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| **CABINET OF MINISTERS OF UKRAINE****RESOLUTION** |
| **from January 13, 2016 № 94****Kyiv** |

**About the statement of the Technical regulation of legally regulated means of measuring equipment**

{With changes made in accordance with the Resolutions of the Cabinet of Ministers
[№ 852 of 03.10.2018](https://zakon.rada.gov.ua/laws/show/852-2018-%D0%BF#n14)
[№ 598 of 10.07.2019](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n11)
[№ 102 of 12.02.2020](https://zakon.rada.gov.ua/laws/show/102-2020-%D0%BF#n73) }

In accordance with [the first part of](https://zakon.rada.gov.ua/laws/show/124-19#n72) Article 5 of the Law of Ukraine “On Technical Regulations and Conformity Assessment”, the Cabinet of Ministers of Ukraine **resolves** :

1. To approve the attached [Technical regulations of legally regulated measuring instruments](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n10) .

2. The Ministry of Economic Development, Trade and Agriculture to ensure the implementation of the Technical Regulations approved by this resolution.

*{Item 2 as amended in accordance with the Resolution of the Cabinet of Ministers*[*№ 102 of 12.02.2020*](https://zakon.rada.gov.ua/laws/show/102-2020-%D0%BF#n74)*}*

3. This Resolution shall enter into force six months after its publication.

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| **The Prime Minister of Ukraine** | **А.ЯЦЕНЮК** |
| **Ind. 75** |  |

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|  | **APPROVED by the****Resolution of the Cabinet of Ministers of Ukraine****of January 13, 2016 № 94** |

**TECHNICAL REGULATIONS of**
**legally regulated measuring equipment**

**The general part**

1. This Technical Regulation lays down the requirements to be met by measuring instruments intended for use in the field of regulated metrology (hereinafter referred to as measuring instruments) when they are placed on the market and / or put into operation to perform tasks related to with measurements.

2. This Technical Regulation shall apply to measuring instruments, the list of which is given in [Annex 1](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n200) .

This Technical Regulation does not apply to legally regulated measuring instruments that are medical devices and / or medical devices for in vitro diagnostics.

*{Item 2 as amended by the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n12)*}*

3. This Technical Regulation contains more detailed requirements for the resistance of measuring equipment to electromagnetic interference than the [Technical Regulation on electromagnetic compatibility of equipment](https://zakon.rada.gov.ua/laws/show/1077-2015-%D0%BF#n13) , approved by the Cabinet of Ministers of Ukraine dated December 16, 2015 № 1077. The requirements of the Technical Regulation on electromagnetic compatibility of equipment measuring instruments must also be performed.

4. In this Technical Regulation, the terms are used in the following meaning:

1) commissioning - the use of measuring equipment as intended by the consumer (user) in Ukraine for the first time;

2) revocation - any measure aimed at ensuring the return of measuring equipment that has already been provided to the consumer (user);

3) node - a hardware device, referred to as such in national standards and technical specifications, for certain measuring instruments, which operates independently and forms a measuring instrument together with other nodes with which it is compatible or with a compatible measuring instrument;

4) conformity assessment - the process of proving that the essential requirements of this Technical Regulation relating to measuring equipment have been met;

5) technical specifications - documents (including international standards, normative documents of the International Organization of Legislative Metrology), which establish the technical requirements that must be met by measuring equipment.

5. Other terms are used in the meaning given in the Laws of Ukraine [“On General Safety of Non-Food Products”](https://zakon.rada.gov.ua/laws/show/2736-17) , [“On Standardization”](https://zakon.rada.gov.ua/laws/show/1315-18) , [“On Technical Regulations and Conformity Assessment”](https://zakon.rada.gov.ua/laws/show/124-19) and [“On Metrology and Metrological Activity”](https://zakon.rada.gov.ua/laws/show/1314-18) .

**Applicability to nodes**

6. Where national standards and technical specifications for certain measuring instruments establish essential requirements for units, the provisions of this Technical Regulation shall apply mutatis mutandis to such units.

7. Units and means of measuring equipment may be assessed independently and separately in order to establish compliance.

**Essential requirements**

8. Measuring instruments shall meet the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) and in the relevant national standards and technical specifications for certain measuring instruments.

**Marketing and / or commissioning**

9. The placing on the market and / or putting into operation on the territory of Ukraine of any measuring equipment that meets the requirements of these Technical Regulations may not be prohibited for reasons arising from these Technical Regulations.

10. Measuring equipment may be placed on the market and / or put into operation only if they meet the requirements of this Technical Regulation.

11. Measuring equipment must comply with the provisions governing their commissioning, taking into account local climatic conditions. To do this, select the appropriate upper and lower temperature limits from [table 1 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n228) Annex 2 and determine the humidity conditions (with or without condensation), as well as take into account the openness or closedness of the intended place of use.

12. If different accuracy classes are defined for measuring equipment:

1) national standards or technical specifications for certain measuring instruments may specify the accuracy classes to be used for a particular field of application of such instruments;

2) in all other cases, the accuracy classes are determined, which must be used for a certain field of application of measuring equipment within certain accuracy classes, provided that the use of all accuracy classes is allowed in Ukraine.

In the cases specified in subparagraphs 1 or 2 of this paragraph, measuring instruments of a higher accuracy class may be used, if the owner makes such a choice.

13. Demonstration and / or demonstration of measuring instruments that do not meet the requirements of this Technical Regulation during fairs, exhibitions, demonstrations or other demonstrations are possible provided that the visible indication clearly indicates that such measuring instruments may not be placed on the market and / or put into operation until they are brought into compliance with the requirements of this Technical Regulation.

**Responsibilities of manufacturers**

14. Manufacturers shall, when putting measuring instruments into service and / or operation, ensure that they have been designed and manufactured in accordance with the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) and the requirements specified in the relevant national standards and technical specifications for certain measuring instruments.

15. Manufacturers shall draw up the technical documentation referred to in [paragraphs 48 to 52 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n88) this Technical Regulation and carry out the appropriate conformity assessment procedure referred to in [paragraph 47 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n86) this Technical Regulation or ensure its implementation.

16. If the conformity of measuring instruments with the requirements of this Technical Regulation applicable to them has been confirmed by the established conformity assessment procedure, manufacturers shall draw up a declaration of conformity in accordance with [paragraphs 53-56 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n107) this Technical Regulation and affix a mark of conformity and additional metrological marking in accordance with [paragraphs 57 -70 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n113) this Technical Regulation.

17. Manufacturers shall keep the technical documentation and the declaration of conformity for a period of 10 years after the measuring instruments have been put into circulation.

18. Manufacturers shall ensure that the procedures applied in the mass production sites of measuring instruments are maintained in accordance with this Technical Regulation. Changes in the design of measuring instruments or their characteristics, as well as changes in the relevant national standards and technical specifications for certain measuring instruments, by reference to which the conformity of such instruments is declared, must be taken into account.

19. In view of the risks posed by measuring instruments, manufacturers shall carry out appropriate sample tests of measuring instruments placed on the market and, if necessary, consider complaints, keep a register of complaints and measuring instruments that do not meet the established requirements and withdrawals of measuring instruments. , as well as inform distributors about the results of any monitoring.

20. Manufacturers shall ensure that measuring instruments which they have placed on the market are marked with the type, batch number or serial number or other element enabling them to be identified, or if the size or nature of the measuring instruments does not allow application of such data, - provide the necessary information in the accompanying documentation and on the packaging, if any, in accordance with [paragraph 31 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n296) Annex 2.

21. Manufacturers shall indicate on measuring instruments their name, registered trade name or registered trade mark (mark for goods and services) and postal address or, if this is not possible, indicate such information in the accompanying documentation and on the packaging, if any, to [paragraph 31 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n296) Annex 2. Contact details shall be provided in accordance with language legislation.

22. Manufacturers shall ensure that measuring instruments which they put into circulation are accompanied by a copy of the declaration of conformity and by instructions and information in accordance with [paragraph 32 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n297) Annex 2, which are carried out in accordance with the legislation on languages. Such instructions and information, as well as any markings, must be clear, understandable and obvious.

23. Manufacturers who consider or have reason to believe that a measuring instrument they have put into circulation do not comply with the requirements of this Technical Regulation shall immediately (taking into account the level of non-conformity of such instrument) take the corrective measures necessary to bring it into line with the established requirements, withdrawal from circulation or revocation. If the specified measuring instrument poses a risk, manufacturers must immediately inform the state market surveillance authorities (hereinafter referred to as market surveillance authorities), providing detailed information, in particular on the non-compliance of such instrument with the requirements of this Technical Regulation and any corrective measures taken.

24. Manufacturers shall, at the reasoned request of the market surveillance authority, provide it with all the information and documents in paper or electronic form necessary to prove the conformity of the measuring instruments with the requirements of these Technical Regulations. At the request of that authority, manufacturers shall cooperate with that authority in respect of any action taken to eliminate the risks posed by measuring instruments which they have put into circulation.

**Duties of authorized representatives**

25. The manufacturer may, on the basis of a written order, appoint an authorized representative.

The obligations set out in [paragraph 14 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n37) this Technical Regulation and the obligation to draw up the technical documentation set out in [paragraph 15 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n38) this Technical Regulation shall not be part of the power of attorney received by the authorized representative.

26. The authorized representative shall perform the tasks specified in the order received from the manufacturer. On the basis of the power of attorney, the authorized representative must perform at least the following actions:

1) keep the declaration of conformity and technical documentation for submission at the request of market surveillance authorities for 10 years after the introduction of measuring instruments into circulation;

2) upon a substantiated request of the market surveillance authority, provide it with all the information and documentation necessary to prove the conformity of the measuring equipment to the requirements of these Technical Regulations;

3) at the request of the market surveillance authority, cooperate with it in relation to any measures to eliminate the risks posed by measuring instruments, which are covered by the power of attorney received by the authorized representative.

**Responsibilities of importers**

27. Importers shall put into circulation only those measuring instruments that meet the requirements of these Technical Regulations.

28. Before putting measuring instruments into circulation and / or putting them into service, importers shall make sure that the relevant conformity assessment procedure set out in [paragraph 47 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n86) this Technical Regulation has been carried out by the manufacturer. They must also ensure that the manufacturer has drawn up the technical documentation, that the measuring equipment bears the mark of conformity and additional metrological markings and that they are accompanied by a copy of the declaration of conformity and other necessary documents, and that the manufacturer meets the requirements of [paragraphs 20.](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n43) and [21 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n44) this Technical Regulation.

If the importer considers or has reason to believe that measuring instruments do not meet the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) and the requirements set out in the relevant national standards and technical specifications for certain measuring instruments, he shall not put such measuring instruments into circulation or into operation until they are brought into compliance with the following requirements. In addition, if the measuring equipment poses a risk, the importer must notify the manufacturer and the market surveillance authorities.

29. Importers shall indicate on measuring instruments their name, registered trade name or registered trade mark (mark for goods and services) and postal address or, if this is not possible, indicate such information on the accompanying document and packaging, if any, in accordance with [paragraph 31 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n296) Annex 2. Contact details are provided in accordance with the language legislation.

30. Importers shall ensure that measuring instruments are accompanied by instructions and information in accordance with [paragraph 32 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n297) Annex 2, drawn up in accordance with the legislation on languages. Such instructions and information, as well as any markings, must be clear, understandable and obvious.

31. Importers shall ensure that the conditions of storage or transport of measuring instruments while they are under their responsibility do not jeopardize their compliance with the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) and the requirements set out in the relevant national standards and technical specifications for certain measuring instruments. techniques.

32. In view of the risks posed by measuring instruments, importers shall carry out appropriate selective tests of measuring instruments placed on the market and, if necessary, consider complaints, keep a register of complaints and measuring instruments that do not meet the established requirements and withdrawals of measuring instruments. , as well as inform distributors about the results of any monitoring.

33. Importers who consider or have reason to believe that a measuring instrument they have put into circulation do not meet the requirements of this Technical Regulation shall immediately (taking into account the level of non-conformity of such instrument) take the corrective measures necessary to bring it into line with the established requirements, withdrawal from circulation or revocation. If the specified measuring instrument poses a risk, importers must immediately inform the market surveillance authorities, providing detailed information, in particular on the non-compliance of such measuring instrument with the requirements of this Technical Regulation and any corrective measures taken.

34. Importers shall keep a copy of the declaration of conformity for circulation at the request of market surveillance authorities for 10 years after the measuring instruments have been put into circulation, and shall ensure that technical documentation is provided to such authorities upon request.

35. At the reasoned request of the market surveillance authority, importers must provide it with all the information and documentation (in paper or electronic form) necessary to prove the conformity of measuring instruments with the requirements of these Technical Regulations. At the request of that authority, importers shall cooperate with that authority in respect of any measures taken to eliminate the risks posed by measuring instruments which they have put into circulation.

**Responsibilities of distributors**

36. Distributors shall act with due care in relation to the requirements of this Technical Regulation when making measuring instruments available on the market and / or putting them into operation.

37. Before making measuring instruments available on the market and / or during their commissioning, distributors shall check that such means are marked with a conformity mark and additional metrological marking, that measuring instruments are accompanied by a declaration of conformity and other necessary documents, instructions and information. defined in [paragraph 32 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n297) Annex 2, drawn up in accordance with the legislation on languages, as well as that the manufacturer and importer have complied with the requirements set out in [paragraphs 20](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n43) , [21](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n44) and [29 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n59) this Technical Regulation.

If a distributor considers or has reason to believe that measuring instruments do not meet the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) and the requirements specified in the relevant national standards and technical specifications for certain measuring instruments, he shall not make them available on the market or introduce them into the market. operation until such means are brought into conformity with such requirements. In addition, if measuring instruments pose a risk, the distributor must notify the manufacturer or importer, as well as market surveillance authorities.

38. Distributors shall ensure that the conditions of storage or transport of measuring instruments while they are under their responsibility do not jeopardize their compliance with the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) and the requirements set out in the relevant national standards and technical specifications for certain measuring instruments. techniques.

39. Distributors who consider or have reason to believe that a measuring instrument they have put into circulation or put into operation do not meet the requirements of this Technical Regulation shall immediately (taking into account the level of non-compliance of such instrument) take the corrective measures necessary to bring it into service. compliance with the established requirements, withdrawal from circulation or revocation. If the specified measuring instrument poses a risk, distributors shall immediately inform the market surveillance authorities, providing detailed information, in particular on the non-compliance of such measuring instrument with the requirements of this Technical Regulation and any corrective measures taken.

40. At the reasoned request of the market surveillance authority, distributors shall provide it with all information and documentation (in paper or electronic form) necessary to prove the conformity of measuring instruments with the requirements of these Technical Regulations. At the request of that authority, distributors shall cooperate with that authority in respect of any measures taken to eliminate the risks posed by measuring instruments which they have made available on the market.

**Cases of imposing obligations of producers on importers and distributors**

41. If the importer or distributor puts measuring instruments into circulation under his name or trademark (mark for goods and services) or modifies the measuring instruments already put into circulation in such a way that it may affect their compliance with the requirements of this Technical regulations, he is considered a manufacturer and must perform the duties of the manufacturer set out in [paragraphs 14-24 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n37) this Technical Regulation.

**Identification of business entities**

42. Entities should provide market surveillance authorities with information at their request to identify:

1) any business entity that has supplied them with measuring equipment;

2) any business entity to which they have supplied measuring equipment.

Business entities shall provide this information within 10 years after receipt and / or delivery of measuring equipment.

**Presumption of conformity of measuring instruments**

43. The list of national standards for the purposes of application of this Technical Regulation (hereinafter - the list of national standards) shall be approved and published in accordance with the law.

*{Item 43 in the wording of the Resolution of the Cabinet of Ministers*[*№ 102 of 12.02.2020*](https://zakon.rada.gov.ua/laws/show/102-2020-%D0%BF#n76)*}*

44. Compliance of measuring instruments with the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) may be ensured by applying technical specifications, the references to which (or lists of parts of which) are posted on the official website of the Ministry of Economy.

*{Paragraph 44 as amended in accordance with the Resolution of the Cabinet of Ministers*[*№ 102 of 12.02.2020*](https://zakon.rada.gov.ua/laws/show/102-2020-%D0%BF#n78)*}*

45. The conformity of measuring instruments with national standards from the list of national standards or parts thereof, as well as the technical specifications referred to in [paragraph 44 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n82) this Technical Regulation, or parts thereof gives the presumption of conformity of such instruments with the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) . technical specifications or parts thereof.

*{Paragraph 45 as amended in accordance with the Resolution of the Cabinet of Ministers*[*№ 102 of 12.02.2020*](https://zakon.rada.gov.ua/laws/show/102-2020-%D0%BF#n79)*}*

46. ​​The manufacturer may use any technical solution that meets the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) .

**Conformity assessment procedures**

47. The assessment of conformity of measuring instruments with the essential requirements applicable to them shall be carried out at the choice of the manufacturer by applying one of the conformity assessment procedures set out in [Annex 1](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n200) , in accordance with [Annex 3](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n322) .

**Technical documentation**

48. The technical documentation shall reflect the design, the manufacturing process and the operation of the measuring instruments and shall enable an assessment to be made of their compliance with the requirements of this Technical Regulation that apply to them.

49. The technical documentation must be sufficiently detailed to ensure compliance with the following requirements:

1) determination of metrological characteristics;

2) reproducibility of metrological characteristics of manufactured measuring instruments, provided that proper regulation is carried out using the means intended for this purpose;

3) the integrity of the measuring equipment.

50. The technical documentation shall, as far as relevant for the assessment and identification of the type and / or instrumentation, contain the following information:

1) a general description of the measuring instrument;

2) sketch design and production drawings, layout of components, assemblies, electrical diagrams, etc .;

3) production operations to ensure stable production of measuring equipment;

4) if necessary, descriptions of electronic devices with drawings, diagrams, diagrams of transmission of logical and general information of the software, explaining their characteristics and operation;

5) descriptions and explanations necessary for understanding the information set forth in [sub-clauses 2-4 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n95) clause 50 of these Technical Regulations, including the operation of measuring equipment;

6) a list of national standards from the list of national standards or a list of technical specifications referred to in [paragraph 44 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n82) this Technical Regulation, which are applied in full or in part;

7) descriptions of technical solutions adopted in order to comply with the essential requirements, if the national standards from the list of national standards or technical specifications referred to in [paragraph 44 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n82) this Technical Regulation have not been applied in full or in part;

8) results of design calculations, research, etc .;

9) if necessary, the results of appropriate tests to prove that the type and / or means of measuring equipment meets the requirements of this Technical Regulation in the declared standard operating conditions and under the established environmental impact;

10) type-examination certificates for measuring instruments, which contain parts identical to those given in the design documentation.

51. The manufacturer determines the place of application of seals and markings of measuring equipment.

52. The manufacturer must indicate the compatibility clauses with interfaces and components (if applicable).

**Declaration of conformity**

53. The declaration of conformity shall state that the fulfillment of the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) and the requirements set out in the relevant national standards and technical specifications for certain measuring instruments has been demonstrated.

54. The declaration of conformity shall be drawn up in accordance with the model structure set out in [Annex 4](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n504) and shall contain the information specified by the relevant conformity assessment modules set out in [Annex 3](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n322) and shall be kept up to date.

55. Where measuring instruments are subject to several technical regulations requiring a declaration of conformity, a single declaration of conformity shall be drawn up for all such technical regulations. Such declaration of conformity shall specify the relevant technical regulations, including information on their official publication.

The single declaration of conformity may take the form of a dossier consisting of separate declarations of conformity.

56. The manufacturer, by drawing up a declaration of conformity, assumes responsibility for the conformity of measuring instruments to the requirements established in these Technical Regulations.

**Conformity marking**

57. Compliance of measuring instruments with this Technical Regulation shall be certified by affixing the mark of conformity and additional metrological markings provided for in [paragraphs 58-70 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n115) this Technical Regulation.

**General principles of marking of conformity and additional metrological marking**

58. The mark of conformity must be affixed only by the manufacturer or his authorized representative.

59. The manufacturer, by affixing the mark of conformity by himself or his authorized representative, states that he assumes responsibility for the conformity of measuring instruments to all requirements applicable to those instruments and defined in the relevant technical regulations which provide for the marking of conformity.

60. The mark of conformity must be the only marking certifying the conformity of measuring instruments to the requirements applicable to those instruments and defined in the relevant technical regulations which provide for the affixing of the mark of conformity.

61. The application of other markings, signs or inscriptions on measuring instruments, which may mislead third parties as to the meaning or form of the mark of conformity, shall be prohibited. Any other marking may be affixed to the measuring equipment provided that it does not adversely affect the visibility, legibility and meaning of the mark of conformity.

62. Additional metrological marking shall consist of the sign of the legally regulated measuring instrument, the shape and dimensions of which are given in [Annex 5](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n506) , and the last two digits of the year of its application, surrounded by a rectangle. The height of the rectangle must be equal to the height of the mark of conformity.

63. When applying additional metrological markings, it is necessary to adhere to the general principles established in [paragraphs 58-61 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n115) this Technical Regulation.

**Rules and conditions of application of the mark of conformity and additional metrological marking**

64. The mark of conformity and additional metrological marking must be visible, legible and must not be erased, be applied on measuring instruments or on a plate with technical data. Where this is not possible or not justified by the nature of the measuring equipment, such marking must be affixed to the accompanying documentation and packaging, if any.

65. If a measuring instrument consists of a set of devices that are not its components that function together, the marking of the mark of conformity and additional metrological marking shall be applied to the main unit of the measuring instrument.

66. The mark of conformity and additional metrological marking must be applied before the introduction of measuring equipment into circulation.

67. The mark of conformity and additional metrological markings may be applied during production, if justified.

68. Additional metrological markings should follow the mark of conformity directly.

69. The mark of conformity and the additional metrological marking shall be accompanied by the identification number of the notified body, if such body has been involved at the stage of production control, as set out in [Annex 3](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n322) .

The identification number of the designated body must be affixed by such body independently or in accordance with its instructions by the manufacturer or his authorized representative.

The identification number of the notified body involved must be indelible or self-destructing during its removal.

70. The mark of conformity, the additional metrological marking and the identification number of the notified body may be accompanied by any other symbol indicating a special risk or special use.

**Appointment of conformity assessment bodies**

71. The designation of conformity assessment bodies for the performance by them as third parties of conformity assessment tasks in accordance with these Technical Regulations shall be carried out in accordance with the law.

**Requirements for designated bodies**

72. In order to obtain a designation, a conformity assessment body must meet the general requirements for designated bodies specified by law, as well as the special requirements set out in [paragraphs 73-80 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n135) these Technical Regulations.

73. The conformity assessment body must be a third party, a person who is independent of the person providing the object of conformity assessment and of the person interested in such object as the consumer (user).

A conformity assessment body that is a member of an association of entrepreneurs representing legal entities and / or natural persons - entrepreneurs involved in the design, manufacture, supply, installation, use or maintenance of measuring equipment, which it assesses, may be considered such a third party, provided that the independence of that body is proved and that there is no conflict of interest.

74. The conformity assessment body, its head, deputy heads and personnel responsible for carrying out conformity assessment tasks shall not be the designer, manufacturer, importer, distributor, installer, buyer, owner, user or responsible for the maintenance of measuring equipment that they are evaluated, or by a representative of either party. This requirement does not preclude the use of assessed measuring instruments that are necessary for the work of the conformity assessment body, or the use of such instruments for personal purposes.

The conformity assessment body, its head, deputy heads and personnel responsible for carrying out conformity assessment tasks shall not be directly involved in the design, manufacture or assembly, sale, installation, use or maintenance of the measuring equipment they assess or represent parties involved in such activities. They shall not engage in any activity that may conflict with the independence of their judgments or their integrity in relation to the conformity assessment activities for which they are assigned or assigned. This requirement applies in particular to counseling services.

However, these requirements do not preclude the possibility of exchanging technical information between the manufacturer and the notified body for the purpose of conformity assessment.

Conformity assessment bodies shall ensure that the activities of subcontractors or subsidiaries engaged by them in carrying out conformity assessment work do not affect the confidentiality of information, objectivity and impartiality of the conformity assessment activities of such bodies.

75. Conformity assessment bodies and their staff should carry out conformity assessment activities with due diligence and technical competence in a particular field and be free from any pressure and incentives, including financial ones, that could affect their judgments or the results of their activities. on conformity assessment, especially by persons or groups of persons interested in the results of such activities.

76. The conformity assessment body shall be able to perform the conformity assessment tasks set out in [Annex 3](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n322) for which it is or has been appointed, whether such tasks are performed by the conformity assessment body itself or on its behalf and under its responsibility. responsibility.

The conformity assessment body shall at all times and for each conformity assessment procedure and each group of measuring instruments for which it is or has been assigned, must:

have qualified and experienced staff to perform conformity assessment tasks;

have descriptions of the procedures under which conformity assessment is carried out, ensuring the transparency and reproducibility of such procedures. The conformity assessment body shall apply appropriate policies and procedures to distinguish between the activities of the designated body and other activities;

apply procedures for conformity assessment activities taking into account the size of the enterprise ordering conformity assessment, the industry in which such enterprise operates, its structure, the degree of complexity of production technology and mass or serial nature of the production process.

The conformity assessment body must have the means necessary to perform at the appropriate level the technical and administrative tasks of conformity assessment and have access to all other necessary equipment or facilities.

77. Personnel responsible for performing conformity assessment tasks shall have:

thorough technical and professional training for carrying out the conformity assessment activity in respect of which the conformity assessment body has been appointed;

sufficient level of knowledge about the requirements for conformity assessment work, as well as the relevant powers;

relevant knowledge and understanding of the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) and the requirements set out in the relevant national standards and technical specifications for certain measuring instruments, as well as the relevant provisions of the legislation of Ukraine and the European Union;

skills of drawing up certificates, protocols and reports confirming the conformity assessment work.

78. The impartiality of conformity assessment bodies, their managers, deputy managers and staff responsible for carrying out conformity assessment tasks should be guaranteed.

Remuneration of the head, deputy heads of the conformity assessment body and his staff responsible for the performance of conformity assessment tasks shall not depend on the number of performed conformity assessment works or their results.

79. The personnel of the conformity assessment body shall keep trade secrets in respect of all information obtained in the course of their tasks in accordance with [Annex 3](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n322) , except for its provision in the cases specified by law to the relevant competent authorities or in the cases provided for in this Technical Regulation. conformity assessment procedures.

80. Conformity assessment bodies should participate in relevant standardization activities or ensure that their personnel responsible for performing conformity assessment tasks are aware of such activities.

The notified body must take part in the relevant activities of the sectoral or cross-sectoral group (s) of designated bodies formed in accordance with [paragraphs 98](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n185) and [99 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n186) this Technical Regulation, keep its personnel responsible for conformity assessment tasks informed of such activities, and should also use the documents prepared as a result of the work of the specified group (groups) as general guidelines.

**Involvement of subcontractors and subsidiaries by designated bodies**

81. Where a designated body engages a subcontractor to perform certain conformity assessment activities or uses the resources of a subsidiary, it shall verify that the specified subcontractor or subsidiary complies with the requirements set out in [paragraphs 72 to 80](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n134) (except for participation in activities). sectoral or intersectoral group (groups) of designated bodies) of this Technical Regulation, and notify the appointing authority thereof.

82. The designated authorities shall be fully responsible for the work performed by subcontractors or subsidiaries, regardless of their location.

83. A subcontractor or a subsidiary may be involved in conformity assessment work only with the consent of the customer.

84. The designated authorities shall keep, at the request of the designating authority, the relevant documents relating to the assessment of the qualifications of the subcontractors or subsidiaries involved and the work carried out by them in accordance with [Annex 3](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n322) .

**Responsibilities of designated bodies in relation to their activities**

85. The notified bodies shall carry out the conformity assessment in accordance with the conformity assessment procedures set out in [Annex 3](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n322) .

86. Conformity assessment should be carried out in a proportionate manner without imposing an unnecessary burden on economic operators. Designated bodies must carry out their activities with due regard to the size of the enterprise ordering conformity assessment work, the industry in which it operates, its structure, the degree of complexity of the technology of production of appropriate measuring equipment and mass or serial production process.

In this case, the designated bodies must comply with the degree of requirements and the level of protection that are necessary for the compliance of measuring instruments with this Technical Regulation.

87. If the notified body considers that the manufacturer has not complied with the essential requirements set out in [Annex 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) and the requirements set out in the relevant national standards and technical specifications for certain measuring instruments, the notified body must require the manufacturer to take appropriate corrective action; do not issue a document of conformity.

88. If, during the monitoring of conformity after the issuance of the document of conformity, the notified body finds that the measuring equipment no longer meets the requirements, the notified body must require the manufacturer to take appropriate corrective measures and, if necessary, suspend or revoke the conformity documents. .

89. If corrective measures have not been taken or have not yielded the required results, the designated authority shall, as the case may be, limit the scope, suspend or revoke the documents of compliance.

**Consideration of appeals against decisions of appointed bodies**

90. A person who provides measuring instruments for conformity assessment has the right to appeal to the designated authority requesting a review of any decision taken by that authority with respect to those instruments.

91. The notified body shall examine the appeal in accordance with the provisions of national standards relating to the examination of appeals by conformity assessment bodies.

92. In case of disagreement of the applicant with the decision of the appointed body, adopted as a result of the appeal, this decision may be appealed by filing an appeal to the appeal commission formed by the Ministry of Economy.

*{Paragraph 92 as amended in accordance with the Resolution of the Cabinet of Ministers*[*№ 102 of 12.02.2020*](https://zakon.rada.gov.ua/laws/show/102-2020-%D0%BF#n80)*}*

93. The lodging of an appeal with the appointed body and the appeal commission does not restrict the applicant's right to go to court. The decision of the appeal commission may be appealed in court.

94. The costs of lodging an appeal and re-assessing compliance shall be borne by the applicant. If the results of the re-assessment of conformity differ from the results of the previous one, the costs of the applicant shall be reimbursed by the designated authority which received the inaccurate results of the preliminary conformity assessment.

**Responsibilities of designated bodies for providing information**

95. The designated authorities shall inform the designating authority of any:

refusals to issue, restriction of scope, suspension of documents on compliance or their cancellation;

circumstances affecting the scope and conditions of their appointment;

requests for information on conformity assessment activities received by them from market surveillance authorities.

At the request of the designating authority, the designated authorities shall also inform it of the conformity assessment activities carried out within the scope of their designation and of any other activities, including cross-border and subcontracting.

96. Designated bodies shall provide other conformity assessment bodies designated in accordance with this Technical Regulation and carry out similar conformity assessment activities, covering the same measuring instruments, with relevant information on issues related to negative conformity assessment results. inquiry - also for positive results of conformity assessment.

97. The information referred to in [paragraphs 95](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n177) and [96 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n182) these Technical Regulations shall be provided by the designated authorities no later than five working days from the date of their decision, occurrence of circumstances or receipt of requests.

**Coordination of designated bodies**

98. Coordination and cooperation between conformity assessment bodies designated in accordance with this Technical Regulation regarding the commissioning and proper operation of measuring instruments shall take the form of a sectoral or intersectoral group or groups of designated bodies.

99. Designated bodies shall participate in the work of a sectoral or intersectoral group or groups of designated bodies directly or through designated representatives.

**State market supervision and control of measuring equipment**

100. State market supervision over the compliance of measuring instruments with the requirements of technical regulations and control of such instruments shall be carried out in accordance with the law.

**Formal discrepancy**

101. Measures to eliminate formal non-compliance shall be taken when the market surveillance authority establishes:

1) that the mark of conformity and / or additional metrological marking is applied in violation of the requirements of these Technical Regulations;

2) that the mark of conformity and / or additional metrological marking is not applied;

3) that the identification number of the designated body (if such body was involved at the stage of production control) is applied in violation of the provisions of these Technical Regulations or not;

4) the fact that the declaration of conformity has not been drawn up or the declaration of conformity does not accompany the measuring instrument;

5) that the declaration of conformity has been drawn up in violation of the requirements of these Technical Regulations;

6) lack of access to technical documentation, incomplete volume of such documentation;

7) absence, falsity or incompleteness of the information specified in [paragraphs 21](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n44) or [29 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n59) these Technical Regulations;

8) non-compliance with other requirements provided for in [paragraphs 14-24](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n37) or [paragraphs 27-35 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n56) these Technical Regulations.

|  |  |
| --- | --- |
|  | Annex 1to the Technical Regulation |

**LIST**
**of measuring instruments intended for use in the field of legally regulated metrology, which are subject to the**[**Technical Regulations of legally regulated measuring instruments**](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n10)

|  |  |
| --- | --- |
| A group of measuring instruments intended for use in the field of legally regulated metrology | Conformity assessment procedures \* |
| 1. Automated systems for control and accounting of energy and material resources (electricity and heat, gas, water, petroleum products, etc.) for electromechanical systems | F1 or G |
| 2. Automated systems for control and accounting of energy and material resources (electricity and heat, gas, water, petroleum products, etc.) for electronic systems or systems containing a software product | F1 or G |
| 3. Automobile tanks for oil and food products | B + D or F1 |
| *{Item 4 is excluded on the basis of the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n16)*}* |
| 5. Analyzers of indicators of agricultural and food products: milk, grain, sugar beets, oilseeds and products of their processing | B + D, or B + F, or G |
| 6. Turbidimetric and nephelometric liquid analyzers for water control | B + D, or B + F, or G |
| 7. Spectrum analyzers and characteristics of communication systems | B + D, or B + F, or G |
| 8. Pure tone audiometers | B + D, or B + F, or G |
| 9. Ionizing radiation detection units | B + D, or B + F, or G |
| 10. Measuring antennas and receivers used by state supervision (control) bodies during technical information protection works | B + D, or B + F, or G |
| 11. Measuring channels of radiation control systems | F1 or G |
| 12. Measuring current and voltage transformers | B + D, or B + F, or G |
| *{Item 13 is excluded on the basis of the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n16)*}* |
| 14. Meters of alcohol content in blood and exhaled air | B + D, or B + F |
| 15. Electricity and current meters (voltmeters and ammeters 3-4-bit) | B + D, or B + F, or G |
| 16. Measuring instruments of electrical parameters of electrical installations | B + D or B + F, or F1, or G |
| 17. Measuring instruments of electromagnetic field parameters | B + D, or B + F, or G |
| 18. Power meters and radio interference | B + D, or B + F, or G |
| 19. Meters: | B + D, or B + F, or F1, or G |
| electrostatic charges; |  |
| impedance; |  |
| ground circuit resistance; |  |
| insulation resistance; |  |
| parameters of relay protection; |  |
| the impedance of the phase-zero loop or current in the electrical network; |  |
| leakage current in the electrical network |  |
| 20. Meters of time, frequency (frequency meters) and time intervals | B + D, or B + F or G |
| 21. Devices of control over observance of rules of traffic with functions of photo, video fixing: | B + D, or B + F, or G |
| remote speed meters; |
| space-time parameters measuring the location of vehicles remotely |
| 22. Moisture meters, hygrometers, hygrographs (used during the control of storage conditions of food, medicines, bank vaults, during the sale of coal, wood and natural gas) | B + D, or B + F or G |
| 23. Vibrometers | B + D, or B + F, or G |
| 24. Gas analyzers (except for exhaust gas analyzers), gas detectors | B + D, or B + F or G |
| 25. Generators | B + D, or B + F, or G |
| 26. Kettlebells | B + D, or B + F, or G |
| 27. Global satellite navigation systems for geodetic purposes | B + D, or B + F, or G |
| 28. Density meters (used in determining the mass of packaged goods in packaging, oil, petroleum products and the volume of natural gas in the process of its supply and / or consumption) | B + D, or B + F or G |
| 29. Load sensors weighing | B + D, or B + F |
| 30. Defectoscopes | B + D, or B + F, or G |
| 31. Dynamometers, force sensors | B + D, or B + F |
| *{Item 32 is excluded on the basis of the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n16)*}* |
| 33. Network equivalents | B + D, or B + F, or G |
| *{Item 34 is excluded on the basis of the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n16)*}* |
| *{Item 35 is excluded on the basis of the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n16)*}* |
| 36. Gas calorimeters (used when calculating for supplied and / or consumed natural gas) | B + D, or B + F or G |
| *{Item 37 is excluded on the basis of the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n16)*}* |
| 38. Conductometers, pH-meters, titrators, ionomers (used in laboratories of ecological, phytosanitary and veterinary control) | B + D, or B + F or G |
| 39. Kegi | B + D or F1 |
| 40. Counters of gaseous chemicals | B + D, or B + F, or G |
| 41. Meters of active (accuracy classes 0.5-2.0; 0.2S; 0.5S) and reactive (accuracy classes 0.5-3.0) electricity | B + D, or B + F, or G |
| 42. Lightmeters, luminance meters used in measuring the level of illumination of workplaces and the brightness of computer monitors | B + D, or B + F, or G |
| 43. Manometers and other means for measuring pressure and vacuum | B + D or B + F |
| *{Item 44 is excluded on the basis of the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n18)*}* |
| 45. Measures of electrical resistance (unambiguous and ambiguous) | B + D, or B + F, or G |
| 46. ​​Measures of electrical capacity, inductance and mutual inductance | B + D, or B + F, or G |
| 47. Technical meters (including for wine and alcohol) | B + D or F1 |
| *{Item 48 is excluded on the basis of the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n18)*}* |
| 49. Levels | B + D, or B + F, or G |
| 50. Oscilloscopes | B + D, or B + F, or G |
| 51. Fuel dispensers for refueling cars with compressed gas | B + D, or B + F, or G |
| 52. Automatic devices for weighing road vehicles in motion and measuring axle loads | B + D, or B + F, or G |
| 53. Devices for measuring relay protection and automation in the subway | B + D, or B + F, or G |
| *{Item 54 is excluded on the basis of the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n18)*}* |
| 55. Purks are working | B + D or B + F, or G |
| 56. Radiometers, radiometric installations, dosimeters and dose rate meters | B + D, or B + F, or G |
| *{Item 57 is excluded on the basis of the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n18)*}* |
| 58. Refractometers | B + D, or B + F, or F1, or G |
| 59. Level gauges | B + D, or B + F, or G |
| 60. Selective voltmeters | B + D, or B + F, or G |
| 61. Systems for measuring the duration of telephone conversations, the speed of transmission and accounting of information during the provision of telecommunications services, synchronization devices | B + D, or B + F, or F1 or G |
| 62. Alpha-, beta-, gamma-ray spectrometers, Sich spectrometers | B + D, or B + F, or G |
| 63. Spectroradiometers, radiometers for measuring the level of radiation in spas and beauty salons | B + D, or B + F, or G |
| 64. Stationary tanks for commercial accounting: | B + D, or B + F, or F1 |
| petroleum products (horizontal and vertical cylindrical, spherical); |  |
| liquefied gas (horizontal cylindrical) |  |
| 65. Current measuring tongs | B + D, or B + F, or G |
| 66. Total stations | B + D, or B + F, or G |
| 67. Tachographs | B + D, or B + F, or F1 |
| 68. Theodolites | B + D, or B + F, or G |
| 69. Parking terminals | B + D, or B + F, or G |
| 70. Thermometers (for control of foodstuffs, safety of working conditions and carrying out forensic examinations on behalf of pre-trial investigation bodies, prosecutor's offices and courts) | B + D or B + F |
| 71. Teslameters | B + D, or B + F, or G |
| *{Item 72 is excluded on the basis of the Resolution of the Cabinet of Ministers*[*№ 598 of July 10, 2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n20)*}* |
| 73. Installations signaling radioactive contamination and radiation level control systems | B + D, or B + F, or G |
| 74. Photometers, spectrophotometers for environmental control and air control of the working area | B + D, or B + F, or G |
| 75. Gas and liquid chromatographs | B + D, or B + F, or G |
| 76. Railway tanks | B + D, or B + F, or F1 |
| 77. Noise meters | B + D, or B + F, or G |

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\* In accordance with [Annex 3 of the](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n322)Technical Regulations of Legislatively Regulated Measuring Equipment.

*{Annex 1 as amended in accordance with the Resolutions of the Cabinet of Ministers*[*№ 852 of 03.10.2018*](https://zakon.rada.gov.ua/laws/show/852-2018-%D0%BF#n14)*,*[*№ 598 of 10.07.2019*](https://zakon.rada.gov.ua/laws/show/598-2019-%D0%BF#n15)*}*

|  |  |
| --- | --- |
|  | Annex 2to the Technical Regulation |

**ESSENTIAL REQUIREMENTS**

**The general part**

1. Measuring equipment, which is intended for use in the field of legally regulated metrology (hereinafter - measuring equipment), must provide a high level of metrological reliability, so that any party is confident in the measurement, it must be designed and manufactured with a high level quality in terms of measurement technology and security of measurements.

The essential requirements that measuring instruments must meet are given below. They may be supplemented, if necessary, by special requirements from the relevant national standards and technical specifications for certain measuring instruments, which set out in more detail some aspects of the general requirements.

Decisions taken to comply with the requirements must take into account the intended use of measuring equipment and any alleged misuse.

The terms used in these requirements have the following meanings:

measured value - a specific value that is the object of measurement;

influential quantity - a quantity that is not a measurable quantity, but affects the measurement result;

normalized operating conditions - the values ​​of the measured value and the influential values ​​that form the normal operating conditions for measuring equipment;

obstacle - an influential value that has a value within the limits set by the relevant requirements, but outside the established standard operating conditions for measuring equipment. The influential quantity is an obstacle if for this influential quantity the standardized working conditions are not established;

direct sale - a trade operation during which:

- the measurement result is the basis for determining the amount of payment;

- at least one of the parties involved in the measurement operation is a consumer or any other party in need of the same level of protection;

- all parties involved in the operation, record the measurement result simultaneously in the same place;

climatic conditions - conditions under which the measuring equipment can be operated;

an economic entity that provides utilities is an entity that is considered to be a supplier of electricity, gas, heat or water.

**Permissible errors**

2. Under normal operating conditions and in the absence of obstacles, the measurement error shall not exceed the value of the maximum permissible error established by the special requirements of the relevant national standards and technical specifications for certain measuring instruments.

Unless otherwise specified in the relevant national standards and technical specifications for certain measuring instruments, the maximum permissible error is expressed as a two-way deviation from the true value of the measured value.

3. Under normal operating conditions and in the presence of an obstacle, the performance requirements shall be as set out in the relevant national standards and technical specifications applicable to certain measuring instruments.

If the measuring instrument is intended for use under conditions of constant exposure to an electromagnetic field, the permissible value of the performance must be within the maximum permissible error during tests on the effect of the emitted amplitude-modulated electromagnetic field.

4. The manufacturer must determine the climatic, mechanical and electromagnetic conditions for which the measuring instrument is intended, the power supply and other influences that affect its accuracy, taking into account the requirements of the relevant national standards and technical specifications applicable to certain means of measuring equipment.

**Climatic conditions of the environment**

5. The manufacturer must determine the maximum and minimum temperature limits from any of the values ​​given in Table 1, unless otherwise specified in the relevant national standards and technical specifications for certain measuring instruments, and indicate whether the measuring instrument is intended to operate in humidity with or without condensation, as well as in open or closed place.

Table 1

|  |  |
| --- | --- |
| Temperature limit | Temperature limits |
| The biggest limit | 30 ° C | 40 ° C | 55 ° C | 70 ° C |
| The smallest limit | 5 ° C | -10 ° C | -25 ° C | -40 ° C |

**External mechanical conditions**

6. External mechanical conditions are classified into classes M1 to M3 as described below.

|  |  |
| --- | --- |
| M1 | This class includes measuring equipment used in areas subject to vibration and low impact, for example, measuring equipment mounted on lightweight supporting structures exposed to minor vibrations and shocks transmitted by gusts of wind or gusts associated with with local explosions or piles, door knocks, etc. |
| M2 | This class includes measuring equipment used in places with a significant or high level of vibration and shock, for example, from mechanisms and machines passing nearby, or nearby heavy machinery, conveyor belts and the like. |
| M3 | This class includes measuring equipment used in places where the level of vibration and shock is high or very high, for example, for measuring equipment installed directly on machines, conveyor belts and the like. |

7. With regard to external mechanical conditions, the following influences are taken into account:

vibration;

mechanical shock.

**External electromagnetic conditions**

8. External electromagnetic conditions are classified in classes E1, E2 or E3 as described below, unless otherwise specified in the relevant national standards and technical specifications for certain measuring instruments.

|  |  |
| --- | --- |
| E1 | This class includes measuring equipment used in areas with electromagnetic interference corresponding to interference that may occur in residential, commercial and light industrial buildings. |
| E2 | This class includes measuring equipment used in places with electromagnetic interference corresponding to interference that may occur in other industrial buildings. |
| E3 | This class includes measuring equipment that is powered by a car battery. Such devices must meet the requirements of E2 and the following additional requirements: |
|  | voltage drop caused by the connection of the starter-motor of the internal combustion engine; |
|  | transients due to load drop in case of discharge of the battery disconnected when the engine is running. |

9. With regard to external electromagnetic conditions, the following influences are taken into account:

voltage interruption;

short-term voltage drop;

transients in power and / or signal circuits;

electrostatic discharges;

radio frequency electromagnetic fields;

radio frequency electromagnetic fields on power lines and / or signal circuits are given;

voltage and current emissions in power lines and / or signal circuits.

**Other influential quantities**

10. Other influential values ​​that need to be considered if necessary are:

voltage fluctuations;

fluctuations in the frequency of the supply voltage;

frequency electromagnetic fields of the power supply;

any other quantity that may significantly affect the accuracy of the measuring instrument.

**Basic rules for testing and error detection**

11. The essential requirements referred to in [paragraphs 2](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n221) and [3 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n223) this Annex shall be verified for each relevant impact value. Unless otherwise specified in the relevant national standards and technical specifications for certain measuring instruments, these essential requirements apply, provided that each influence value is used and its impact is assessed separately, and all other influence values ​​are maintained relatively unchanged at their nominal level. values.

The tests must be carried out during or after the action of the influential quantity, depending on the condition which corresponds to the normal operating condition of the measuring instrument in the event of the action of the influential quantity.

**Humidity of the environment**

12. In accordance with the climatic operating conditions for which the measuring equipment is intended, tests for the effects of wet heating (without condensation) or wet cyclic heating (with condensation) may be carried out.

13. Tests for wet cycling are carried out if condensation is important or if steam penetration is accelerated by ventilation. In conditions where humidity without condensation is the determining factor, wet heating is more suitable.

**Reproducibility**

14. The degree of closeness of the results of successive measurements of the same measured value in the case of a change in the place of measurement or the consumer (user), when all other measurement conditions remain unchanged, is reproducibility. The discrepancy of the measurement results should be insignificant compared to the maximum permissible error.

**Frequency**

15. The degree of closeness of the results of successive measurements of the same measured value, performed under the same measurement conditions, is repeatability. The discrepancy of the measurement results should be insignificant compared to the maximum permissible error.

**Response threshold and sensitivity**

16. Measuring equipment must be sufficiently sensitive and have a sufficiently low response threshold to perform the intended measurement task.

**Durability**

17. The design of measuring instruments must ensure the stability of their metrological characteristics for a period of time set by the manufacturer, provided that they are properly installed, serviced and used in accordance with the manufacturer's instructions and in the environmental conditions for which they are intended.

**Reliability**

18. The design of measuring instruments shall reduce, as far as possible, the effect of the obstacle, which leads to inaccurate measurement results, if the presence of such an obstacle is not obvious.

**Suitability**

19. Measuring equipment should not have characteristics that facilitate their use for fraudulent purposes, with the possibility of unintentional misuse should be minimal.

20. To obtain the correct results, the measuring equipment must be suitable for the intended application, taking into account the real working conditions and must not meet the unreasonable requirements of the consumer (user) to obtain the correct result.

21. Errors of measuring equipment, the measurement results of which are used for calculations for utilities, when the values ​​of flow or current are outside the controlled measuring range, should not deviate excessively.

22. If measuring instruments are designed to measure values ​​that are constant over time, they must be insensitive to small changes in the value of the measured value or must respond accordingly.

23. The design of measuring instruments must be strong and the materials from which they are made must comply with the conditions under which the measuring instruments are likely to be used.

24. The design of measuring equipment should facilitate the control of measurement tasks after they are put into circulation or operation. If necessary, special equipment or software must be part of the measuring equipment to carry out such control. Test procedures should be described in the operation manual.

If the measuring equipment has additional software that supports functions other than measuring, the software that is in this case critical to the metrological characteristics must be identified and must not be subjected to unacceptable exposure to additional software.

**Protection against unauthorized interference**

25. The metrological characteristics of a measuring instrument shall not be subjected to the unacceptable effects of another device connected to it, any function of the connected device or any remote device connected to such a device.

26. A component of a measuring instrument that affects metrological characteristics must be designed with safety requirements in mind. The safety measures provided must provide evidence of unauthorized interference with the measuring instrument.

27. Software critical to metrological characteristics must be identified as such and protected.

Its identification must be easily ensured by means of measuring equipment.

Evidence of intervention must be available for a reasonable period of time.

28. Measurement data, software critical to measurement characteristics and important metrological characteristics stored or transmitted shall be adequately protected against accidental or intentional interference.

29. For measuring equipment, the measurement results of which are used for settlements for utilities, readings of the total delivered quantity or indications from which the total quantity of delivered production can be determined, full or partial reference to which is the basis for payment, should not allow readjustment during operation.

**Information applied to or accompanying measuring equipment**

30. The following inscriptions shall be applied to measuring instruments:

1) registered commercial name or registered trademark (mark for goods and services);

2) information about their characteristics of accuracy.

And also if necessary:

3) data on operating conditions;

4) measurement limits;

5) range of measurements;

6) identification marking;

7) type verification certificate number;

8) information on compliance (or non-compliance) of additional devices that provide metrological results with the provisions of the [Technical Regulations of Legislatively Regulated Measuring Equipment](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n10) (hereinafter - the Technical Regulations).

31. If measuring instruments are too small or too sensitive to be marked with the relevant information, this information shall be applied to the accompanying documentation and to the packaging, if any, as required by the provisions of the Technical Regulation.

32. Measuring equipment should be accompanied by information about their work, unless the ease of handling does not make it unnecessary. The information should be easy to understand and, if necessary, include:

1) standardized working conditions;

2) classes on mechanical and electromagnetic conditions;

3) upper and lower temperature limits, indicating whether condensation is possible or not, data on whether the room is open or closed;

4) instructions for installation, maintenance, repair and allowable adjustment;

5) instructions for proper use and all special conditions of use;

6) conditions of compatibility with interfaces, components, units or other means of measuring equipment.

33. It is allowed not to provide a separate operating manual for a group of identical measuring equipment used in the same place or for measuring equipment, the measurement results of which are used for billing for utilities.

34. The range of the scale of the measured value, unless otherwise specified in the relevant national standards or technical specifications for certain measuring instruments, shall be 1 x 10n; 2 x 10n or 5 x 10n, where n is any integer or zero. The unit of measurement or its designation must be given next to the numerical value.

35. The units of measurement used and their designation must comply with the law.

36. Markings and inscriptions must be clear, indelible, unambiguous and non-transferable.

**Indication**

37. The result of measurements should be deduced on the indicating device or printed out.

38. Any indications must be clear and unambiguous, accompanied by such markings and inscriptions that allow to inform the consumer (user) about the value of the measurement result. Under normal conditions of use, this result should be easy to read. Additional indications may be used provided that they cannot be mistaken for metrologically controlled indications.

39. When using a paper copy, the seal or record must be clear and not erased.

40. Measuring equipment intended for direct sales shall be designed in such a way that the measurement result is provided to both parties at the same time, if the measuring equipment is correctly installed. In case of criticality for direct sales, any check issued to the consumer (user) by an additional device that does not meet the requirements of the Technical Regulation applicable to it must contain the relevant restrictive information.

41. Measuring equipment intended for use by an entity providing utilities, with or without a remote reading system, must be equipped with a metrologically controlled indication system, available without special tools for the consumer (user). The data read from the display is the result of a measurement, which is the basis for setting the payment.

**Further data processing for the purpose of a trade transaction**

42. Measuring instruments not intended for use by a utility providing a utility shall record the result of the measurements by means of long-term operation, together with information enabling the identification of a specific trade transaction when:

1) the measurement is not repeated;

2) measuring equipment is intended for normal use in the absence of one of the parties to the operation.

43. In addition, reliable proof of measurement results and transaction identification information should be available upon request at the time of completion of measurements.

**Conformity assessment**

44. Measuring equipment must be designed in such a way as to enable assessments of their compliance with the requirements of the Technical Regulation.

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|  | Annex 3to the Technical Regulation |

**CONFORMITY ASSESSMENT PROCEDURES**

**Module B**
**(type check)**

1. Type-examination - part of the conformity assessment procedure, according to which the notified body examines the technical design of measuring instruments intended for use in the field of legally regulated metrology (hereinafter - measuring instruments), and verifies and confirms its compliance with the [Technical Regulations measuring equipment](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n10) (hereinafter - the Technical Regulation), which are applied to the specified tool.

2. The type examination may be carried out in one of the following ways:

1) research of the sample representing the complete means of measuring equipment planned for production (the made standard sample);

2) assessment of the adequacy of the technical design of the measuring equipment by examining the technical documentation and supporting documents specified in [paragraph 3 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n330) this Annex, with the study of samples of one or more critical components of the specified tool intended for production (combination of manufactured standard sample and draft sample);

3) assessment of the adequacy of the technical design of the measuring instrument by examining the technical documentation and supporting documents specified in [paragraph 3 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n330) this Annex, without examining the sample (draft model).

The decision on the appropriate method of checking the type and the required number of samples shall be taken by the notified body.

3. The manufacturer must lodge an application for type examination with a notified body of his choice, which must contain:

1) the name and address of the manufacturer, as well as in the case of submission of the application by his authorized representative - the name and address of such a representative;

2) a written statement that the same application has not been submitted to another designated body;

3) technical documentation in accordance with the description given in [paragraphs 48-52 of the](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n88) Technical Regulations. The technical documentation must make it possible to assess the conformity of the measuring instrument with the requirements of the Technical Regulation applicable to it and must include an adequate analysis and assessment of the risk (s). The technical documentation shall specify the requirements that apply and cover, as far as such assessment, design, manufacture and operation of the measuring instrument is concerned.

The application must be accompanied, if necessary:

4) samples of measuring equipment planned for production. The notified body may, if necessary, require additional samples to carry out the test program;

5) supporting documents to prove the adequacy of the decision on the technical project. Such supporting documents must indicate all the documents used, especially if the relevant national standards from the list of national standards for the purposes of applying the Technical Regulation, compliance with which presupposes compliance of measuring instruments with the essential requirements set out in [Annex 2 of the](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n204) Technical Regulation were applied completely. The supporting documents must, where appropriate, contain the results of tests carried out in accordance with the relevant technical specifications by the appropriate laboratory of the manufacturer or on his behalf and under his responsibility by another testing laboratory.

*{Subparagraph 5 of paragraph 3, as amended in accordance with the Resolution of the Cabinet of Ministers*[*№ 102 of 12.02.2020*](https://zakon.rada.gov.ua/laws/show/102-2020-%D0%BF#n81)*}*

4. The notified body must:

1) in respect of a means of measuring equipment - to conduct an examination of technical documentation and supporting documents to assess the adequacy of the technical design of such a tool;

2) in respect of samples:

check the conformity of the manufactured sample to the technical design and identify the components that have been developed in accordance with national standards from the list of national standards, and components that have been developed in accordance with the relevant technical specifications;

carry out appropriate examinations and tests or have them carried out in order to check the correct application of the provisions of the relevant national standards selected by the manufacturer from the list of national standards;

carry out appropriate examinations and tests or have them carried out in order to verify that, in the event of non-application of the relevant national standards from the list of national standards, the manufacturer's decisions to apply the relevant technical specifications meet the essential requirements of the Technical Regulation;

agree with the manufacturer on the location of research and testing;

3) in respect of other parts of the measuring equipment - to conduct an examination of the technical documentation and supporting documents in order to assess the adequacy of the technical design of other parts of such equipment.

5. The notified body must draw up a report on the results of the evaluation, indicating the types of work carried out in accordance with [paragraph 4 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n337) this Annex and their results. The notified body may, in the performance of its obligations vis-à-vis the designating authority, disclose the contents of such report in full or in part only with the agreement of the manufacturer.

6. If the type of measuring equipment meets the requirements of the Technical Regulation, the notified body shall issue to the manufacturer a certificate of inspection of measuring equipment (hereinafter - type examination certificate), which must contain the name and address of the manufacturer, inspection results, conditions (if any) validity and the necessary data to identify the approved type. One or more attachments may be attached to the type-examination certificate.

The type-examination certificate and its annexes must contain all the necessary information to enable the conformity of the manufactured measuring instruments with the approved type to be assessed and to be inspected under the conditions of their operation.

In particular, to ensure the assessment of conformity of manufactured measuring instruments to the approved type in terms of reproducibility of their metrological characteristics with their proper regulation with the use of appropriate technical means, the content of the type-examination certificate must include:

metrological characteristics of the type of measuring equipment;

measures necessary to ensure the integrity of measuring equipment (seals, software product identification, etc.);

information on other elements necessary for identification of measuring equipment and visual verification of their conformity to the type;

if necessary, any special information necessary to verify the characteristics of the manufactured measuring equipment;

in the case of assemblies, all the necessary information to ensure compatibility with other assemblies or measuring instruments.

The type-examination certificate shall be issued for a period of 10 years from the date of issue and may be renewed for a further period of 10 years.

If the type does not meet the requirements of the applicable Technical Regulation, the notified body shall refuse to issue a type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body must keep under constant review any changes in the state of the art which indicate that the approved type may no longer meet the requirements of the applicable Technical Regulation and shall determine whether there is a need for further examination of such changes. In this case, the notified body shall inform the manufacturer of its decision.

8. The manufacturer shall inform the notified body which holds the technical documentation of the type-examination certificate of any changes in the approved type which may affect the conformity of the measuring instrument with the essential requirements of the Technical Regulation or with the conditions of validity of that certificate. Such changes may require additional approval in the form of an addition to the original type-examination certificate.

9. The notified body shall inform the designating authority of the type-examination certificates issued and withdrawn or / or any additions thereto, and shall, periodically or at the request of the designating authority, provide it with a list of such certificates and / or any additions to them, the issuance of which such a designated body has refused, the effect of which it has suspended or imposed other restrictions on them.

The designating authority, the market surveillance authorities (hereinafter referred to as the market surveillance authority) and other designated authorities shall have the right to receive, upon request, a copy of the type-examination certificates and / or annexes thereto. The designating authority and the market surveillance authorities shall have the right to receive on request a copy of the technical documentation and the results of the examinations carried out by the designated authority.

The notified body must keep a copy of the type-examination certificate, copies of its annexes and additions, as well as technical documentation, including the documentation submitted by the manufacturer, until the expiry date of such certificate.

10. The manufacturer must, for a period of 10 years after the measuring instrument has been put into circulation, keep a copy of the type-examination certificate, its annexes and additions together with the technical documentation at the request of the market surveillance authorities.

11. The manufacturer's authorized representative may lodge an application in accordance with [paragraph 3 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n330) this Annex and fulfill the obligations set out in [paragraphs 8](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n357) and [10 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n361) this Annex, provided that such obligations are specified in the authorization received from the manufacturer.

**Module D**
**(conformity to type by ensuring the quality of the production process)**

12. Conformity to type by quality assurance of the manufacturing process - part of the conformity assessment procedure by which the manufacturer fulfills the obligations set out in [paragraphs 13](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n366) , [23](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n399) and [24 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n400) this Annex and guarantees and declares under his sole responsibility that the measuring instruments conform to the type , described in the type-examination certificate, and the requirements of the Technical Regulation applicable to the specified measuring equipment.

**Production**

13. The manufacturer must operate an approved quality management system for production, final product inspection and testing of measuring instruments as defined in [paragraphs 14 to 18 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n368) this Annex and shall be subject to surveillance in accordance with [paragraphs 19 to 22 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n392) this Annex.

**Quality management system**

14. The manufacturer shall lodge an application for assessment of his quality management system with a notified body of his choice, for the relevant measuring equipment, which shall include:

1) the name and address of the manufacturer, and in case of submission of the application by his authorized representative - the name and address of such a representative;

2) a written statement that the same application has not been submitted to another designated body;

3) the necessary information for the category of measuring equipment under consideration;

4) documentation regarding the quality management system;

5) technical documentation concerning the approved type and a copy of the type-examination certificate.

15. The quality management system must ensure compliance of the measuring instrument with the type described in the type-examination certificate and with the requirements of the Technical Regulation applicable to those measuring instruments.

The elements, requirements and provisions of the quality management system accepted by the manufacturer must be systematized and organized in the form of written documents, procedures and instructions. The documentation for such a quality management system should ensure an adequate understanding of the quality control programs, plans and protocols.

Such documentation must contain, in particular, an adequate description of:

goals in the field of quality and organizational structure, responsibilities and powers of management in relation to product quality;

appropriate production methods, quality management and quality assurance systems, processes and system actions to be used;

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

such quality records (records) as inspection reports, test and calibration data, qualification reports of the personnel concerned;

monitoring tools to achieve the required product quality and effective functioning of the quality management system.

16. The notified body must assess the quality management system to determine whether it satisfies the requirements referred to in [paragraph 15 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n374) this Annex.

The notified body must presume conformity with the requirements of the quality management system which satisfy the technical requirements of the relevant national standard or technical specification.

The audit team must have experience in managing quality management systems, and at least one of its specialists must have experience in assessing the relevant measuring equipment and manufacturing technology, as well as knowledge of the requirements of the applicable Technical Regulations. The audit should, in particular, include visits to the manufacturer's plant to assess them.

The audit team shall review the technical documentation referred to in [subparagraph 5 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n373) paragraph 14 of this Annex, and verify the manufacturer's ability to determine the relevant requirements of the Technical Regulation and conduct the necessary inspections to ensure compliance of measuring instruments with such requirements.

The notified body must inform the manufacturer of its decision. The notification should contain the conclusions of the audit and a reasoned decision based on the results of the evaluation.

17. The manufacturer must undertake to fulfill the obligations arising out of the quality management system as approved and to uphold it so that it remains adequate and efficient.

18. The manufacturer must keep the notified body that has approved the quality management system informed of any intended change of the quality management system.

The notified body must assess any changes proposed and decide whether the modified quality management system is in conformity with the requirements referred to in [paragraph 15 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n374) this Annex or whether such a system needs to be reassessed.

The notified body must inform the manufacturer of its decision. This notification shall contain the conclusions of the examination and the reasoned assessment decision.

**Supervision by a designated body**

19. The purpose of surveillance is to make sure that the manufacturer duly fulfills the obligations laid down in the approved quality management system.

20. For the purpose of carrying out the assessment, the manufacturer must provide the notified body with access to the production sites, carry out production control, ensure the testing and storage of measuring instruments, and provide the necessary information, in particular:

1) documentation on the quality management system;

2) such quality records (records) as inspection reports, test and calibration data, qualification reports of the personnel concerned, etc.

21. The notified body must periodically carry out audits to make sure that the manufacturer applies and maintains the quality management system and must provide an audit report to the manufacturer.

22. The notified body may pay visits to the manufacturer without notice, during which it may, if necessary, carry out tests on measuring instruments or have them carried out in order to check the proper functioning of the quality management system. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

**Conformity marking and declaration of conformity**

23. The manufacturer shall affix the mark of conformity and additional metrological markings provided for in the Technical Regulation and, under the responsibility of the designated authority referred to in [paragraph 14 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n368) this Annex, his identification number for each measuring instrument corresponding to the type described in the type-examination certificate. applicable requirements of the Technical Regulation.

24. The manufacturer shall draw up a written declaration of conformity for each modification of the measuring instrument and keep it for 10 years after the measuring instrument has been put into circulation for submission to market surveillance authorities upon request. The declaration of conformity must identify the modification of the measuring instrument for which it was drawn up.

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

A copy of the declaration of conformity must be supplied with each measuring instrument that is put into circulation. At the same time, in case one consumer (user) is supplied with a large number of measuring equipment, copies of the declaration of conformity are allowed to be delivered with a batch of these devices.

25. The manufacturer must, for a period of 10 years after the measuring instrument has been put into circulation, keep in order to provide the market surveillance authorities with:

1) the documentation specified in [paragraph 14 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n368) this Annex;

2) information on the approved changes specified in [paragraph 18 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n388) this Annex;

3) decisions and reports of the appointed body specified in [paragraphs 18](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n388) , [21](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n396) and [22 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n397) this Annex.

26. The notified body must inform the designating authority of the quality management system approval decisions issued or withdrawn, and shall, periodically or upon request, provide the designating authority with a list of decisions to refuse, suspend or restrict the quality management system approvals. way.

**Authorized representative**

27. The manufacturer's obligations set out in [paragraphs 14](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n368) , [18](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n388) , [23](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n399) , [24](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n400) and [25 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n403) this Annex may be fulfilled by his authorized representative on his behalf and under his responsibility, provided that they are specified in the mandate received from the manufacturer.

**Module F**
**(conformity of type according to the results of verification of measuring equipment)**

28. Conformity of type according to the results of verification of measuring instruments - part of the conformity assessment procedure by which the manufacturer fulfills the obligations set out in [paragraphs 29](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n413) , [33](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n423) , [38](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n433) and [39 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n434) this Annex, and guarantees and declares under his sole responsibility that measuring instruments the equipment which has been tested in accordance with the provisions of [paragraph 30 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n415) this Annex shall conform to the type described in the type-examination certificate and to the requirements of the Technical Regulation applicable to those devices.

**Production**

29. The manufacturer must take the measures necessary to ensure that the manufacturing process and its control ensure conformity of the manufactured measuring instruments with the approved type described in the type-examination certificate and with the requirements of the Technical Regulation applicable to those instruments.

**Audit**

30. The notified body chosen by the manufacturer shall carry out the appropriate examinations and tests (or have them carried out) in order to verify the conformity of the measuring instrument with the type described in the type-examination certificate and the relevant requirements of the Technical Regulation.

Examinations and tests to check the conformity of measuring instruments with the applicable requirements shall be carried out at the choice of the manufacturer either by carrying out examinations and tests of each measuring instrument as specified in [paragraphs 31](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n418) and [32 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n420) this Annex or by conducting research and testing of measuring instruments. statistical verification of conformity as specified in [paragraphs 33-37 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n423) this Annex.

**Verification of conformity by examination and testing of each measuring instrument**

31. Measuring instruments must be individually tested and subjected to the tests and / or equivalent tests established in the relevant technical specifications, in accordance with the relevant national (national) standard (s), in order to verify the conformity of the measuring instruments. equipment of the approved type described in the type-examination certificate and the requirements of the Technical Regulation applicable to the specified means.

In the absence of a national standard or technical specification, the decision to carry out the relevant tests shall be taken by the relevant notified body.

32. The notified body shall issue a certificate of conformity for the examinations and tests carried out, and shall affix its identification number to each measuring instrument tested or have it affixed under its responsibility.

The manufacturer must keep the certificate of conformity for 10 years after the measuring instruments have been put into circulation for submission to the relevant market surveillance authorities.

**Statistical verification of compliance**

33. The manufacturer must take all measures necessary in order that the manufacturing process and the control thereof ensure the homogeneity of each lot produced and provide his measuring instruments for verification in the form of homogeneous lots.

34. Samples of measuring equipment shall be taken at random from each batch in accordance with the requirements of [paragraph 35 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n425) this Annex. The selected measuring instruments must be individually examined and subjected to the tests established in the relevant national standards and / or equivalent tests established in the relevant technical specifications, in order to verify the conformity of measuring instruments with the type described in the type-examination certificate and the requirements of the Technical Regulation. , as well as approval of the decision on acceptance or rejection of the specified batch of measuring equipment. In the absence of a national standard or technical specification, the decision to carry out the relevant tests shall be taken by the relevant notified body.

35. Statistical verification of conformity should be based on the quality characteristics of measuring instruments. The sampling system must provide:

a quality level corresponding to a probability of acceptance of 95 percent, with a mismatch of less than 1 percent;

a quality limit corresponding to a probability of acceptance of 5 percent, with a mismatch of less than 7 percent.

36. In the case of acceptance of a batch, all measuring instruments of such batch shall be considered as tested, except for those measuring instruments from the sample that have not been tested.

The notified body must issue a certificate of conformity in respect of the examinations and tests carried out, and affix its identification number to each measuring instrument which has been inspected or have it carried out under its responsibility.

The manufacturer must keep the certificates of conformity for 10 years after the measuring instruments have been put into circulation for submission to the market surveillance authorities.

37. If a party is not accepted, the designated authority shall take appropriate measures to prevent the introduction of such a party. In the event of frequent recurrence of non-acceptance of lots, the notified body may suspend the statistical conformity check and take appropriate measures.

**Conformity marking and declaration of conformity**

38. The manufacturer shall affix the mark of conformity and additional metrological markings provided for in the Technical Regulation and, under the responsibility of the designated authority referred to in [paragraph 30 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n415) this Annex, his identification number for each measuring instrument corresponding to the approved type described in the type-examination certificate. and the requirements of the Technical Regulation applicable to those instruments and under the responsibility of the designated authority referred to in [paragraph 14 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n368) this Annex, its identification number for each individual measuring instrument corresponding to the type described in the type examination certificate and the requirements of the Technical Regulation, applicable.

39. The manufacturer shall draw up a written declaration of conformity for each modification of the measuring instrument and keep it for 10 years after the measuring instrument has been put into circulation for submission to market surveillance authorities. The declaration of conformity must identify the modification of the measuring instrument for which it was drawn up.

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

A copy of the declaration of conformity must be supplied with each measuring instrument that is put into circulation. At the same time, in case one consumer (user) is supplied with a large number of measuring equipment, a copy of the declaration of conformity is allowed to be delivered with the batch of the specified equipment.

With the consent of the notified body referred to in [paragraph 30 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n415) this Annex and under its responsibility, the manufacturer may also affix the identification number of the notified body to the measuring instrument.

40. With the consent of the notified body referred to in [paragraph 30 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n415) this Annex and under its responsibility, the manufacturer may affix the designated body's identification number to the measuring instrument during the manufacturing process.

**Authorized representative**

41. The manufacturer's duties may be performed by his authorized representative on his behalf and under his responsibility, provided that they are specified in the authorization received from the manufacturer. The authorized representative may not fulfill the obligations of the manufacturer set out in [paragraphs 29](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n413) and [33 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n423) this Annex.

**Module F1**
**(compliance with the results of the test of measuring equipment)**

42. Conformity based on the results of inspections of measuring instruments - the conformity assessment procedure by which the manufacturer fulfills the obligations set out in [paragraphs 43](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n444) , [44](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n447) , [48](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n457) , [53](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n468) and [54 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n469) this Annex, and guarantees and declares under his sole responsibility that the relevant instruments measuring equipment, which have been tested in accordance with [paragraph 45 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n449) this Annex, meet the requirements of the Technical Regulation applicable to these means.

**Technical documentation**

43. The manufacturer shall develop the technical documentation in accordance with [paragraphs 48-52 of the](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n88) Technical Regulation, which shall allow the conformity of the measuring instrument to be assessed and meet the results of the analysis and risk assessment. The technical documentation shall specify the applicable requirements and contain information on the design, manufacture and operation of the measuring instrument to the extent necessary for the assessment.

The manufacturer must keep the technical documentation for 10 years after the measuring instrument has been put into circulation for submission to the market surveillance authorities.

**Production**

44. The manufacturer must take the measures necessary to ensure that the manufacturing process and its control ensure that the manufactured measuring instruments comply with the requirements of the Technical Regulation applicable to those instruments.

**Audit**

45. The notified body chosen by the manufacturer shall carry out the relevant examinations and tests (or have them carried out) in order to check the conformity of the measuring instruments with the requirements of the Technical Regulation applicable to those instruments.

Tests and tests to verify the conformity of measuring instruments with the applicable requirements shall be carried out at the choice of the manufacturer either by carrying out examinations and tests of each measuring instrument in accordance with [paragraphs 46](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n452) and [47 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n454) this Annex or by examining and testing measuring instruments on the basis of statistical verification of compliance in accordance with [paragraphs 48-52 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n457) this Annex.

**Verification of conformity by examination and testing of each measuring instrument**

46. ​​Measuring instruments must be individually examined and subjected to the tests and / or equivalent tests established in the relevant national specifications in the relevant national standards, in order to verify the measuring instruments' requirements applicable to those instruments.

In the absence of a national standard or technical specification, the test decision shall be taken by the relevant notified body.

47. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each measuring instrument tested or have it affixed under its responsibility.

The manufacturer must keep this certificate of conformity for 10 years after the measuring instrument has been put into circulation for submission to the market surveillance authorities.

**Statistical verification of compliance**

48. The manufacturer must take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced and provides his measuring instruments for verification in the form of homogeneous lots.

49. Samples of measuring equipment shall be taken at random from each batch in accordance with the requirements of [paragraph 51 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n460) this Annex.

50. All selected measuring instruments must be individually examined and subjected to the tests established in the relevant national standards from the list of national standards and / or equivalent tests established in the relevant technical specifications, in order to verify compliance of measuring instruments with the requirements of the Technical Regulation of the specified means, and also approval of the decision on acceptance or rejection of the specified party of means of measuring equipment. In the absence of a national standard or technical specification, the test decision shall be taken by the relevant notified body.

51. Statistical verification of conformity should be based on the quality characteristics of measuring instruments. The sampling system must provide:

a quality level corresponding to a probability of acceptance of 95 percent, with a mismatch of less than 1 percent;

a quality limit corresponding to a probability of acceptance of 5 percent, with a mismatch of less than 7 percent.

52. In the case of acceptance of a batch, all measuring equipment of such batch shall be considered as tested, except for those measuring equipment from the sample that has not been tested.

The notified body must issue a certificate of conformity in respect of the examinations and tests carried out, and affix its identification number to each measuring instrument which has been inspected or have it carried out under its responsibility.

The manufacturer must keep the certificate of conformity for 10 years after the measuring instrument has been put into circulation for submission to the market surveillance authorities.

If a lot is not accepted, the notified body must take appropriate measures to prevent the introduction of such a lot. In the event of frequent recurrence of non-acceptance of lots, the notified body may suspend the statistical conformity check and take appropriate measures.

**Conformity marking and declaration of conformity**

53. The manufacturer shall affix the mark of conformity and additional metrological markings established in the Technical Regulation and, under the responsibility of the designated authority referred to in [paragraph 45 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n449) this Annex, his identification number for each individual measuring instrument that meets the requirements of the Technical Regulation .

54. The manufacturer shall draw up a written declaration of conformity for each modification of the measuring instrument and keep it for 10 years after the measuring instrument has been put into circulation for submission to the market surveillance authorities. The declaration of conformity must identify the modification of the measuring instrument for which it was drawn up.

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

A copy of the declaration of conformity must be supplied with each measuring instrument that is put into circulation. At the same time, in case one consumer (user) is supplied with a large number of measuring equipment, a copy of the declaration of conformity is allowed to be delivered with the batch of the specified equipment.

With the consent of the notified body referred to in [paragraph 45 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n449) this Annex and under its responsibility, the identification number of the notified body may also be affixed to the measuring equipment by the manufacturer.

55. With the consent of the designated body and under its responsibility, the manufacturer may affix the identification number of the designated body to the measuring equipment during the production process.

**Authorized representative**

56. The manufacturer's obligations on his behalf and under his responsibility may be fulfilled by his authorized representative, provided that such obligations are specified in the mandate received from the manufacturer. The authorized representative may not fulfill the obligations of the manufacturer set out in the [first paragraph of paragraph 43](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n444) , [paragraphs 44](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n447) and [48 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n457) this Annex.

**MODULE G**
**(compliance with the results of inspection of each individual measuring equipment)**

57. Conformity in the verification of each individual measuring instrument is the conformity assessment procedure by which the manufacturer fulfills the obligations set out in [paragraphs 58](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n479) , [59](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n482) , [61](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n488) and [62 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n489) this Annex and guarantees and declares under his sole responsibility that the instrument in question measuring equipment, which has been tested in accordance with [paragraph 60 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n484) this Annex, meets the requirements of the Technical Regulation applicable to the specified means.

**Technical documentation**

58. The manufacturer shall develop the technical documentation in accordance with [paragraphs 48 to 52 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n88) this Technical Regulation and make it available to the notified body referred to in [paragraph 60 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n484) this Annex. The technical documentation must enable the assessment of the conformity of the measuring instrument with the relevant requirements and contain the results of the analysis and risk assessment, determine the applicable requirements and contain information on the design, manufacture and operation of the measuring instrument to the extent necessary for the assessment.

The manufacturer must keep the technical documentation for a period of 10 years after the measuring instrument has been put into circulation for submission to market surveillance authorities upon request.

**Production**

59. The manufacturer must take all measures necessary in order that the manufacturing process and its control ensure compliance of the manufactured measuring instrument with the requirements of the Technical Regulation applicable to that instrument.

**Audit**

60. The notified body chosen by the manufacturer shall carry out the examinations and tests required by the relevant national standards from the list of national standards and / or other relevant technical specifications (or commission them) to verify the conformity of measuring instruments with the applicable Technical Regulations. In the absence of a national standard or technical specification, the notified body shall decide on the tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each measuring instrument tested or have it affixed under its responsibility.

The manufacturer must keep the certificate of conformity for 10 years after the measuring instrument has been put into circulation for submission to the market surveillance authorities.

**Conformity marking and declaration of conformity**

61. The manufacturer shall affix the mark of conformity and additional metrological markings established in the Technical Regulation and, under the responsibility of the designated authority referred to in [paragraph 60 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n484) this Annex, his identification number for each measuring instrument that meets the requirements of the Technical Regulation applicable to that Regulation. means.

62. The manufacturer shall draw up a written declaration of conformity for each modification of a measuring instrument and keep it for 10 years after the measuring instrument has been put into circulation for submission to market surveillance authorities. The declaration of conformity must identify the modification of the measuring instrument for which it was drawn up.

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

A copy of the declaration of conformity must be supplied with the measuring instrument.

**Authorized representative**

63. The manufacturer's obligations set out in [paragraphs 58](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n479) , [61](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n488) and [62 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n489) this Annex may, on his behalf and under his responsibility, be fulfilled by his authorized representative, provided that such obligations are specified in the mandate received from the manufacturer.

**Terms**

64. Conformity assessment under [modules D](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n363) , [F](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n410) , [F1](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n441) or [G](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n476) may be carried out at the manufacturer's premises or at any other place, if transportation to the place of use does not require disassembly of the measuring equipment, and if commissioning at the place of use does not require assembling the measuring instrument or other technical installation work that is likely to affect the operation of the measuring instrument, and if the proper functioning of the measuring instrument depends on the conditions of its installation or use. In all other cases, the conformity assessment must be carried out at the place of use of the measuring instrument.

65. If the operation of a measuring instrument depends on the conditions of its installation or use, the procedures referred to in [paragraph 64 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n495) this Annex may be carried out in two stages, the second stage including all inspections and tests, the results of which depend on the conditions of its installation or use, and the first stage - all other inspections and tests. The second stage is performed at the place of use of measuring equipment.

66. If the manufacturer decides to perform one of the procedures referred to in [paragraph 64 of](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n495) this Annex in two stages and to carry out both such stages by different parties, the measuring instrument which has passed the first stage of the procedure shall bear the identification number of the notified body involved. at this stage.

67. The party who carried out the first stage of the procedure shall issue for each measuring instrument a certificate containing the data necessary for the identification of the measuring instrument and indicating the research and tests carried out.

The party conducting the second stage of the procedure must conduct those studies and tests that have not yet been conducted.

The manufacturer or his authorized representative must ensure that certificates of conformity issued by the notified body are provided on request.

68. The manufacturer who has chosen [module D](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n363) in the first step may use the same procedure in the second step or decide to use in the second step [module F](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n410) or [F1,](https://zakon.rada.gov.ua/laws/show/94-2016-%D0%BF/print#n441) respectively.

Marking with the mark of conformity and additional metrological marking must be applied to the measuring instrument after the end of the second stage together with the identification number of the designated body that was involved in the second stage.

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|  | Annex 4to the Technical Regulation |

**[DECLARATION OF CONFORMITY](https://zakon.rada.gov.ua/laws/file/text/43/f453603n517.doc)**

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|  | Annex 5to the Technical Regulation |

**SHAPE AND DIMENSIONS of the**
**sign of the legally regulated measuring instrument**

The shape and dimensions of the sign of the legally regulated measuring instrument with a diameter of 100 millimeters must correspond to those indicated in the figure. The dimensions of the sign are given in millimeters.

The given sizes are relative. The actual diameter of the circle described around the marking should be chosen from the following: 2.5; 4; 6; 10; 16; 25; 40; 60; 100 millimeters.