to any approved body; and
- (c) the design documentation,

and the person making the application shall, when requested by the Secretary of State, provide an instrument which is representative of the production envisaged (in this regulation referred to as “the type”).

(3) On an application made to him under this regulation the Secretary of State shall—

- (a) examine the design documentation and check that the type has been manufactured in conformity with that documentation;
- (b) agree with the applicant the places where the examinations and tests shall be carried out;
- (c) carry out, or have carried out, examinations and tests to check—
  - (i) where the manufacturer has chosen to apply the relevant national standards, whether the instrument has been manufactured wholly in conformity with those standards in such a manner that it satisfies the essential requirements; or
  - (ii) if it has not been so manufactured, whether the instrument nevertheless satisfies the essential requirements.

(4) Where the Secretary of State, after carrying out his functions under paragraph (3) above, is satisfied that the type complies with the provisions of the NAWI Directive which apply to it, he shall grant to the applicant an EC type-approval certificate in respect of that type.

(5) Subject to paragraph (7) below and to any restrictions imposed by paragraph (6) below, an EC type-approval certificate issued under paragraph (4) above shall be valid for a period of ten years and its validity may be extended for successive periods of ten years:

Provided that its validity shall not be extended after the date of the entry into force of any amendment to the NAWI Directive if it could not have been granted on the basis of the NAWI Directive as so amended.

(6) Where new techniques are employed or other fundamental changes are made to the design of an approved type, a further application may be made under this regulation and a further EC type-approval certificate may be issued in respect of the type for a specified period; and—

- (a) the initial period for which a certificate is issued under this paragraph shall be restricted to a period of two years; and
- (b) only one extension of that period, for a period of three years, may be issued:

Provided that its validity shall not be extended after the date of the entry into force of any amendment to the NAWI Directive if it could not have been granted on the basis of the NAWI Directive as so amended.

(7) Where an EC type approval certificate granted by the Secretary of State under paragraph (4) above, not being a certificate to which paragraph (6) above applies, has expired not having been extended for any period or further period of ten years under paragraph (5) above, the certificate shall remain in force in respect of any instrument which was first put into service at a time when the certificate was in force otherwise than by virtue of this paragraph; and an EC type approval certificate which remains in force by virtue of this paragraph may be withdrawn under regulation 25(6)(a).

(8) Any EC type-approval certificate issued by the Secretary of State shall—

- (a) state the conclusions of the EC type-examination carried out by the Secretary of State;
- (b) indicate any conditions subject to which the certificate is granted; and
- (c) be accompanied by the data and descriptions necessary for identification of the approved type,

and there shall be annexed to the certificate all relevant drawings and layouts.

(9) Where the Secretary of State, after carrying out his functions under paragraph (3) above, refuses to issue an EC type-approval certificate or to extend its period of validity, he shall inform the applicant in writing of his decision and the grounds for his decision.

(10) Where—

- (a) an EC type-approval certificate granted under this regulation is in force in respect of an approved type; and
- (b) it is proposed that any modifications or additions should be made to the approved type,

the manufacturer or his authorised representative (instead of making an application under this regulation for an EC type-approval certificate) shall notify the Secretary of State in writing of all such proposed modifications or additions to the approved type.

(11) On receipt of a notification under paragraph (10) above, the Secretary of State shall consider whether the proposed modifications or additions might influence the conformity of the approved type with the essential requirements or with any conditions for use indicated in the EC type-approval certificate, and if it appears to him that those modifications or additions might have that effect, he shall conduct an examination of the approved type with those modifications or additions; and, in a case where—

- (a) he is satisfied that the approved type with those modifications or additions complies with the provisions of the NAWI Directive that apply to it, the Secretary of State shall—
  - (i) subject to the provisions of this regulation, approve the modifications or additions; and
  - (ii) issue an addition to the original EC type-approval certificate in respect thereof; or

(b) he is not so satisfied, the Secretary of State shall notify the person who gave the notification of his decision and of the grounds for it.

(12) No person shall make an application under this regulation if—

- (a) he has previously made an application; or
- (b) he has reasonable cause to believe that an application has previously been made by any other person,

in respect of the same type to any approved body.

(13) The Secretary of State shall not consider an application which appears to him to contravene paragraph (12) above.

(14) The Secretary of State shall periodically send to the other member States a list of—

- (a) applications received by him for EC type-examination;
- (b) EC type-approval certificates issued by him;
- (c) refusals by him to issue EC type-approval certificates; and
- (d) additions and amendments relating to documents already issued,

and, on request, shall send to other member States a copy of any EC type-approval certificates that he has issued.

## **EC verification**

**11.**—(1) The manufacturer or his authorised representative shall take all necessary measures to secure that the manufacturing process for instruments intended for EC verification shall ensure conformity with the approved type, where appropriate, and with the requirements of the NAWI Directive which apply to them.

(2) The manufacturer or his authorised representative shall—

- (a) affix the CE marking and the sticker to each instrument (by way of confirmation that the instrument may be used for a Schedule 3 application) in accordance with regulation 18; and
- (b) draw up a written declaration of conformity that the instrument conforms with the requirements of the NAWI Directive which apply to it.

(3) Subject to paragraphs (6) and (7) below, an application for the carrying out of the appropriate examinations and tests with a view to EC verification shall be made to an approved body by the manufacturer or his authorised representative; and each application shall, if the approved body so requests, be accompanied—

- (a) in the case of instruments manufactured in conformity with an approved type, by a copy of the EC type-approval certificate in respect of that approved type; or
- (b) in the case of an instrument which does not use electronic devices and of which the load measuring device does not use one or more springs to balance the load, by the design documentation relating to that instrument.

(4) Where the approved body is satisfied, on application made to it under paragraph (3) above and after carrying out, or after having had carried out, the appropriate examinations and tests, that the instruments (if properly installed and used for the purposes for which they are intended)—

- (a) where appropriate, have been manufactured in conformity with the approved type; and
- (b) satisfy the provisions of the NAWI Directive which apply to them,

the approved body shall affix or cause to be affixed to each instrument the identification number of the approved body in accordance with regulation 18, and shall provide to the manufacturer or his authorised representative a written certificate of conformity relating to the tests carried out; and the

manufacturer or his authorised representative shall ensure that he is able to provide the certificate to any person entitled to see it.

(5) Where the approved body is not so satisfied, it shall decline to affix its identification number to the instrument and to provide to the manufacturer or his authorised representative a written certificate of conformity under paragraph (4) above; and it shall in writing inform the applicant of its decision and of the grounds for its decision.

(6) In the case of an instrument—

(a) to which the CE marking, identification number and sticker have been affixed; and

(b) either—

(i) to which a disqualification sticker has been affixed under regulation 23, 24 or 27 or under any corresponding provision in the law of a member State other than the United Kingdom; or

(ii) which, having ceased to satisfy the essential requirements, has been subjected to any adjustment, alteration, addition, repair or replacement, notwithstanding that a disqualification sticker had not been affixed,

the foregoing provisions of this regulation shall have effect as modified under paragraph (7) below.

(7) In a case to which paragraph (6) above applies an application under paragraph (3) above may be made by any person established in the Community and—

(a) in paragraph (3) above, the words after the first semi-colon shall not have effect; and

(b) in paragraph (4) above, for the words “the approved body shall affix” to the end there shall be substituted the words “the approved body shall affix or cause to be affixed to each instrument the identification number of the approved body and the re-qualification sticker in accordance with regulation 18.”.

### **EC unit verification**

**12.**—(1) The manufacturer or his authorised representative shall ensure that instruments intended for EC unit verification conform with the requirements of the NAWI Directive which apply to them.

(2) Where the manufacturer or his authorised representative is satisfied that the requirements of the NAWI Directive that apply to an instrument are satisfied in relation to it, he may—

(a) affix the CE marking and the sticker to the instrument (by way of confirmation that it may be used for a Schedule 3 application) in accordance with regulation 18; and

(b) draw up a written declaration of conformity that the instrument conforms with the requirements of the NAWI Directive which apply to it.

(3) Subject to paragraphs (6) and (7) below, an application for the carrying out of the appropriate examinations and tests with a view to EC unit verification shall be made by the manufacturer or his authorised representative in writing to the Secretary of State or to an approved body designated for the purpose of EC unit verification by another member State; and each application shall be accompanied by the design documentation relating to the instrument.

(4) Where the Secretary of State is satisfied, on application made to him under paragraph (3) above and after carrying out, or after having had carried out, the appropriate examinations and tests, that the instrument (if properly installed and used for the purposes for which it is intended) satisfies the provisions of the NAWI Directive that apply to it—

(a) the Secretary of State shall in accordance with regulation 18—

(i) affix, or cause to be affixed, his identification number to the instrument; and

- (ii) provide to the manufacturer or his authorised representative a written certificate of conformity relating to the tests carried out; and
  - (b) the manufacturer or his authorised representative shall ensure that he is able to provide the certificate to any person entitled to see it.
- (5) Where the Secretary of State is not so satisfied, he shall decline to affix his identification number to the instrument and to provide to the manufacturer or his authorised representative a written certificate of conformity under paragraph (4) above; and he shall in writing inform the applicant of his decision and of the grounds for his decision.
- (6) In the case of an instrument—
- (a) to which the CE marking, identification number and sticker have been affixed; and
  - (b) either—
    - (i) to which a disqualification sticker has been affixed under regulation 23, 24 or 27 or under any corresponding provision in the law of a member State other than the United Kingdom,
    - (ii) which, having ceased to satisfy the essential requirements, has been subjected to any adjustment, alteration, addition, repair or replacement, notwithstanding that a disqualification sticker had not been affixed,
- the foregoing provisions of this regulation shall have effect as modified under paragraph (7) below.
- (7) In a case to which paragraph (6) above applies an application under paragraph (3) above may be made by any person established in the Community and—
- (a) in paragraph (3) above, the words after the first semi-colon shall not have effect; and
  - (b) in paragraph (4) above, for sub-paragraphs (a) and (b) there shall be substituted the words “the Secretary of State shall in accordance with regulation 18 affix, or cause to be affixed, to the instrument his identification number and the re-qualification sticker.”.

### **Quality system approval and EC declaration of type conformity**

- 13.—**(1) An application for approval of a quality system as provided in paragraph 2.3 of Annex II to the NAWI Directive shall be made in writing to an approved body; and each application shall be accompanied by an undertaking by the manufacturer—
- (a) to carry out the obligations arising from the approved quality system; and
  - (b) to maintain the approved quality system to ensure its continuing suitability and effectiveness.
- (2) The manufacturer shall make available to the approved body all relevant information including in particular—
- (a) the documentation of the quality system presented in a systematic and orderly manner in the form of written rules, procedures and instructions with a view to ensuring a proper understanding of the quality programmes, plans, manuals and records; and
  - (b) the design documentation of the instruments.
- (3) On application made to it under paragraph (1) above, the approved body shall evaluate the quality system to determine whether it satisfies the requirements referred to in paragraph 2.3.2 of Annex II to the NAWI Directive and, if it conforms with the relevant national standard, it shall be taken to conform to those requirements.
- (4) Where the approved body is satisfied, on application made to it under paragraph (1) above and after examining and evaluating the quality system, that the system satisfies the requirements referred to in paragraph 2.3.2 of Annex II to the NAWI Directive it shall grant to the manufacturer

an approval of the quality system; and accordingly the manufacturer shall have authority to make EC declarations of type conformity in accordance with paragraph (7) below.

- (5) The approved body shall—
- (a) include in the approval the conclusions of the examination and evaluation carried out by it; and
  - (b) inform the Secretary of State of the granting of the approval with a view to his notifying the other member States.
- (6) Where the approved body, after carrying out its duties under paragraph (3) above, refuses to grant an approval of the quality system it shall in writing inform the manufacturer and the Secretary of State of its decision and the grounds for its decision.
- (7) Where the manufacturer makes an EC declaration of type conformity, that is to say—
- (a) he has adequately implemented an approved quality system;
  - (b) he has carried out such examinations and tests as are consistent with his obligations in sub-paragraph (a) above (and where appropriate with such frequency as is consistent with those obligations); and
  - (c) he is satisfied that the instruments concerned, where appropriate, have been manufactured in conformity with the approved type and satisfy the provisions of the NAWI Directive that apply to them,

the manufacturer or his authorised representative shall, in accordance with regulation 18, affix to each such instrument—

- (i) the CE marking;
- (ii) the inscriptions;
- (iii) the sticker by way of confirmation that the instrument may be used for a Schedule 3 application; and
- (iv) the identification number of the approved body which approved the manufacturer's quality system,

and shall draw up a written declaration of conformity.

- (8) In the case of an instrument—
- (a) to which the CE marking, identification number and sticker have been affixed; and
  - (b) either—
    - (i) to which a disqualification sticker has been affixed under regulation 23, 24 or 27 or under any corresponding provision in the law of a member State other than the United Kingdom;
    - (ii) which, having ceased to satisfy the essential requirements, has been subjected to any adjustment, alteration, addition, repair or replacement, notwithstanding that a disqualification sticker had not been affixed,

the foregoing provisions of this regulation shall have effect as modified under paragraph (9) below.

(9) In a case to which paragraph (8) above applies, in paragraph (7) above for the words “the manufacturer or his authorised representative shall affix” to the end there shall be substituted the words

“the manufacturer or his authorised representative shall affix to each such instrument—

- (a) the re-qualification sticker; and

- (b) the identification number of the approved body which approved the manufacturer's quality system if that number is different from the number already fixed to the instrument."

### **Provisions supplemental to regulations 11, 12 and 13**

**14.**—(1) Subject to paragraphs (2) and (3) below, the procedures referred to in regulations 11(4), 12(4) and 13(7) ("the procedures") shall be carried out at the place of use of the instrument unless—

- (a) the instrument does not have to be dismantled for transport or any such dismantling is not likely to affect its performance; or
- (b) before the instrument is taken into service, no work is required which is likely to affect its performance,

in which case they may be carried out at any place.

(2) In the case of an instrument the performance of which is sensitive to differences in gravity, either—

- (a) any difference between the gravity at the place where the procedures are carried out and that at the place where the instrument is to be used shall be taken into account in carrying out the procedures; or
- (b) the procedures shall be carried out in two stages in accordance with paragraph (4) below.

(3) In the case of an instrument the performance of which is not sensitive to differences in gravity and if the manufacturer so desires, the procedures may be carried out in two stages in accordance with paragraph (4) below.

(4) The two stages referred to in paragraphs (2) and (3) above are—

- (a) a first stage ("the first stage") which shall comprise all examinations and tests not within the second stage and which may be carried out at any place; and
- (b) a second stage ("the second stage") which—
  - (i) in the case of an instrument whose performance is sensitive to differences in gravity, shall comprise all examinations and tests of which the outcome is gravity dependent and which shall be carried out at the place of use of the instrument or, if gravity zones<sup>(1)</sup> have been established, elsewhere within the gravity zone in which that place is situated; and
  - (ii) in the case of any other instrument, may be carried out at any place.

(5) Where the manufacturer has made an EC declaration of type conformity under regulation 13 in relation to an instrument and the procedures in the first stage are carried out under that regulation, those carried out in the second stage shall be those specified in regulation 11 or 13.

(6) Where an approved body carries out the procedures in the first stage under regulation 11, that body or another approved body may carry out the procedures in the second stage.

(7) Where in pursuance of paragraph (5) or (6) above, the procedures in the first stage are carried out by the manufacturer or an approved body ("the first party") and the procedures in the second stage are carried out by a different manufacturer (being a manufacturer having the authority to make the relevant EC declaration of type conformity) or approved body ("the second party")—

- (a) the first party shall issue a certificate to the second party identifying the instrument in question and specifying the procedures it has carried out and shall affix, or cause to be affixed, its identification number; and
- (b) the second party—

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(1) The United Kingdom has not established gravity zones within its territory.

- (i) shall carry out the examinations and tests not carried out by the first party; and
- (ii) shall be responsible for completion of whichever of the procedures is appropriate.

(8) For the purposes of regulations 11(4) and 12(4), the appropriate examinations and tests shall include those specified in the relevant national standard or equivalent tests.

### **EC surveillance**

**15.—**(1) Where a manufacturer has made an EC declaration of type conformity under regulation 13, the approved body to which the manufacturer made an application for approval of the quality system shall carry out EC surveillance and in particular—

- (a) shall periodically carry out audits in order to ensure that the manufacturer is maintaining and applying the quality system and provide the manufacturer with an audit report; and
- (b) shall, from time to time, carry out visits at the places of manufacture, inspection, testing and storage and—
  - (i) check whether the manufacturer is maintaining and applying the quality system, and
  - (ii) at its discretion, carry out full or partial audits,

and shall provide the manufacturer with a report on each such visit and on any such audit.

(2) For the purpose of assisting the approved body to carry out the audits and checks specified in paragraph (1) above the manufacturer shall, in respect of each instrument, keep available for inspection by the approved body all necessary information, including—

- (a) the documentation of the quality system;
- (b) the design documentation of the instrument; and
- (c) all related quality records,

and shall inform the approved body of any changes in its quality system.

### **Suspension of authority to make EC declarations of type conformity**

**16.—**(1) If it appears to an authorised person that there are instruments to which CE markings or stickers have been, or are being, affixed otherwise than in conformity with these Regulations or the corresponding provisions of the law of another member State, he may give to the manufacturer or his authorised representative a notice suspending the manufacturer's or his authorised representative's authority to make the EC declarations of type conformity in question (either generally or in relation to particular areas and places) for a period not exceeding twenty-eight days.

(2) Where an authorised person gives a notice under paragraph (1) above he shall forthwith—

- (a) inform the approved body which approved the quality system of the effect of the notice;
- (b) send a copy of the notice to the Secretary of State; and
- (c) inform the manufacturer or his authorised representative in writing of—
  - (i) the circumstances which have led to the issuing of the notice;
  - (ii) the date on which the notice took effect;
  - (iii) the manufacturer's or his authorised representative's right to apply to the authorised person for the early removal of the notice as provided for in paragraph (3) below; and
  - (iv) the right to apply for a review of the decision to issue the notice as provided for in regulation 20.

(3) Where the manufacturer or his authorised representative can demonstrate that steps have been taken which adequately rectify the position described in paragraph (1) above he may apply to the authorised person who gave the notice under paragraph (1) above for its removal before the expiry



of the period of suspension provided for in it and the authorised person shall decide whether it is appropriate in all the circumstances to take steps for the removal of the notice before the expiry of the said period.

(4) If the manufacturer or his authorised representative contravenes a notice under paragraph (1) above—

- (a) he shall be guilty of an offence; and
- (b) all instruments to which the offence relates shall be liable to be forfeited.

### **Withdrawal of approval of quality system**

17.—(1) If it appears to an approved body, in relation to any quality system approved by it, that—

- (a) an undertaking given pursuant to regulation 13(1) has not been complied with; or
- (b) by reason of the refusal or neglect of the manufacturer, it is not able to carry out its functions under regulation 15(1); or
- (c) regulation 15(2) has not been complied with; or
- (d) the Secretary of State has informed the approved body under regulation 25(7)(a) that he is of the opinion that consideration should be given to withdrawal of any relevant quality system approval,

it may, after giving the manufacturer the opportunity of making representations as to why it should not be withdrawn, by notice given to the manufacturer withdraw approval of the quality system.

(2) A notice under paragraph (1) above shall be in writing and shall—

- (a) specify the date on which it is to take effect; and
- (b) specify the grounds for the decision.

(3) The approved body shall send to the Secretary of State a copy of any notice given by it under paragraph (2) above with a view to his notifying the other member States.

### **Affixing of CE marking etc**

18.—(1) The CE marking and each sticker, inscription or identification number mentioned in paragraph (3) below shall be affixed on—

- (a) each instrument to which it relates; or
- (b) on a data plate attached to the instrument in such a way that the plate—
  - (i) cannot be removed without being destroyed, or
  - (ii) is capable of being sealed with a control mark,

and shall satisfy the requirements of paragraph (2) below and, as the case may require, of paragraph (3) below.

(2) The requirement of this paragraph is that each CE marking, identification number, sticker or inscription shall be clearly visible, easily legible and indelible.

(3) The requirements of this paragraph, in the case of—

- (a) the CE marking, are those specified in sub-paragraphs (a), (c) and (d) of paragraph (4) below;
- (b) the identification number, are those specified in sub-paragraph (a) of paragraph (4) below;
- (c) all inscriptions referred to in paragraph 1.1(c) of Annex IV to the NAWI Directive, are those specified in sub-paragraphs (c) and (d) of paragraph (4) below; and

- (d) the inscriptions “Max”, “Min”, “e” and “d” referred to in paragraph 1.4 of Annex IV to the NAWI Directive, are those specified in sub-paragraphs (b), (c) and (d) of paragraph (4) below.
- (4) The requirements referred to in paragraph (3) above in relation to the CE marking, identification number or inscription are—
- (a) a requirement that it be grouped together with all other such information;
  - (b) a requirement that it be placed near the display of the result of the operation of the instrument;
  - (c) a requirement that it be impossible to remove without damaging the marking or inscription;
  - (d) a requirement that it be clearly visible when the instrument is in its regular operating position.
- (5) The CE marking consists of the symbol “CE” of which a form is shown for purposes of illustration in Schedule 4.
- (6) Each load measuring device which is connected, or can be connected, to one or more load receptors shall also bear the inscriptions which apply to each such load receptor.
- (7) Where the manufacturer or his authorised representative affixes a CE marking and sticker under paragraph (1) above to an instrument which—
- (a) is used for a Schedule 3 application; and
  - (b) includes or is connected to any device exempted from the essential requirements by virtue of the Preliminary observation in Annex I to the NAWI Directive which is set out in Schedule 2,

each such device shall bear the restrictive use symbol referred to in paragraph 3 of Annex IV to the NAWI Directive.

- (8) Any person who—
- (a) gives information in connection with an instrument, by means of a misleading mark or inscription or otherwise, which is likely to be confused with the CE marking; or
  - (b) affixes any other mark to the instrument which obscures the visibility or legibility of the CE marking,

shall be guilty of an offence.

- (9) Where a re-qualification sticker is affixed to an instrument in accordance with—
- (a) regulation 11(4) as modified by regulation 11(7)(b);
  - (b) regulation 12(4) as modified by regulation 12(7)(b); or
  - (c) regulation 13(7) as modified by regulation 13(9),

then the sticker shall be so affixed so that it—

- (i) is clearly visible when the instrument is in its regular operating position; and
- (ii) obliterates as far as possible any disqualification sticker.

### **Conformity with other directives**

**19.**—(1) Subject to paragraph (2) below, where a CE marking is affixed to an instrument, the affixing of that marking shall indicate that the instrument conforms also with any directive other than the NAWI Directive which provides for the affixing of the CE marking.

(2) Where, during a relevant transitional period specified in any such other directive a manufacturer chooses not to apply provisions adopted pursuant to the directive in question, paragraph (1) shall not apply if that fact and particulars of that directive as published in the Official

Journal of the European Communities are stated in the documents, notices or instructions required to accompany the instrument.