Republic of Latvia

Cabinet

Regulation No. 582

Adopted 10 October 2023

**Regulations Regarding In Vitro Diagnostic Medical Devices**

*Issued pursuant to*

*Section 34, Paragraph two, Clauses 2, 3, 4, and 5 of the Medical Treatment Law and Section 7, Paragraphs one and two of the law On Conformity Assessment*

**I. General Provisions**

1. The Regulation prescribes:

1.1. the essential requirements for in vitro diagnostic medical devices;

1.2. the procedures by which in vitro diagnostic medical devices shall be placed on the market and put into service (introduced);

1.3. the procedures for the registration of information on manufacturers of in vitro diagnostic medical devices, in vitro diagnostic medical devices manufactured by them, and also distributors of in vitro diagnostic medical devices;

1.4. the procedures for the distribution, vigilance, post-market surveillance, and service of in vitro diagnostic medical devices.

2. The essential requirements for in vitro diagnostic medical devices, the procedures by which in vitro diagnostic medical devices shall be placed on the market and put into service (introduced), and also information on manufacturers of in vitro diagnostic medical devices, in vitro diagnostic medical devices manufactured by them, and distributors of in vitro diagnostic medical devices shall be registered, the basic provisions of the procedures for the distribution, vigilance, post-market and technical surveillance of in vitro diagnostic medical devices shall be determined by Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (hereinafter – Regulation No 2017/746).

3. The terms used in this Regulation shall correspond to the terms used in Regulation No 2017/746 and also in the directly applicable legal acts of the European Union issued on the basis thereof.

4. If the authorised representative has registered the place of commercial activity in the Republic of Latvia, it shall, prior to the placing an in vitro diagnostic medical device on the market, provide the following information to the State Agency of Medicines (hereinafter – the Agency) and also immediately inform of changes in such information:

4.1. the name, registration number, and legal address, and also the single registration number (if any) assigned by the European Database on Medical Devices EUDAMED (hereinafter – EUDAMED);

4.2. the registered address of the place of commercial activity;

4.3. the manufacturer on whose behalf in vitro diagnostic medical devices are placed on the market – the name, registration number, and legal address, and also the single registration number (if any);

4.4. a copy of a written mandate of the manufacturer in accordance with Article 11(3) of Regulation No 2017/746;

4.5. information on in vitro diagnostic medical devices of the manufacturer referred to in Sub-paragraph 4.3 of this Regulation which are intended to be placed on the market in the territory of the European Union – the name, trade mark (if any), the code of the European Medical Device Nomenclature, the modifications (if any), the intended purpose, the specific parameters (composition, dimensions, and other essential information), the basic identifier of an in vitro diagnostic medical device (UDI-DI), and also the EU declaration of conformity and, in the relevant case, a copy of the certificate issued in accordance with Article 51 of Regulation No 2017/746.

5. In order to ascertain whether this Regulation applies to an in vitro diagnostic medical device, it shall be taken into account whether the particular device corresponds to the definition referred to in Article 2(2) of Regulation No 2017/746. This Regulation shall also apply to the accessories for an in vitro diagnostic medical device referred to in Section 2(4) of Regulation No 2017/746.

6. The information indicated in Section 20 of Annex I to Regulation No 2017/746 shall be ensured to users and patients in the official language. The information indicated in Section 20 of Annex I to Regulation No 2017/746 and other documentation of an in vitro diagnostic medical device need not be in the official language if it is intended to use the in vitro diagnostic medical device only in a medical treatment institution and it will be used only by appropriately qualified and trained medical practitioners, provided that a consent of the particular medical treatment institution for the use of the particular language in the documentation of the in vitro diagnostic medical device has been received. In implementing the supervision and control of conformity with the requirements laid down for in vitro diagnostic medical devices in this Regulation, Regulation No 2017/746, and the directly applicable legal acts of the European Union issued on the basis thereof, and also in carrying out market surveillance of in vitro diagnostic medical devices and control of devices in service, the Health Inspectorate (hereinafter – the Inspectorate) is entitled to request that the manufacturer, authorised representative, importer, or distributor ensures all information and documentation necessary for proving the conformity of the in vitro diagnostic medical device in the official language or any other language upon choice of the Inspectorate. When requesting the submission of the technical documentation and also translation of its parts, the Inspectorate shall determine a period of 30 days for the submission unless a shorter term is justified due to detection of serious and immediate risk.

7. In commencing manufacture of in vitro diagnostic medical devices, a medical treatment institution shall, in accordance with Article 5(5) of Regulation No 2017/746, submit a declaration to the Agency, indicating the type, the intended purpose, and the most essential parameters of the in vitro diagnostic medical device to be manufactured. The medical treatment institution shall also submit a relevant declaration to the Agency in case if such manufacture is discontinued or the intended purpose or essential parameters of the in vitro diagnostic medical device change.

**II. Notification Procedure of In Vitro Diagnostic Medical Devices**

8. Persons who commence the placing of Class B, C, and D and also List A, List B, and self-testing in vitro diagnostic medical devices on the market in the territory of the Republic of Latvia shall submit a completed notification form (Annex 1) to the Agency and append a copy of the EC (EU) declaration of conformity, and also copies of valid certificates issued by the notified bodies (hereinafter – the notification procedure). One notification shall contain information on the in vitro diagnostic medical devices included in one certificate of one manufacturer.

9. The Agency shall check the conformity of the EC (EU) declaration of conformity of the in vitro diagnostic medical device and the certificates issued by the notified bodies (if applicable) received within the scope of the notification procedure with the requirements of this Regulation, Regulation No 2017/746, and the directly applicable legal acts of the European Union issued on the basis thereof, and also the information indicated in the notification form. In detecting non-conformity of the information submitted or missing documents, the Agency shall inform the submitter thereof and request that corresponding specifications or supplements are submitted.

10. The Agency shall, within 10 working days after receipt of the information indicated in Paragraph 8 of this Regulation, ensure public availability on its website of at least the data on the in vitro diagnostic medical device received within the scope of the notification procedure, its manufacturer, authorised representative (if applicable) or notifier, and the notification number assigned by the Agency. After publishing this information on the website of the Agency, the notification procedure shall be considered to be completed.

11. The persons referred to in Paragraph 8 of this Regulation are entitled, after completion of the notification procedure, to place the in vitro diagnostic medical device on the market of the Republic of Latvia without a decision or approval of the Agency.

12. The persons referred to in Paragraph 8 of this Regulation need not carry out the notification procedure if, within the period which starts six months after the day when the European Commission has notified of full commencement of the operation of the functions of EUDAMED and ends 18 months afterwards, the manufacturer has complied with the requirements laid down in Article 28(1) of Regulation No 2017/746 in relation to entering of the information referred to in Section 1 of Part A of Annex 6 to Regulation No 2017/746 in EUDAMED.

13. Medical treatment institutions shall provide information to the Agency according to the notification procedure in relation to the acquired and introduced in vitro diagnostic medical devices which are referred to in Paragraph 8 of this Regulation and marked with the CE marking, appending an EC (EU) declaration of conformity and the certificates issued by the notified bodies (if such are available) if the notification procedure has not been carried out yet in relation to the acquired in vitro diagnostic medical device and the medical treatment institution acquires the device:

13.1. directly from a manufacturer whose place of commercial activity is not located in any Member State of the European Union or European Economic Area;

13.2. in exhibitions;

13.3. using services of web shops;

13.4. in another way without the intermediation of the person who is responsible for placing the in vitro diagnostic medical device on the market in the territory of the Republic of Latvia in accordance with Paragraph 8 of this Regulation.

14. A medical treatment institution which has acquired an in vitro diagnostic medical device in accordance with the procedures laid down in Paragraph 13 of this Regulation and which alienates such in vitro diagnostic medical device afterwards shall transfer all documentation related thereto to the acquirer in order to ensure traceability of such in vitro diagnostic medical device.

15. The Agency is entitled to request translations in the official language of the documents submitted in the notification procedure.

16. The persons referred to in Paragraph 8 of this Regulation:

16.1. shall be responsible for traceability of the in vitro diagnostic medical devices referred to in Paragraph 8 of this Regulation after placing them on the market in the territory of the Republic of Latvia and for withdrawal from the market of the in vitro diagnostic medical devices placed on the market in the cases referred to in this Regulation or Regulation No 2017/746;

16.2. shall list each transaction performed (except for transactions with natural persons, i.e. consumers) with in vitro diagnostic medical devices (date, other party of the transaction, nature of the transaction, and information identifying the in vitro diagnostic medical devices involved in the transaction) and immediately provide such information to the Agency or the Inspectorate upon their request;

16.3. shall, without delay, notify the Agency and the Inspectorate of any activities carried out by them in order to stop the distribution of in vitro diagnostic medical devices or to request withdrawal of in vitro diagnostic medical devices from the market, and also of reasons for the relevant action.

**III. Rights and Obligations of State Administration Institutions**

17. In accordance with the procedures laid down in this Regulation, the Agency:

17.1. shall receive and store information on manufacturers of in vitro diagnostic medical devices whose place of commercial activity is in the Republic of Latvia and on the in vitro diagnostic medical devices manufactured by them;

17.2. shall maintain the electronic database of the LATMED register of in vitro diagnostic medical devices (hereinafter – LATMED);

17.3. shall perform vigilance of in vitro diagnostic medical devices;

17.4. shall aggregate and include information in LATMED on the in vitro diagnostic medical devices manufactured by medical treatment institutions;

17.5. shall receive, examine, and aggregate information on the in vitro diagnostic medical devices which are on the market of Latvia and which are referred to in Paragraph 8 of this Regulation;

17.6. shall propose that the Ministry of Health refers to the European Commission for it to determine by implementing acts whether or not a specific product, or category or group of products, falls within the definitions of an in vitro diagnostic medical device or an accessory for an in vitro diagnostic medical device;

17.7. shall check the data entered in EUDAMED in accordance with Article 28(1) of Regulation No 2017/746, obtain the single registration number from EUDAMED, and issue it to the manufacturer, authorised representative, or importer accordingly;

17.8. shall check the data referred to in Section 1 of Part A of Annex 6 to Regulation No 2017/746;

17.9. shall issue an authorisation for the placing on the market or putting into service of individual in vitro diagnostic medical devices for which the conformity assessment procedures referred to in Article 48 of Regulation No 2017/746 have not been performed;

17.10. when performing the tasks specified in this Regulation and Regulation No 2017/746, is entitled to develop and publish programmes, guidelines, lists, instructions, and documents for the exchange of information which are necessary for ensuring the operation of the vigilance system of in vitro diagnostic medical devices, and also to establish and maintain an electronic database of reports on incidents or suspected incidents provided by health care specialists, users, or patients;

17.11. shall perform the tasks and exercise the rights specified in Article 5(5), Article 10(7), Article 11(3) and (6), Article 16(4), Article 28(2), (6), and (8), Article 47(2), Article 54(1), Article 82(1), (9), (10), and (11), Article 83(2), Article 84(1), (2), (3), (4), (5), (6), (7), (8), (9), (10), and (11), the second paragraph of Article 85, Article 87(1), (2), (4), (5), (6), (7), and (8) of Regulation No 2017/746.

18. The persons referred to in Paragraphs 4, 25, and 27 of this Regulation shall, in accordance with the procedures and in the amount laid down in the laws and regulations regarding the price list of paid services of the Agency, cover expenditures of the Agency for each calendar year which are related to the performance of the tasks referred to in Chapter VI of this Regulation, ensuring operation of the vigilance system of in vitro diagnostic medical devices.

19. In accordance with the procedures laid down in this Regulation, the Inspectorate:

19.1. as a market surveillance authority shall perform market surveillance of in vitro diagnostic medical devices in accordance with the Law on the Safety of Goods and Services, the law On Conformity Assessment, and Regulation No 2017/746;

19.2. shall perform controls at manufacturing sites, retail points of sale of in vitro diagnostic medical devices, and also with persons distributing or importing in vitro diagnostic medical devices and with authorised representatives and, in case of non-conformities, request that the possessor (holder) of in vitro diagnostic medical device carries out corrective actions accordingly to ensure their conformity;

19.3. shall assess the documentation of the in vitro diagnostic medical devices manufactured within a medical treatment institution in accordance with Section 5(5) of Regulation No 2017/746;

19.4. shall monitor the activity of any such person who places in vitro diagnostic medical devices on the market or uses them in a professional environment;

19.5. is entitled to develop and publish the programmes, guidelines, and documents for the exchange of information necessary for ensuring the distribution and service of in vitro diagnostic medical devices;

19.6. is entitled to check the conformity of the manufacturing process of in vitro diagnostic medical devices with their technical documentation, harmonised standards, and common specifications;

19.7. is entitled to check whether the requirements of this Regulation and Regulation No 2017/746 are complied with in the process of service of in vitro diagnostic medical devices and, in case of non-conformities, request that the possessor (holder) of the in vitro diagnostic medical device takes corrective actions accordingly to ensure conformity;

19.8. is entitled to suspend the placing on the market, distribution, import, or service (use) of the relevant in vitro diagnostic medical device if the in vitro diagnostic medical device is qualified as unsafe or dangerous and its subsequent use endangers the health or life of a patient, a user, or a third party;

19.9. in implementing the supervision and control of conformity with the requirements laid down for in vitro diagnostic medical devices in this Regulation and Regulation No 2017/746 and in performing market surveillance of in vitro diagnostic medical devices, is entitled to request and receive, free of charge, information, including a copy of the EC (EU) declaration of conformity, certificates of conformity assessment and other certificates issued by the notified body, the circulation documentation of the in vitro diagnostic medical device (bills of lading, inventory cards, write-off deeds, and other similar documents), and also a copy of the technical documentation or its part which is necessary for the performance of supervision of in vitro diagnostic medical devices on the market and in service in accordance with the requirements laid down in this Regulation and Regulation No 2017/746;

19.10. is entitled to request and receive, free of charge, samples of in vitro diagnostic medical devices from the manufacturer, importer, or distributor or, if it is not possible, to request that a possibility of accessing the in vitro diagnostic medical device is ensured (if it is possible and is not in contradiction with this Regulation and Regulation No 2017/746. After all necessary checks and activities are carried out, the Inspectorate shall return the samples to the manufacturer or importer, or distributor accordingly, if possible);

19.11. may request that the medical treatment institutions referred to in the first subparagraph of Article 5(5) of Regulation No 2017/746 submit any additional information on such in vitro diagnostic medical devices which have been manufactured and used in their territory and also is entitled to enter these medical treatment institutions in order to check their activities;

19.12. shall propose that the Ministry of Health refers to the European Commission for it to determine by implementing acts whether or not a specific product, or category or group of products, falls within the definitions of an in vitro diagnostic medical device or an accessory for an in vitro diagnostic medical device;

19.13. shall perform the tasks and exercise the rights specified in Article 5(5), Article 6(3) and (4), Article 10(7), (11), and (13), Article 11(3) and (6), Article 13(2), (7), and (10), Article 14(2), (4), and (6), Article 22(2), Article 78(4), Article 80, Article 88(1), (2), (3), (4), (5), (6), (7), (8), (9), and (11), the first and second paragraphs of Article 89, Article 90(1), (2), and (4) of Regulation No 2017/746.

20. The Ministry of Health:

20.1. is entitled, upon proposal of the Agency or the Inspectorate, to refer to the European Commission for it to determine by implementing acts whether or not a specific product, or category or group of products, falls within the definitions of an in vitro diagnostic medical device or an accessory for an in vitro diagnostic medical device;

20.2. in accordance with the laws and regulations regarding the procedures for the establishment of the notification commission and the notification of the European Commission of conformity assessment authorities which perform conformity assessment in the regulated sphere, shall establish the notification commission which takes the decision and notifies the European Commission of the conformity assessment authorities performing conformity assessment in the field of in vitro diagnostic medical devices in accordance with Regulation No 2017/746.

21. The Agency, the Inspectorate, medical treatment institutions, manufacturers, authorised representatives, distributors, and notified bodies shall ensure confidentiality and protection of the information received in conformity with this Regulation in accordance with the requirements laid down in the Personal Data Processing Law, the Commercial Law, and the Freedom of Information Law insofar as it has not been laid down otherwise in the directly applicable legal acts of the European Union in relation to medical devices. This condition shall not affect the obligation in relation to mutual exchange of information (also distribution of warnings) and exchange of information with the competent authorities of other European Union Member States or countries of the European Economic Area.

22. Within the meaning of this Regulation, the following information shall not be considered confidential information:

22.1. the data submitted to the Agency within the scope of the notification procedure on the persons who are responsible for the placing on the market of in vitro diagnostic medical devices;

22.2. the information for users on the in vitro diagnostic medical device which has been provided by the manufacturer, authorised representative, or distributor;

22.3. the information included in the certificates issued, corrected, supplemented, suspended, or revoked by the notified bodies;

22.4. the information which has been submitted to the Agency in accordance with Paragraph 27 of this Regulation.

23. The Agency shall, on the basis of the submission submitted by the subject specified in Article 55(1) of Regulation No 2017/746, issue a certificate of free sale after receipt of the submission and corresponding documentation. The expenditures related to the issue of the certificate of free sale shall be covered by the submitter of the submission according to the price list of the paid services of the Agency.

24. The following information shall be indicated in the submission referred to in Paragraph 23 of this Regulation:

24.1. the name and contact details of the submitter (address, telephone number, electronic mail address, given name, surname of the contact person, bank details);

24.2. the name (indicating modifications, if applicable), type, classification class, general description of the in vitro diagnostic medical device to be exported and the intended purpose of the manufacturer, and also the basic identifier (UDI-DI) of the device;

24.3. the country or countries in which it is intended to submit the certificate of free sale and the number of original copies of certificates of free sale to be issued;

24.4. the name (firm name of the merchant), single registration number, legal address, and address of the manufacturing site of the manufacturer, and also the single registration number assigned in EUDAMED (if any).

25. A copy of the document of mandate shall be appended to the submission referred to in Paragraph 23 of this Regulation if the submission is submitted by a representative of the manufacturer and also other documents upon justified request of the Agency.

26. Unless it has been laid down otherwise in Regulation No 2017/746 or the directly applicable legal acts of the European Union issued on the basis thereof, the following information shall be included in the certificate of free sale:

26.1. the name “Certificate of Free Sale”;

26.2. the name (indicating modifications, if applicable), type, classification class of the in vitro diagnostic medical device to be exported, the intended purpose of use by the manufacturer, and also the basic identifier (UDI-DI) of the device;

26.3. the country for which the certificate of free sale is intended (if possible);

26.4. the name (firm name of the merchant), registration number, legal address, and address of the manufacturing site of the manufacturer, and also the single registration number (if any);

26.5. a certification that the manufacturer conducts entrepreneurship in the Republic of Latvia and that the relevant in vitro diagnostic medical device marked with the CE marking in accordance with Regulation No 2017/746 may be placed on the market in the European Union and countries of the European Economic Area;

26.6. the date of issuing the certificate.

**IV. Procedures for the Inclusion of Information in LATMED on Distributors and Manufacturers of In Vitro Diagnostic Medical Devices the Place of Commercial Activity of which is Registered in the Republic of Latvia**

27. When commencing activity, the manufacturers of in vitro diagnostic medical devices the place of commercial activity of which is in the Republic of Latvia shall submit a submission to the Agency in which the following information shall be indicated:

27.1. the name (firm name of the merchant);

27.2. the registration number and the single registration number (if any);

27.3. the legal address;

27.4. the address of the manufacturing site or branch (if any);

27.5. the telephone number and electronic mail address;

27.6. the name, basic identifier (UDI-DI), and intended purpose of the manufactured in vitro diagnostic medical devices.

28. When commencing activity, the distributors of in vitro diagnostic medical devices the place of commercial activity of which is registered in the Republic of Latvia shall submit a submission to the Agency in which the information referred to in Sub-paragraphs 27.1, 27.2, 27.3, and 27.5 of this Regulation and also the classification class, the name and legal address of the manufacturer of such in vitro diagnostic medical devices which are intended to be distributed thereby shall be indicated.

29. The Agency shall examine the submissions referred to in Paragraphs 27 and 28 of this Regulation and, within 10 days after receipt thereof, enter the relevant information in LATMED. If the persons referred to in Paragraphs 4, 27, and 28 of this Regulation do not cover the expenditures referred to in Paragraph 18 of this Regulation within the term stipulated by the Agency, the Agency shall exclude the relevant information on the particular person from LATMED.

30. The persons referred to in Paragraphs 27 and 28 of this Regulation shall, within 10 working days, inform the Agency of changes in the information submitted in accordance with Paragraphs 27 and 28 of this Regulation.

31. When placing in vitro diagnostic medical devices on the market, the manufacturers of in vitro diagnostic medical devices the place of commercial activity of which is registered in the Republic of Latvia shall submit the following information to the Agency:

31.1. the names of the in vitro diagnostic medical device and all its modifications (in Latvian and English);

31.2. the classification class of the in vitro diagnostic medical device;

31.3. the code of the European Medical Device Nomenclature.

32. The manufacturers of in vitro diagnostic medical devices the place of commercial activity of which is registered in the Republic of Latvia shall inform of discontinuation of the placing on the market, discontinuation of manufacture of the in vitro diagnostic medical devices indicated in accordance with Paragraph 27 of this Regulation, and also of changes in the information submitted in accordance with Paragraph 27 of this Regulation within 10 working days from the relevant moment of changes. The Agency shall, within seven days, include the submitted information in LATMED.

**V. Issuing of an Authorisation for the Placing on the Market or Putting into Service of an In Vitro Diagnostic Medical Device Without Performing the Specified Conformity Assessment Procedures**

33. The Agency may issue an authorisation to place on the market or put into service individual in vitro diagnostic medical devices without performing the conformity assessment procedures referred to in Article 48 of Regulation No 2017/746 if the use of such devices has a significant importance for public health or patient safety or health interests. The authorisation shall be issued for the period necessary for performing the necessary conformity assessment procedures for the in vitro diagnostic medical device or until the moment when an alternative in vitro diagnostic medical device is available, or until the moment when the use thereof is no longer of significant importance for public health or patient safety or health interests.

34. In order to receive the authorisation referred to in Paragraph 33 of this Regulation for the placing on the market or putting into service of in vitro diagnostic medical devices, a submission including the following information shall be submitted to the Agency:

34.1. the name, address (legal address and address of the place of commercial activity), contact telephone, and electronic mail address of the manufacturer of the in vitro diagnostic medical device;

34.2. the names of the in vitro diagnostic medical device and all its modifications which are intended to be placed on the market and used;

34.3. the type of the in vitro diagnostic medical device in accordance with the classification specified in Regulation No 2017/746 (if known);

34.4. the description and purpose of use of the in vitro diagnostic medical device;

34.5. information on the number of in vitro diagnostic medical devices planned to be placed on the market and used and also their serial numbers and batch numbers (if known);

34.6. information as to why the conformity assessment procedures referred to in Article 48 of Regulation No 2017/746 have not been performed or fully completed for the in vitro diagnostic medical device;

34.7. certification that an alternative in vitro diagnostic medical device for which conformity assessment procedures in accordance with the requirements laid down in Regulation No 2017/746 have been performed is not available;

34.8. information on the conformity of the in vitro diagnostic medical device with the harmonised standards, common specifications, or other technical solutions which ensure the conformity of the in vitro diagnostic medical device with the essential (general safety and performance) requirements laid down in Regulation No 2017/746;

34.9. results of the checks performed which certify the conformity of the in vitro diagnostic medical device with the harmonised standards, common specifications, or other technical solutions.

35. The Agency shall refuse to issue the authorisation referred to in Paragraph 33 of this Regulation if:

35.1. placing on the market or putting into service of the in vitro diagnostic medical device does not have a significant importance for ensuring public health or patient safety;

35.2. alternative in vitro diagnostic medical devices for which conformity assessment procedures in accordance with the requirements laid down in Regulation No 2017/746 have been performed are available on the market;

35.3. information on the conformity of the in vitro diagnostic medical device with the harmonised standards, common specifications, or other technical solutions which ensure the conformity of the device with the essential (general safety and performance) requirements laid down in Regulation No 2017/746 has not been submitted;

35.4. there is no data on the results of the inspections performed which certify the conformity of the in vitro diagnostic medical device with the harmonised standards, common specifications, or other technical solutions.

36. Examination of the information and documents referred to in Paragraph 34 of this Regulation shall be a paid service of the Agency. The amount of payment shall be determined in accordance with the laws and regulations regarding the price list of paid services provided by the Agency.

37. If necessary, the Agency is entitled to request a statement from the Central Medical Ethics Committee, the professional association of physicians, or another competent authority on the in vitro diagnostic medical devices referred to in Paragraph 33 of this Regulation.

**VI. Distribution, Use, and Service of In Vitro Diagnostic Medical Devices**

38. A distributor of in vitro diagnostic medical devices is entitled to make in vitro diagnostic medical devices available on the market of the Republic of Latvia if information on the relevant distributor has been included in LATMED. The distributor who performs commercial activity in the territory of Latvia has the following obligations:

38.1. if the distributor is of the opinion that an in vitro diagnostic medical device distributed thereby causes serious risk or it is counterfeit, it shall inform the Inspectorate and the Agency, and also the competent authorities in other Member States in which such devices have been placed on the market and point towards the particular non-conformity, and also inform of any corrective actions taken;

38.2. to preserve and, upon request, make available information to the Agency and the Inspectorate on the time, person, and type of in vitro diagnostic medical devices being alienated (this provision shall not apply to cases if the relevant device is alienated from a natural person as the final consumer);

38.3. upon request of the Agency or the Inspectorate, to provide information on the number of in vitro diagnostic medical devices of a particular type and model sold within a specific period and the selling value thereof;

38.4. in supplying in vitro diagnostic medical devices to a medical treatment institution, to transfer also a list to such medical treatment institution with the unique identifier (UDI) of the devices supplied.

39. When using in vitro diagnostic medical devices, a possessor (holder) and user of in vitro diagnostic medical devices shall comply with the instructions of the manufacturer of the particular device on the use and service of the device. Medical treatment institutions shall, for at least two years, store the lists transferred thereto in accordance with Sub-paragraph 38.4 of this Regulation with the unique identifier (UDI) of the in vitro diagnostic medical devices supplied.

40. The Agency shall inform the Inspectorate if:

40.1. the Agency has information at its disposal that the in vitro diagnostic medical device has been recalled, is distributed or could be distributed in the territory of the Republic of Latvia without conforming to the procedures laid down in this Regulation, or there are suspicions of counterfeit, or the in vitro diagnostic medical device causes or may cause unacceptable risk to the health or safety of patients, users, or other persons or to public health;

40.2. the medical treatment institution, distributor, or another person involved in the vigilance system in relation to the in vitro diagnostic medical device does not fulfil the requirements laid down in this Regulation for ensuring the vigilance system.

41. Medical treatment institutions which use in vitro diagnostic medical devices shall:

41.1. appoint the responsible person who notifies of incidents related to the use of such devices;

41.2. store electronically the unique identifiers (UDI) of in vitro diagnostic medical devices supplied thereto.

42. The head of a medical treatment institution shall be responsible for compliance with this Regulation in the medical treatment institution.

43. When commencing the service of an in vitro diagnostic medical device for the first time and also throughout the service of the device, the possessor or holder of such device shall ensure:

43.1. unequivocal identification of the device and its permanent location;

43.2. metrological control of devices according to the instructions of the manufacturer;

43.3. technical servicing of the device during the specified period of guarantee and also after the end of the period of guarantee;

43.4. appointing of the responsible person who as the contact person of the possessor or holder solves the issues related to conformity with the specified requirements and cooperates with the Agency, the Inspectorate, and other authorities;

43.5. training of users of the particular devices and responsible persons appointed for devices as intended by the manufacturer;

43.6. availability of the instructions for use of the device to users at the location of the device.

44. An in vitro diagnostic medical device shall be installed and put into service by its manufacturer or authorised representative, or distributor, or importer, and also the following shall be ensured (this condition shall not apply to a natural person as the final consumer of the device):

44.1. inspection of the characteristics of the environment for the use of the device requested in the technical documentation of the supplied device and the guaranteed mode of electricity supply and transfer of such notes to the possessor or holder of the device;

44.2. training of the user of the device and issuing of a document certifying it. The given name, surname, and date of birth of the trained person and the person who performed training, and also the date when training was performed shall be indicated in the document;

44.3. transfer of the instructions for use of the device and other documentation in the original language and the official language and explanation of the operation of the vigilance system to the user in relation to the particular device;

44.4. issuing of the certification regarding availability of certified spare parts of the manufacturer of the device and the technical servicing of the device within the period of guarantee and the resource period of the device notified by the manufacturer if such has been determined and if the possessor or holder of the device chooses such servicing during the resource period of the device.

45. If the Inspectorate draws a conclusion that the CE marking has been used in relation to an in vitro diagnostic medical device without justification or incorrectly or is not used at all, thus violating the requirements of this Regulation or Regulation No 2017/746, the Inspectorate shall inform the manufacturer (or authorised representative if the legal address of the manufacturer is outside the European Union or the European Economic Area), the relevant notified body (if any), the European Commission, and other European Union Member States and countries of the European Economic Area thereof. The manufacturer or authorised representative has the obligation to eliminate the violation detected.

46. If the Inspectorate draws a conclusion that the manufacturer or authorised representative has not eliminated the violation referred to in Paragraph 45 of this Regulation within the term stipulated by the Inspectorate or that in vitro diagnostic medical devices bearing the CE marking have not even been installed, maintained, and used correctly according to the intended purpose, may harm the health of patients, users, or third parties, the Inspectorate shall, without delay, take the necessary measures to recall and withdraw such devices from the market, and also inform the European Commission thereof, indicating whether the non-conformity with the requirements referred to in this Regulation and Regulation No 2017/746 is related to:

46.1. non-compliance with the essential requirements;

46.2. incorrect application of the harmonised standards or common specifications (if it is being claimed that the harmonised standards or common specifications have been applied);

46.3. deficiencies of the harmonised standards or common specifications.

47. If any in vitro diagnostic medical device not conforming to the essential requirements has been marked with the CE marking, the Inspectorate shall inform the relevant notified body, the European Commission, and also other European Union Member States and countries of the European Economic Area thereof.

48. The Inspectorate shall inform the European Commission and the Member States of the decision taken in relation to the withdrawal of a particular product or group of products from trade or the restriction, prohibition imposed, or of special requirements for their placing on the market or putting into service in order to ensure the public health protection requirements laid down in this Regulation.

49. The Agency is entitled to create and maintain an electronic database on the use of individual groups of in vitro diagnostic medical devices with increased risk.

**VII. Incidents and the Vigilance System**

50. The purpose of measures of the vigilance system is:

50.1. to preclude repeated incidents;

50.2. to protect patients and users of devices;

50.3. by using the incident reporting system in all European Union Member States or countries of the European Economic Area, to ensure an opportunity for the Member States to simultaneously recognise the non-conforming in vitro diagnostic medical devices on the market and in use.

51. A representative of a medical treatment institution shall, within three days after a serious incident or suspected serious incident with an in vitro diagnostic medical device, send a report to the Agency on a serious incident or suspected serious incident (hereinafter – the signal report), using the sample provided in Annex 2 to this Regulation or the electronic reporting form available on the website of the Agency, and also inform the manufacturer or authorised representative, or distributor of any deterioration of parameters or malfunction of an in vitro diagnostic medical device, and also of all inaccuracies on labels or in instructions for use which may cause or have caused death of a patient, a user, or a third party or serious health disorders. If possible, documents certifying quality of the in vitro diagnostic medical device (copies of the EC (EU) declaration of conformity and certificates issued by the notified bodies), copies of the packaging, label, and instructions for use of the in vitro diagnostic medical device, and also other information in relation to the particular incident shall appended to the signal report. If significant facts are discovered later, the signal report shall be supplemented without delay and sent to the Agency.

52. After an incident at a medical treatment institution or a laboratory, the user of an in vitro diagnostic medical device or the person responsible for these devices accordingly shall:

52.1. without delay, discontinue the use of the in vitro diagnostic medical device;

52.2. turn off the in vitro diagnostic medical device and disconnect it from the grid system and other devices;

52.3. take all necessary actions to prevent the use of the in vitro diagnostic medical device by another person and (if possible) attach a warning inscription in a clearly visible place;

52.4. aggregate and store the following information on malfunctions of the in vitro diagnostic medical device:

52.4.1. the name of the in vitro diagnostic medical device and the unique identifier (UDI), if any;

52.4.2. the name, registration number, and legal address of the manufacturer or authorised representative, distributor of the in vitro diagnostic medical device;

52.4.3. a description of malfunctions;

52.4.4. the time when malfunctions were detected;

52.4.5. a description of the possible causes and consequences;

52.4.6. the measures taken for the elimination of malfunctions;

52.4.7. the person who detected the malfunction (given name, surname, and position);

52.4.8. a justification for sending or failure to send the signal report;

52.5. ensure keeping of the packaging (if possible), instructions for use, and documentation certifying the quality of the relevant in vitro diagnostic medical device and transfer thereof to the manufacturer or authorised representative for carrying out an investigation, documenting the fact of acceptance and transfer of the abovementioned information;

52.6. document and keep data on all activities performed in relation to the incident involving the in vitro diagnostic medical device and also data on the exchange of information with the authorities involved in ensuring the operation of the vigilance system, information requested by and provided to the relevant authorities;

52.7. not perform any such activities during the course of which the in vitro diagnostic medical device or a sample of the relevant batch is changed in a way that may affect further investigation of causes of the incident.

53. The owner or holder of an in vitro diagnostic medical device shall document information on incidents involving the particular device and shall store it throughout the service of the device and also for three years after the end of service of the device. The following information on the device involved in an incident shall be indicated when documenting the incident:

53.1. the description, date, and consequences of the incident;

53.2. the assessment of the link of the incident to the quality problems of the device and the justification of the assessment in order to ensure recording and traceability of incidents within the scope of supervision of the service and the vigilance system.

54. A person who is using the in vitro diagnostic medical device independently or according to instructions of a medical practitioner, or his or her representative, after a serious incident or suspected serious incident which is related to the use of the in vitro diagnostic medical device:

54.1. shall, within three days, inform the Agency thereof, submitting the signal report (using the sample appended in Annex 3 to this Regulation);

54.2. shall, without delay, inform the medical practitioner according to whose instructions the in vitro diagnostic medical device is being used of the circumstances of the incident and provide other necessary information in order to evaluate the potential link of the state of health and the damage caused to the malfunctions of the in vitro diagnostic medical device;

54.3. shall provide additional information to the Agency that is necessary for investigating the reason for the incident;

54.4. shall store the in vitro diagnostic medical device involved in the incident, the sample of its packaging, the instructions for use, and other information for transfer to the manufacturer or authorised representative of the medical device for further assessment and also shall not take any actions due to which the medical device is changed in a way which may affect further assessment of the causes for the incident.

55. The possessor or holder of an in vitro diagnostic medical device shall, after sending the signal report of an incident during investigation of the incident in cooperation with the manufacturer or authorised representative of the device, continue investigating the circumstances of the incident, inform the Agency of the evidence obtained, and ensure free access to the abovementioned device for the Agency or other experts, the manufacturer, and representatives of the notified body, and also all documents related to the particular device.

56. After receipt of the first report of the manufacturer on a serious incident that has occurred in the Republic of Latvia in which an in vitro diagnostic medical device is involved, the Agency:

56.1. shall register the report received and draw up a file of the vigilance system;

56.2. shall assess the content of the report received and also request additional information if the data received is not sufficient for ensuring the operation of the vigilance system;

56.3. in case of receipt of the signal report, shall inform the manufacturer or authorised representative and, if necessary, distributor of the relevant in vitro diagnostic medical device;

56.4. shall ensure the exchange of information with the user of the in vitro diagnostic medical device involved in the incident;

56.5. shall monitor the course of investigation of a serious incident, i.e. follow the investigation process of incidents, observe its course, direction, type, and development, and also follow its outcome, whether the results of investigation are satisfactory;

56.6. shall perform coordinating activities to ensure that the incident is investigated by several manufacturers if in vitro diagnostic medical devices of several manufacturers are involved in one incident;

56.7. is entitled to cooperate with the relevant notified body to assess any information on a serious incident which has occurred in the territory of the Republic of Latvia;

56.8. is entitled to become involved in any investigation implemented by the manufacturer or to commence an independent investigation;

56.9. shall receive, register, assess, and append the initial incident report of the manufacturer, the interim reports necessary for supervising the incident and the final report, the information provided by the authorised representative of the manufacturer, distributor, medical treatment institution, and other parties involved to the file;

56.10. shall evaluate the suitability of or need for the field safety corrective action intended by the manufacturer;

56.11. is entitled to request all documents from the manufacturer which are necessary for risk assessment, the essential information on validity of the field safety corrective actions, and also the field safety notice;

56.12. shall evaluate the validity of the decision of the manufacturer not to initiate the field safety corrective actions and, in case if the Agency does not agree to the decision of the manufacturer, request that the manufacturer ensures the performance of the relevant field safety corrective action;

56.13. after receipt of information on completion of the field safety corrective actions intended by the manufacturer, shall close the relevant file of the vigilance system.

57. If the initial incident report sent to the Agency is incomplete, the manufacturer shall determine a term within which a complete report shall be submitted. If the investigation period of the incident exceeds the term specified in the initial report, the manufacturer may send an interim report to the Agency.

58. The manufacturer of an in vitro diagnostic medical device shall assess all serious incident reports received (including reports on inappropriate use and use errors of the device). The assessment results shall be stored and they shall be available upon request of the supervisory State authorities and notified bodies.

59. If in vitro diagnostic medical devices of several manufacturers are involved in a serious incident, each manufacturer shall perform investigation of the incident and other activities in accordance with the requirements laid down in this Chapter.

60. For drawing up of the reports referred to in this Chapter, the manufacturer of an in vitro diagnostic medical device shall use the report forms applicable to the reports of manufacturers published on the website of the Agency (www.zva.gov.lv).

61. After completing the investigation of a serious incident, the manufacturer shall:

61.1. prepare and submit a final report to the Agency on the investigation results and the necessary field safety corrective actions or a justification as to why field safety corrective actions are not necessary;

61.2. ensure the preparation of the field safety notice with the help of which users of the relevant in vitro diagnostic medical device are informed of the field safety corrective actions to be taken;

61.3. inform the Agency of completion of field safety corrective actions.

62. The manufacturer shall ensure the return of the in vitro diagnostic medical device involved in a serious incident to the possessor (holder) of such device if it does not agree to the investigation results of the accident of the manufacturer and has decided to invite independent experts for the performance of expert-examination.

63. The manufacturer shall, without delay, inform the notified body involved in conformity assessment of the in vitro diagnostic medical device involved in a serious incident of the serious risk caused by the device, non-conformities, and of any field safety corrective actions taken by the manufacturer.

64. The manufacturer or authorised representative is entitled to request and receive the in vitro diagnostic medical device involved in a serious incident from the user, medical treatment institution, or another institution in which the in vitro diagnostic medical device was used. If it is not possible, the user, medical treatment institution, or another institution in which the in vitro diagnostic medical device was used shall grant access to the device during the working hours thereof and provide other available information related to the in vitro diagnostic medical device (for example, packaging, instructions for use) for performing the investigatory activities of a serious incident.

65. If the possessor or holder of the in vitro diagnostic medical device has doubts or it does not agree to the investigation results of a serious incident of the manufacturer, it has the right to invite independent experts or to request repeated expert-examination of the in vitro diagnostic medical device related to an incident.

66. Confidentiality shall be observed when preparing the documents referred to in this Chapter and its drafts or when taking the decision on the technical means applicable to the distribution of documents.

67. If the initial serious incident report of the competent authority of in vitro diagnostic medical devices of the European Union Member States or countries of the European Economic Area or the manufacturer or authorised representative of the in vitro diagnostic medical device on a serious incident which has occurred outside the Republic of Latvia or on the intended field safety corrective actions has been received, the Agency:

67.1. shall register the report and draw up a file of the vigilance system;

67.2. shall check the information included in the report and LATMED on availability of the in vitro diagnostic medical device involved in a serious incident on the market in the Republic of Latvia;

67.3. if there is no indication in the report and LATMED on the availability of the device on the market of the Republic of Latvia, the file of the vigilance system shall be closed, a justification for closing the file shall be drawn up in writing and appended to the file;

67.4. if there is indication in the report or LATMED on the availability of the in vitro diagnostic medical device on the market of Latvia or the abovementioned information is not known, the Agency:

67.4.1. shall receive and append interim reports of the manufacturer and the competent authorities and the final reports of the manufacturer to the file of the vigilance system, evaluate the information included therein, including information on the field safety corrective actions intended by the manufacturer and the need for additional restrictive measures;

67.4.2. shall post the information related to a serious incident on its website, ensuring recognition of the in vitro diagnostic medical device involved in the serious incident, and also other information which is necessary for ensuring safe use of the in vitro diagnostic medical device by the user.

68. If the Inspectorate or the Agency becomes aware of the information on newly discovered risks of threat to the health or life of a patient which have not been researched yet or on non-conformity of the relevant in vitro diagnostic medical devices with the requirements of the harmonised standards, the Inspectorate or the Agency shall, without delay, inform the manufacturer of in vitro diagnostic medical devices thereof.

**VIII. Closing Provisions**

69. Sub-paragraphs 17.7 and 17.8 of this Regulation shall be applied from the day which corresponds to six months after the day when the European Commission has notified of the complete functionality of EUDAMED.

70. Distributors of in vitro diagnostic medical devices which have commenced operation until the day of coming into force of this Regulation shall submit the submission referred to in Paragraph 26 of this Regulation to the Agency within three months after the day of coming into force of this Regulation.

Acting Prime Minister, Minister for Justice I. Lībiņa-Egnere

Minister for Health H. Abu Meri

**Annex 1**

Cabinet Regulation No. 582

10 October 2023

**Paziņojums Zāļu valsts aģentūrai par *in vitro*diagnostikas medicīniskās ierīces laišanas Latvijas tirgū uzsākšanu/*Statement to the State Agency of Medicinesconcerning beginning placing medical devices on the Latvian market***

|  |  |  |
| --- | --- | --- |
| 1. | **Ziņas par iesniedzēju**(atzīmēt vienu no piedāvātajiem variantiem)  *Submitter information (please specify one of the offered versions)* | |
| 1.1. | ▢ A1 – Ražotājs  *Manufacturer* | ▢ A3 – Izplatītājs  *Distributor* |
| ▢ A2 – Ražotāja pilnvarotais pārstāvis ES  *Authorized representative of manufacturer in EU* | ▢ A4 – Cits (precizēt)  *Other (specify)*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1.2. | Iesniedzēja nosaukums  *Name of submitter* | |
| 1.3. | Iesniedzēja reģistrācijas Nr.  *Submitter registration No.* | |
| 1.4. | Valsts  *Country* | |
| 1.5. | Pilsēta/novads/pagasts  *City/region* | |
| 1.6. | Iela, mājas Nr., dzīvokļa Nr.  *Street, house number, flat number* | |
| 1.7. | Pasta indekss  *Postal code* | |
| 1.8. | Kontaktpersonas vārds, uzvārds  *Name, surname of contact person* | |
| 1.9. | Telefons, fakss  *Phone, fax* | |
| 1.10. | E-pasts  *e-mail* | |
| 2. | **Ziņas par *in vitro*diagnostikas medicīnisko ierīci**  Information on medical device | |
| 2.1. | Nosaukums (ja iespējams, norādīt modeli(-ļus))  *Name (specify model, if possible)* | |
| 3. | **Ziņas par ražotāju**(aizpildīt, ja ražotājs nav paziņojuma iesniedzējs)  *Information on manufacturer (please to fill in if submitter is some other entity, not manufacturer)* | |
| 3.1. | Ražotāja nosaukums  *Name of manufacturer* | |
| 3.2. | Ražotāja reģistrācijas Nr.  *Manufacturer registration No.* | |
| 3.3. | Valsts  *Country* | |
| 3.4. | Pilsēta/novads/pagasts  *City/region* | |
| 3.5. | Iela, mājas Nr.  *Street, house number* | |
| 3.6. | Pasta indekss  *Postal code* | |
| 3.7. | Telefons, fakss  *Phone, fax* | |
| 3.8. | E-pasts  *e-mail* | |
| 4. | **Ziņas par ražotāja pilnvaroto pārstāvi ES**(aizpildīt, ja ražotāja reģistrētā uzņēmējdarbības vieta nav ES un ja pilnvarotais pārstāvis nav paziņojuma iesniedzējs)  *Information on manufacturer's authorized representative in the EU (please to fill in if manufacturer's registered place of business is established outside EU and if submitter is some other entity, not authorized representative)* | |
| 4.1. | Pilnvarotā pārstāvja nosaukums  *Name of authorized representative* | |
| 4.2. | Pilnvarotā pārstāvja reģistrācijas Nr.  *Authorized representative Registration No.* | |
| 4.3. | Valsts  *Country* | |
| 4.4. | Pilsēta/novads/pagasts  *City/region* | |
| 4.5. | Iela, mājas Nr.  *Street, house number* | |
| 4.6. | Pasta indekss  *Postal code* | |
| 4.7. | Telefons, fakss  *Phone, fax* | |
| 4.8. | E-pasts  *e-mail* | |
| 5. | **Pielikumā pievienotie dokumenti:**  *Attached documentation*  1.  2.  3.  ... | |
| **Apliecinu, ka paziņojumā sniegtā informācija ir patiesa.**  *I confirm that the information in the Statement is correct.* | | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (vārds, uzvārds, amats)  *(name, surname, position)* | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (datums)  *(date)* |

**Annex 2**

Cabinet Regulation No. 582

10 October 2023

**Signal Report of the Vigilance System of the Medical Treatment Institution on a Serious Incident or Suspected Serious Incident Related to the In Vitro Diagnostic Medical Device1**

|  |  |
| --- | --- |
| **Competent authority in Latvia** | **State Agency of Medicines** |
| **Address of the competent authority** | **Jersikas iela 15, Rīga, LV-1003, Latvija**  **telephone 67078424, 67078410, fax 67078428**  **e-mail: info@zva.gov.lv** |

**1. INFORMATION REGARDING THE REPORTER**

|  |
| --- |
| Code of the institution included in the Register of Medical Treatment Institutions |
| Name of the medical treatment institution |
| Address of the medical treatment institution which is represented by the reporter |
| Address of the branch of the medical treatment institution which is represented by the reporter (if applicable) |
| Given name, surname of the submitter of the report |
| Position of the submitter of the report |
| Contact telephone of the submitter of the report |
| E-mail address of the submitter of the report |
| E-mail address of the medical treatment institution which is represented by the reporter |

**2. Information on the in vitro diagnostic medical device** (hereinafter – the device)

|  |  |
| --- | --- |
| Name of the device | |
| Model of the device | |
| Purpose of use of the device (indicate the purpose of use indicated by the manufacturer of the device) | |
| Classification class of the device (mark as appropriate): | |
| ▢ A | ▢ List A |
| ▢ B | ▢ List B |
| ▢ C | ▢ self-testing |
| ▢ D | ▢ other (*remaining ones*) |
| Catalogue number (REF) | |
| Serial number (SN) | |
| Lot or batch number (LOT) | |
| Date when the device was manufactured (if known) | |
| Term of validity of the device (if known) | |
| CE marking | ▢ yes ▢ no ▢ unknown |
| Has the device been preserved | ▢ yes ▢ no ▢ partially |
| Is the device available for inspection | ▢ yes ▢ no ▢ partially |
| Is the packaging of the device available for inspection | ▢ yes ▢ no ▢ partially |
| Current location of the device (please specify where the device involved in the incident is currently located):  ▢ at the medical treatment institution where the incident occurred  ▢ transferred to the distributor  ▢ sent to the manufacturer  ▢ with the patient  ▢ destroyed  ▢ at another location \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (please specify) | |

**3. Manufacturer of the device**

|  |
| --- |
| Name |
| Address |

**4. Authorised representative of the manufacturer of the device in the European Union**

(To be filled in if the manufacturer is located outside the European Union; information on the authorised representative is indicated on the packaging, on the label, or in the instructions for use)

|  |
| --- |
| Name |
| Address |

**5. Distributor of the device/supplier of the device/pharmacy/marketing facility where the device was acquired**

|  |
| --- |
| Name (if information is not available, indicate “unknown”) |

**6. Information on a serious incident or suspected serious incident**

|  |
| --- |
| Date of the incident |
| Consequences of the incident:  ▢ serious health impairments  ▢ potential serious health impairments (there is a possibility that an incident might occur)  ▢ death |
| Description of the incident and the harm caused to the patient/health care professional/another person |
| Relation of the device to the incident:  ▢ definitely ▢ possible ▢ difficult to say |
| Is there information on similar incidents with this device  ▢ yes ▢ no |
| Description of the possible defect of the device |
| Has a signal report been sent to the manufacturer of the device, its authorised representative and/or distributor  ▢ yes ▢ no |
| Signal report has been sent (mark if the answer to the previous question is “yes”):  ▢ to the manufacturer  ▢ to the authorised representative  ▢ to the distributor/supplier |
| Description of the measures taken (measures taken by the medical treatment institution after the incident for the prevention of a potential subsequent harm caused by the device) |
| Possible date when the next report on the investigation results of the incident could be provided (to be filled in if incomplete information has been provided) |
| Is a counterfeit device suspected   ▢ yes ▢ no |

Documents attached in annex (please, attach the documents at the disposal of the reporter or their copies certifying the quality of the device (for example, EC declaration of conformity, certificates issued by the notified bodies), copies of the documents of an exchange of information that has taken place between the patient, manufacturer, distributor, and other parties involved (including electronic mail correspondence), a copy of the instructions for use, images of the packaging and marking (if possible), and also other information which is important in the opinion of the reporter and necessary for the supervision of investigation of the incident. If initially it is not possible to include all information in the report, the report may be supplemented as soon as the missing information becomes available):

1.

2.

3.

..

Space for notes and other information to be provided to the State Agency of Medicines

|  |
| --- |
|  |

|  |  |
| --- | --- |
| Submitter of the signal report  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (given name, surname)  (signature) | Date of submitting the signal report  \_\_\_\_\_.\_\_\_\_\_.\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Notes.

1The signal report may also be sent if all information indicated in the report is not available at the moment of the incident.

2The details of the document “date” and “signature” need not be completed if the document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

**Annex 3**

Cabinet Regulation No. 582

10 October 2023

**Signal Report of the Vigilance System of a Person who is Using the In Vitro Diagnostic Medical Device Independently or According to Instructions of a Medical Practitioner on a Serious Incident or Suspected Serious Incident which is Related to the Use of the In Vitro Diagnostic Medical Device1**

|  |  |
| --- | --- |
| **Competent authority in Latvia** | **State Agency of Medicines** |
| **Address of the competent authority** | **Jersikas iela 15, Rīga, LV-1003, Latvija**  **telephone 67078424, 67078410, fax 67078428**  **e-mail: info@zva.gov.lv** |

**1. Information on the user (patient) of the in vitro diagnostic medical device (hereinafter – the device)**

|  |
| --- |
| Given name, surname |

**2. Information on the submitter of the signal report**

(To be filled in if the report is filled in and submitted by a representative of the user (patient) of the medical device on his or her behalf)

|  |
| --- |
| Given name, surname |
| Address |
| Contact phone |
| E-mail address |

**3. Information on the device**

|  |  |
| --- | --- |
| Name | |
| Model | |
| Purpose of use (indicate the purpose of use indicated by the manufacturer of the device) | |
| Catalogue number (REF) | |
| Serial number (SN) | |
| Lot or batch number (LOT) | |
| Date when IVD MD was manufactured (if known) | |
| Term of validity of IVD MD (if known) | |
| CE marking | ▢ yes ▢ no ▢ unknown |
| Has the device been preserved | ▢ yes ▢ no ▢ partially |
| Is the device available for inspection | ▢ yes ▢ no ▢ partially |
| Is the packaging of the device available for inspection | ▢ yes ▢ no ▢ partially |
| Current location of the device (please specify where the device involved in the incident is currently located):  ▢ with the patient  ▢ at the medical treatment institution  ▢ transferred to the distributor  ▢ sent to the manufacturer  ▢ destroyed  ▢ at another location \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (please specify) | |

**4. Manufacturer of the device**

|  |
| --- |
| Name |
| Address |

**5. Authorised representative of the manufacturer of the device in the European Union**

(To be filled in if the manufacturer is located outside the European Union; information on the authorised representative is indicated on the packaging, on the label, or in the instructions for use)

|  |
| --- |
| Name |

**6. Distributor of the device/supplier of the device/pharmacy/marketing facility where the device was acquired**

|  |
| --- |
| Name (if information is not available, indicate “unknown”) |

**7. Information on a serious incident or suspected serious incident**

|  |
| --- |
| Date of the incident |
| Description of the incident and the harm caused |
| Description of the measures taken (measures taken for the prevention of a potential subsequent harm caused by the device) |
| Is a counterfeit device suspected   ▢ yes ▢ no |

Documents attached in annex (please, attach the documents at the disposal of the patient or their copies: a copy of the instructions for use, images of the packaging, marking (if possible), copies of the documents of an exchange of information that has taken place between the manufacturer, distributor, and other parties involved (including electronic mail correspondence), and also other information which is important in the opinion of the reporter for the investigation of the incident. If initially it is not possible to include all information in the report, the report may be supplemented as soon as the missing information becomes available):

1.

2.

3.

..

Space for notes and other information to be provided to the State Agency of Medicines

|  |
| --- |
|  |

|  |  |
| --- | --- |
| Person who filled in the signal report  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (given name, surname)  (signature) | Date of submitting the signal report  \_\_\_\_\_.\_\_\_\_\_.\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Notes.

1The signal report may also be sent if all information indicated in the report is not available at the moment of the incident.

2The details of the document “date” and “signature” need not be completed if the document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.