Republic of Latvia

Cabinet

Regulation No. 212

Adopted 12 April 2016

**Metrological Requirements for Measuring Instruments and the Procedures for the Metrological Control Thereof**

*Issued pursuant to*

*Section 7, Paragraphs one and two of the law On Conformity Assessment and Section 6, Paragraph two of the law On Uniformity of Measurements*

**1. General Provisions**

1. The Regulation prescribes the metrological requirements for the measuring instruments subject to the State metrological control – water meters, gas meters, and volume conversion devices, active electrical energy meters, thermal energy meters, measuring systems for liquids (other than water), automatic weighing instruments, taximeters, material measures, dimensional measuring instruments, and exhaust gas analysers (hereinafter – the measuring instruments) – so that they could be placed on the market and put into use, and also the procedures for the metrological control and market supervision of the measuring instruments.

2. The following terms are used in the Regulation:

2.1. measuring instrument – a device which is intended for measuring independently or together with additional devices;

2.2. additional device – an ancillary device of the measuring instrument which operates independently and connects the measuring instrument to another device or measuring instrument;

2.3. normative document – a document containing technical specifications of the measuring instruments adopted by the International Organisation of Legal Metrology;

2.4. making available on the market – any supply of the measuring instruments for distribution or use on the European Union market in the course of economic activity, whether in return for payment or free of charge;

2.5. placing on the market – the first making available of the measuring instruments on the European Union market;

2.6. putting into use – the first use of a measuring instrument intended for the end-user for the purposes for which it was intended;

2.7. manufacturer – any natural or legal person that manufactures the measuring instruments or has the measuring instruments designed or manufactured, and markets such measuring instruments under its name or trade mark;

2.8. authorised representative – any natural or legal person established within the European Union that has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks;

2.9. importer – any natural or legal person established within the European Union that places the measuring instruments from a third country on the market;

2.10. distributor – any natural or legal person established within the European Union, other than the manufacturer or the importer, that makes the measuring instruments available on the market;

2.11. economic operators – the manufacturer, the authorised representative, the importer, and the distributor;

2.12. technical specification – a document that prescribes technical requirements to be fulfilled by the measuring instruments;

2.13. notified authority – a conformity assessment authority of the measuring instruments which has been accredited by the national accreditation authority and which has been notified to the European Commission in accordance with the laws and regulations regarding the procedures for establishing a notification commission and also the procedures for taking a decision by the commission and notifying the European Commission of conformity assessment authorities which carry out conformity assessment in the regulated sphere, or another conformity assessment authority of the measuring instruments which has been notified by another European Union Member State or the European Economic Area;

2.14. recall – any measure aimed at achieving the return of the measuring instruments that have already been made available to the end-user;

2.15. withdrawal from the market – any measure aimed at preventing the measuring instruments in the supply chain from being made available on the market;

2.16. CE conformity marking – a marking by which the manufacturer indicates that the measuring instrument conforms to the applicable requirements laid down in the laws and regulations providing for its affixing to the product.

3. The economic operator may place on the market or make available on the market, or put into use only such measuring instruments and their additional devices which conform to the requirements of this Regulation and also to the laws and regulations regarding the metrological requirements for a particular measuring instrument and the laws and regulations regarding electromagnetic compatibility if conformity assessment (Annex 1) has been performed for the measuring instruments and their additional devices and they have been marked with a CE marking and a supplementary marking.

4. If a measuring instrument does not conform to the requirements of this Regulation and the laws and regulations regarding the metrological requirements for a particular measuring instrument, the showing thereof at trade fairs, exhibitions, and annual fairs shall not be restricted if it is marked with a sign that indicates its non-availability for placing on the market and also putting into use until it is brought into conformity with the requirements of this Regulation and the laws and regulations regarding the metrological requirements for a particular measuring instrument.

5. The measuring instruments which conform to the requirements of the applicable standards or their parts or normative documents or their parts references to which have been published in the Official Journal of the European Union shall be considered as conforming to the essential requirements referred to in Annex 2 to this Regulation encompassed in these standards, normative documents or their parts.

6. The national standardisation authority shall publish a list of the applicable standards on its website which have been adapted in the status of national standards and the National Metrology Authority shall publish a list of the normative documents on its website.

**2. Obligations of the Economic Operators**

7. Economic operators shall, upon request of the market surveillance authority, provide information on the measuring instruments, indicating:

7.1. all the economic operators which have supplied the measuring instruments to them;

7.2. all the economic operators to which they have supplied the measuring instruments.

8. Economic operators shall ensure the availability of the information indicated in Paragraph 7 of this Regulation to the market surveillance authority for 10 years after the measuring instruments have been supplied to them or by them.

**2.1. Obligations of the Manufacturer**

9. Within the meaning of this Regulation an importer and a distributor shall be considered a manufacturer and it shall be subject to the obligations referred to in this Chapter if it places the measuring instruments on the market under its name or trademark or modifies the measuring instruments already placed on the market in such a way that conformity with the essential safety requirements referred to in Annex 2 to this Regulation may be affected.

10. Upon placing the measuring instruments on the market, the manufacturer shall ensure that they are designed and manufactured in accordance with the essential requirements referred to in Annex 2 to this Regulation.

11. The manufacturer shall draw up the technical documentation referred to in Chapter 4 of this Regulation for the measuring instrument and shall carry out the relevant conformity assessment procedure referred to in Annex 1 to this Regulation or have it carried out.

12. If conformity of the measuring instrument with the essential requirements has been demonstrated by that conformity assessment procedure, the manufacturer shall draw up a declaration of conformity and affix the CE conformity marking and the supplementary metrology marking on the measuring instrument.

13. The manufacturer shall keep the technical documentation and the declaration of conformity for 10 years after the measuring instrument has been placed on the market.

14. If the measuring instrument is produced in series, the manufacturer shall draw up the control procedures to ensure the conformity of the measuring instrument with the requirements of this Regulation and shall adequately take into account changes in the measuring instrument design or characteristics and also changes in the normative documents or in other technical specifications by reference to which conformity of the measuring instruments with the requirements of this Regulation is declared.

15. If it is necessary to assess the risk presented by the measuring instrument, the manufacturer shall carry out testing and assessment of the measuring instruments made available on the market, keep a register of complaints, of non-conformities, and of measuring instrument recalls, and also shall keep the distributors informed of the carrying out of any such activities.

16. The manufacturer shall ensure that the marking of the measuring instruments which they have placed on the market bears a type, batch, or serial number or other element allowing their identification. If the size of the measuring instrument does not allow it, the manufacturer shall indicate such information in a document accompanying the measuring instrument and on the packaging, if any.

17. The manufacturer shall indicate on the measuring instrument its name or registered trade mark and the contact address at which the manufacturer can be contacted. If it is not possible to indicate it on the measuring instrument, the abovementioned information shall be indicated in a document accompanying the measuring instrument and on the packaging, if any.

18. The manufacturer shall ensure that the measuring instruments are accompanied by the declaration of conformity, the instructions for use, and the information referred to in Paragraphs 20 and 22 of Annex 2 to this Regulation in the official language. The instructions for use and the information referred to in Paragraphs 20 and 22 of Annex 2 to this Regulation, and also any other information indicated on the measuring instruments shall be clear and understandable.

19. The manufacturer who considers or has reason to believe that the measuring instruments which it has placed on the market do not conform to the requirements of this Regulation shall immediately take the corrective measures necessary to ensure the conformity of the measuring instruments with the requirements of this Regulation or to withdraw or recall them, if appropriate. If the measuring instruments present a risk, the manufacturer shall immediately inform the market surveillance authority thereof, giving details, in particular, of the non-conformity and of any corrective measures taken.

20. The manufacturer shall, upon request of the market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity of the measuring instrument with the requirements of this Regulation, in the official language.

21. The manufacturer shall cooperate with the market surveillance authority, upon request of the market surveillance authority, to eliminate the risks presented by the measuring instruments placed on the market.

**2.2. Authorised Representatives**

22. A manufacturer may, by a written mandate, appoint an authorised representative. The obligations referred to in Paragraphs 10 and 11 of this Regulation shall not form part of the mandate.

23. An authorised representative shall fulfil at least the following obligations:

23.1. keep the declaration of conformity and the technical documentation available to the market surveillance authority for 10 years after the measuring instrument has been placed on the market;

23.2. upon a reasoned request of the market surveillance authority, provide all the information and documentation necessary to demonstrate the conformity of the measuring instrument;

23.3. cooperate with the market surveillance authority, upon request of the market surveillance authority, to eliminate the risks presented by the measuring instrument covered by their mandate.

**2.3. Obligations of an Importer**

24. An importer shall place such measuring instruments on the market which conform to the requirements of this Regulation.

25. Before placing the measuring instrument on the market and putting the measuring instrument into use the importer shall ensure that the manufacturer has carried out the appropriate conformity assessment procedure referred to in Chapter 3 of this Regulation, has drawn up the appropriate technical documentation, has appended the declaration of conformity, has marked the measuring instrument with the CE marking and the supplementary metrology marking, has appended the necessary documentation, and also has fulfilled the obligations referred to in Paragraphs 16 and 17 of this Regulation.

26. If the importer considers or has reason to believe that the measuring instruments are not in conformity with the essential requirements referred to in Annex 2 to this Regulation, it shall not place the measuring instruments on the market or put them into use until the relevant economic operator has brought them into conformity with the essential requirements referred to in Annex 2 to this Regulation. If the measuring instruments present a risk, the importer shall inform the manufacturer and the market surveillance authority to that effect.

27. The importer shall indicate on the measuring instrument its name or registered trade mark and the contact address at which the importer can be contacted. If it is not possible to indicate it on the measuring instrument, the abovementioned information shall be indicated in a document accompanying the measuring instrument and on the packaging, if any.

28. The importer shall ensure that the measuring instrument is accompanied by the instructions for use and the information referred to in Paragraphs 20 and 22 of Annex 2 to this Regulation in the official language.

29. The importer shall ensure that, while the measuring instruments are under its responsibility, their storage and transport conditions do not jeopardise their conformity with the essential requirements referred to in Annex 2 to this Regulation.

30. If it is necessary to assess the risk presented by the measuring instruments, the importer shall, for the purpose of protecting the health, safety, and interests of consumers, carry out sample testing and assessment of the measuring instruments made available on the market, register complaints and information on non-conforming measuring instruments and on measuring instrument recalls, and also shall keep distributors informed of the carrying out of any such activities.

31. The importer who considers or has reason to believe that the measuring instruments which it has placed on the market do not conform to the requirements of this Regulation shall immediately take the corrective measures necessary to ensure the conformity of the measuring instruments with the requirements of this Regulation or to withdraw or recall them, if appropriate. If the measuring instruments present a risk, the importer shall immediately inform the market surveillance authority thereof, giving details, in particular, of the non-conformity and of any corrective measures taken.

32. The importer shall, for 10 years after the measuring instrument has been placed on the market, make a copy of the declaration of conformity available to the market surveillance authorities and also ensure that the technical documentation can be made available to the market surveillance authority, upon request.

33. The importer shall, upon request of the market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity of the measuring instrument with the requirements of this Regulation in the official language.

34. The importer shall cooperate with the market surveillance authority, upon request of the market surveillance authority, to eliminate the risks presented by the measuring instruments placed on the market.

**2.4. Obligations of a Distributor**

35. When making the measuring instruments available on the market, a distributor shall act with due care to conform to the requirements of this Regulation.

36. Before making the measuring instruments available on the market the distributor shall verify that the measuring instruments bear the CE conformity marking and the supplementary metrology marking, that they are accompanied by the declaration of conformity and the necessary documentation, the instructions for use, and the information referred to in Paragraphs 20 and 22 of Annex 2 to this Regulation in the official language, and also that the manufacturer has conformed to the requirements referred to in Paragraphs 16 and 17 of this Regulation, in turn, the importer – with the requirements referred to in Paragraph 27 of this Regulation.

37. If the distributor considers or has reason to believe that the measuring instruments are not in conformity with the essential requirements referred to in Annex 2 to this Regulation, it shall not place the measuring instruments on the market and put them into use until the relevant economic operator has brought them into conformity with the essential requirements referred to in Annex 2 to this Regulation. If the measuring instruments present a risk, the distributor shall inform the manufacturer or the importer and the market surveillance authority to that effect.

38. The distributor shall ensure that, while the measuring instruments are under its responsibility, their storage and transport conditions do not jeopardise their conformity with the essential requirements referred to in Annex 2 to this Regulation.

39. The distributor who considers or has reason to believe that the measuring instruments which it has placed on the market or put into use do not conform to the requirements of this Regulation shall ensure that the corrective measures necessary to ensure the conformity of the measuring instruments with the requirements of this Regulation or to withdraw or recall them, if appropriate, are taken. If the measuring instruments present a risk, the distributors shall immediately inform the market surveillance authority thereof, giving details, in particular, of the non-conformities and of any corrective measures taken.

40. The distributor shall, upon request of the market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity of the measuring instrument with the requirements of this Regulation in the official language.

41. The distributor shall cooperate with the market surveillance authority, upon request of the market surveillance authority, to eliminate the risks presented by the measuring instruments made available on the market.

**3. Conformity Assessment Procedures**

42. Conformity assessment of the measuring instrument with the essential requirements shall be carried out by the application, at the choice of the manufacturer, of one of the modules of conformity assessment procedures specified in the law or regulation regarding the metrological requirements for a particular measuring instrument (Annex 1).

43. For ensuring the conformity of the measuring instrument the manufacturer may select any technical solution conforming to the requirements referred to in Annex 2 to this Regulation and the essential requirements laid down in the laws and regulations regarding the metrological requirements for a particular measuring instrument, concurrently also conforming to the requirements of the applicable standards and normative documents.

44. If testing has been carried out in accordance with the requirements of the applicable standards and applicable normative documents, the testing results must attest that the measuring instrument, its type or the measuring instrument and its type conform to the requirements of this Regulation and the laws and regulations regarding the metrological requirements for a particular measuring instrument, and also to the specifications of durability of gas meters, water meters, and thermal energy meters and measuring systems for liquids (other than water).

45. The conformity assessment procedure (Module A2 and Module C2) referred to in Annex 1 to this Regulation may be carried out by a separate in-house body of the manufacturer which does not participate in the design, production, supply, installation, use, or maintenance of the measuring instruments it assesses and constitutes a distinct part of the undertaking, if it conforms to the following requirements:

45.1. the body has been accredited with the national accreditation authority in accordance with the laws and regulations regarding the assessment, accreditation, and supervision of conformity assessment authorities;

45.2. the body and its employees are organisationally identifiable and the body has developed reporting methods which ensure their impartiality;

45.3. neither the body nor its employees are responsible for the design, manufacture, supply, installation, operation, or maintenance of the measuring instruments they assess nor are they engaged in any activities that might conflict with their independence of judgment or integrity in relation to their assessment activities;

45.4. the body supplies its services exclusively to the manufacturer of which it forms a part.

46. Information on accreditation of the body referred to in Paragraph 45 of this Regulation shall be given by the manufacturer of which the body forms a part or by the national accreditation authority to the notifying commission upon request.

47. Conformity assessment of the measuring instruments and their additional devices may be carried out separately if it is provided for by the law or regulation regarding the metrological requirements for a particular measuring instrument.

48. The documents which are related to the conformity assessment procedures referred to in this Chapter shall be prepared in the official language of the country where the relevant conformity assessment procedure will be carried out or in a language accepted by the notified authority.

**4. Technical Documentation**

49. The technical documentation shall include information on the design, manufacture, and operation of the measuring instrument to permit an assessment of its conformity.

50. The technical documentation shall be sufficiently detailed to ensure:

50.1. the metrological characteristics;

50.2. the reproducibility of the metrological performance of the produced measuring instruments when properly adjusted using appropriate intended means;

50.3. the serveability of the measuring instrument.

51. The technical documentation shall include all the necessary information, insofar as relevant for the assessment and identification of the measuring instrument, and also its type:

51.1. a general description of the measuring instrument;

51.2. conceptual designs, manufacturing drawings of the structure and placement plans and diagrams of components;

51.3. manufacturing procedures to ensure consistent production;

51.4. if applicable, descriptions of the electronic devices with drawings, diagrams, traceability diagrams of software information explaining the characteristics and operation of such devices;

51.5. descriptions and explanations necessary for the understanding of the operation of the measuring instrument;

51.6. a list of the applicable standards, and also normative documents applied in full or in part;

51.7. the solutions used and their descriptions to meet the requirements of this Regulation if the applicable standards and normative documents have not been applied;

51.8. results of design calculations and examinations;

51.9. the test results, where necessary, to demonstrate that the measuring instrument and its type:

51.9.1. conform to the requirements of the laws and regulations regarding the metrological requirements for a particular measuring instrument under declared operating conditions and environmental circumstances;

51.9.2. comply with the durability specified in the specifications for gas and water meters, thermal energy meters, and measuring systems for liquids (other than water);

51.10. the EU-type examination certificates or EU design examination certificates containing parts identical to those in the design.

52. The manufacturer shall indicate the location of the seal and marking in the technical documentation.

53. The manufacturer shall indicate the interface and the conditions for compatibility of additional devices, where relevant.

**5. Declaration of Conformity**

54. The declaration of conformity shall state that the conformity of the measuring instrument with the essential requirements referred to in Annex 2 to this Regulation has been proven.

55. The declaration of conformity shall be prepared in accordance with Annex 3 to this Regulation, shall be supplemented with the necessary information arising from the relevant conformity assessment procedure, and shall be continuously updated. The declaration of conformity shall be ensured in the language or languages of such European Union Member State in which the measuring instrument is placed or made available on the market.

56. If several laws and regulations requiring a declaration of conformity apply to the measuring instruments, a single declaration of conformity is drawn up in respect of all the applicable laws and regulations. The relevant laws and regulations and their publication references shall be specified in the declaration of conformity.

57. By drawing up the declaration of conformity, the manufacturer shall assume responsibility for the conformity of the measuring instruments with the requirements referred to in this Regulation.

**6. Marking**

58. The conformity of the measuring instruments with the requirements of this Regulation shall be indicated by the CE conformity marking and the supplementary metrology marking.

59. The CE conformity marking and by analogy the supplementary metrology marking are subject to the general principles laid down in Article 30 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (hereinafter – Regulation No 765/2008).

60. The supplementary metrology marking shall consist of the capital letter “M” and the last two digits of the year of affixing the marking, surrounded by a rectangle. The height of the rectangle shall be equal to the height of the CE conformity marking.

61. The CE conformity marking and the supplementary metrology marking shall be affixed visibly, legibly, and indelibly to each measuring instrument or to its data plate.

62. If the measuring instrument is too small or too sensitive to affix the CE marking and the supplementary metrology marking to it, it shall be indicated on the packaging, if any, and in the accompanying documents provided for in this Regulation and the laws and regulations regarding the metrological requirements for a particular measuring instrument.

63. If the measuring instrument consists of a set of devices, not being additional devices, and operates in conjunction with them, the marking shall be affixed on the main device of the measuring instrument.

64. The CE conformity marking and the supplementary metrology marking shall be affixed to the measuring instruments before placement thereof on the market or during the fabrication process of the measuring instruments, if justified.

65. The supplementary metrology marking shall be placed directly behind the CE conformity marking.

66. The identification number of the notified authority (or authorities) which was involved in the production phase in the conformity assessment procedures of the measuring instruments referred to in Annex 1 to this Regulation shall be placed behind the CE conformity marking and the supplementary metrology marking. The identification number of the notified authority shall be affixed by the authority itself or, under its instructions, by the manufacturer or its authorised representative. The identification number of the notified authority shall be indelible or such which cannot be changed without damaging it.

67. Any other marking, indicating information on special risks or use, may be placed behind the CE conformity marking, the supplementary metrology marking, and the identification number of the notified authority.

**7. Requirements for the Notified Authority**

68. The notified authority shall conform to the following requirements:

68.1. the authority has the status of a legal person and it is operating as a third party which is independent from the performer of economic activity (their association) the measuring instruments of which it is assessing;

68.2. the authority has demonstrated its independence and the absence of any conflict of interest if it is a participant (member) of an association or a foundation related to the design, manufacture, supply, installation, use, or maintenance of the measuring instruments to be assessed;

68.3. the management and employees of the authority responsible for the conformity assessment, are not the designers, manufacturers, suppliers, installers, purchasers, owners, users, or maintainers of the measuring instruments to be assessed, nor the authorised representatives thereof. This shall not preclude them from the use of the assessed measuring instruments that are necessary for the operations of the conformity assessment authority or the use of such measuring instruments for personal purposes;

68.4. the management and employees of the authority responsible for the conformity assessment are not directly involved in the design, manufacture or construction, marketing, installation, use, or maintenance of such measuring instruments, and do not represent the parties engaged in such activities;

68.5. the management and employees of the authority do not engage in any activity (especially consulting) that may conflict with their independence of judgement and integrity in relation to the assessment activities specified for such authority;

68.6. the authority ensures that the activity of its branches and sub-contractors will not affect the confidentiality, objectivity, and impartiality of the conformity assessment;

68.7. the authority and its employees shall carry out the conformity assessment professionally, with integrity, and shall have the technical expertise. The relevant personnel shall be free of any influence (especially financial) in decision-making and conformity assessment and from the influence of such persons or groups of persons who are interested in the result of such activities;

68.8. the authority is capable of carrying out all the conformity assessment tasks assigned to it in Annex 1 to this Regulation and in relation to which it has been notified, regardless of whether such tasks are carried out by the authority itself or on its behalf and under its responsibility;

68.9. according to the conformity assessment procedures to be carried out and the categories of the measuring instruments in relation to which it has been notified, the authority has the following at its disposal:

68.9.1. the necessary employees with technical knowledge and appropriate experience to carry out the necessary conformity assessment activities;

68.9.2. a description of the procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of repeating such procedures. The authority shall have appropriate policy and procedures in place whereby the tasks it carries out as the notified authority are separated from other activities;

68.9.3. procedures drawn up for the performance of activities which take due account of the size of a performer of economic activity, the sector in which it operates, its structure, the degree of complexity of the measuring instrument manufacturing technology in question and the mass or serial nature of the production process;

68.10. the authority has the means necessary to perform the technical and administrative tasks in relation to the conformity assessment activities in an appropriate manner and has access to all the necessary equipment and facilities;

68.11. the employees responsible for the carrying out of the conformity assessment activities have:

68.11.1. been provided with technical and vocational training covering the relevant conformity assessment activities;

68.11.2. the knowledge and corresponding mandate to fulfil the requirements applying to the conformity assessment activities to be carried out;

68.11.3. the knowledge and understanding of the essential requirements referred to in Annex 2 to this Regulation and the requirements laid down in the laws and regulations regarding the metrological requirements for a particular measuring instrument, the applicable standards, and the normative documents;

68.11.4. the necessary knowledge to draw up certificates, documentation, and conformity assessment reports;

68.12. the objectivity of the authority, its management, and employees is ensured upon carrying out the conformity assessment activities;

68.13. the remuneration of the management and employees of the authority who are carrying out conformity assessment activities does not depend on the number of assessments carried out or their results;

68.14. the authority has insured civil liability in respect of the activities which it is entitled to carry out;

68.15. the employees of the authority comply with professional confidentiality with regard to all the information obtained upon carrying out the conformity assessment activities, except for the information which is provided to the market surveillance authorities;

68.16. the authority participates in standardisation activities and in the work groups of the notified authorities organised by the European Commission regarding measuring instruments or ensures that the information on the abovementioned activities is available to its employees. The authority shall use the decisions and documents prepared by the work group of the notified authorities as the guidelines in its work.

69. If the notified authority demonstrates its conformity with the criteria laid down in the relevant applicable standards or parts thereof the references to which have been published in the Official Journal of the European Union, it shall be presumed to conform to the requirements referred to in Paragraph 68 of this Regulation insofar as the applicable standards cover such requirements.

70. If the notified authority enters into a contract with a sub-contractor for the carrying out of specific conformity assessment tasks or transfers the carrying out of such tasks to a branch, the authority shall ensure that the sub-contractor and the branch conform to the requirements laid down in Paragraph 68 of this Regulation and shall inform the notification commission thereof which is established in accordance with the laws and regulations regarding the procedures for establishing a notification commission, and also the procedures for taking a decision by the commission and notifying the European Commission of the conformity assessment authorities which carry out conformity assessment in the regulated sphere. The notified authority shall take full responsibility for the operation of the sub-contractor and the branch.

71. The notified authority shall transfer the carrying out of a particular conformity assessment activity to the sub-contractor or the branch only with the agreement of the client.

72. The notified authority shall keep the documents concerning the assessment of the competence of the sub-contractor or the branch and the conformity assessment activities carried out by them and shall ensure the availability of such documents to the notification commission.

73. The notified authority shall carry out conformity assessment in accordance with the conformity assessment procedures referred to in Annex 1 of this Regulation.

74. The notified authority shall carry out conformity assessment in a proportionate manner, avoiding unnecessary burdens for economic operators, taking into account the sector in which it operates, the organisational structure, the degree of complexity of the manufacturing technology of the relevant measuring instruments and the mass or serial nature of the manufacturing process, however, shall respect the degree of rigour and the level of protection required for the conformity of the measuring instrument with the requirements of this Regulation.

75. If the notified authority establishes that the essential requirements laid down in Annex 2 of this Regulation and the requirements laid down in the laws and regulations regarding the metrological requirements for a particular measuring instrument or the basic requirements of the corresponding applicable standards, normative documents or referred to in other technical specifications have not been met by the manufacturer, it shall require the manufacturer to take appropriate measures to eliminate such non-conformities and shall not issue a certificate.

76. If, in the course of monitoring the conformity of the measuring instruments with the requirements of this Regulation following the issue of a relevant certificate, the notified authority establishes that the measuring instruments no longer conform to the requirements of this Regulation and the laws and regulations regarding the metrological requirements for a particular measuring instrument, it shall require the manufacturer to take appropriate measures to eliminate the non-conformities and shall suspend or withdraw the certificate if health, safety, and interests of customers are endangered.

77. If corrective activities are not carried out or do not have the required effect, the notified authority shall restrict, suspend, or withdraw the certificate, as appropriate.

78. The notified authority shall inform the Ministry of Economics of the following:

78.1. any refusal, restriction, suspension, or withdrawal of a certificate;

78.2. any circumstances affecting the scope of or the conditions for notification;

78.3. any request for information received from market surveillance authorities in relation to conformity assessment activities;

78.4. conformity assessment activities carried out within the scope of their notification and any other activity carried out, including cross-border activities and subcontracting (upon request).

79. The notified authority shall provide the other notified authorities that carry out similar conformity assessment activities covering the same measuring instruments with relevant information on issues relating to negative and, upon request, positive conformity assessment results.

**8. Market Surveillance**

80. Market surveillance of the measuring instruments shall be performed by the Consumer Rights Protection Centre which is to be considered as the market surveillance authority within the meaning of this Regulation.

81. The requirements laid down in Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to the market surveillance of the measuring instruments.

82. The manufacturer and the importer shall, upon request of the market surveillance authority, provide translation of the technical documentation or its parts in the official language. The market surveillance authority, upon requesting to submit the technical documentation, and also translation of its parts, shall determine a submission deadline of 30 days, unless it is necessary to specify a shorter time period to detect a serious and immediate risk.

83. The notified authorities shall, upon request of the market surveillance authority, provide information on certificates which that authority has issued, withdrawn, or refused, including shall provide test reports and technical documentation.

84. The relevant economic operator has the obligation to eliminate the non-conformities within a commensurate and objectively necessary period of time stipulated by the market surveillance authority if the market surveillance authority establishes any of the following non-conformities of administrative nature:

84.1. the CE conformity marking and the supplementary metrology marking do not conform to the requirements referred to in Chapter 6 of this Regulation;

84.2. the CE conformity marking and the supplementary metrology marking have not been affixed;

84.3. the marking referred to in Paragraphs 17 and 27 of this Regulation has not been affixed or has been affixed inappropriately;

84.4. the identification number of the notified authority, where that authority was involved in the conformity assessment procedure of the production phase of the measuring instruments, has not been affixed or has been affixed in violation of the requirements referred to in Chapter 6 of this Regulation;

84.5. the declaration of conformity has not been appended, has not been drawn up, or has not been drawn up correctly;

84.6. technical documentation is either not available or not complete;

84.7. any other administrative requirement referred to in Sub-chapters 2.1 and 2.3 of this Regulation is not fulfilled.

85. If the market surveillance authority establishes that the measuring instrument presents a risk to the society, the authority shall carry out an assessment of the relevant measuring instrument, taking into account the abovementioned risk and covering all the requirements laid down in this Regulation. Economic operators have the obligation to cooperate with the market surveillance authority in the abovementioned assessment.

86. Upon instructions of the market surveillance authority and within the time period stipulated thereby which is commensurate with the risk caused by the relevant non-conformity, an economic operator has the obligation to carry out all the necessary corrective activities to ensure the conformity of the measuring instrument with the requirements of this Regulation or, if necessary, to withdraw or recall it from the market, and also to inform the relevant notified authority if, upon carrying out the assessment of the measuring instrument referred to in Paragraph 85 of this Regulation, the market surveillance authority establishes one of the following situations:

86.1. the measuring instrument does not conform to the requirements laid down in this Regulation and in the laws and regulations regarding the metrological requirements for a particular measuring instrument;

86.2. the measuring instrument conforms to the requirements laid down in this Regulation and in the laws and regulations regarding the metrological requirements for a particular measuring instrument, however, still presents a risk to the society.

87. If the relevant economic operator does not eliminate the non-conformity referred to in Paragraph 84 of this Regulation within the time period stipulated by the market surveillance authority or does not fulfil the obligations referred to in Paragraph 86 of this Regulation, the market surveillance authority shall, in accordance with the laws and regulations regarding the uniformity of measurements, take a decision to prohibit the placing or making available of the measuring instrument on the market or, if necessary, to withdraw or recall it from the market.

**9. Cooperation with the European Commission and the European Union Member States**

**9.1. Measuring Instruments Non-conforming to the Requirements of this Regulation**

88. If the market surveillance authority has a reason to believe that the measuring instrument in respect of which the assessment referred to in Paragraph 85 of this Regulation has been carried out and in respect of which it has been established that it does not conform to the requirements laid down in this Regulation and in the laws and regulations regarding the metrological requirements for a particular measuring instrument is made available also in other European Union Member States, the market surveillance authority shall, after obtaining all the necessary information, immediately inform the European Commission and other European Union Member States of the results of the assessment carried out and the measures stipulated by the market surveillance authority to be carried out, indicating all the necessary information, including:

88.1. the information necessary for identification of the measuring instrument;

88.2. the details on the origin of the measuring instrument;

88.3. the nature of the non-conformity and the risk presented;

88.4. the information on the nature and duration of the stipulated measures to be taken and also the explanations and arguments provided by the economic operator;

88.5. the information as to whether the measuring instrument does not conform to the requirements of this Regulation and the laws and regulations regarding the metrological requirements for a particular measuring instrument, or the requirements of the applicable standards and normative documents.

89. If, within three months after receipt of the information referred to in Paragraph 88 of this Regulation, no objection has been raised by either a European Union Member State or the European Commission in respect of the measures stipulated by the market surveillance authority to be taken, they shall be deemed to be justified.

90. If the European Commission takes a decision that the measures stipulated by the market surveillance authority are unjustified, they shall be revoked.

91. If the market surveillance authority receives the information referred to in Paragraph 88 of this Regulation from another European Union Member State, it shall immediately inform the European Commission and other European Union Member States of the measures taken and shall provide the information at the disposal thereof on the non-conformity of the relevant measuring instrument, and shall also inform of its objections if it does not agree with the measures to be taken which are stipulated by another market surveillance authority of the European Union.

**9.2. Measuring Instruments Non-conforming to the Requirements of this Regulation and Presenting a Risk**

92. If the market surveillance authority has a reason to believe that the measuring instrument in respect of which the assessment referred to in Paragraph 85 of this Regulation has been carried out and in respect of which it has been established that it conforms to the requirements of this Regulation and the laws and regulations regarding the metrological requirements for a particular measuring instrument, however, presents a risk to the society, the market surveillance authority shall, after obtaining all the necessary information, immediately inform the European Commission and other European Union Member States, indicating all the information available, including:

92.1. the information necessary for the identification of the measuring instrument;

92.2. the details on the origin of the measuring instrument;

92.3. the nature of the non-conformity and the risk presented;

92.4. the information on the nature and duration of the measures to be taken and also the explanations and arguments provided by the economic operator.

93. If, upon receipt of the information referred to in Paragraph 92 of this Regulation, the European Commission takes a decision that the measures stipulated by the market surveillance authority are unjustified, they shall be revoked.

**10. Closing Provisions**

94. Cabinet Regulation No. 673 of 22 August 2006, Regulations Regarding the Metrological Requirements for Measuring Instruments (*Latvijas Vēstnesis*, 2006, No. 137; 2007, No. 72), is repealed.

95. The measuring instruments which have been placed on the market until the day of coming into force of this Regulation may be made available on the market and put into use if they conform to the requirements of Cabinet Regulation No. 673 of 22 August 2006, Regulations Regarding the Metrological Requirements for Measuring Instruments.

96. The certificates which have been issued in accordance with Cabinet Regulation No. 673 of 22 August 2006, Regulations Regarding the Metrological Requirements for Measuring Instruments, shall be valid until expiry of the time period indicated therein.

97. The Regulation shall come into force on 20 April 2016.

**Informative Reference to the European Union Directives**

The Regulation contains legal norms arising from:

1) Directive 2014/32/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;

2) Commission Delegated Directive (EU) 2015/13 of 31 October 2014 amending Annex III to Directive 2014/32/EU of the European Parliament and of the Council, as regards the flowrate range of water meters.

Prime Minister Māris Kučinskis

Deputy Prime Minister, Minister for Economics Arvils Ašeradens

**Annex 1**

Cabinet Regulation No. 212

12 April 2016

**Conformity Assessment Procedures**

**I. Conformity Based on Internal Production Control (Module A)**

1. Conformity based on internal production control is the conformity assessment procedure whereby the manufacturer fulfils the requirements laid down in this Regulation and in the laws and regulations regarding the requirements for particular measuring instruments (hereinafter – the relevant laws and regulations) and declares that the measuring instrument conforms to the abovementioned requirements.

2. The manufacturer shall fulfil the following obligations:

2.1. establish the technical documentation. The technical documentation shall make it possible to assess the conformity of the measuring instruments with the requirements of this Regulation and it shall include an analysis and assessment of the risk. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, and operation of the measuring instruments;

2.2. take all measures necessary to ensure the conformity of the manufactured measuring instruments with the requirements of this Regulation and the relevant laws and regulations;

2.3. affix the CE conformity marking and the supplementary metrology marking to each individual measuring instrument which conforms to the requirements of this Regulation;

2.4. draw up a declaration of conformity for each individual type of the measuring instrument and ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration shall identify the relevant measuring instrument. A copy of the declaration shall be supplied with each measuring instrument that is placed on the market. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

3. The authorised representative of the manufacturer may fulfil the obligations referred to in Sub-paragraphs 2.3 and 2.4 of this Annex provided that they are specified in the mandate.

**II. Conformity Based on Internal Production Control and Measuring Instrument Checks at Random Intervals (Module A2)**

4. Conformity based on internal production control plus measuring instrument checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the requirements laid down in this Regulation and in the relevant laws and regulations and declares that the measuring instrument conforms to the abovementioned requirements.

5. The manufacturer shall fulfil the following obligations:

5.1. establish the technical documentation. The technical documentation shall make it possible to assess the conformity of the measuring instrument with the requirements of this Regulation and it shall include an analysis and assessment of the risk. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, and operation of the measuring instruments;

5.2. take all measures necessary to ensure the conformity of the manufactured measuring instruments with the requirements of this Regulation and the relevant laws and regulations;

5.3. affix the CE conformity marking and the supplementary metrology marking, and also the identification number of the notified authority, if it carries out the procedure referred to in Paragraph 6 of this Annex, to each individual measuring instrument which conforms to the requirements of this Regulation;

5.4. draw up a declaration of conformity for each individual type of the measuring instrument and ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration shall identify the relevant measuring instrument. A copy of the declaration shall be supplied with each measuring instrument that is placed on the market. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

6. For the carrying out of conformity assessment procedure, the manufacturer shall choose one notified authority or the body referred to in Paragraph 45 of this Regulation which shall fulfil the following obligations:

6.1. taking into account the technological complexity of the measuring instruments and the quantity of production, determine the frequency of routine checks and carry out or ensure that product checks are carried out in order to verify the quality of the internal checks of the measuring instruments;

6.2. prior to placing of the product on the market, samples of the relevant quantity of the final product shall be examined and tested in accordance with the requirements of the parts of the applicable standards and the normative documents or equivalent tests set out in other relevant technical specifications shall be carried out to verify the conformity of the measuring instrument with the type described in the EU-type examination certificate and the requirements of this Regulation;

6.3. if relevant applicable standards or normative documents are not available, the decision on tests to be carried out shall be taken;

6.4. if the product does not conform to the requirements of this Regulation according to the test results, appropriate measures shall be taken.

7. The authorised representative of the manufacturer may fulfil the obligations referred to in Sub-paragraphs 5.3 and 5.4 of this Annex provided that they are specified in the mandate.

**III. EU-type Examination (Module B)**

8. EU-type examination is a conformity assessment procedure that is the part of a conformity assessment procedure in which a notified authority examines the technical design of the measuring instrument and attests that the technical design meets the requirements laid down in the relevant laws and regulations.

9. EU-type examination shall be carried out, using one of the following methods:

9.1. examination of a specimen of the complete envisaged measuring instrument;

9.2. assessment of the adequacy of the technical design of the measuring instrument through examination of the technical documentation and supporting evidence referred to in Paragraph 10 of this Annex, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the measuring instrument (combination of production type and design type);

9.3. assessment of the adequacy of the technical design of the measuring instrument through examination of the technical documentation and supporting evidence referred to in Paragraph 10 of this Annex, without examination of a specimen (design type). The notified authority shall take a decision on the most appropriate method and the specimens required.

10. The manufacturer shall submit an application for EU-type examination with a single notified authority of its choice. The application shall include the following information and documentation:

10.1. the name and address of the manufacturer and, if the application is submitted by the authorised representative, his or her name and address as well;

10.2. a written declaration that the same application has not been submitted to any other notified authority;

10.3. the technical documentation that makes it possible to assess the conformity of the measuring instruments with the requirements of this Regulation and which includes an analysis and assessment of the risk. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, and operation of the measuring instruments;

10.4. the application shall contain at least the following elements, wherever applicable:

10.4.1. the specimens of the measuring instrument envisaged or its parts requested by the notified authority;

10.4.2. the evidence for the adequacy of the technical design solution mentioning any documents that have been used, in particular if the relevant applicable standards or normative documents have not been applied in full and, where necessary, the results of tests carried out by the laboratory of the manufacturer or by another laboratory on his behalf and under his responsibility shall be submitted.

11. The notified authority shall fulfil the following obligations:

11.1. according to the method referred to in Sub-paragraph 9.1 of this Annex:

11.1.1. examine the technical documentation and supporting evidence;

11.1.2. verify that the specimen has been manufactured in accordance with the technical documentation and identify the elements which have been designed in accordance with the requirements of the applicable standards or normative documents and also the elements which have been designed in accordance with other relevant technical specifications;

11.1.3. carry out appropriate examinations and tests or have them carried out, to assess whether the manufacturer has applied the solutions in accordance with the requirements of the applicable standards or the applicable normative documents;

11.1.4. carry out appropriate examinations and tests or have them carried out, to assess whether, if the solutions specified in the relevant applicable standards or normative documents have not been applied, the technical solutions chosen by the manufacturer meet the requirements laid down in the relevant laws and regulations;

11.1.5. agree with the applicant on the location where the examinations and tests will be carried out;

11.2. in accordance with the method referred to in Sub-paragraph 9.2 of this Annex, examine the technical documentation and supporting evidence to assess the conformity of the parts of the measuring instrument with the technical design;

11.3. in accordance with the method referred to in Sub-paragraph 9.3 of this Annex, examine the technical documentation to ascertain that the manufacturer has adequate resources for ensuring systematic manufacture.

12. The notified authority shall draw up an assessment report that records the activities undertaken in accordance with Paragraph 11 of this Annex and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified authority shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

13. If the type meets the requirements of this Regulation which apply to the particular measuring instruments, the notified authority shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions for the validity of the certificate, if any, and the necessary data for identification of the approved type.

14. 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 measuring instruments with the examined type to be assessed and to allow for in-service control.

15. The certificate and annexes shall include all the necessary information to assess the conformity of the measuring instrument with the approved type:

15.1. the metrological characteristics of the type of the measuring instrument;

15.2. the measures required for ensuring the integrity of the measuring instrument (for example, sealing, identification of software);

15.3. information on other elements necessary for the identification of the measuring instrument and to check their visual conformity;

15.4. any specific information necessary to verify the characteristics of the manufactured measuring instrument;

15.5. information to ensure the compatibility with additional devices or other measuring instruments, if any.

16. The EU-type examination certificate shall have a validity of 10 years and it may be renewed for subsequent periods of 10 years.

17. If the type does not satisfy the requirements of this Regulation which apply to the particular measuring instruments, the notified authority shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for such refusal.

18. The notified authority shall keep itself apprised of any changes in the generally acknowledged standards which indicate that the approved type may no longer conform to the requirements of this Regulation and shall determine whether such changes require further investigation. If so, the notified authority shall inform the manufacturer accordingly.

19. The manufacturer shall inform the notified authority 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 measuring instruments with the essential requirements of this Regulation or the conditions for the validity of the abovementioned certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

20. The notified authority shall, once a quarter or upon request, inform the Ministry of Economics concerning the EU-type examination certificates and any additions thereto which it has issued or withdrawn and shall submit the list of certificates and additions thereto in which the refused certificates and the certificates the operation of which has been suspended or otherwise restricted are indicated.

21. Upon request, the European Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified authority. The notified authority shall keep a copy of the EU-type examination certificate, its annexes and additions, the technical documentation, and the documentation submitted by the manufacturer until expiry of the term of validity of the abovementioned certificate.

22. The manufacturer shall ensure the availability of a copy of the EU-type examination certificate, its annexes and additions, and the technical documentation to the market surveillance authority for 10 years after the measuring instruments have been placed on the market.

23. The authorised representative of the manufacturer may submit the application referred to in Paragraph 10 of this Annex and fulfil the obligations referred to in Paragraphs 19 and 22 of this Annex provided that they are specified in the mandate.

**IV. Conformity to Type Based on Internal Production Control (Module C)**

24. Conformity to type based on internal production control is a conformity assessment procedure whereby the manufacturer meets the requirements laid down in the relevant laws and regulations, ensures and declares that the measuring instruments concerned conform to the type described in the EU-type examination certificate and the requirements of this Regulation.

25. The manufacturer shall fulfil the following obligations:

25.1. take all measures necessary to ensure the conformity of the manufactured measuring instruments with the type described in the EU-type examination certificate and the requirements of this Regulation;

25.2. affix the CE conformity marking and the supplementary metrology marking to each individual measuring instrument that conforms to the type referred to in EU-type examination certificate and the requirements of this Regulation;

25.3. draw up a declaration of conformity for each individual type of the measuring instrument and ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration shall identify the relevant measuring instrument. A copy of the declaration shall be supplied with each measuring instrument that is placed on the market. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

26. The authorised representative of the manufacturer may fulfil the obligations referred to in Sub-paragraphs 25.2 and 25.3 of this Annex provided that they are specified in the mandate.

**V. Conformity to Type Based on Internal Production Control and Measuring Instrument Checks at Random Intervals (Module C2)**

27. Conformity to type based on internal production control plus measuring instrument checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer meets the requirements laid down in the relevant laws and regulations, and also ensures and declares that the measuring instrument concerned conforms to the type described in the EU-type examination certificate and to the requirements of this Regulation.

28. The manufacturer shall fulfil the following obligations:

28.1. take all measures necessary to ensure the conformity of the manufactured measuring instruments with the type described in the EU-type examination certificate and the requirements of this Regulation;

28.2. affix the CE conformity marking and the supplementary metrology marking, and also the identification number of the notified authority, if it carries out the procedure referred to in Paragraph 29 of this Annex, to each individual measuring instrument that conforms to the type described in the EU-type examination certificate and to the requirements of this Regulation;

28.3. draw up a declaration of conformity for each individual type of the measuring instrument and ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration shall identify the relevant measuring instrument. A copy of the declaration shall be supplied with each measuring instrument that is placed on the market. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

29. For the carrying out of conformity assessment procedure, the manufacturer shall choose one notified authority or the body referred to in Paragraph 45 of this Regulation which shall fulfil the following obligations:

29.1. taking into account the technological complexity of the measuring instruments and the quantity of production, determine the frequency of routine checks and carry out or ensure that product checks are carried out in order to verify the quality of the internal checks of the measuring instruments;

29.2. prior to placing of the product on the market, samples of the relevant quantity of the final product shall be examined and tested in accordance with the requirements of the parts of the applicable standards and the normative documents or equivalent tests set out in other relevant technical specifications shall be carried out to verify the conformity of the measuring instrument with the type described in the EU-type examination certificate and the requirements of this Regulation;

29.3. if the product does not conform to the requirements of this Regulation according to the test results, appropriate measures shall be taken;

29.4. sampling procedure shall be applied to determine whether the relevant manufacturing process of the measuring instrument is occurring in acceptable quality and the conformity of the measuring instruments with the requirements of this Regulation shall be ensured.

30. The authorised representative of the manufacturer may fulfil the obligations referred to in Sub-paragraphs 28.2 and 28.3 of this Annex provided that they are specified in the mandate.

**VI. Conformity to Type Based on Quality Assurance of the Production Process (Module D)**

31. 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 Paragraphs 32, 42, 43, and 44 of this Annex and also ensures and declares on his sole responsibility that the measuring instruments concerned conform to the type described in the EU-type examination certificate and the requirements of this Regulation that apply to them.

32. The manufacturer shall operate an approved quality assurance system for production, final product inspection, and testing of the measuring instruments concerned as specified in Paragraph 33 of this Annex, and the manufacturer shall be subject to surveillance as specified in Paragraphs 42, 43, and 44 of this Annex.

33. The manufacturer shall submit an application for the assessment of the quality assurance system for the measuring instruments concerned with one notified authority of its choice. The application shall include the following:

33.1. the name and address of the manufacturer and, if the application is submitted by the authorised representative, the name and address of such representative;

33.2. a written declaration that the same application has not been submitted to any other notified authority;

33.3. all relevant information for the measuring instrument category envisaged;

33.4. the documentation concerning the quality assurance system;

33.5. the technical documentation of the approved type and a copy of the EU-type examination certificate.

34. The quality assurance system shall ensure the conformity of the measuring instruments with the type described in the EU-type examination certificate and the requirements of this Regulation.

35. The manufacturer shall document all the adopted elements, requirements, and conditions of the quality assurance system in a systematic and orderly manner in the form of written policies, procedures, and instructions. The quality assurance system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals, and records and it shall contain an adequately described information:

35.1. the quality assurance objectives and the organisational structure, responsibilities, and powers of the management with regard to product quality;

35.2. the manufacturing, quality control, and quality assurance techniques, processes, and systematic actions that will be used;

35.3. the examinations and tests that will be carried out before, during, and after manufacture, and also the frequency with which they will be carried out;

35.4. the quality records, such as inspection reports and test data, calibration data, and also qualification reports on the personnel concerned;

35.5. the means of monitoring the achievement of the required product quality and the effective operation of the quality assurance system.

36. The notified authority shall assess the quality assurance system to determine whether it meets the requirements of Paragraphs 33 and 35 of this Annex. Such elements of the quality assurance system that comply with the corresponding specifications of the applicable standard shall conform to the abovementioned requirements.

37. In addition to experience in quality assurance systems, the auditing team shall have at least one member with experience of assessment in the relevant measuring instrument field and product technology concerned, and knowledge of the requirements of this Regulation and the relevant law or regulation.

38. The audit shall include an assessment visit to the premises of the manufacturer. The auditing team shall review the technical documentation referred to in Sub-paragraph 33.5 of this Annex in order to verify the ability of the manufacturer to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring the conformity of the measuring instrument with the abovementioned requirements. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

39. The manufacturer shall undertake to fulfil the obligations arising out of the quality assurance system as approved and to maintain it so that it remains adequate and efficient.

40. The manufacturer shall continuously keep the notified authority that has approved the quality assurance system informed of any intended changes of the quality assurance system.

41. The notified authority shall assess any proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in Paragraphs 33 and 35 of this Annex or whether a re-assessment is necessary. The notified authority shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment.

42. The purpose of surveillance of the notified authority is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality assurance system.

43. The manufacturer shall, for assessment purposes, allow the representatives of the notified authority access to the manufacture, inspection, testing, and storage sites, and shall provide it with all necessary information, in particular:

43.1. the quality assurance system documentation;

43.2. the quality records, such as inspection reports and test data, calibration data, and qualification reports on the personnel concerned.

44. The notified authority shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality assurance system and shall provide the manufacturer with an audit report. Representatives of the notified authority may pay unexpected visits to the manufacturer. During such visits the notified authority may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality assurance system is functioning correctly. The notified authority shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

45. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking, and also, under the responsibility of the notified authority referred to in Paragraph 33 of this Annex, the identification number of the latter to each individual measuring instrument that conforms to the type described in the EU-type examination certificate and the requirements of this Regulation.

46. The manufacturer shall draw up a written declaration of conformity for each model of the measuring instrument and shall ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration of conformity shall identify the measuring instrument model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the responsible authorities upon request. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

47. The manufacturer shall, for a period ending 10 years after the measuring instrument has been placed on the market, make available information to the market surveillance authority on the assessment of the quality assurance system referred to in Paragraph 33 of this Annex, the information relating to the changes made in the quality assurance system and approved, and also information on the decisions of and reports from the notified authorities in relation to the audits which have been carried out and apply to the quality assurance system of the manufacturer.

48. The notified authority shall, once a quarter or upon request, inform the Ministry of Economics concerning quality assurance system approvals issued or withdrawn and shall submit the list of quality assurance system approvals in which the refused approvals and the approvals the operation of which has been suspended or otherwise restricted are indicated.

49. The authorised representative of the manufacturer may fulfil the obligations of the manufacturer referred to in Paragraphs 33, 40, 41, 45, 46, and 47 of this Annex, on its behalf and under its responsibility, provided that they are specified in the mandate.

**VII. Conformity Based on Quality Assurance of the Production Process (Module D1)**

50. Quality assurance of the production process is a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in Paragraphs 40, 51, 53, and 54 of this Annex and ensures and declares on his sole responsibility that the measuring instruments conform to the requirements of this Regulation and the relevant law or regulation that applies to them.

51. The manufacturer shall draw up the technical documentation that makes it possible to assess the conformity of the measuring instruments with the requirements of this Regulation and the relevant law or regulation, and it shall include an analysis and assessment of the risk. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, and operation of the measuring instruments.

52. The manufacturer shall ensure the availability of the technical documentation to the market surveillance authority for 10 years after the measuring instruments have been placed on the market.

53. The manufacturer shall operate an approved quality assurance system for production, final product inspection, and testing of the measuring instruments concerned as specified in Paragraph 54 of this Annex, and the manufacturer shall be subject to surveillance as specified in Paragraphs 63, 64, and 65 of this Annex.

54. The manufacturer shall submit an application for the assessment of the quality assurance system for the measuring instruments concerned with one notified authority of its choice. The application shall include the following:

54.1. the name and address of the manufacturer and, if the application is submitted by the authorised representative, the name and address of such representative;

54.2. a written declaration that the same application has not been submitted to any other notified authority;

54.3. all relevant information for the measuring instrument category envisaged;

54.4. the documentation concerning the quality assurance system;

54.5. the technical documentation referred to in Paragraph 51 of this Annex.

55. The quality assurance system shall ensure the conformity of the measuring instruments with the requirements of this Regulation and the relevant law or regulation.

56. All the elements, requirements, and conditions of the quality assurance system adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures, and instructions. The quality assurance system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals, and records and it shall contain the following adequately described information:

56.1. the quality assurance objectives and the organisational structure, responsibilities, and powers of the management with regard to product quality;

56.2. the manufacturing, quality control, and quality assurance techniques, processes, and systematic actions that will be used;

56.3. the examinations and tests that will be carried out before, during, and after manufacture, and also the frequency with which they will be carried out;

56.4. the quality records, such as inspection reports and test data, calibration data, and also qualification reports on the personnel concerned;

56.5. the means of monitoring the achievement of the required product quality and the effective operation of the quality assurance system.

57. The notified authority shall assess the quality assurance system to determine whether it meets the requirements of Paragraphs 55 and 56 of this Annex. Such elements of the quality assurance system that comply with the corresponding specifications of the applicable standard shall conform to the abovementioned requirements.

58. In addition to experience in quality assurance systems, the auditing team shall have at least one member with experience of assessment in the relevant measuring instrument field and product technology concerned, and knowledge of the requirements of this Regulation and the relevant law or regulation.

59. The audit shall include an assessment visit to the premises of the manufacturer. The auditing team shall review the technical documentation referred to in Paragraph 51 of this Annex, to verify the ability of the manufacturer to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring the conformity of the measuring instrument with the abovementioned requirements. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

60. The manufacturer shall undertake to fulfil the obligations arising out of the quality assurance system as approved and to maintain it so that its operation remains adequate and efficient.

61. The manufacturer shall continuously keep the notified authority that has approved the quality assurance system informed of any intended changes of the quality assurance system.

62. The notified authority shall assess any proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in Paragraphs 55 and 56 of this Annex or whether a re-assessment is necessary. The notified authority shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment.

63. The purpose of surveillance of the notified authority is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality assurance system.

64. The manufacturer shall, for assessment purposes, allow the representatives of the notified authority access to the manufacture, inspection, testing, and storage sites, and shall provide it with all necessary information, in particular:

64.1. the quality assurance system documentation;

64.2. the technical documentation referred to in Paragraph 51 of this Annex;

64.3. the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

65. The notified authority shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality assurance system and shall provide the manufacturer with an audit report. Representatives of the notified authority may pay unexpected visits to the manufacturer. During such visits the notified authority may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality assurance system is functioning correctly. The notified authority shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

66. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking, and also, under the responsibility of the notified authority referred to in Paragraph 54 of this Annex, the identification number of the latter to each individual measuring instrument which conforms to the requirements of this Regulation.

67. The manufacturer shall draw up a written declaration of conformity for each model of the measuring instrument and shall ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration of conformity shall identify the measuring instrument model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the responsible authorities upon request. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

68. The manufacturer shall, for a period ending 10 years after the measuring instrument has been placed on the market, make available information to the market surveillance authority on the assessment of the quality assurance system referred to in Paragraph 54 of this Annex, the information relating to the changes made in the quality assurance system and approved, and also information on the decisions of and reports from the notified authorities in relation to the audits which have been carried out and apply to the quality assurance system of the manufacturer.

69. The notified authority shall, once a quarter or upon request, inform the Ministry of Economics concerning quality assurance system approvals issued or withdrawn and shall submit the list of quality assurance system approvals in which the refused approvals and the approvals the operation of which has been suspended or otherwise restricted are indicated.

70. The authorised representative of the manufacturer may fulfil the obligations of the manufacturer referred to in Paragraphs 52, 54, 61, 66, 67, and 68 of this Annex, on his behalf and under his responsibility, provided that they are specified in the mandate.

**VIII. Conformity to Type Based on Quality Assurance of the Final Product (Module E)**

71. Conformity to type based on quality assurance of the final product is a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex in relation to the manufacture of the measuring instruments, and declares on his sole responsibility that the measuring instruments conform to the type described in the EU-type examination certificate and also the requirements of this Regulation, and the applicable law or regulation that apply to them.

72. The manufacturer shall operate an approved quality assurance system for production, final product inspection, and testing of the measuring instruments concerned as specified in Paragraphs 73, 74, 75, and 76 of this Annex, and the manufacturer shall be subject to surveillance as specified in Paragraphs 82, 83, and 84 of this Annex.

73. The manufacturer shall submit an application for the assessment of the quality assurance system for the measuring instruments concerned with one notified authority of its choice. The application shall include the following:

73.1. the name and address of the manufacturer and, if the application is submitted by the authorised representative, the name and address of such representative;

73.2. a written declaration that the same application has not been submitted to any other notified authority;

73.3. all relevant information for the measuring instrument category envisaged;

73.4. the documentation concerning the quality assurance system;

73.5. the technical documentation of the approved type and a copy of the EU-type examination certificate.

74. The quality assurance system shall ensure the conformity of the measuring instruments with the type described in the EU-type examination certificate and the requirements of this Regulation.

75. All the elements, requirements, and conditions of the quality assurance system adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures, and instructions. The quality assurance system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals, and records and it shall contain the following adequately described information:

75.1. the quality assurance objectives and the organisational structure, responsibilities, and powers of the management with regard to product quality;

75.2. the examinations and tests that will be carried out after manufacture;

75.3. the quality records, such as inspection reports and test data, calibration data, and also qualification reports on the personnel concerned;

75.4. the means of monitoring the achievement of the required product quality and the effective operation of the quality assurance system.

76. The notified authority shall assess the quality assurance system to determine whether it meets the requirements of Paragraphs 74 and 75 of this Annex. Such elements of the quality assurance system that comply with the corresponding specifications of the applicable standard shall conform to the abovementioned requirements.

77. In addition to experience in quality assurance systems, the auditing team shall have at least one member with experience of assessment in the relevant measuring instrument field and product technology concerned, and knowledge of the requirements of this Regulation and the relevant law or regulation.

78. The audit shall include an assessment visit to the premises of the manufacturer. The auditing team shall review the technical documentation referred to in Sub-paragraph 73.5 of this Annex, to verify the ability of the manufacturer to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring the conformity of the measuring instrument with the abovementioned requirements. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

79. The manufacturer shall undertake to fulfil the obligations arising out of the quality assurance system as approved and to maintain it so that its operation remains adequate and efficient.

80. The manufacturer shall continuously keep the notified authority that has approved the quality assurance system informed of any intended changes of the quality assurance system.

81. The notified authority shall assess any proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in Paragraphs 72 and 73 of this Annex or whether a re-assessment is necessary. The notified authority shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment.

82. The purpose of surveillance of the notified authority is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality assurance system.

83. The manufacturer shall, for assessment purposes, allow the representatives of the notified authority access to the manufacture, inspection, testing, and storage sites, and shall provide it with all necessary information, in particular:

83.1. the quality assurance system documentation;

83.2. the quality records, such as inspection reports and test data, calibration data, and qualification reports on the personnel concerned.

84. The notified authority shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality assurance system and shall provide the manufacturer with an audit report. Representatives of the notified authority may pay unexpected visits to the manufacturer. During such visits the notified authority may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality assurance system is functioning correctly. The notified authority shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

85. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking, and also, under the responsibility of the notified authority referred to in Paragraph 54 of this Annex, the identification number of the latter to each individual measuring instrument that conforms to the type described in the EU-type examination certificate and the requirements of this Regulation.

86. The manufacturer shall draw up a written declaration of conformity for each model of the measuring instrument and shall ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration of conformity shall identify the measuring instrument model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the responsible authorities upon request. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

87. The manufacturer shall, for a period ending 10 years after the measuring instrument has been placed on the market, make available information to the market surveillance authority on the assessment of the quality assurance system referred to in Paragraph 73 of this Annex, the information relating to the changes made in the quality assurance system and approved, and also information on the decisions of and reports from the notified authorities in relation to the audits which have been carried out and apply to the quality assurance system of the manufacturer.

88. The notified authority shall, once a quarter or upon request, inform the Ministry of Economics concerning quality assurance system approvals issued or withdrawn and shall submit the list of quality assurance system approvals in which the refused approvals and the approvals the operation of which has been suspended or otherwise restricted are indicated.

89. The authorised representative of the manufacturer may fulfil the obligations of the manufacturer referred to in Paragraphs 73, 80, 86, and 87 of this Annex, on its behalf and under its responsibility, provided that they are specified in the mandate.

**IX. Conformity Based on Quality Assurance of Measuring in Inspections and Testing (Module E1)**

90. Conformity based on quality assurance of measuring in inspections and testing is a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in Paragraphs 90, 93, 106, and 107 of this Annex and also ensures and declares on his sole responsibility that the measuring instruments concerned conform to the requirements of this Regulation and the relevant law or regulation that apply to them.

91. The manufacturer shall draw up the technical documentation that makes it possible to assess the conformity of the measuring instruments with the requirements of this Regulation and the relevant law or regulation, and it shall include an analysis and assessment of the risk. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, and operation of the measuring instruments.

92. The manufacturer shall ensure the availability of the technical documentation to the market surveillance authority for 10 years after the measuring instrument has been placed on the market.

93. The manufacturer shall operate an approved quality assurance system for production, final product inspection, and testing of the measuring instruments concerned as specified in Paragraphs 94, 95, 96, 97, 98, and 99 of this Annex, and the manufacturer shall be subject to surveillance as specified in Paragraphs 103, 104, and 105 of this Annex.

94. The manufacturer shall submit an application for the assessment of the quality assurance system for the measuring instruments concerned with one notified authority of its choice. The application shall include the following:

94.1. the name and address of the manufacturer and, if the application is submitted by the authorised representative, the name and address of such representative;

94.2. a written declaration that the same application has not been submitted to any other notified authority;

94.3. all relevant information for the measuring instrument category envisaged;

94.4. the documentation concerning the quality assurance system;

94.5. the technical documentation specified in Paragraph 91 of this Annex.

95. The quality assurance system shall ensure the conformity of the measuring instruments with the requirements of this Regulation and the relevant law or regulation.

96. All the elements, requirements, and conditions of the quality assurance system adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures, and instructions. The quality assurance system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals, and records and it shall contain the following adequately described information:

96.1. the quality assurance objectives and the organisational structure, responsibilities, and powers of the management with regard to product quality;

96.2. the examinations and tests that will be carried out after manufacture;

96.3. the quality records, such as inspection reports and test data, calibration data, and also qualification reports on the personnel concerned;

96.4. the means of monitoring the achievement of the required product quality and the effective operation of the quality assurance system.

97. The notified authority shall assess the quality assurance system to determine whether it meets the requirements of Paragraphs 95 and 96 of this Annex. Such elements of the quality assurance system that comply with the corresponding specifications of the applicable standard shall conform to the abovementioned requirements.

98. In addition to experience in quality assurance systems, the auditing team shall have at least one member with experience of assessment in the relevant measuring instrument field and product technology concerned, and knowledge of the requirements of this Regulation and the relevant law or regulation.

99. The audit shall include an assessment visit to the premises of the manufacturer. The auditing team shall review the technical documentation referred to in Paragraph 91 of this Annex, to verify the ability of the manufacturer to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring the conformity of the measuring instrument with the abovementioned requirements. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

100. The manufacturer shall undertake to fulfil the obligations arising out of the quality assurance system as approved and to maintain it so that its operation remains adequate and efficient.

101. The manufacturer shall continuously keep the notified authority that has approved the quality assurance system informed of any intended changes of the quality assurance system.

102. The notified authority shall assess any proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in Paragraphs 95 and 96 of this Annex or whether a re-assessment is necessary. The notified authority shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment.

103. The purpose of surveillance of the notified authority is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality assurance system.

104. The manufacturer shall, for assessment purposes, allow the representatives of the notified authority access to the manufacture, inspection, testing, and storage sites, and shall provide it with all necessary information, in particular:

104.1. the quality assurance system documentation;

104.2. the technical documentation referred to in Paragraph 91 of this Annex;

104.3. the quality records, such as inspection reports and test data, calibration data, and qualification reports on the personnel concerned.

105. The notified authority shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality assurance system and shall provide the manufacturer with an audit report. Representatives of the notified authority may pay unexpected visits to the manufacturer. During such visits the notified authority may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality assurance system is functioning correctly. The notified authority shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

106. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking, and also, under the responsibility of the notified authority referred to in Paragraph 94 of this Annex, the identification number of the latter to each individual measuring instrument which conforms to the requirements of this Regulation.

107. The manufacturer shall draw up a written declaration of conformity for each model of the measuring instrument and shall ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration of conformity shall identify the measuring instrument model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the responsible authorities upon request. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

108. The manufacturer shall, for a period ending 10 years after the measuring instrument has been placed on the market, make available information to the market surveillance authority on the assessment of the quality assurance system referred to in Paragraph 94 of this Annex, the information relating to the changes made in the quality assurance system and approved, and also information on the decisions of and reports from the notified authorities in relation to the audits which have been carried out and apply to the quality assurance system of the manufacturer.

109. The notified authority shall, once a quarter or upon request, inform the Ministry of Economics concerning quality assurance system approvals issued or withdrawn and shall submit the list of quality assurance system approvals in which the refused approvals and the approvals the operation of which has been suspended or otherwise restricted are indicated.

110. The authorised representative of the manufacturer may fulfil the obligations of the manufacturer referred to in Paragraphs 92, 94, 101, 102, 106, 107, and 108 of this Annex, on his behalf and under his responsibility, provided that they are specified in the mandate.

**X. Conformity to Type Based on Product Verification (Module F)**

111. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in Paragraphs 112, 119, 123, and 124 of this Annex and ensures and declares on his sole responsibility that the measuring instruments concerned conform to the type described in the EU-type examination certificate and the requirements of this Regulation, and the relevant law or regulation that apply to them.

112. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the conformity of the manufactured measuring instruments with the approved type described in the EU-type examination certificate and the requirements of this Regulation and the relevant law or regulation.

113. A notified authority chosen by the manufacturer shall carry out the appropriate examinations and tests to verify the conformity of the measuring instrument with the type as described in the EU-type examination certificate and the requirements of this Regulation, and the relevant law or regulation.

114. The examinations and tests to verify the conformity of the measuring instrument with the relevant requirements shall be carried out according to one of the following methods at the choice of the manufacturer:

114.1. verification of each measuring instrument;

114.2. statistical verification.

115. In the verification of the measuring instrument, each individual measuring instrument shall be examined and appropriate tests set out in the relevant applicable standards or normative documents, and also equivalent tests shall be carried out in order to verify the conformity of the measuring instrument with the approved type described in the EU-type examination certificate and the requirements of this Regulation, and the relevant law or regulation. If the corresponding documents are not available, the notified authority shall decide on the tests to be carried out.

116. The notified authority shall issue a certificate of conformity in respect of the examinations and tests carried out in Paragraph 115 of this Annex and shall affix its identification number to the approved measuring instruments or have it affixed under its responsibility.

117. The manufacturer shall ensure the availability of the certificates of conformity to the market surveillance authority for 10 years after the measuring instrument has been placed on the market.

118. Upon carrying out statistical verification, the following shall be ensured:

118.1. a level of quality corresponding to a probability of acceptance of 95 per cent, with a non-conformity of less than one per cent;

118.2. a limit quality corresponding to a probability of acceptance of five per cent, with a non-conformity of the measuring instruments of less than seven per cent.

119. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot of the measuring instruments produced and shall present his measuring instruments for verification in the form of homogeneous lots.

120. Random samples shall be taken from each lot in statistical verification in accordance with the requirements referred to in Paragraph 118 of this Annex and all measuring instruments in a sample shall be individually examined and appropriate tests set out in the relevant applicable standards and normative documents or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the selected measuring instruments with the type described in the EU-type examination certificate and the requirements of this Regulation, and the relevant law or regulation. If the relevant documents are not available, the notified authority shall decide on the tests to be carried out.

121. After the procedure carried out in Paragraph 120 of this Annex the notified authority shall decide on whether the lot is to be accepted or rejected.

122. If a lot is accepted, all measuring instruments of the lot shall be considered approved, except for such measuring instruments that have been found not to satisfy the testing criteria. The notified authority shall issue a certificate of conformity and shall affix its identification number to each approved measuring instrument or have it affixed under its responsibility. If a lot is rejected, the notified authority shall take appropriate measures to prevent the placing on the market of that lot. In the event of frequent rejection of lots the notified authority shall suspend the statistical verification and take appropriate measures.

123. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking, and also, under the responsibility of the notified authority referred to in Paragraph 113 of this Annex, the identification number of the latter to each individual measuring instrument that conforms to the type described in the EU-type examination certificate and the requirements of this Regulation.

124. The manufacturer shall draw up a written declaration of conformity for each model of the measuring instrument and shall ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration of conformity shall identify the measuring instrument model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the responsible authorities upon request. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

125. If the notified authority referred to in Paragraph 113 of this Annex agrees and under its responsibility, the manufacturer may also affix the identification number of the notified authority to the measuring instruments.

126. If it has been agreed with the notified authority referred to in Paragraph 113 of this Annex, the manufacturer may, under its responsibility, affix the identification number of the notified authority to the measuring instruments during the manufacturing process.

127. The authorised representative of the manufacturer may, on the behalf and under the responsibility of the manufacturer, fulfil the obligations of the manufacturer referred to in Paragraphs 112 and 119 of this Annex provided that they are specified in the mandate.

**XI. Conformity Based on Product Verification (Module F1)**

128. Conformity based on product verification is a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in Paragraphs 129, 131, 137, 143, 144, and 145 of this Annex and ensures and declares on his sole responsibility that the measuring instruments conform to the requirements of this Regulation and the relevant law or regulation that applies to them.

129. The manufacturer shall draw up the technical documentation that makes it possible to assess the conformity of the measuring instruments with the requirements of this Regulation and it shall include an analysis and assessment of the risk. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, and operation of the measuring instruments.

130. The manufacturer shall ensure the availability of the technical documentation to the market surveillance authority for 10 years after the measuring instrument has been placed on the market.

131. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the conformity of the manufactured measuring instruments with the requirements of this Regulation and the relevant law or regulation.

132. A notified authority chosen by the manufacturer shall carry out the appropriate examinations and tests to verify the conformity of the measuring instruments with the requirements of this Regulation and the relevant law or regulation.

133. The examinations and tests to verify the conformity of the measuring instruments with the relevant requirements shall be carried out according to one of the following methods at the choice of the manufacturer:

133.1. verification of each measuring instrument;

133.2. statistical verification.

134. In the verification of the measuring instrument, each individual measurement instrument shall be examined and appropriate tests set out in the relevant applicable standards or normative documents and also equivalent tests shall be carried out in order to verify the conformity of the measuring instrument with the requirements of this Regulation and the relevant law or regulation. If the corresponding documents are not available, the notified authority shall decide on the tests to be carried out.

135. The notified authority shall issue a certificate of conformity in respect of the examinations and tests carried out in Paragraph 134 of this Annex and shall affix its identification number to the approved measuring instruments or have it affixed under its responsibility.

136. The manufacturer shall ensure the availability of the certificates of conformity to the market surveillance authority for 10 years after the measuring instrument has been placed on the market.

137. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot of the measuring instruments produced, and shall present his measuring instruments for verification in the form of homogeneous lots.

138. Upon carrying out statistical verification, the following shall be ensured:

138.1. a level of quality corresponding to a probability of acceptance of 95 per cent, with a non-conformity of less than one per cent;

138.2. a limit quality corresponding to a probability of acceptance of five per cent, with a non-conformity of the measuring instruments of less than seven per cent.

139. Random samples shall be taken from each lot in statistical verification in accordance with the requirements referred to in Paragraph 138 of this Annex and all measuring instruments in a sample shall be individually examined and appropriate tests set out in the relevant applicable standards and normative documents or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the selected measuring instruments with the requirements of this Regulation and the relevant law or regulation. If the relevant documents are not available, the notified authority shall decide on the tests to be carried out.

140. After the procedure carried out in Paragraph 139 of this Annex the notified authority shall decide on whether the lot is to be accepted or rejected.

141. If a lot is accepted, all measuring instruments of the lot shall be considered approved, except for such measuring instruments that have been found not to satisfy the testing criteria. The notified authority shall issue a certificate of conformity and shall affix its identification number to each approved measuring instrument or have it affixed under its responsibility.

142. If a lot is rejected, the notified authority shall take appropriate measures to prevent the placing on the market of that lot. In the event of frequent rejection of lots the notified authority shall suspend the statistical verification and take appropriate measures.

143. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking, and also, under the responsibility of the notified authority referred to in Paragraph 132 of this Annex, the identification number of the latter to each individual measuring instrument which conforms to the requirements of this Regulation and the relevant law or regulation.

144. The manufacturer shall draw up a written declaration of conformity for each model of the measuring instrument and shall ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration of conformity shall identify the measuring instrument model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the responsible authorities upon request. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

145. If the notified authority referred to in Paragraph 132 of this Annex agrees and under its responsibility, the manufacturer may also affix the identification number of the notified authority to the measuring instruments.

146. If it has been agreed with the notified authority referred to in Paragraph 132 of this Annex, the manufacturer may, under its responsibility, affix the identification number of the notified authority to the measuring instruments during the manufacturing process.

147. The authorised representative of the manufacturer may, on the behalf and under the responsibility of the manufacturer, fulfil the obligations of the manufacturer referred to in Paragraphs 129, 131, and 137 of this Annex provided that they are specified in the mandate.

**XII. Conformity Based on Unit Verification (Module G)**

148. Conformity based on unit verification is a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in Paragraphs 149, 150, 151, 155, 156, and 157 of this Annex and ensures and declares on his sole responsibility that the measuring instruments conform to the requirements of this Regulation and the relevant law or regulation that applies to them.

149. The manufacturer shall draw up the technical documentation that makes it possible to assess the conformity of the measuring instruments with the requirements of this Regulation and the relevant law or regulation and shall make it available to the notified authority referred to in Paragraph 152 of this Annex. The technical documentation shall specify the risk analysis, assessment, and applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, and operation of the measuring instruments.

150. The manufacturer shall ensure the availability of the technical documentation to the market surveillance authority for 10 years after the measuring instruments have been placed on the market.

151. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the conformity of the manufactured measuring instruments with the applicable requirements of this Regulation and the relevant law or regulation.

152. A notified authority chosen by the manufacturer shall carry out the appropriate examinations and tests set out in the relevant applicable standards or normative documents, or equivalent tests set out in other relevant technical specifications, to verify the conformity of the measuring instruments with the applicable requirements of this Regulation and the relevant law or regulation, or shall ensure that they are carried out. If relevant applicable standards or normative documents are not available, the notified authority shall decide on the appropriate tests to be carried out.

153. The notified authority shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved measuring instruments or have it affixed under its responsibility.

154. The manufacturer shall ensure the availability of the certificates of conformity to the market surveillance authority for 10 years after the measuring instrument has been placed on the market.

155. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking, and also, under the responsibility of the notified authority referred to in Paragraph 132 of this Annex, the identification number of the latter to each individual measuring instrument which conforms to the requirements of this Regulation and the relevant law or regulation.

156. The manufacturer shall draw up a written declaration of conformity for each individual measuring instrument and shall ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration of conformity shall identify the measuring instrument model for which it has been drawn up. A copy of the declaration of conformity shall accompany the measuring instrument.

157. A copy of the declaration of conformity shall be made available to the responsible authorities upon request.

158. The authorised representative of the manufacturer may fulfil the obligations of the manufacturer referred to in Paragraphs 149, 155, 156, and 157 of this Annex, on its behalf and under its responsibility, provided that they are specified in the mandate.

**XIII. Conformity Based on Full Quality Assurance (Module H)**

159. Conformity based on full quality assurance is a conformity assessment procedure whereby the manufacturer meets the requirements laid down in the relevant laws and regulations and declares that the measuring instruments conform to the requirements of this Regulation.

160. The manufacturer shall operate an approved quality assurance system for design, manufacture, final product inspection, and testing of the measuring instruments concerned as specified in Paragraphs 161, 162, 163, 164, 165, 166, 167, and 168 of this Annex, and the manufacturer shall be subject to surveillance as specified in Paragraphs 170, 171, 172, and 172 of this Annex.

161. The manufacturer shall submit an application for the assessment of the quality assurance system for the measuring instruments concerned with one notified authority of its choice. The application shall include the following:

161.1. the name and address of the manufacturer and, if the application is submitted by the authorised representative, the name and address of such representative;

161.2. the technical documentation that makes it possible to assess the conformity of the measuring instruments with the requirements of this Regulation and it shall include an analysis and assessment of the risk. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, and operation of the measuring instruments;

161.3. the quality assurance system documentation;

161.4. a written declaration that the same application has not been submitted to any other notified authority.

162. The quality assurance system shall ensure the conformity of the measuring instruments with the applicable requirements of this Regulation and the relevant laws and regulations.

163. All the elements, requirements, and conditions of the quality assurance system adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures, and instructions. The quality assurance system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals, and records and it shall contain the following adequately described information:

163.1. the quality assurance objectives and the organisational structure, responsibilities, and powers of the management with regard to product quality;

163.2. the technical design specifications, applicable standards, and normative documents or, if the solutions specified in the relevant applicable standards or normative documents have not been applied, the technical solutions chosen by the manufacturer which have been applied to meet the requirements of this Regulation, including a list of other relevant technical specifications;

163.3. the design control and design verification techniques, processes, and systematic actions that will be used when designing the measuring instruments of the relevant category;

163.4. the project control and verification methods, processes, and systematic measures in the designing of the measuring instrument;

163.5. the examinations and tests that will be carried out before, during, and after manufacture, and also the frequency with which they will be carried out;

163.6. the quality records, such as inspection reports and test data, calibration data, and also qualification reports on the personnel concerned;

163.7. the means of monitoring the achievement of the required product quality and the effective operation of the quality assurance system.

164. The notified authority shall assess the quality assurance system to determine whether it meets the requirements of Paragraphs 162 and 163 of this Annex. Such elements of the quality assurance system that comply with the corresponding specifications of the applicable standard shall conform to the abovementioned requirements.

165. In addition to experience in quality assurance systems, the auditing team shall have at least one member with experience of assessment in the relevant measuring instrument field and product technology concerned, and knowledge of the requirements of this Regulation and the relevant law or regulation.

166. The audit shall include an assessment visit to the premises of the manufacturer. The auditing team shall review the technical documentation referred to in Sub-paragraph 161.2 of this Annex, to verify the ability of the manufacturer to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring the conformity of the measuring instrument with the abovementioned requirements. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

167. The manufacturer shall undertake to fulfil the obligations arising out of the quality assurance system as approved and to maintain it so that its operation remains adequate and efficient.

168. The manufacturer shall continuously keep the notified authority that has approved the quality assurance system informed of any intended changes of the quality assurance system.

169. The notified authority shall assess any proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in Paragraphs 162 and 163 of this Annex or whether a re-assessment is necessary. The notified authority shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment.

170. The purpose of surveillance of the notified authority is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality assurance system.

171. The manufacturer shall, for assessment purposes, allow the representatives of the notified authority access to the manufacture, inspection, testing, and storage sites, and shall provide it with all necessary information, in particular:

171.1. the quality assurance system documentation;

171.2. the quality records as provided for by the design part of the quality assurance system, such as the results of analyses, calculations, tests;

171.3. the quality records, such as inspection reports and test data, calibration data, and qualification reports on the personnel concerned.

172. The notified authority shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality assurance system and shall provide the manufacturer with an audit report. Representatives of the notified authority may pay unexpected visits to the manufacturer. During such visits the notified authority may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality assurance system is functioning correctly. The notified authority shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

173. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking, and also, under the responsibility of the notified authority referred to in Paragraph 161 of this Annex, the identification number of the latter to the measuring instruments which conform to the requirements of this Regulation.

174. The manufacturer shall draw up a written declaration of conformity for each model of the measuring instrument and shall ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration of conformity shall identify the measuring instrument model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the responsible authorities upon request. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

175. The manufacturer shall, for a period ending 10 years after the measuring instrument has been placed on the market, make available information to the market surveillance authority on the assessment of the quality assurance system referred to in Paragraph 161 of this Annex, the information relating to the changes made in the quality assurance system and approved, and also information on the decisions of and reports from the notified authorities in relation to the audits which have been carried out and apply to the quality assurance system of the manufacturer.

176. The notified authority shall, once a quarter or upon request, inform the Ministry of Economics concerning quality assurance system approvals issued or withdrawn and shall submit the list of quality assurance system approvals in which the refused approvals and the approvals the operation of which has been suspended or otherwise restricted are indicated.

177. The authorised representative of the manufacturer may fulfil the obligations of the manufacturer referred to in Paragraphs 161, 168, 173, 174, and 175 of this Annex, on its behalf and under its responsibility, provided that they are specified in the mandate.

**XIV. Conformity Based on Full Quality Assurance Supplemented by Design Examination (Module H1)**

178. Conformity based on full quality assurance plus design examination is a conformity assessment procedure whereby the manufacturer meets the requirements laid down in the relevant laws and regulations and declares that the particular measuring instruments conform to the requirements of this Regulation.

179. The manufacturer shall operate an approved quality assurance system for design, production, final product inspection, and testing of the measuring instruments concerned as specified in Paragraphs 181, 182, 183, 184, 185, 186, 187, and 188 of this Annex, and the manufacturer shall be subject to surveillance as specified in Paragraphs 202, 203, and 204 of this Annex.

180. The adequacy of the technical design of the measuring instrument shall be examined in accordance with Paragraphs 191, 192, 193, 194, 195, 196, 197, and 198 of this Annex.

181. The manufacturer shall submit an application for the assessment of the quality assurance system for the measuring instruments concerned with one notified authority of its choice. The application shall include the following:

181.1. the name and address of the manufacturer and, if the application is submitted by the authorised representative, the name and address of such representative;

181.2. all relevant information for the measuring instrument category envisaged;

181.3. the quality assurance system documentation;

181.4. a written declaration that the same application has not been submitted to any other notified authority.

182. The quality assurance system shall ensure the conformity of the measuring instruments with the requirements of this Regulation and the relevant laws and regulations.

183. All the elements, requirements, and conditions of the quality assurance system adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures, and instructions. The quality assurance system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals, and records and it shall contain the following adequately described information:

183.1. the quality assurance objectives and the organisational structure, responsibilities, and powers of the management with regard to product quality;

183.2. the technical design specifications, applicable standards, and normative documents or, if the solutions specified in the relevant applicable standards or normative documents have not been applied, the technical solutions chosen by the manufacturer which have been applied to satisfy the requirements of this Regulation, including a list of other relevant technical specifications;

183.3. the design control and design verification techniques, processes, and systematic actions that will be used when designing the measuring instruments of the relevant category;

183.4. the project control and verification methods, processes, and systematic measures in the designing of the measuring instrument;

183.5. the examinations and tests that will be carried out before, during, and after manufacture, and also the frequency with which they will be carried out;

183.6. the quality records, such as inspection reports and test data, calibration data, and also qualification reports on the personnel concerned;

183.7. the means of monitoring the achievement of the required product quality and the effective operation of the quality assurance system.

184. The notified authority shall assess the quality assurance system to determine whether it meets the requirements of Paragraphs 182 and 183 of this Annex. Such elements of the quality assurance system that comply with the corresponding specifications of the applicable standard shall conform to the abovementioned requirements.

185. In addition to experience in quality assurance systems, the auditing team shall have at least one member with experience of assessment in the relevant measuring instrument field and product technology concerned, and knowledge of the requirements of this Regulation and the relevant law or regulation.

186. The audit shall include an assessment visit to the premises of the manufacturer. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

187. The manufacturer shall undertake to fulfil the obligations arising out of the quality assurance system as approved and to maintain it so that its operation remains adequate and efficient.

188. The manufacturer shall continuously keep the notified authority that has approved the quality assurance system informed of any intended changes of the quality assurance system.

189. The notified authority shall assess any proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in Paragraphs 182 and 183 of this Annex or whether a re-assessment is necessary. The notified authority shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment.

190. The notified authority shall, once a quarter or upon request, inform the Ministry of Economics concerning quality assurance system approvals issued or withdrawn and shall submit the list of quality assurance system approvals in which the refused approvals and the approvals the operation of which has been suspended or otherwise restricted are indicated.

191. The manufacturer shall submit an application for examination of the design with the notified authority referred to in Paragraph 181 of this Annex. The application shall make it possible to understand the design, manufacture, and operation of the measuring instrument, and to assess the conformity with the requirements of this Regulation that apply to it. The application shall include the following:

191.1. the name and address of the manufacturer;

191.2. a written declaration that the same application has not been submitted to any other notified authority;

191.3. the technical documentation that makes it possible to assess the conformity of the measuring instruments with the requirements of this Regulation and the relevant law or regulation and that includes an analysis and assessment of the risk. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture, and operation of the measuring instruments;

191.4. the supporting evidence for the adequacy of the technical design, mentioning any documents that have been used, in particular if the relevant applicable standards or normative documents have not been applied in full, and 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 its behalf and under its responsibility.

192. The notified authority shall examine the application specified in Paragraph 191 of this Annex and if the design meets the requirements laid down in the relevant laws and regulation it shall issue an EU design examination certificate to the manufacturer. The abovementioned certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions for the validity of the certificate (if any), and the necessary data for the identification of the approved design. The abovementioned certificate may have one or more annexes attached.

193. The certificate referred to in Paragraph 192 of this Annex and its annexes shall contain all relevant information which is necessary to allow the conformity of manufactured measuring instruments with the examined design to be assessed and to allow for in-service control. In order for it to be possible to assess the conformity of the manufactured measuring instruments with the examined design regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, the following information shall be indicated:

193.1. the metrological characteristics of the design of the measuring instrument;

193.2. measures required for ensuring the integrity of the measuring instruments (sealing, identification of software, etc.);

193.3. information on other elements necessary for the identification of the measuring instruments and to check its visual external conformity to the design;

193.4. any specific information necessary to verify the characteristics of the manufactured measuring instruments;

193.5. in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.

194. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified authority shall release the content of the draft inspection report, in full or in part, only with the agreement of the manufacturer.

195. The EU design examination certificate shall have a validity of 10 years from the date of its issue and it may be renewed for subsequent periods of 10 years.

196. If the design does not meet the requirements of this Regulation and the relevant laws and regulations, the notified authority shall refuse to issue an EU design examination certificate and shall inform the applicant accordingly, giving detailed reasons for such refusal.

197. The notified authority shall keep itself apprised of any changes in the generally acknowledged standards which indicate that the approved design may no longer conforms to the applicable requirements of this Regulation and shall determine whether such changes require further investigation. If so, the notified authority shall inform the manufacturer accordingly.

198. The manufacturer shall inform the notified authority that has issued the EU design examination certificate of all modifications to the approved design that may affect the conformity thereof with the requirements of this Regulation or the conditions for the validity of the abovementioned certificate. Such modifications shall require additional approval in the form of an addition to the original EU design examination certificate.

199. The notified authority shall, once a quarter or upon request, inform the Ministry of Economics concerning the EU design examination certificates issued or withdrawn and shall submit the list of EU design examination certificate approvals in which the refused certificates and the certificates the operation of which has been suspended or otherwise restricted are indicated.

200. Upon request, the European Commission and the Member States may obtain copies of the EU design examination certificates and additions thereto and copies of the technical documentation and the results of the examinations carried out by the notified authority. The notified authority shall keep a copy of the EU design examination certificate, its annexes and additions, and also the technical documentation and the documentation submitted by the manufacturer until expiry of the term of validity of the abovementioned certificate.

201. The manufacturer shall ensure the availability of a copy of the EU-type examination certificate, its annexes and additions, and the technical documentation to the market surveillance authority for 10 years after the measuring instruments have been placed on the market.

202. The purpose of surveillance of the notified authority is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality assurance system.

203. The manufacturer shall, for assessment purposes, allow the representatives of the notified authority access to the manufacture, inspection, testing, and storage sites, and shall provide it with all necessary information, in particular:

203.1. the quality assurance system documentation;

203.2. the quality records as provided for by the design part of the quality assurance system, such as the results of analyses, calculations, tests;

203.3. the quality records, such as inspection reports and test data, calibration data, and qualification reports on the personnel concerned.

204. The notified authority shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality assurance system and shall provide the manufacturer with an audit report. Representatives of the notified authority may pay unexpected visits to the manufacturer. During such visits the notified authority may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality assurance system is functioning correctly. The notified authority shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

205. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking, and also, under the responsibility of the notified authority referred to in Paragraph 181 of this Annex, the identification number of the latter to each individual measuring instrument which conforms to the requirements of this Regulation.

206. The manufacturer shall draw up a written declaration of conformity for each model of the measuring instrument and shall ensure its availability to the market surveillance authority for 10 years after the measuring instrument has been placed on the market. The declaration of conformity shall identify the measuring instrument model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the responsible authorities upon request. If a large batch of the measuring instruments is delivered to one user, one copy of the declaration shall be appended to the relevant batch or consignment of the measuring instruments.

207. The manufacturer shall, for a period ending 10 years after the measuring instrument has been placed on the market, make available information to the market surveillance authority on the assessment of the quality assurance system referred to in Paragraph 181 of this Annex, the information relating to the changes made in the quality assurance system and approved, and also information on the decisions of and reports from the notified authorities in relation to the audits which have been carried out and apply to the quality assurance system of the manufacturer.

208. The authorised representative of the manufacturer may fulfil the obligations of the manufacturer referred to in Paragraphs 181, 188, 191, 198, 201, 205, 206, and 207 of this Annex, on his behalf and under his responsibility, provided that they are specified in the mandate.

Deputy Prime Minister, Minister for Economics Arvils Ašeradens

**Annex 2**

Cabinet Regulation No. 212

12 April 2016

**Essential Requirements for the Measuring Instrument**

1. This Annex specifies the essential requirements for the measuring instrument. If special requirements have been specified for the measuring instrument in other laws and regulations regarding the metrological requirements for a particular measuring instrument, they must be conformed to together with the essential requirements specified in this Annex.

2. The following terms are used in the Annex:

2.1. measurand – the particular quantity subject to measurement;

2.2. influence quantity – a quantity that is not the measurand but that affects the result of measurement;

2.3. rated operating conditions – the conditions for the use of the measuring instrument conforming to which the values for the measurand and influence quantities are within the specified limits;

2.4. disturbance – an influence quantity having values within the specified limits but outside the specified rated operating conditions of the measuring instrument. An influence quantity is a disturbance if the rated operating conditions are not specified for that influence quantity;

2.5. critical change value – the value at which the change in the measurement result is considered undesirable;

2.6. direct sales – a trading transaction in which:

2.6.1. the measurement result serves as the basis for the price to pay;

2.6.2. at least one of the parties involved in the transaction related to measurement is a consumer or any other party requiring a similar level of protection;

2.6.3. all the parties in the transaction accept the measurement result at that time and place;

2.7. climatic environment – the conditions in which measuring instruments may be used;

2.8. utility – a service related to the supply of electricity, gas, thermal energy, or water;

2.9. reproducibility – close agreement of the measurement results, upon applying the same measurand in different locations or by different users, all other conditions being the same. The difference between the measurement results shall be small in comparison with with the maximum permissible error;

2.10. repeatability – close agreement of the successive measurement results of the same measurand under the same conditions of measurement. The difference between the measurement results shall be small in comparison with the maximum permissible error.

3. The measuring instrument shall ensure an adequate level of metrological safety so that the involved parties would be able to trust the measurement results and they shall be designed and manufactured in conformity with high quality standards by taking into account the measurement technology and data safety.

4. The solutions adopted in the pursuit of the essential requirements shall take account of the intended use of the measuring instrument and any foreseeable misuse thereof.

5. In compliance with the determined operating conditions and in the absence of a disturbance, the error of a measurement shall not exceed the maximum permissible error value as laid down in the laws and regulations regarding the metrological requirements for a particular measuring instrument. Unless stated otherwise in the relevant law or regulation, it shall be expressed as a bilateral value of the deviation from the true measurement value.

6. The measuring instrument must conform to the laws and regulations regarding the metrological requirements for a particular measuring instrument if the determined operating conditions have been conformed to and the potential disturbances are taken into account. If the measuring instrument is intended to be used in a specified permanent continuous electromagnetic field, the measurement results obtained by performing the radiated electromagnetic field-amplitude modulated test may not exceed the maximum permissible error.

7. The manufacturer shall specify the climatic, mechanical, and electromagnetic environments in which the measuring instrument is intended to be used, and also power supply and other influence quantities likely to affect the accuracy of measurements laid down in the laws and regulations regarding the metrological requirements for a particular measuring instrument.

8. The manufacturer shall specify the upper temperature limit and the lower temperature limit in accordance with Table 1 of this Annex unless otherwise specified in the laws and regulations regarding the metrological requirements for a particular measuring instrument and shall also indicate whether the measuring instrument is designed for work in the environment with condensing or non-condensing humidity, and shall specify the intended location for the measuring instrument (open or closed).

Table 1.

**Temperature Limits**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Upper temperature limit | + 30 °C | + 40 °C | + 55 °C | + 70 °C |
| Lower temperature limit | + 5 °C | – 10 °C | – 25 °C | – 40 °C |

9. The mechanic environment shall be divided into the following classes, depending on the intensity of potential influence quantity (vibration and mechanical impact):

9.1. Class M1 shall be applied to the measuring instruments used in locations with vibration and shocks of low significance;

9.2. Class M2 shall be applied to the measuring instruments used in locations with significant or high levels of vibration and shock;

9.3. Class M3 shall be applied to the measuring instruments used in locations if the level of vibration and shock is high and very high.

10. Electromagnetic environments are classified into the following classes depending on the influence quantity (voltage interruptions, short voltage reductions, voltage transients on supply lines or signal lines, electrostatic discharges, radio frequency electromagnetic fields, conducted radio frequency electromagnetic fields on supply lines or signal lines, and also surges on supply lines or signal lines), unless otherwise laid down in the laws and regulations regarding the metrological requirements for a particular measuring instrument:

10.1. E1 class shall be applied to the measuring instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in residential, commercial, and light industrial buildings;

10.2. E2 class shall be applied to the measuring instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in industrial buildings that are not light industrial buildings;

10.3. E3 class shall be applied to the measuring instruments for which the battery of a vehicle is used as the source of energy supply. They must conform to the requirements of E2 class and in addition must be resilient against:

10.3.1. voltage reductions caused by energising the starter-motor circuits of internal combustion engines;

10.3.2. load dump transients occurring in the event of a discharged battery being disconnected while the engine is running.

11. Other influence quantities shall be considered, where appropriate:

11.1. voltage variations;

11.2. main frequency variations;

11.3. power frequency magnetic fields;

11.4. any other quantity likely to influence in a significant way the accuracy of the measuring instrument.

12. Upon carrying out the tests as provided for in this Regulation, the following requirements shall be satisfied:

12.1. each essential influence quantity specified in Paragraphs 5 and 6 of this Annex shall be checked. Unless otherwise specified in the laws and regulations regarding the metrological requirements for a particular measuring instrument, the essential requirements shall be applied when each influence quantity and its effect are assessed separately, all other influence quantities being kept constant at their reference value;

12.2. metrological tests shall be carried out during or after the application of the influence quantity, whichever condition corresponds to the normal operational status of the measuring instrument when that influence quantity is likely to occur;

12.3. depending on the climatic operating environment in which the measuring instrument is intended to be used, either the damp heat cyclic (condensing) test or the damp heat-steady state (non-condensing) shall be carried out. The damp heat cyclic test is appropriate where condensation is important or when penetration of vapour will be accelerated by the effect of breathing. In conditions where non-condensing humidity is a factor the condition is adequate.

13. A measuring instrument shall be designed in a way that it:

13.1. maintains an adequate stability of its metrological characteristics over a period of time estimated by the manufacturer, provided that it is properly installed, maintained, and used according to the instructions of the manufacturer when in the environmental conditions for which it is intended;

13.2. reduces as far as possible the effect of a defect that would lead to an inaccurate measurement result, unless the presence of such a defect is obvious.

14. The measuring instrument shall have no feature likely to facilitate fraudulent use and the possibilities for unintentional misuse of the measuring instrument must be reduced as far as possible.

15. The measuring instrument shall be:

15.1. suitable for its intended use taking account of the practical working conditions. It shall not be permissible to bring forward unreasonable demands of the user in order to obtain a correct measurement result;

15.2. robust and its materials of construction shall be suitable for the conditions in which it is intended to be used;

15.3. designed so as to allow the control of the measuring tasks after the instrument has been placed on the market and put into use. If necessary, special equipment or software for such control shall be part of the measuring instrument. The testing procedure shall be described in the operation manual;

15.4. sufficiently sensitive and the discrimination threshold shall be sufficiently low for the intended measurement task.

16. If the measuring instrument is used for the accounting of utilities, its errors at flows or currents outside the controlled measuring range shall not be unduly biased.

17. If the measuring instrument is designed for the measurement of values of the measurand that are constant over time, the measuring instrument shall be insensitive to small fluctuations of the value of the measurand or shall take appropriate action.

18. If the measuring instrument has associated software which provides other functions besides the measuring function, the software that is critical for the metrological characteristics shall be identifiable and shall not be inadmissibly influenced by the associated software.

19. The measuring instrument shall ensure the following protection against damages:

19.1. the metrological characteristics of the measuring instrument shall not be influenced in any inadmissible way by the connection to it of another device or any other device located within a certain distance from the measuring instrument and is connected to it;

19.2. a hardware component which can significantly affect the metrological characteristics of the measuring instrument shall be designed so that it can be secure and any intervention could be identified;

19.3. software which significantly affects metrological characteristics shall be marked appropriately and shall be secured;

19.4. software of the measuring instrument shall be easily identifiable;

19.5. evidence of an intervention shall be available for a reasonable period of time;

19.6. measurement data, software that is critical for measurement characteristics, and metrologically important parameters stored or transmitted shall be adequately protected against accidental or intentional damages;

19.7. if the measuring instrument is intended for utilities, its readings shall display the total quantity supplied or from which the total quantity supplied can be derived, or the readings provide a whole or partial basis for payment. It shall not be possible to reset the readings during use of the measuring instrument.

20. The measuring instrument shall bear the following information:

20.1. the trade mark or name of the manufacturer;

20.2. information in respect of its accuracy;

20.3. where appropriate, information in respect of the conditions of use, measuring capacity and measuring range, identity marking, number of the EU-type examination certificate or the EU design examination certificate, and information whether or not additional devices providing metrological results comply with the provisions of this Regulation and the laws and regulations regarding the metrological requirements for a particular measuring instrument.

21. The dimensional measuring instruments which are too small or too sensitive shall be allowed to bear the significant information on its packaging, if any, and the accompanying documents specified this Regulation.

22. The measuring instruments shall be accompanied by information on their operation (except for the measuring instrument the operation of which is simple and unambiguous). Information shall be easily understandable and shall include:

22.1. the determined operating conditions;

22.2. mechanical and electromagnetic environment classes;

22.3. the upper and lower temperature limits and also whether condensation is possible or not (in open or closed location);

22.4. instructions for installation, maintenance, and repairs and also permissible adjustments;

22.5. instructions for correct operation and any special conditions of use;

22.6. conditions for compatibility with interfaces, sub-assemblies, or other measuring instruments.

23. If several identical measuring instruments are used in the same location or used for utility measurements, it shall not be necessary to append individual instruction manuals to each of them.

24. Unless specified otherwise in this Regulation and the laws and regulations regarding the metrological requirements for a particular measuring instrument, the scale interval for a measured value shall be in the form 1 x 10n, 2 x 10n, or 5 x 10n, where n is any integer or zero. The unit of measurement or its symbol shall be shown close to the numerical value.

25. A material measure shall be marked with a nominal value or a scale, accompanied by the unit of measurement used.

26. The units of measurement used and their symbols shall conform to the requirements of the laws and regulations regarding units of measurement and their symbols.

27. All marks and inscriptions shall be clear, non-erasable, unambiguous, and non-transferable.

28. Readings of measurement results shall be taken in conformity with the following conditions:

28.1. readings of the results shall be taken from a display or hard copy;

28.2. the readings of any result shall be clear and unambiguous, supplemented by such marks and inscriptions necessary to inform the user of the significance of the result. Easy reading of the presented result shall be permitted under normal conditions of use. Additional indications may be shown provided they cannot be confused with the metrologically controlled readings;

28.3. in the case of a hard copy, the print or record shall also be easily legible and non-erasable;

28.4. the measuring instrument for direct sales trading transactions shall be designed to present the measurement result to both parties in the transaction when installed as intended. It is important in direct sales that any ticket provided to the consumer by an ancillary device not conforming to the requirements of this Regulation and the laws and regulations regarding the metrological requirements for a particular measuring instrument would include appropriate references to restrictions of the information obtained;

28.5. whether or not the measuring instrument intended for utility measurement purposes has been equipped with a device for remote reading, it shall in any case be fitted with a metrologically controlled display accessible to the consumer without the use of additional tools. The reading of the display of the measuring instruments is the measurement result that serves as the basis for determining the payment.

29. If the measuring instrument is not used for the accounting of utilities and it is normally intended for use in the absence of one of the trading parties, and the measurement is non-repeatable, the measurement result shall be durably stored together with the information on the particular transaction.

30. A durable proof of the measurement results and the information on the particular transaction shall be available upon request at the time the measurement is concluded.

31. The design of the measuring instrument shall ensure the possibility of performing the assessment of its conformity in accordance with the requirements of this Regulation and the laws and regulations regarding the metrological requirements for a particular measuring instrument.

Deputy Prime Minister, Minister for Economics Arvils Ašeradens

**Annex 3**

Cabinet Regulation No. 212

12 April 2016

**Declaration of Conformity**

1. Model of the measuring instrument, number of the product, type, batch, or serial number.

2. Name and address of the manufacturer and, where applicable, its authorised representative.

3. Certification that the declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration of conformity (identification of the measuring instrument allowing traceability; it may, where necessary for the identification of the measuring instrument, include an image).

5. Certification that the measuring instrument is in conformity with the relevant laws and regulations.

6. References to the applicable standards and normative documents or references to the other technical specifications in relation to which conformity is declared.

7. Information on the notified authority involved, indicating the name and number of the authority, the conformity assessment activities performed and the certificates issued by the authority.

8. Additional information.

9. Information on preparation of the declaration of conformity:

9.1. the place and date of issue;

9.2. given name, surname, position, signature.

Deputy Prime Minister, Minister for Economics Arvils Ašeradens