VERŻJONI ELETTRONIKA

Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 19,556, 12 ta' April, 2016
Taqsima B

L.N. 123 of 2016

METROLOGY ACT
(CAP. 454)

Non-Automatic Weighing Instruments, 2016

In exercise of the powers conferred by article 19 of the Metrology Act, the Minister for Social Dialogue, Consumer Affairs and Civil Liberties, acting on the advice of the Malta Competition and Consumer affairs Authority, has made the following regulations:-

Citation and commencement.

1. (1) The title of these regulations is the Non–Automatic Weighing Instruments, 2016.

(2) These regulations shall come into force on the 20th April, 2016.

Scope.

2. (1) These regulations:

(a) implement Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast);

(b) cover non-automatic weighing instruments which are new to the Union market when they are placed on the market; that is to say they are either new non-automatic weighing instruments made by a manufacturer established in the Union or non-automatic weighing instruments, whether new or second-hand, imported from a third country; and

(c) apply to all non-automatic weighing instruments.

(2) For the purposes of these regulations, the following categories of use of non-automatic weighing instruments shall be distinguished:

(a) the determination of mass for commercial transactions;

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

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

proceedings;

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

(e) the determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories;

(f) the determination of price on the basis of mass for the purposes of direct sales to the public and the making-up of pre-packages;

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

Interpretation.

3. In these regulations, unless the context otherwise requires:

"accreditation" means accreditation as defined in paragraph 10 of Article 2 of Regulation (EC) No 765/2008;

"authorised representative" means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

"Authority" means the Standards and Metrology Institute of the Malta Competition and Consumer Affairs Authority;

"CE marking" means a marking by which the manufacturer indicates that the instrument is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

"conformity assessment" means the process demonstrating whether the essential requirements of these regulations relating to an instrument have been fulfilled;

"conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

"distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an instrument available on the market;

"economic operators" means the manufacturer, the authorised representative, the importer and the distributor;

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

"importer" means any natural or legal person established within the Union who places an instrument from a third country on the Union market;

"making available on the market" means any supply of an instrument for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

"manufacturer" means any natural or legal person who manufactures an instrument or has an instrument designed or manufactured, and markets that instrument under his name or trade mark;

"National Accreditation Board (Malta)" means the National Accreditation Board (Malta) established in terms of regulation 3 of the National Accreditation Board (Malta) (Establishment) Regulations; S.L. 419.07.

"non-automatic weighing instrument" or "instrument" means a weighing instrument requiring the intervention of an operator during weighing;

"placing on the market" means the first making available of an instrument on the Union market;

"recall" means any measure aimed at achieving the return of an instrument that has already been made available to the end-user;

"technical specification" means a document that prescribes technical requirements to be fulfilled by an instrument;

"Union harmonisation legislation" means any Union legislation harmonising the conditions for the marketing of products;

"Weighing instrument" means a measuring instrument serving to determine the mass of a body by using the action of gravity on that body. A weighing instrument may also serve to determine other mass-related magnitudes, quantities, parameters or characteristics;

"withdrawal" means any measure aimed at preventing an instrument in the supply chain from being made available on the market.

Making available on the market and putting into service.

4. (1) The Authority shall take all steps to ensure that only instruments that meet the applicable requirements of this regulation may be made available on the market.

(2) The Authority shall take all steps to ensure that instruments may not be put into service for the uses referred to in paragraphs (a) to (f) of regulation 2(3) unless they meet the requirements of these regulations.

(3) The Authority shall take all steps to ensure that instruments put into service for the uses referred to in paragraphs (a) to (f) of regulation 2(3) continue to conform to the applicable requirements of these regulations.

Essential requirements.

5. Instruments used or intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) shall satisfy the essential requirements set out in Schedule I.

Where the instrument includes, or is connected to, devices which are not used or intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), such devices shall not be subject to those essential requirements.

Free movement of instruments.

6. (1) The Authority shall not impede the making available on the market of instruments which meet the requirements of these regulations.

(2) The Authority shall not impede the putting into service, for the uses referred to in paragraphs (a) to (f) of regulation 2(3), of instruments which meet the requirements of these regulations.

Obligations of manufacturers.

7. (1) When placing on the market their instruments intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Schedule I.

(2) For the instruments intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), manufacturers shall draw up the technical documentation referred to in Schedule II and carry out the relevant conformity assessment procedure referred to in regulation 14 or have it carried out.

Where compliance of an instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) with the applicable requirements has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking and the supplementary

metrology marking.

(3) For the instruments intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the instrument has been placed on the market.

(4) Manufacturers shall ensure that procedures are in place for series production to remain in conformity with these regulations. Changes in instrument design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of an instrument is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by an instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), manufacturers shall carry out sample testing of instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming instruments and instrument recalls, and shall keep distributors informed of any such monitoring.

(5) Manufacturers shall ensure that instruments which they have placed on the market bear a type, batch or serial number or other element allowing their identification, as set out in Schedule III.

For the instruments intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), manufacturers shall affix the inscriptions provided for in point 1 of Schedule III.

For the instruments not intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), manufacturers shall affix the inscriptions provided for in point 2 of Schedule III.

Where an instrument which is intended to be used for any of the applications listed in paragraphs (a) to (f) of regulation 2(3) includes, or is connected to, devices which are not used or intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), manufacturers shall affix to each of those devices the restrictive use symbol as provided for in regulation 19 and in point 3 of Schedule III.

(6) Manufacturers shall indicate on the instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted. The address shall indicate a single paragraph at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and the

Authority.

(7) Manufacturers shall ensure that the instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) is accompanied by instructions and information in a language which can be easily understood by end-users, as determined by the Authority. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

(8) Manufacturers who consider or have reason to believe that an instrument which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the instrument presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(9) Manufacturers shall, further to a reasoned request from the Authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the instrument with these regulations, in at least English and, or Maltese. The Authority at its request, on any action taken to eliminate the risks posed by instruments which they have placed on the market.

Authorised representatives.

8. (1) A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in regulation 7(1) and the obligation to draw up technical documentation referred to in regulation 7(2) shall not form part of the authorised representative's mandate.

(2) An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of the Authority for 10 years after the instrument has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an instrument;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by instruments covered by the authorised representative's mandate.

Obligations of importers.

9. (1) Importers shall place only compliant instruments on the market.

(2) Before placing on the market an instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), importers shall ensure that the appropriate conformity assessment procedure referred to in regulation 14 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the instrument bears the CE marking and the supplementary metrology marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in regulation 7(5) and (6).

Where an importer considers or has reason to believe that an instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) is not in conformity with the essential requirements set out in Schedule I, he shall not place the instrument on the market until it has been brought into conformity. Furthermore, where the instrument presents a risk, the importer shall inform the manufacturer and the Authority to that effect.

Before placing on the market an instrument not intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) importers shall ensure that the manufacturer has complied with the requirements set out in regulation 7(5) and (6).

(3) Importers shall indicate on the instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted. Where this would require the packaging to be opened, those indications may be given on the packaging and in a document accompanying the instrument. The contact details shall be in at least English and, or Maltese.

(4) Importers shall ensure that the instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) is accompanied by instructions and information in a language which can be easily understood by end-users, as determined by the Authority.

(5) Importers shall ensure that, while an instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential

requirements set out in Schedule I.

(6) When deemed appropriate with regard to the risks presented by an instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), importers shall carry out sample testing of instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming instruments and instrument recalls, and shall keep distributors informed of any such monitoring.

(7) Importers who consider or have reason to believe that an instrument which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the instrument presents a risk, importers shall immediately inform the Authority, giving details, in particular, of the non-compliance and of any corrective measures taken.

(8) For the instruments intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), importers shall, for 10 years after the instrument has been placed on the market keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

(9) Importers shall, further to a reasoned request from the Authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of an instrument in at least English and, or Maltese. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by instruments which they have placed on the market.

Obligations of distributors.

10. (1) When making an instrument available on the market distributors shall act with due care in relation to the requirements of these regulations.

(2) Before making an instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) available on the market, distributors shall verify that the instrument bears the CE marking, and the supplementary metrology marking, that it is accompanied by the required documents and by instructions and information in at least English and, or Maltese, and that the manufacturer and the importer have complied with the requirements set out in regulation 7(5) and (6) and regulation 9(3) respectively.

Where a distributor considers or has reason to believe that an instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) is not in conformity with the essential requirements set out in Schedule I, he shall not make the instrument available on the market until it has been brought into conformity. Furthermore, where the instrument presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the Authority.

Before making an instrument not intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) available on the market, distributors shall verify that the manufacturer and the importer have complied with the requirements set out in regulation 7(5) and (6) and regulation 9(3) respectively.

(3) Distributors shall ensure that, while an instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Schedule I.

(4) Distributors who consider or have reason to believe that an instrument which they have made available on the market is not in conformity with these regulations shall make sure that the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the instrument presents a risk, distributors shall immediately inform the Authority to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

Cases in which obligations of manufacturers apply to importers and distributors.

11. An importer or distributor shall be considered a manufacturer for the purposes of these regulations and he shall be subject to the obligations of the manufacturer under regulation 7, where he places an instrument on the market under his name or trade mark or modifies an instrument already placed on the market in such a way that compliance with these regulations may be affected.

Identification of economic operators.

12. (1) For instruments intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3), economic operators shall, on request, identify the following to the Authority:

(a) any economic operator who has supplied them with an instrument;

(b) any economic operator to whom they have supplied an instrument.

(2) Economic operators shall be able to present the information referred to in sub-regulation (1) for 10 years after they have been supplied with the instrument and for 10 years after they have supplied the instrument.

Presumption of conformity of instruments.

13. Instruments which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential requirements set out in Schedule I covered by those standards or parts thereof.

Conformity assessment procedures.

14. (1) The conformity of instruments to the essential requirements set out in Schedule I may be established by either of the following conformity assessment procedures as selected by the manufacturer:

(a) Module B as set out in point 1 of Schedule II, followed either by Module D as set out in point 2 of Schedule II, or by Module F as set out in point 4 of Schedule II:

Provided that Module B shall not be compulsory for instruments which do not use electronic devices and the load-measuring device of which does not use a spring to balance the load. For those instruments not submitted to Module B, Module D1 as set out in point 3 of Schedule II or Module F1 as set out in point 5 of Schedule II shall apply;

(b) Module G as set out in point 6 of Schedule II.

(2) Any documents and correspondence relating to the conformity assessment procedures referred to in sub-regulation (1) shall be drawn up in at least English and, or Maltese.

EU declaration of conformity.

15. (1) The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Schedule I has been demonstrated.

(2) The EU declaration of conformity shall have the model structure set out in Schedule IV, shall contain the elements specified in the relevant modules set out in Schedule II and shall be continuously updated. It shall be in at least English and, or Maltese.

(3) Where an instrument is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

(4) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the instrument with the requirements laid down in these regulations.

Conformity marking.

16. The conformity of an instrument intended to be used for the applications listed in paragraphs (a) to (f) of regulation 2(3) with these regulations shall be indicated by the presence, on the instrument, of the CE marking and the supplementary metrology marking as specified in regulation 17

General principles of the CE marking and of the supplementary metrology marking.

17. (1) The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008

(2) The supplementary metrology marking shall consist of the capital letter 'M' and the last two digits of the year of its affixing, surrounded by a rectangle. The height of the rectangle shall be equal to the height of the CE marking.

(3) The general principles set out in Article 30 of Regulation (EC) No 765/2008 shall apply, *mutatis mutandis*, to the supplementary metrology marking.

Rules and conditions for affixing the CE marking, the supplementary metrology marking and other markings.

18. (1) The CE marking and the supplementary metrology marking shall be affixed visibly, legibly and indelibly to the instrument or to its data plate.

(2) The CE marking and the supplementary metrology marking shall be affixed before the instrument is placed on the market.

(3) The supplementary metrology marking shall immediately follow the CE marking.

(4) The CE marking and the supplementary metrology marking shall be followed by the identification number(s) of the notified body or bodies involved in the production control phase as set out in Schedule II.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

(5) The CE marking, the supplementary metrology marking and the identification number(s) of the notified body or bodies may be followed by any other mark indicating a special risk or use.

(6) The Authority shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking

and shall take appropriate action in the event of improper use of that marking.

Restrictive use symbol.

19. The symbol referred to in regulation 7(5) and specified in point 3 of Schedule III shall be affixed to the devices in a clearly visible and indelible form.

Notification.

20. The Authority shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under these regulations.

Notifying authorities.

21. (1) The Authority shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with regulation 26.

(2) The assessment and monitoring referred to in sub-regulation (1) shall be carried out by the National Accreditation Board (Malta).

Requirements relating to notifying authorities.

22. (1) The Authority shall ensure that no conflict of interest with conformity assessment bodies occurs.

(2) The Authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

(3) The Authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

(4) The Authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

(5) The Authority shall safeguard the confidentiality of the information it obtains.

(6) The Authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Information obligation on notifying authorities.

23. The Authority shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

Requirements relating to notified bodies.

24. (1) For the purposes of notification, a conformity assessment body shall meet the requirements laid down in sub-regulations (2) to (11).

(2) A conformity assessment body shall be established under the national law of Malta and have legal personality.

(3) A conformity assessment body shall be a third-party body independent of the organisation or the instrument it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of instruments which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body

(4) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the instruments which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed instruments that are necessary for the operations of the conformity assessment body or the use of such instruments for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those instruments, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities

(5) Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

(6) A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Schedule II

and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of instruments in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the instrument technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

(7) The personnel responsible for carrying out conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential requirements set out in Schedule I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;

(d) the ability to draw up certificates, records and

reports demonstrating that assessments have been carried out.

(8) The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

(9) Conformity assessment bodies shall take out liability insurance unless liability is assumed by the Government of Malta in accordance with national law, or the Authority itself is directly responsible for the conformity assessment.

(10) The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Schedule II or any provision of national law giving effect to it, except in relation to the competent authorities of Malta in which its activities are carried out. Proprietary rights shall be protected.

(11) Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Presumption of conformity of notified bodies.

25. Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements set out in regulation 24 in so far as the applicable harmonised standards cover those requirements.

Subsidiaries of and subcontracting by notified bodies.

26. (1) Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in regulation 24 and shall inform the Authority accordingly.

(2) Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

(3) Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

(4) Notified bodies shall keep at the disposal of the Authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Schedule II.

Application for notification.

27. (1) A conformity assessment body established in Malta shall submit an application for notification under these regulations to the Authority.

(2) The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the instrument or instruments for which that body claims to be competent, as well as by an accreditation certificate issued by the National Accreditation Board (Malta) attesting that the conformity assessment body fulfils the requirements laid down in regulation 24.

Notification procedure.

28. (1) The Authority may notify only conformity assessment bodies which have satisfied the requirements laid down in regulation 24

(2) The Authority shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

(3) The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and instrument or instruments concerned and the relevant attestation of competence.

(4) The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used.

Only such a body shall be considered a notified body for the purposes of these regulations.

(5) The Authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Changes to notifications.

29. (1) Where the Authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in regulation 24, or that it is failing to fulfil its obligations, the Authority shall restrict, suspend or withdraw notification as

appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

(2) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the Authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the Authority.

Operational obligations of notified bodies.

30. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Schedule II.

(2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the instrument technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the instrument with these regulations.

(3) Where a notified body finds that the essential requirements set out in Schedule I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

(4) Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that an instrument no longer complies; it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

(5) Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Appeal against decisions of notified bodies.

31. The Authority shall ensure that an appeal procedure against decisions of the notified bodies is available.

Information obligation on notified bodies.

32. (1) Notified bodies shall inform the Authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of or conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

(2) Notified bodies shall provide the other bodies notified under these regulations carrying out similar conformity assessment activities covering the same instruments with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Coordination of notified bodies.

33. Notified bodies shall participate, directly or by means of designated representatives, in the appropriate coordination and cooperation groups for notified bodies organised by the Commission.

Union market surveillance and control of instruments entering the Union market.

34. Regulation 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to instruments covered by regulation 2 of these regulations.

Procedure for dealing with instruments presenting a risk at national level.

35. (1) Where the Authority has sufficient reason to believe that an instrument covered by these regulations presents a risk to aspects of public interest protection covered by these regulations, it shall carry out an evaluation in relation to the instrument concerned covering all relevant requirements laid down in these regulations. The relevant economic operators shall cooperate as necessary with the Authority for that purpose.

Where, in the course of the evaluation referred to above, the Authority finds that the instrument does not comply with the requirements laid down in these regulations, it shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the instrument into compliance with those requirements, to withdraw the instrument from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The Authority shall inform the relevant notified body

accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in this regulation.

(2) Where the Authority considers that non-compliance is not restricted to Malta, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

(3) The economic operator shall ensure that all appropriate corrective action is taken in respect of all the instruments concerned that it has made available on the market throughout the Union.

(4) Where the relevant economic operator does not take adequate corrective action within the period referred to in sub-regulation (1), the Authority shall take all appropriate provisional measures to prohibit or restrict the instrument's being made available on their national market, to withdraw the instrument from that market or to recall it.

The Authority shall inform the Commission and the other Member States, without delay, of those measures.

(5) All information shall include all available details, in particular the data necessary for the identification of the non-compliant instrument, the origin of the instrument, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the Authority shall indicate whether the non- compliance is due to either of the following:

(a) failure of the instrument to meet requirements relating to the aspects of public interest protection laid down in these regulations; or

(b) shortcomings in the harmonised standards referred to in regulation 13 conferring a presumption of conformity.

(6) Member States other than the Member State initiating the procedure under this regulation shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the instrument concerned, and, in the event of disagreement with the adopted national measure, of their objections.

(7) Where, within three months of receipt of the information, no objection has been raised by either a Member State or the

Commission in respect of a provisional measure taken by the Authority, that measure shall be deemed justified.

(8) The Authority shall ensure that appropriate restrictive measures, such as withdrawal of the instrument from the market, are taken in respect of the instrument concerned without delay.

Union safeguard procedure.

36. If the national measure is considered justified, the Authority shall take the necessary measures to ensure that the non-compliant instrument is withdrawn from the market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Authority shall withdraw that measure.

Compliant instruments which present a risk.

37. (1) Where, having carried out an evaluation under regulation 35, the Authority finds that although an instrument is in compliance with these regulations, it presents a risk to aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the instrument concerned, when placed on the market, no longer presents that risk, to withdraw the instrument from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

(2) The economic operator shall ensure that corrective action is taken in respect of all the instruments concerned that he has made available on the market throughout the Union.

(3) The Authority shall immediately inform the Commission and the other Member States that information shall include all available details, in particular the data necessary for the identification of the instrument concerned, the origin and the supply chain of the instrument, the nature of the risk involved and the nature and duration of the national measures taken.

Formal non-compliance.

38. (1) Without prejudice to regulation 35, where the Authority makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking or the supplementary metrology marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of regulation 18 of these regulations;

(b) the CE marking or the supplementary metrology marking has not been affixed;

(c) the inscriptions provided for in regulation 7(5) have

not been affixed or have been affixed in violation of regulation 7(5);

(d) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of regulation 17 or has not been affixed;

(e) the EU declaration of conformity has not been drawn up;

(f) the EU declaration of conformity has not been drawn up correctly;

(g) technical documentation is either not available or not complete;

(h) the information referred to in regulation 7(6) or 9(3) is absent, false or incomplete;

(i) any other administrative requirement provided for in regulation 7 or 9 is not fulfilled.

(2) Where the non-compliance referred to in regulation 38(1) persists, the Authority shall take all appropriate measures to restrict or prohibit the instrument being made available on the market or ensure that it is recalled or withdrawn from the market.

Penalties.

39. Penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to these regulations are stipulated in Part VI of Metrology Act.

Cap. 454.

Transitory provisions.

40. (1) The Authority shall not impede the making available on the market and/or the putting into service of instruments covered by Regulation 2009/23/EC which are in conformity with that Regulation and which were placed on the market before 20th April, 2016.

(2) Certificates issued under Regulation 2009/23/EC shall be valid under these regulations.

SCHEDULE I

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 paragraphs (a) to (f) of regulation 2(3), 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 Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement.*

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

(1) The following accuracy classes have been defined:

(a) I special

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* OJ L 39, 15.2.1980, p. 40.

(b) II high

(c) III medium

(d) IIII ordinary

The specifications of these classes are given in Table 1 The minimum capacity is reduced to 5 e for instruments in classes II and III for determining a conveying tariff.

Table 1

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

(2) Scale intervals

(2.1) The actual scale interval (d) and the verification scale interval (e) shall be in the form: 1×10^{k}, 2×10^{k}, or 5×10^{k} mass units,

k being any integer or zero.

(2.2) For all instruments other than those with auxiliary indicating devices:

d = e.

(2.3) For instruments with auxiliary indicating devices the following conditions apply:

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

$d < e \leq 10$ d.

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

3. Classification

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 g, the maximum capacity of class I may be less than 50 000 e.

(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) Multi – interval instruments

(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.

(3.2) 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 Max_i	with $Max_r = Max$
— its minimum capacity Min_i	with $Min_i = Max_{(i-1)}$ and $Min_1 = Min$

where:

i = 1, 2, … r,

i = partial weighing range number,

r = the total number of partial weighing ranges.

(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

Multi-interval instruments				
i = 1, 2, … r i = partial weighing range number r = total number of partial weighing ranges				
Class	Verification scale interval (e)	Minimum capacity (Min)	Number of verification scale intervals	
		Minimum value	Minimum value (1) $n = ((Max_i)/(e_{(i+1)}))$	Maximum value $n = ((Max_i)/(e_i))$
I	0,001 g ≤ e_i	100 e_1	50 000	—
II	0,001 g ≤ e_i ≤ 0,05 g	20 e_1	5 000	100 000
	0,1 g ≤ e_i	50 e_1	5 000	100 000
III	0,1 g ≤ e_i	20 e_1	500	10 000
IIII	5g ≤ e_i	10 e_1	50	1 000
(1) For i = r, the corresponding column of Table 1 applies, with e replaced by e_r.				

4. Accuracy

(1) On implementation of the procedures laid down in regulation 14, 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

Maximum permissible errors				
Load				Maximum permissible error
Class I	Class II	Class III	Class IIII	
0 ≤ m ≤ 50 000 e	0 ≤ m ≤ 5 000 e	0 ≤ m ≤ 500 e	0 ≤ m ≤ 50 e	± 0,5 e
50 000 e < m ≤ 200 000 e	5 000 e < m ≤ 20 000 e	500 e < m ≤ 2 000 e	50 e < m ≤ 200 e	± 1,0 e
200 000 e < m	20 000 e < m ≤ 100 000 e	2 000 e < m ≤ 10 000 e	200 e < m ≤ 1 000 e	± 1,5 e

(2) The maximum permissible errors in service are twice the maximum permissible errors fixed in Section 4.1.

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.

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6. The instrument shall react to small variations in the load.

7. Influence quantities and time

(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.

(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.

(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.

(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.

(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.

(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

(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.

(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.

(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.

(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.

(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.

(6) Instruments shall be designed to permit ready execution of the statutory controls laid down by this Regulation.

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 Directive 80/181/EEC 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 II

CONFORMITY ASSESSMENT PROCEDURES

1. Module B: EU-type examination

(1) EU-type examination is the part of a conformity assessment procedure in which a notified 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.

(2) EU-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).

(3) The manufacturer shall lodge an application for EU-type examination with a single notified 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 notified body;

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(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 harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised 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 harmonised 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 notified 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 harmonised 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.

(4) The notified body shall:

For the instrument:

(4.1) examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;

For the specimen(s):

(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 harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

(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 harmonised standards, these have been applied correctly;

(4.4) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of these regulations;

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

(5) The notified 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 notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

(6) Where the type meets the requirements of these regulations, that apply to the instrument concerned, the notified body shall issue an EU-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 EU-type examination certificate may have one or more Annexes attached.

The EU-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 EU-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 EU-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 notified body shall refuse to issue an EU-type examination

certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

(7) The notified body shall keep itself appraised 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 notified body shall inform the manufacturer accordingly. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-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 EU- type examination certificate.

(8) Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-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 Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-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.

(9) The manufacturer shall keep a copy of the EU-type examination certificate, its schedules and additions together with the technical documentation at the disposal of the national authorities for

10 years after the instrument has been placed on the market.

(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

(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 EU-type examination certificate and satisfy the requirements of these regulations that apply to them.

(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.

(3) Quality system

(3.1) The manufacturer shall lodge an application for assessment of his quality system with the notified 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 notified 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 EU-type examination certificate.

(3.2) The quality system shall ensure that the instruments are in conformity with the type described in the EU-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.

(3.3) The notified 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 harmonised 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.

(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.

(3.5) The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified 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.

(4) Surveillance under the responsibility of the notified body

(4.1) The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

(4.2) The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, and 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.

(4.3) The notified 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.

(4.4) In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified 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 notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

(5) Conformity marking and EU declaration of conformity

(5.1) The manufacturer shall affix the CE marking and the supplementary metrology marking set out in these regulations, and, under the responsibility of the notified 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 EU-type examination certificate and satisfies the applicable requirements of these regulations.

(5.2) The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

(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 national 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 notified body referred to in points 2.3.5, 2.4.3 and 2.4.4.

(7) Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make

available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

(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

(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.

(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 harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised 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 harmonised 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) 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.

(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.

(5) Quality system

(5.1) The manufacturer shall lodge an application for assessment of his quality system with the notified 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 notified 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.

(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.

(5.3) The notified 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 harmonised 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.

(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.

(5.5) The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified 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.

(6) Surveillance under the responsibility of the notified body

(6.1) The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

(6.2) The manufacturer shall, for assessment purposes, allow the notified 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.

(6.3) The notified 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.

(6.4) In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified 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 notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

(7) Conformity marking and EU declaration of conformity

(7.1) The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in these regulations, and, under the responsibility of the notified 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.

(7.2) The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

(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 national 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 notified body referred to in points 3.5.5, 3.6.3 and 3.6.4.

(9) Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

(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

(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 EU-type examination certificate and satisfy the requirements of these regulations that apply to them.

(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 EU-type examination certificate and with the requirements of these regulations that apply to them.

(3) Verification

A notified 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 EU-type examination certificate and with the appropriate requirements of the Directive 2014/31.

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) Verification of conformity by examination and testing of every instrument

(4.1) All instruments shall be individually examined and appropriate tests set out in the relevant harmonised 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 EU-type examination certificate and with the appropriate requirements of these regulations.

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

(4.2) The notified 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 national authorities for 10 years after the instrument has been placed on the market.

(5) Conformity marking and EU declaration of conformity

(5.1) The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in these regulations, and, under the responsibility of the notified 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 EU-type examination certificate and satisfies the applicable requirements of these regulations.

(5.2) The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities, for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

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

(6) If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the instruments during the manufacturing process.

(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

(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.

(2) Technical documentation

(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 harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised 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 harmonised 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.

(2.2) 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) 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.

(4) Verification

A notified 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) Verification of conformity by examination and testing of every instrument

(5.1) All instruments shall be individually examined and appropriate tests, set out in the relevant harmonised 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 harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

(5.2) The notified 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 national authorities for 10 years after the instrument has been placed on the market.

(6) Conformity marking and EU declaration of conformity

(6.1) The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in these regulations, and, under the responsibility of the notified body referred to in point 5.4, the latter's identification number to each individual instrument that satisfies the applicable requirements of these regulations.

(6.2) The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 5.5 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the instruments.

(7) If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the instruments during the manufacturing process.

(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

(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.

(2) Technical documentation

(2.1) The manufacturer shall establish the technical documentation and make it available to the notified 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 harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised 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 harmonised 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.

(2.2) 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) 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.

(4) Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised 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 harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

The notified 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 national authorities for 10 years after the instrument has been placed on the market.

(5) Conformity marking and EU declaration of conformity

(5.1) The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in these Regulations, and, under the responsibility of the notified body referred to in point 6.4, the latter's identification number to each instrument that satisfies the applicable requirements of these Regulations.

(5.2) The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

(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

(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.

(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. If a Member State has established gravity zones on its territory the expression 'at the place of use of the instrument' may be read as 'in the gravity zone of use of the instrument'.

(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 notified body involved in that stage.

(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 notified body's certificates of conformity on request.

(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.

(2.4) The CE marking and the supplementary metrology marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the notified body which took part in the second stage.

SCHEDULE III

INSCRIPTIONS

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

(1) Those instruments shall bear visibly, legibly and indelibly the following inscriptions:

(i) the number of the EU-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 = …;

(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 = …;

(x) maximum additive tare effect, in the form T = + …;

(xi) maximum subtractive tare effect if it is different from Max, in the form T = – …;

(xii) tare interval if it is different from d, in the form d T = …;

(xiii) maximum safe load if it is different from Max, in the form Lim …;

(xiv) the special temperature limits, in the form … ^{o}C/… ^{o}C;

(xv) ratio between load receptor and load.

(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.

(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.

(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.

(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 paragraphs (a) to (f) of regulation 2(3) 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 19

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 IV

EU DECLARATION OF CONFORMITY (No XXXX)*

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

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 Union harmonisation legislation:

6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:

7. The notified 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):

* It is optional for the manufacturer to assign a number to the declaration of conformity.

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