Republic of Latvia

Cabinet

Regulation No. 461

Adopted 15 August 2023

**Regulations Regarding Medical Devices**

*Issued pursuant to*

*Section 34, Paragraph two, Clauses 2, 3, 4, 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 medical devices;

1.2. the procedures for reprocessing single-use medical devices;

1.3. the procedures by which medical devices shall be placed on the market and put into service;

1.4. the procedures for the registration of information on manufacturers of medical devices, medical devices manufactured by them, and also distributors of medical devices;

1.5. the procedures for the distribution, service, vigilance, post-market and technical surveillance of medical devices.

2. The essential requirements for medical devices, the basic provisions for reprocessing single-use medical devices, the preconditions for placing medical devices on the market and putting them into service, the basic provisions for the distribution, vigilance, and post-market surveillance of medical devices shall be determined by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter – Regulation No 2017/745).

3. The terms used in this Regulation shall correspond to the terms used in Regulation No 2017/745 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 placing a 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 single registration number (hereinafter – the SRN) (if such has been assigned);

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

4.3. the manufacturer on whose behalf medical devices are placed on the market – the name, registration number, legal address, and also the SRN (if such has been assigned);

4.4. the written mandate of the manufacturer referred to in Article 11(3) of Regulation No 2017/745;

4.5. information on class I medical devices of the manufacturer referred to in Sub-paragraph 4.3 of this Regulation and also procedure packs intended for the placing on the market in the territory of the European Union or the European Economic Area, i.e. the name, trade mark (if any), the code of the European Medical Device Nomenclature, modifications (if any), the intended purpose, the specific parameters (composition, dimensions, and other essential information), the unique device identifier specific to the manufacturer and the medical device (hereinafter – UDI-DI).

5. In order to ascertain whether this Regulation applies to a medical device, it shall be taken into account whether the particular device corresponds to the definition referred to in Article 2(1) of Regulation No 2017/745. This Regulation shall also apply to the accessories and products referred to in Article 1(4) of Regulation No 2017/745.

6. The information indicated in Section 23 of Annex 1 to Regulation No 2017/745 is ensured to users and patients in the official language. The information indicated in Section 23 of Annex 1 to Regulation No 2017/745 and other documentation of a medical device need not be in the official language only in cases if it is intended to use the medical device only in a medical treatment institution and it may only be used 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 medical device has been received. When implementing the supervision and control of conformity with the requirements laid down for medical devices in this Regulation, Regulation No 2017/745, and the directly applicable legal acts of the European Union issued on the basis thereof and also when carrying out market surveillance of 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 necessary for proving the conformity of the medical device and the documentation in the official language or any other appropriate 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 required due to detection of a serious and immediate risk.

7. When commencing manufacture of medical devices, a medical treatment institution shall, in accordance with Article 5(5) of Regulation No 2017/745, submit a declaration to the Agency, indicating the type of the device to be manufactured, the intended purpose, and the most essential parameters. The medical treatment institution shall submit a relevant declaration to the Agency also if such manufacturing is discontinued or if the intended purpose or essential parameters of the intended devices change.

8. On the basis of Article 5(5) of Regulation No 2017/745, it is prohibited to manufacture active medical devices and implantable medical devices in medical treatment institutions.

**II. Notification Procedure of Medical Devices**

9. Persons who commence the placing of class IIa, IIb, and III 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 certificates issued by the notified bodies (hereinafter – the notification procedure). One statement shall contain information on the medical devices included in one certificate of one manufacturer.

10. The Agency shall check the conformity of the EC (EU) declaration of conformity received in the notification procedure and the certificates issued by the notified bodies with the requirements of this Regulation, Regulation No 2017/745, and the directly applicable legal acts of the European Union issued on the basis thereof, and also the information indicated in the notification form (Annex 1). In detecting non-conformity of the information submitted or missing documents, the Agency shall inform the submitter thereof, requesting that corresponding specifications or additions are submitted.

11. The Agency shall, within 10 working days after receipt of the information referred to in Paragraph 9 of this Regulation, ensure public availability of at least the data received within the scope of the notification procedure on the medical device, its manufacturer, authorised representative (where applicable) or notifier, and the notification number assigned by the Agency on its website. After publishing this information on the website of the Agency, the notification procedure shall be considered as completed.

12. The persons referred to in Paragraph 9 of this Regulation are entitled, after completion of the notification procedure, to place the medical device on the market of the Republic of Latvia without a decision or approval of the Agency.

13. The persons referred to in Paragraph 9 of this Regulation need not perform 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 the European Database on Medical Devices EUDAMED (hereinafter – the EUDAMED database) and ends 18 months afterwards, the manufacturer has complied with the requirements laid down in Article 29(4) of Regulation No 2017/745 in relation to entering of the information referred to in Section 2 of Part A of Annex 6 to Regulation No 2017/745 in the EUDAMED database.

14. In relation to the acquired and imported medical devices referred to in Paragraph 9 of this Regulation which are marked with the CE marking, medical treatment institutions shall provide information to the Agency according to the notification procedure, appending the EC (EU) declaration of conformity and the certificates issued by the notified bodies (where such are available) if the notification procedure has not yet been performed in relation to the acquired medical device and the medical treatment institution acquires the medical device:

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

14.2. in exhibitions;

14.3. using services of web shops;

14.4. in another way without the intermediation of the person who is responsible for placing the medical device on the market in the territory of the Republic of Latvia in accordance with Paragraph 9 of this Regulation.

15. A medical treatment institution which has acquired a medical device in accordance with the procedures specified in Paragraph 14 of this Regulation and which alienates such medical device afterwards shall transfer all the documentation related to such medical device to the acquirer in order to ensure traceability of such medical device.

16. The Agency is entitled to request translations of the documents submitted in the notification procedure.

17. The persons referred to in Paragraph 9 of this Regulation:

17.1. shall be responsible for the traceability of the medical devices referred to in Paragraph 9 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 medical devices placed on the market in the cases specified in this Regulation or Regulation No 2017/745;

17.2. shall list each transaction carried out (except for the transactions with consumers who are natural persons) with medical devices (date, counterparty, nature of the transaction, information identifying the medical devices involved in the transaction) and immediately provide such information to the Agency or the Inspectorate upon request thereof;

17.3. shall, without delay, notify the Agency of any actions taken by them in order to stop the distribution of medical devices or to request withdrawal of medical devices from the market and also of the reasons for the relevant actions.

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

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

18.1. when performing the tasks referred to in Chapter VII of this Regulation, is entitled to develop and publish programmes, guidelines, instructions, and documents for the exchange of information which are necessary for ensuring the operation of the system on vigilance for medical devices and also to establish and maintain an electronic database on the reports provided by health care professionals, users, or patients on incidents or suspected incidents;

18.2. shall receive and store information on manufacturers of class I medical devices and the assemblers of devices referred to in Article 22(1) of Regulation No 2017/745 the place of commercial activity of which is in the Republic of Latvia and the medical devices manufactured by them;

18.3. shall perform the tasks of the supervisory body specified in the Law on Information Society Services and also is entitled to exercise the rights specified for the supervisory body in the abovementioned Law in relation to a provider of the information society service;

18.4. shall maintain the electronic LATMED database of the Register of Medical Devices (hereinafter – the LATMED database);

18.5. shall perform vigilance of medical devices;

18.6. shall aggregate and include information in the LATMED database on the medical devices manufactured by medical treatment institutions;

18.7. shall receive, examine, and aggregate information on class IIa, IIb, and III medical devices which are on the market of Latvia;

18.8. shall issue authorisations for the placing on the market or putting into service of individual medical devices without performing the conformity assessment procedures referred to in Article 52 of Regulation No 2017/745;

18.9. shall issue certificates of free sale;

18.10. shall propose that the Ministry of Health refers to the European Commission for it to determine by implementing acts whether a particular product or category or group of products corresponds to the definition of a medical device or the definition of an accessory for a medical device;

18.11. shall check the data entered in the EUDAMED database in accordance with Article 31(1) of Regulation No 2017/745, obtain the SRN from the EUDAMED database, and issue it to the manufacturer, authorised representative, importer, or the assembler of devices referred to in Article 22(1) of Regulation No 2017/745;

18.12. shall check the data referred to in Section 1 of Part A of Annex 6 to Regulation No 2017/745;

18.13. shall perform the tasks and exercise the rights specified in Articles 5(5), 11(3)(1) and 11(6), 13(10), 16(4), 21(2), 31(2), (5), (6), and (8), 40(2), 51(2), 54(3), 57(2), 59(1) and (2), 83(4), 86(2) and (3), 87(1), (9), (10), and (11), 88(2), 89(1), (2), (3), (4), (5), (6), (7), (8), (9), (10), and (11), 90, 92(2), (5), (6), (7), and (8), 109(2) of Regulation No 2017/745.

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

19.1. as the market surveillance authority shall perform market surveillance of medical devices in accordance with the Law on the Safety of Goods and Services, the law On Conformity Assessment, and Regulation No 2017/745;

19.2. shall control the service of medical devices;

19.3. shall perform controls at manufacturing sites of medical devices, including places where custom-made medical devices are manufactured, at retail points of sale of medical devices, with the persons distributing or importing medical devices, and also with authorised representatives;

19.4. shall assess the documentation of medical devices manufactured within a medical treatment institution in accordance with Article 5(5) of Regulation No 2017/745;

19.5. shall perform the tasks of the supervisory body specified in the Law on Information Society Services and also is entitled to exercise the rights specified for the supervisory body in the abovementioned Law in relation to a provider of the information society service;

19.6. shall monitor the activity of any such person who places medical devices on the market or uses them in a professional environment, or performs maintenance of medical devices;

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

19.8. is entitled to verify the conformity of the manufacturing process of medical devices with the technical documentation and harmonised standards of the device;

19.9. is entitled to check whether this Regulation and the requirements of Regulation No 2017/745 are complied with in the process of distribution and service of medical devices and, when establishing a non-conformity, to request that the possessor (holder) of the medical device takes corrective actions to ensure conformity;

19.10. is entitled to suspend the placing on the market, distribution, or use of the relevant medical device if the 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;

19.11. when implementing the supervision and control of conformity with the requirements laid down for medical devices in this Regulation and Regulation No 2017/745 and when performing market surveillance of medical devices and also control of devices in service, is entitled to request and receive, free of charge, information, including a copy of the EC (EU) declaration of conformity, certificates certifying quality of the medical device which have been issued by the notified body, the circulation documentation of the medical device (bills of lading, inventory cards, write-off deeds, and other similar documents), and also a copy of technical documentation or its part which is necessary for the performance of supervision of medical devices on the market and in use in accordance with the requirements laid down in this Regulation and Regulation No 2017/745;

19.12. is entitled to request and receive, free of charge, samples of medical devices from the manufacturer, importer, or distributor or, if it is not possible, to request that a possibility of accessing the medical device is ensured (if it is possible and is not in contradiction with this Regulation and Regulation No 2017/745, the Inspectorate shall return the samples to the manufacturer or importer, or distributor accordingly after performance of all the necessary checks and activities);

19.13. may request that medical treatment institutions which are referred to in Article 5(5)(1) of Regulation No 2017/745 submit any relevant additional information on the devices which have been manufactured and used in their territory and also is entitled to enter these medical treatment institutions in order to check such activities;

19.14. shall perform the tasks and exercise the rights specified in Articles 5(5)(1), 6(3) and (4), 10(5), (8), (12), and (14), 11(3)(1), 11(2)(b), (d), (e), and (f), and 11(6), 13(2)(2), 13(7) and (10), 14(2)(2), 14(4), and 14(6), 22(5), 23(1), 25(2), 40(2), 46(9)(a), 55(1) and (2), 57(2), 83(4), 85, 93(1), (2), (3), (4), (5), (6), (7), (9), and (11), 94, 95(1), (2), and (4), 96(1), 97(1), 99(1), (2), and (4), 100(2), 109(2) of Regulation No 2017/745.

20. The Agency shall maintain the LATMED database. The Agency is the LATMED State information system manager within the meaning of the Law on State Information Systems. The following information is stored in the LATMED database:

20.1. information on manufacturers of class I medical devices and the assemblers of devices referred to in Article 22(1) of Regulation No 2017/745 the place of commercial activity of which is registered in the Republic of Latvia;

20.2. information on the notified medical devices, their manufacturers and distributors;

20.3. information on the authorised representatives of such manufacturers of medical devices which do not have a registered place of commercial activity in any European Union Member State or country of the European Economic Area;

20.4. information on incidents related to the use of medical devices;

20.5. other information which the Agency has the obligation or the right to obtain and store in accordance with this Regulation and Regulation No 2017/745.

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 accordance 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 European Union legal acts 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. The following information shall not be considered confidential information within the meaning of this Regulation:

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

22.2. information for users on the 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 28 of this Regulation.

23. The Agency shall, on the basis of a submission and corresponding documentation submitted by the subject specified in Article 60(1) of Regulation No 2017/745, issue a certificate of free sale. 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 and surname of the contact person, bank details);

24.2. the name (indicating modifications, where applicable), type, classification class, general description of the medical device to be exported and the intended purpose of the manufacturer, and also the UDI-DI of the medical 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 the certificates of free sale to be issued;

24.4. the name (firm name of the merchant), registration number, legal address, and address of the manufacturing site, and also the SRN (if such has been granted) of the manufacturer.

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 2017/745 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, where applicable), type, classification class of the medical device to be exported, the intended purpose of the manufacturer, and also the UDI-DI of the medical device;

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

26.4. the name (firm name of the merchant), registration number, legal address, and address of the manufacturing site, and also the SRN (if such has been granted) of the manufacturer;

26.5. a certification that the manufacturer conducts entrepreneurship in the Republic of Latvia and that the relevant medical device marked with the CE marking in accordance with Regulation No 2017/745 may be placed on the market in the European Union and countries of the European Economic Area;

26.6. the date of granting the certificate.

27. The Ministry of Health:

27.1. in accordance with the laws and regulations regarding the procedures for establishing a notification commission and also the procedures by which the commission shall take a decision and notify the European Commission of conformity assessment authorities which carry out conformity assessment in the regulated field, shall establish a notification commission which shall take a decision and notify the European Commission of conformity assessment authorities which carry out conformity assessment in the field of medical devices in accordance with Regulation No 2017/745;

27.2. upon proposal of the Agency or the Inspectorate, is entitled to refer to the European Commission for it to determine by implementing acts whether a particular product or category or group of products corresponds to the definition of a medical device or the definition of an accessory for a medical device.

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

28. When commencing activity, the manufacturers of class I medical devices and the assemblers of devices referred to in Article 22(1) of Regulation No 2017/745 the place of commercial activity of which is registered in the Republic of Latvia shall submit a submission to the Agency in which the following information shall be indicated:

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

28.2. the registration number and the SRN (if such has been granted);

28.3. legal address;

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

28.5. telephone number and electronic mail address;

28.6. the name of the manufactured or assembled medical devices, UDI-DI and intended purpose of the medical device.

29. When commencing activity, the distributors of 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 28.1, 28.2, 28.3, and 28.5 of this Regulation and also the classification class and the name and legal address of the manufacturer of such medical devices which are intended for distribution shall be indicated.

30. The persons referred to in Paragraphs 4, 28, and 29 of this Regulation shall, for each calendar year, cover the expenditures of the Agency which are related to the performance of the tasks specified in Chapter VII of this Regulation, ensuring the operation of the system on vigilance for medical devices, in accordance with such procedures and in such amount which are laid down in the laws and regulations regarding the price list of paid services of the Agency.

31. The Agency shall examine the submissions referred to in Paragraphs 28 and 29 of this Regulation and, within 10 days after receipt thereof, enter the relevant information in the LATMED database. If the persons referred to in Paragraphs 4, 28, and 29 of this Regulation do not cover the expenditures referred to in Paragraph 30 of this Regulation within the term stipulated by the Agency, the Agency shall exclude the relevant information on the particular person from the LATMED database.

32. The persons referred to in Paragraphs 28 and 29 of this Regulation shall, within 10 working days, inform the Agency of changes in the information submitted in accordance with Paragraphs 28 and 29 of this Regulation.

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

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

33.2. the type of the medical device in accordance with the division specified in Regulation No 2017/745;

33.3. the code of the European Medical Device Nomenclature.

34. The manufacturers of medical devices the place of commercial activity of which is registered in the Republic of Latvia shall inform of discontinuation of placing on the market and discontinuation of manufacture of the medical devices referred to in Paragraph 33 of this Regulation, and also of changes in the information submitted in accordance with Paragraph 33 of this Regulation within 10 working days from the moment when the relevant changes occurred. The Agency shall, within seven days, include the submitted information in the LATMED database.

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

35. The Agency may issue an authorisation to place on the market or put into service individual medical devices without performing the conformity assessment procedures referred to in Article 52 of Regulation No 2017/745 if the use of the abovementioned devices has a significant importance in ensuring public health or patient safety or health interests. The authorisation shall be issued for the period necessary for performing the necessary conformity assessment procedures or until the moment when an alternative medical device is available, or until the moment when the use thereof no longer has a significant importance in ensuring public health or patient safety or health interests.

36. When taking the decision to issue the authorisation referred to in Paragraph 35 of this Regulation or to refuse to issue the authorisation, the Agency shall also check whether the licence for activities with sources of ionising radiation has been issued to the submitter if the submission applies to a medical device considered as a source of ionising radiation.

37. In order to receive the authorisation for the placing on the market or putting into service of the medical devices referred to in Paragraph 35 of this Regulation, a submission shall be submitted to the Agency in which the following information shall be included:

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

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

37.3. the type of the medical device in accordance with the division specified in Regulation No 2017/745 (if known);

37.4. the description and intended purpose of the medical device;

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

37.6. information as to why the conformity assessment procedures referred to in Article 52 of Regulation No 2017/745 of this Regulation have not been performed or fully completed for the medical device;

37.7. certification that an alternative medical device for which conformity assessment procedures in accordance with the requirements laid down in Regulation No 2017/745 have been performed is not available for the medical treatment of patients;

37.8. information on the conformity of the medical device with the harmonised standards, common specifications, or other technical solutions which ensure the conformity of the medical device with the essential (general safety and performance) requirements laid down in Annex 1 to Regulation No 2017/745;

37.9. results of the inspections performed which certify the conformity of the medical device with the harmonised standards, common specifications, or other technical solutions.

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

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

38.2. an alternative medical device for which conformity assessment procedures in accordance with the requirements laid down in Regulation No 2017/745 have been performed is available on the market for the medical treatment of patients;

38.3. information on the conformity of the medical device with the harmonised standards, common specifications, or other technical solutions which ensure the conformity of the medical device with the essential (general safety and performance) requirements laid down in Annex 1 to Regulation No 2017/745 has not been submitted;

38.4. there are no data on the results of the inspections performed which certify the conformity of the medical device with the harmonised standards, common specifications, or other technical solutions.

39. Examination of the information and documents referred to in Paragraph 37 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.

40. If necessary, the Agency is entitled to request a statement of the Central Medical Ethics Committee, the professional association of physicians, or another competent authority on the medical devices referred to in Paragraph 35 of this Regulation.

**VI. Distribution, Use, and Service of Medical Devices**

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

41.1. to inform the Inspectorate and the Agency if the distributor is of the opinion that the medical device distributed by it on the market of Latvia causes serious risk or that it is counterfeit;

41.2. the distributor which performs any of the activities referred to in Article 16(2)(a) and (b) of Regulation No 2017/745 – to inform the Agency, at least 28 days before making a newly marked or repackaged medical device available on the market of Latvia, of the intention to make the newly marked or repackaged device available and, upon request, to provide the Agency with a sample or mock-up of the newly marked or repackaged device, including any translated label and instructions for use;

41.3. within the term of 28 days referred to in Sub-paragraph 41.2 of this Regulation, to submit a certificate to the Agency which has been issued by the notified body and which is intended for such type of devices for which the measures referred to in Article 16(2)(a) and (b) of Regulation No 2017/745 are taken and which certifies that the quality management system of the distributor conforms to the requirements laid down in Article 16(3) of Regulation No 2017/745;

41.4. to ensure service and repair services of the supplied medical device throughout the period of service intended for such medical device (if such has been specified) and also to ensure the recipient with the information on the measures of technical supervision to be taken for the medical device and their intervals;

41.5. to store and, upon request, make available information to the Agency and the Inspectorate as to the time, person, and type of active class IIa, active class IIb, and active class III medical devices, and also implantable and active implantable medical devices being alienated (this provision shall not apply to cases if the medical device is alienated from a natural person as the final user);

41.6. upon request of the Agency or the Inspectorate, to provide information on the number of medical devices of a specific type and make that have been sold within a specific period and the selling value thereof.

42. If an importer which performs commercial activity in the Republic of Latvia is of the opinion or has a reason to be of the opinion that the medical device imported and placed on the market of Latvia by it causes serious risk or that it is counterfeit, the importer shall inform the Inspectorate and the Agency thereof.

43. In case of damage to the medical device, its owner, possessor, or holder has the right to request that the manufacturer, authorised representative, or distributor supplies certified spare parts and acts accordingly in order to avoid undue demurrage of medical devices, taking into account that:

43.1. in case of damage to an active class IIa, active class IIb, and active class III medical device, only change of certified modular spare parts of the manufacturer is permitted, registering the changed spare parts in the relevant section of the logbook of the medical device referred to in Paragraph 44 of this Regulation;

43.2. repair of modular spare parts without a written consent of the manufacturer and their reuse in the medical device are not permissible.

44. Within the meaning of this Regulation, the logbook of a medical device is information stored in electronic or printed form that includes at least the following data:

44.1. the name, make, and also batch or serial number of the medical device;

44.2. the name and address of the manufacturer, authorised representative (if any) of the medical device, and also the identification data of the supplier, i.e. the name, registration number, and address;

44.3. the name of the technical supervision institution, the date of performing the implemented technical supervision, the given name and surname of the specialist, the number of the technical supervision protocol;

44.4. the date of performing technical maintenance and repair, the name (firm name of the merchant), registration number, legal address of the performer of repair, short description of the activity performed, and the given name and surname of the person who has carried out the relevant work;

44.5. the name of the performer of calibration, the date of calibration, the given name and surname of the specialist, the number of the calibration protocol;

44.6. malfunctions of the medical device which have occurred during service and the measures taken for the elimination thereof.

45. A description of the work carried out and parts changed during technical maintenance and service, and also copies of protocols of electrical safety and functional inspections carried out shall be appended to the logbook of the medical device referred to in Paragraph 44 of this Regulation. The numerical values obtained during measuring of the particular parameters and units of measurement and also the conformity criteria (limit values) according to which conformity of the device has been determined shall be indicated in the protocols of electrical safety and functional inspections.

46. The Agency shall inform the Inspectorate if:

46.1. the Agency has information at its disposal that the medical device 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 if there are suspicions of counterfeit, or the medical device causes or may cause unacceptable risk to the health or safety of patients, users, or other persons or to public health;

46.2. the medical treatment institution, distributor, or another person involved in the vigilance system does not fulfil the requirements laid down in this Regulation for ensuring the operation of the vigilance system.

47. Medical treatment institutions which are registered in the Register of Medical Treatment Institutions and the Register of Medical Practitioners and which, in providing health care services, use active class IIa, active class IIb, and active class III medical devices, and also implantable and active implantable medical devices which, according to the instructions of the manufacturer, may be used for a patient only by appropriately trained medical practitioners, and also persons who use the products referred to in Annex 16 to Regulation No 2017/745:

47.1. shall ensure traceability from the acquisition of such device to its use for a particular person;

47.2. shall appoint the responsible person who shall notify of incidents related to the use of such devices;

47.3. shall develop and introduce a system for the use of medical devices in which at least the following processes are included and described:

47.3.1. the principles for the selection and acquisition of medical devices;

47.3.2. the registration and notification of incidents related to medical devices;

47.3.3. ensuring of disinfection and sterility of medical devices;

47.3.4. the modification and design of medical devices;

47.3.5. the reuse of medical devices;

47.3.6. the technical service work of medical devices, technical supervision during the service of the medical device, documentation of the measures taken;

47.3.7. the identification and record-keeping of medical devices;

47.3.8. actions in cases of damages to medical devices and replacement of the damaged devices;

47.3.9. the service of the leased and lent medical devices;

47.3.10. the lease or lending of medical devices to third parties;

47.3.11. the training of personnel in the use of medical devices;

47.3.12. the provision with the documentation necessary for the service of medical devices;

47.4. shall maintain and update the list of such devices in service (indicating the name of the manufacturer, serial number, and year of manufacture of each device, and also information on the last electrical safety and functional inspections performed), and also issue it to the officials of the Inspectorate upon request;

47.5. shall, for at least two years, electronically store the unique identifiers of the active class IIa, active class IIb, and class III medical devices supplied to them.

48. The list referred to in Sub-paragraph 47.4 of this Regulation shall be updated as necessary but not less than once a year.

49. The medical treatment institution shall issue an implant card together with the information referred to in Article 18(1) of Regulation No 2017/745 to the patient electronically or in printed form.

50. The head of the medical treatment institution shall be responsible for compliance with this Regulation in the medical treatment institution and also for compliance with the system for the service of medical devices developed and introduced in the medical treatment institution.

51. The owner or holder of the medical device shall ensure the following in starting the service of an active class IIa, active class IIb, and active class III medical device in order to provide a health care service and also throughout the service of the medical device:

51.1. unmistakable identification of the medical device and its permanent location;

51.2. calibration and technical supervision of medical devices in accordance with the instructions of the manufacturer and Paragraph 56 of this Regulation;

51.3. calibration of medical devices according to the instructions of the manufacturer (if the manufacturer has provided for more frequent calibration than laid down by the laws and regulations in force);

51.4. technical service work of the medical device within the period of guarantee and also after expiry of guarantee;

51.5. appointing of the responsible person who solves matters concerning the compliance with the specified requirements and cooperates with the Agency, the Inspectorate, and other authorities as the contact person of the owner or holder;

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

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

52. When providing a health care service, only a registered medical practitioner with a corresponding education shall be permitted to use an implantable medical device and active implantable medical device in a medical treatment institution registered in the Register of Medical Treatment Institutions if the particular medical practitioner has received a document certifying competence from the manufacturer or authorised representative of the medical device after corresponding special training in use of the particular active implantable medical device.

53. Only a registered medical practitioner or medical treatment support person with a corresponding education shall be permitted to use an active class IIa, active class IIb, and active class III medical device in a medical treatment institution registered in the Register of Medical Treatment Institutions if:

53.1. the device has been installed according to the instructions of the manufacturer;

53.2. the characteristics of the micro-environment for the use of the device specified by the manufacturer have been ensured, the electricity supply mode is guaranteed (if such requirement is referred to in the documentation of the medical device), and the device is being used according to its intended purpose;

53.3. the particular medical practitioner has received a document certifying competence after corresponding special training in use of the particular medical device (if the manufacturer has specified such requirement in the documentation of the device);

53.4. service and repair services of specially trained technical personnel are ensured for adequate maintenance of the medical device on the basis of the documentation of the manufacturer.

54. An active class IIa, active class IIb, and active class III medical device shall be installed and transferred in service by its manufacturer or authorised representative, or distributor, or importer, ensuring:

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

54.2. training of the user of the medical device and issuing a certifying document in which the person trained, the person who performed training, and the date of undergoing training have been indicated;

54.3. transfer of the instructions for use and other documentation of the medical device 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 medical device;

54.4. transfer of the logbook of the medical device referred to in Paragraph 44 of this Regulation (if such has been intended by the manufacturer) in which entries of the performed functional and electrical safety inspections of the medical device and also testing of functions and calibration of the device (if, in commencing its service, such requirements are provided for in the technical documentation of the device) have been made;

54.5. issuing of a certification of the availability of certified spare parts of the manufacturer of the device and the technical servicing of the medical device within the specified period of guarantee and during the service life of the medical device notified by the manufacturer if such has been specified and if the owner or holder of the medical device chooses such servicing during the service life of the medical device.

55. The owner or holder of a medical device which uses the medical device for the provision of health care services or for cosmetic procedures shall ensure that each active class IIa, active class IIb, and active class III medical device is registered in individual logbook referred to in Paragraph 44 of this Regulation and that the abovementioned logbook together with the protocols of the performed inspections are stored for three years after terminating the service of the device.

56. Technical supervision of medical devices is an aggregate of measures specified by the manufacturer in relation to the electrical safety and functional inspections to be performed for the particular medical device during its service in conformity with all conformity criteria (limit values) specified by the manufacturer, according to the terms and amount specified by the manufacturer, and also after every such use, maintenance, and repair procedure which may affect the technical parameters of the device. The abovementioned technical supervision shall not be applicable to class I devices, inactive devices, and implantable devices.

57. The relevant electrical safety and functional inspections which are referred to in Annex 2 to this Regulation shall be performed for the medical device once a year if at least one of the following circumstances exists:

57.1. the active class IIa, active class IIb, and active class III device has not been marked with the CE marking;

57.2. the documentation of the medical device on the electrical safety or functional inspections specified by the manufacturer and to be performed or their intervals is not available;

57.3. the services of the manufacturer, authorised representative, or representative of the manufacturer (distributor) of the medical device are not available in Latvia.

58. Technical supervision of medical devices shall be performed by the technical supervision authorities, i.e. manufacturers, authorised representatives, or representatives of manufacturers (distributors) of medical devices, or technical supervision authorities which have been accredited with the national accreditation authority in accordance with the laws and regulations regarding the evaluation, accreditation, and supervision of conformity assessment authorities. Only such representatives of manufacturers are entitled to perform technical supervision to which the right to perform technical servicing of the relevant medical devices has been granted by the manufacturer.

59. If technical supervision of medical devices is performed by the manufacturer or representative of the manufacturer, the following information shall be indicated in the protocols of electrical safety and functional inspections:

59.1. the name, make, and batch or serial number of the medical device;

59.2. the given name and surname of the performer of the inspection;

59.3. the names, makes, and batch or serial numbers of all measuring equipment used for the performance of the inspection;

59.4. the calibration or verification dates of all measuring equipment used for the performance of the inspection, the names of the performers of calibration or verification;

59.5. the number of the adhesive label granted (if any);

59.6. the date when the inspection was performed;

59.7. the numerical values of the measured parameter in accordance with the laws and regulations in force regarding the coherence of measurements;

59.8. the name and address of the medical treatment institution.

60. A copy of the certification issued to the performer of the inspection of the training conducted in technical supervision, servicing, and repair of the particular medical devices shall be appended to the protocol referred to in Paragraph 59 of this Regulation, indicating therein the date of issuance thereof, the name of the issuer, the subject-matter of the training, the make (group of makes) of the medical device to which training is attributable, the duration of the training conducted, and the term of validity (if any).

61. If technical supervision of medical devices is performed by a technical supervision authority which has been accredited with the national accreditation authority in accordance with the laws and regulations regarding the evaluation, accreditation, and supervision of conformity assessment authorities, it shall indicate the information referred to in Paragraph 59 of this Regulation in the protocols of electrical safety and functional inspections.

62. In performing measurements of operating parameters of medical devices, the value of the particular parameter shall be indicated in the protocol according to the system of units used in Latvia.

63. If the Inspectorate draws a conclusion that the CE marking has been used without justification or incorrectly or is not used at all, thus violating the requirements of this Regulation, the Inspectorate shall inform the manufacturer (or the 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 the authorised representative has the obligation to eliminate the violation detected.

64. If the Inspectorate draws a conclusion that the manufacturer or authorised representative has not eliminated the violation referred to in Paragraph 63 of this Regulation within the term stipulated by the Inspectorate or that the medical devices bearing the CE marking and also the custom-made medical devices, even if installed, maintained, and used according to the intended purpose, may harm the health of patients, users, or third parties, the Inspectorate shall, without delay, take the necessary measures in order to withdraw such medical devices from the market, and also inform the European Commission thereof, indicating whether such non-conformity with the requirements referred to in this Regulation is related to:

64.1. non-fulfilment with the essential requirements;

64.2. incorrect application of the harmonised standards (if it is being claimed that the harmonised standards have been applied);

64.3. deficiencies of the harmonised standards.

65. If any 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.

66. 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.

67. The possessor or holder of a medical device shall ensure the correct use of active class IIa, active class IIb, and active class III medical devices, active and inactive implantable medical devices and materials, and also invasive medical devices regardless of whether the medical device is being used in a medical treatment institution or another institution and regardless of whether it is being used only according to the medical indications or due to other reasons.

68. The Agency is entitled to create and maintain an electronic database on the use of medical devices of separate groups, i.e. active and inactive implantable devices, devices in which human blood or human plasma derivatives are used, devices manufactured using the components of animal tissues, and other devices of increased medical risk.

**VII. Incidents and Vigilance System**

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

69.1. to preclude repeated incidents;

69.2. to protect patients and users of devices;

69.3. by using the incident reporting system in all European Union Member States and member countries of the European Economic Area, to ensure an opportunity for the Member States and countries to simultaneously recognise the make and series of the non-conforming medical device on the market and in use.

70. A representative of a medical treatment institution shall, within three days after a serious incident or suspected serious incident with a medical device, send an incident report of the user of the medical device (hereinafter – the signal report) to the Agency, using the sample provided in Annex 3 to this Regulation or the electronic reporting form available on the website of the Agency, and inform the manufacturer or authorised representative, or distributor of any deterioration of parameters or malfunctions of the 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.

71. Where possible, documents certifying the quality of the 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 medical device, and also other information in relation to the particular incident shall be appended to the signal report. If significant facts are discovered later, the signal report shall be supplemented without delay and sent to the Agency.

72. After an incident at a medical treatment institution, the user of the medical device or the person responsible for medical devices accordingly:

72.1. shall, without delay, discontinue the use of the medical device;

72.2. shall turn off the medical device and disconnect it from the grid system and other devices;

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

72.4. shall aggregate and store the following information on the malfunctions of the medical device:

72.4.1. the name of the medical device, the UDI-DI of the medical device (if any);

72.4.2. the name, registration number, and legal address of the manufacturer or authorised representative and distributor of the medical device;

72.4.3. a description of malfunctions;

72.4.4. the time when malfunctions were detected;

72.4.5. a description of the possible causes and consequences;

72.4.6. the measures taken for the elimination of malfunctions;

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

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

72.5. shall ensure keeping of the packaging (where possible), instructions for use, and documentation certifying the quality of the relevant medical device and transfer thereof to the manufacturer or authorised representative (the fact of acceptance and transfer of the abovementioned information shall be documented) for carrying out an investigation;

72.6. shall document and keep data on all activities performed in relation to the incident involving the 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;

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

73. The owner or holder of a medical device shall, in addition to the data referred to in Paragraph 44 of this Regulation, document information in the logbook of the medical device on incidents involving the medical device and shall store the abovementioned logbook throughout the service of the medical device and also for three years after the end of service of the medical device. The following information on the medical device involved in an incident shall be indicated in the logbook:

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

73.2. the assessment of the link of the incident to the quality problems of the medical 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.

74. A person who is using the medical device independently or according to the instructions of a medical practitioner or his or her representative (if justified) after a serious incident or suspected serious incident which is related to the use of the medical device:

74.1. shall, within three days, inform the Agency thereof, submitting the signal report (using the sample indicated in Annex 4 to this Regulation);

74.2. shall, without delay, inform the medical practitioner according to whose instructions the 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 medical device;

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

74.4. shall store the 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 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.

75. The possessor or holder of a medical device shall, after sending the signal report during investigation of an incident in cooperation with the manufacturer or authorised representative, 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 medical device.

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

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

76.2. 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;

76.3. if the signal report has been received, shall inform the manufacturer or authorised representative and, if necessary, distributor of the relevant medical device;

76.4. shall ensure the exchange of information with the user of the medical device involved in the incident;

76.5. 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;

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

76.7. 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;

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

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

76.10. shall evaluate the suitability of and need for the field safety corrective actions intended by the manufacturer;

76.11. 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;

76.12. shall evaluate the validity of the decision of the manufacturer not to initiate the field safety corrective actions and, 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 actions;

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

77. 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 incident report, the manufacturer may send an interim report to the Agency.

78. The manufacturer of a medical device shall assess all incident reports received, including reports on inappropriate use and use errors of the medical device. The assessment results shall be stored and they shall be available upon request of the supervisory State authorities and conformity assessment authorities.

79. If medical devices of several manufacturers are involved in an incident, each manufacturer shall perform investigation of the incident and other activities in accordance with the requirements referred to in this Chapter.

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

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

81.1. prepare and submit a final investigation report to the Agency in which the investigation results and an indication on the necessary field safety corrective actions (if necessary) or a justification as to why field safety corrective actions are not necessary are included;

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

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

82. The manufacturer shall ensure the return of the medical device involved in an incident to the possessor of the medical 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 an expert-examination.

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

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

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

86. 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.

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

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

87.2. shall check the information included in the report and the LATMED database on the availability of the medical device involved in an incident on the market in the Republic of Latvia;

87.3. if there is no indication in the report and the LATMED database on the availability of the device on the market of the Republic of Latvia, the file of the vigilance system shall be closed, drawing up the justification for closing the file in writing and appending it to the file;

87.4. if there is no indication in the report or the LATMED database on the availability of the device on the market of the Republic of Latvia or the abovementioned information is not known, the Agency:

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

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

87.5. 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.

88. 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 makes with the requirements of the harmonised standards, the Inspectorate or the Agency shall, without delay, inform the manufacturer of medical devices thereof.

**VIII. Reprocessing of Single-use Medical Devices**

89. The provisions of this Chapter shall be applicable to the reprocessing of single-use medical devices insofar as it has not been laid down otherwise in Regulation No 2017/745 and the directly applicable legal acts of the European Union issued on the basis thereof.

90. Such persons are entitled to perform reprocessing of single-use medical devices which have fulfilled the requirements laid down in this Regulation, Regulation No 2017/745, and the directly applicable legal acts of the European Union issued on the basis thereof and which have a corresponding certificate issued by the notified body certifying the fulfilment of these requirements (hereinafter – the reprocessor).

91. The reprocessor shall bear the same responsibility for the reprocessed medical devices as laid down by the laws and regulations for the manufacturer in respect of new medical devices. The responsibility of the manufacturer of a single-use medical device for the particular medical device shall end from the moment when such device is not disposed of according to the instructions of the manufacturer and instead reprocessing of such device is commenced.

92. Repeated placing on the market of a reprocessed single-use medical device is prohibited. A single-use medical device may be used repeatedly only at the same medical treatment institution regardless of whether the single-use medical device is reprocessed at the same medical treatment institution or it is done by another person under assignment of the medical treatment institution. It shall also apply to cases when the rights specified in Article 17(3) of Regulation No 2017/745 are being exercised.

93. It shall be permitted to reprocess single-use medical devices in Latvia imported from other European Union Member States or countries of the European Economic Area and also from third countries. Only such single-use medical devices are permitted for use in Latvia that are reprocessed in accordance with this Regulation.

94. A reprocessed single-use medical device shall be used only for one patient in one medical treatment procedure. A clearly visible and indelible labelling on the prohibition of reuse (Annex 5) and also a labelling that it is a reprocessed single-use medical device shall be placed on the packaging of the reprocessed single-use medical device.

95. A single-use medical device may be reprocessed and reused for a limited number of times. The permissible number of the reprocessing times shall be determined in the technical documentation by the reprocessor, taking into account the legal acts in force, its technical capabilities, the overall level of technical development, the latest scientific findings, and the studies conducted in this field.

96. Prior to the provision of the relevant health care service, a medical treatment institution has the obligation to inform (where possible) the patient in writing of the use of a reprocessed single-use medical device.

97. The reprocessing process of a single-use medical device shall be documented in a way that it is possible to trace the activities performed with the device and the results of such activities.

98. The reprocessor shall ensure that such internal regulatory enactments are adopted and in effect which determine actions in case of detecting that the reprocessed single-use medical device does not conform to the requirements of this Regulation, Regulation No 2017/745, or other European Union legal acts.

99. The reprocessor shall withdraw the medical device from circulation and dispose of it if it is not possible to ensure any of the functionality, quality, or safety requirements during its reprocessing process.

100. A clearly legible identifier of the manufacturer of the medical device shall be kept on the reprocessed medical device and also a clearly legible and indelible identifier of the reprocessor of the medical device (serial number or other unique identified of the reprocessed medical device) shall be indicated.

101. It shall be indicated unmistakably on the packaging and in the instructions for use of the reprocessed medical device that it is a reprocessed medical device.

102. If the reprocessor detects or also has justified doubts that the reprocessed medical device has not been immediately returned to the same reprocessor after its use but has been subject to any treatment at any other place, the reprocessor shall, without delay, withdraw such medical device from circulation and ensure the disposal thereof.

103. The reprocessor shall ensure that the reprocessed medical device has technical documentation in which the reprocessor certifies that the reprocessed medical device will operate in the same way as a new medical device, without additional risks to the patient and the user.

104. The notified body shall issue a certificate for the reprocessing process of a single-use medical device of one make or one type, including cleaning, disinfection, sterilisation, packaging, preparation of the documentation, and transportation of the device.

105. The cleaning, disinfection, and sterilisation processes used by the reprocessor shall contain certifications of tests performed in relation to the presence of cytotoxicity, endotoxins, and prions.

106. The reprocessor shall store the documentation on reprocessed medical devices for at least 10 years after the last medical device of the particular make (type) is withdrawn from circulation.

107. The reprocessor shall regularly perform independent audits of the reprocessing process of medical devices in accordance with the harmonised standards in effect.

108. The reprocessor shall fulfil the obligations specified for the manufacturer in laws and regulations in relation to the measures of the vigilance and continuous supervision system.

109. The reprocessor shall ensure a possibility of tracing the circulation of the reprocessed medical device according to both its own identifier and identifier of the manufacturer.

110. If a medical treatment institution wishes to use reprocessed single-use medical devices, it shall either meet the requirements laid down in this Chapter, Regulation No 2017/745, and the directly applicable legal acts of the European Union issued on the basis thereof, or meet the requirements of Article 17(3) of Regulation No 2017/745 and commence reprocessing of single-use medical devices, or enter into a corresponding contract with the reprocessor for the provision of such service. The medical treatment institution which has entered into the abovementioned contract with the reprocessor:

110.1. shall return the used reprocessed medical devices to the reprocessor with which it has entered into the contract for the reprocessing service of medical devices;

110.2. shall not perform any treatment of the used reprocessed medical devices;

110.3. shall not transfer the used reprocessed medical devices into possession of third parties.

**IX. Closing Provisions**

111. Sub-paragraphs 18.11 and 18.12 of this Regulation shall be applied after six months from the day when the European Commission has notified that the operation of the functions of the EUDAMED database has been completely commenced.

112. Starting from 1 January 2025, it is prohibited to use active class IIa, active class IIb, and active class III medical devices without the CE marking. It shall not apply to the medical devices for which an authorisation in accordance with the procedures laid down in Chapter V of this Regulation has been received.

113. Distributors of medical devices which have commenced operation until the day of coming into force of this Regulation shall submit the submission referred to in Paragraph 29 of this Regulation to the Agency within three months after the day of coming into force of this Regulation.

114. Until 31 December 2024, technical supervision institutions are entitled to take technical supervision measures of medical devices on the basis of accreditations issued in accordance with Cabinet Regulation No. 689 of 28 November 2017, Procedures for Registration, Conformity Assessment, Distribution, Operation and Technical Supervision of Medical Devices, unless the term of the relevant accreditation has expired.

115. The technical supervision measures of medical devices taken in accordance with Cabinet Regulation No. 689 of 28 November 2017, Procedures for Registration, Conformity Assessment, Distribution, Operation and Technical Supervision of Medical Devices, and the protocols issued shall be in effect until expiry of the term of validity thereof.

116. Cabinet Regulation No. 689 of 28 November 2017, Procedures for Registration, Conformity Assessment, Distribution, Operation and Technical Supervision of Medical Devices (*Latvijas Vēstnesis*, 2017, No. 237; 2020, No. 79.B), is repealed.

Prime Minister, Acting Minister for Foreign Affairs A. K. Kariņš

Minister for Health L. Meņģelsone

**Annex 1**

Cabinet Regulation No. 461

15 August 2023

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

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| *Paziņojumu iesniedz par II a, II b un III klases medicīniskajām ierīcēm vai aktīvām implantējamām medicīniskajām ierīcēm/ The Statement shall be submitted concerning II a, II b and III class medical devices or active implantable medical devices)* | | |
| 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 reģ. 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 medicīnisko ierīci:**  *Information on medical device* | |
| 2.1. | Medicīniskās ierīces nosaukums (ja iespējams, norādīt modeli(-ļus)):  *Name of medical device/es (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 reģ. 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. 461

15 August 2023

**Electrical Safety and Functional Inspections for Active Class IIa, Active Class IIb, and Active Class III Medical Devices Without the CE Marking or Whereof a Medical Treatment Institution has no Information at its Disposal on the Required Inspections Stipulated by Their Manufacturer or Intervals Thereof**

**I. Electrical safety inspections**

1. The following inspection of electrical safety parameters shall be performed in relation to all active class IIa, active class IIb, and active class III medical devices (except for devices which may only feed of an autonomous source of electricity and also devices of protection class 2 with body made of electrically insulating material):

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| --- | --- | --- | --- |
| Table 1 | **Parameters to be evaluated in electrical safety inspections of medical devices, their minimum conformity criteria, and conditions of measurements** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1. | Protective conductor resistance | < 0.3 Ω | Measurements are performed only for the devices of protection class I in their operating mode according to the connection scheme stipulated by the manufacturer |
| 2. | Leakage current via protective conductor | < 5 mA | Measurements are performed only for the devices of protection class I in their operating mode according to the connection scheme stipulated by the manufacturer |
| 3. | Leakage current of the body | < 0.1 mA | Measurements are performed in the operating mode of devices according to the connection scheme stipulated by the manufacturer |
| 4. | Leakage current patient–protective conductor | Type CF < 0.01 mA  Type BF < 0.1 mA | Measurements are performed in the operating mode of devices according to the connection scheme stipulated by the manufacturer |

**II. Functional inspections**

2. Inspection of the following parameters shall be performed in relation to the medical devices which are intended for the generation and use of electrical energy for stimulating neural or muscular and also cardiac activity, i.e. external cardiac stimulation devices, defibrillators, medical electric shock devices, electroanesthesia (electrosleep) devices, high-frequency electrotherapy devices, stationary neurostimulation devices which are connected to a grid system, and also portable neurostimulation devices the maximum possible stimulation current of which exceeds 70 mA in current-mode control (CC) or 100 V in voltage-mode control (CV):

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| --- | --- | --- | --- |
| Table 2 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| **1. Common group parameters** | | | |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether electrically operated devices have damages to the body of the device which affect the operation or safe use of the device |
| 1.2. | Conformity of the working condition of electrodes for patients | Conforms / Does not conform | Visual inspection is performed and it is detected whether the working surface of electrodes for patients and the electrode wires for patients have damages which affect the operation or safe use of the device |
| 1.3. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| **2. Defibrillators** | | | |
| 2.1. | Value of electric energy supplied to a patient | ≤ ±15 % | Measurements are performed at patient-simulating resistance of 50 Ω with the set maximum available energy value and energy values: 20, 50, 100, 200 J. If it is technically not possible to set any of the abovementioned energy values, a note is made and the nearest possible setting is used.  If a battery that cannot be charged repeatedly has been built into the defibrillator, measurements are performed at patient-simulating resistance of 50 Ω with the set maximum available energy value and energy values: 20 and 100 J. If it is technically not possible to set any of the abovementioned energy values, a note is made and the nearest possible setting is used.  If a defibrillator has automatic defibrillation protocols, measurements shall be performed at patient-simulating resistance of 50 Ω and energy values ensured by protocols |
| 2.2. | Synchronisation (if intended) time of electrical energy impulses supplied to a patient | < 60 ms | Inspection is performed in synchronisation (SYNC) mode at patient-simulating resistance of 50 Ω and the electrical energy value of 100 J supplied to a patient.  Measurements are performed by sending an ECG-simulating signal of a patient simulator with frequencies: 60, 120, 180 beats per minute via:  1) defibrillator pads;  2) ECG electrodes (if intended) |
| 2.3. | Conformity of the functions of the autonomous electricity source (if intended). Charging time until maximum power from the electric storage battery | < 15 sec | Inspection is performed for a device with fully charged battery.  The device is disconnected from an external electrical power network, ensuring feeding from a built-in electric storage battery. When measuring the charging time, 6 discharges are carried out at maximum available energy and 3 discharges – if the defibrillator has a built-in battery that cannot be charged repeatedly. The period between the discharge and the next charging may not be less than 60 seconds. |
| 2.4. | Value of electric energy supplied to a patient at various patient resistances | < ±15 % | Measurements are performed with the set maximum available energy value at patient-simulating resistances: 25, 100, 150, and 175 Ω.  If the device indicates the supplied value of energy, the value measures shall be compared to the value indicated.  If the device does not indicate the supplied energy, it is taken into account in evaluation that the nominal energy value set in the device at patient resistance of 50 Ω is ED50 and the following energy correction factors are used with other patient resistances:  0.86 × ED50 at 25 Ω;  1.09 × ED50 at 100 Ω;  1.12 × ED50 at 150 Ω;  1.135 × ED50 at 175 Ω.  If other energy correction factors are indicated in the documentation of the device, they are the ones taken into account in evaluation |
| **3. External cardiac stimulation devices** | | | |
| 3.1. | Range of voltage/current impulses supplied to a patient | ≤ ±5 % | Measurements of the value of impulse range are performed in ventricular asynchronous (V00) and atrial asynchronous (A00) or equivalent stimulation mode, at 80 % of the maximum value of impulse range, 70 imp/min of impulse frequency, and patient-simulating resistances: 200, 500, and 1000 Ω.  If it is technically not possible to set 80 % of the maximum value of impulse range, a note is made and the nearest possible setting is used.  If it is not possible to set 70 imp/min, a note is made and the nearest possible setting is used |
| 3.2. | Conformity of impulse frequency supplied to a patient | ≤ ±0.5 % | Measurements of impulse frequency are performed in V00, A00, or equivalent modes at 80 % of the maximum value of impulse range, patient-simulating resistance of 500 Ω, and values of impulse frequency: 60, 120 imp/min  If it is technically not possible to set 80 % of the maximum value of impulse range, a note is made and the nearest possible setting is used.  If it is not possible to set 60 and 120 imp/min, the minimum and maximum available settings of impulse frequency are used |
| 3.3. | Conformity of the duration of impulses supplied to a patient | ≤ ±5 % | Measurements of impulse duration are performed in V00, A00, or equivalent modes at 80 % of the maximum value of impulse range, patient-simulating resistance of 500 Ω, and values of impulse frequency: 60, 120 imp/min  If it is technically not possible to set 80 % of the maximum value of impulse range, a note is made and the nearest possible setting is used.  If it is not possible to set 60 and 120 imp/min, the minimum and maximum available settings of impulse frequency are used |
| **4. Neural and muscular stimulation, medical electric shock and electroanesthesia devices** | | | |
| 4.1. | Value of current indicated by the measuring device (if any) built in the device | ≤ ±10 % | Measurements of current are performed at patient-simulating resistance of 500 Ω, at the maximum value of current, and 50 % of the maximum value of current.  If another value of resistance is indicated in the documentation of the device, this value is used in measurements.  Measurements are performed in at least one of the direct current modes and one of the impulse modes (if the relevant modes are intended) |
| 4.2. | Maximum current supplied to a patient | ≤ 80 mA at direct current  ≤ 50 mA at frequencies ≤ 400 Hz  ≤ 80 mA at frequencies from > 400 Hz to  ≤ 1500 Hz  ≤ 100 mA at frequencies > 1500 Hz | Measurements are performed at the maximum available value of current and patient-simulating resistance of 500 Ω.  Measurements are performed in at least one of the direct current modes and one of the impulse modes (if the relevant modes are intended) |
| 4.3. | Maximum output voltage of the device | ≤ 500 V | Measurements are performed with the mode which conforms to the maximum available value of current in the open circuit.  Measurements are performed in at least one of the direct current modes and one of the impulse modes (if the relevant modes are intended) |
| 4.4. | Conformity of the duration of impulses supplied to a patient (if an impulse mode is intended) | ≤ ±20 % | Measurements are performed at the maximum value of current to be set and patient-simulating resistance of 500 Ω.  If another value of resistance is indicated in the specification of the device, this value is used in measurements |
| 4.5. | Conformity of the frequency of impulses supplied to a patient (if an impulse mode is intended) | ≤ ±20 % | Measurements are performed at the maximum value of current to be set and patient-simulating resistance of 500 Ω.  If another value of resistance is indicated in the specification of the device, this value is used in measurements |
| **5. High-frequency electrotherapy devices** | | | |
| 5.1. | Conformity of power supplied to a patient | ≤ ±20 % | Measurements are performed at the maximum available power value in available modes of the device |

3. Inspection of the following parameters shall be performed in relation to the medical devices which are intended for the generation and use of electrical energy for the performance of direct coagulation, tissue destruction, or breaking down of residue in organs, i.e. laser surgery and laser therapy devices, photocoagulation devices, and high-frequency electrosurgical devices:

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| --- | --- | --- | --- |
| Table 3 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| **1. Common parameters** | | | |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device.  Inspection of the presence of warning notices and marking is performed |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| **2. High-frequency electrosurgical devices** | | | |
| 2.1. | Conformity of the working condition of neutral electrodes and electrosurgical instruments (electrodes) | Conforms / Does not conform | Visual inspection is performed and it is detected whether the neutral electrode to be attached to patients, electrosurgical instruments, electrode wires, and wire connections have no mechanical damage |
| 2.2. | Conformity of the value of power supplied to a patient with the selected value | ≤ ±20 % | Measurements are performed in one of monopolar cutting modes, one of monopolar coagulation modes, one of bipolar cutting modes, and one of bipolar coagulation modes (if the relevant modes are intended and the medical treatment institution has such electrodes at its disposal which are suitable for the modes).  If measurements are not performed in any of the modes due to the absence of electrodes, it shall be indicated in the inspection protocol.  Measurements are performed at patient-simulating resistances of 100, 200, 500, 1000, 2000 Ω and the nominal patient-simulating resistance value as specified in the instructions for use, setting the maximum value of power and 50 % of the maximum value of power, in each mode.  It is taken into account in evaluation that the conformity criterion is applicable if values of output power at the abovementioned resistances are indicated in the documentation of the manufacturer and the power supplied at the abovementioned resistances is > 10 % of the value of nominal power at the nominal resistance of the relevant mode |
| 2.3. | Conformity of the value of maximum voltage supplied to a patient with the selected value | ≤ ±20 % | Measurements are performed in one of monopolar cutting modes, one of monopolar coagulation modes, one of bipolar cutting modes, and one of bipolar coagulation modes (if the relevant modes are intended and the medical treatment institution has such electrodes at its disposal which are suitable for the modes).  If measurements are not performed in any of the modes due to the absence of electrodes, it shall be indicated unmistakably on the title page of the inspection protocol.  Measurements are performed at settings and loads which ensure maximum voltage peak value |
| **3. Laser surgery and laser therapy devices, photocoagulation devices** | | | |
| 3.1. | Conformity of the working condition of applicators/emitters, protective equipment | Conforms / Does not conform | Visual inspection is performed and it is detected whether the applicators of the emitter have no mechanical damage.  Inspection is performed whether goggles with a marking that certifies protection against the wavelength of radiation emitted by the device are available |
| 3.2. | Conformity of the value of power supplied to a patient (if to be set) | ≤ ±20 % | Measurements of radiation power are performed at values of power equal to the maximum value of power and 50 % of the maximum value of power.  If it is not possible to set 50 % of the maximum value of power, the relevant measurement need not be performed.  Measurements are performed in the continuous radiation mode, but if such is not intended – in impulse mode |
| 3.3. | Conformity of the value of energy supplied to a patient (if to be set) | ≤ ±20 % | Measurements of radiation energy are performed at values of energy equal to the maximum value of energy and 50 % of the maximum value of energy.  If it is not possible to set 50 % of the maximum value of energy, the relevant measurement need not be performed.  Measurements are performed in the continuous radiation mode, but if such is not intended – in impulse mode |

4. Inspection of the following parameters shall be performed in relation to the medical devices which are intended for direct administration of substances and liquids into blood circulation, moreover these substances and liquids may also be prepared or specifically processed substances and liquids of one’s own body the administration of which is directly linked to their sampling function, i.e. jet injectors, syringe infusion pumps, infusion pumps:

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| Table 4 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| **1. Common parameters** | | | |
| 1.1. | Inspection of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device and the liquid administration mechanism have damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| **2. Syringe infusion pumps, infusion pumps, jet injectors** | | | |
| 2.1. | Conformity of substance or liquid flow accuracy | ≤ ±2 % for syringe infusion pumps  ≤ ±6 % for infusion pumps, jet injectors | Measurements for syringe infusion pumps and infusion pumps are performed with the following settings:  1) 125 ml per hour, 20 ml;  2) 60 ml per hour, 10 ml.  If it is technically not possible to set any of the abovementioned flow rate values, a note is made and the nearest possible setting is used.  Measurements for jet injectors are performed with the following settings:  1) 8 ml per second, 100 ml;  2) 2 ml per second, 30 ml.  If it is technically not possible to set any of the abovementioned flow rate or volume values, a note is made and the nearest possible setting is used |
| 2.2. | Conformity of substance or liquid dosing accuracy | ≤ ±3 % for syringe infusion pumps  ≤ ±6 % for infusion pumps, jet injectors | Measurements for syringe infusion pumps and infusion pumps are performed with the following settings:  1) 125 ml per hour, 20 ml;  2) 60 ml per hour, 10 ml.  If it is technically not possible to set any of the abovementioned flow rate values, a note is made and the nearest possible setting is used.  Measurements for jet injectors are performed with the following settings:  1) 8 ml per second, 100 ml;  2) 2 ml per second, 30 ml.  If it is technically not possible to set any of the abovementioned flow rate or volume values, a note is made and the nearest possible setting is used |
| 2.3. | Conformity of the occlusion pressure value with the setting made | ≤ ±200 mbar for syringe infusion and infusion pumps  ≤ ±1.2 bar for jet injectors | Measurements for syringe infusion pumps and infusion pumps are performed with the setting of 125 ml per hour.  If it is technically not possible to set the abovementioned flow rate value, a note is made and the nearest possible setting is used.  Measurements for jet injectors are performed with the setting of 2 ml per second |

5. Inspection of the following parameters shall be performed in relation to electrically powered artificial respiration devices with or without anaesthesia, i.e. inhalation anaesthesia devices and respiratory devices:

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| Table 5 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the protection (if such is intended) functions provided by the manufacturer against incorrect use of the device | Conforms / Does not conform | Mechanical protection against accidental turning-off of the device is inspected |
| 1.3. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| 1.4. | Conformity of audible and visual alerts | Conforms / Does not conform | Inspection is performed by setting parameters outside the set warning thresholds, disconnecting the artificial lung from the breathing circuit, obstructing the breathing circuit |
| 1.5. | Conformity of the functions of the autonomous electricity source (if intended) | > 30 min | Inspection is performed with fully charged battery of the device, turning off the device from the network at the beginning of the inspection procedure |
| 1.6. | Values of the set and indicated maximum inspiratory pressure | Accuracy of the value indicated by the built-in quantifier: ≤ ±(2 hPa + 4 % of the measured value) | Measurements are performed in the following modes (if the relevant modes are intended):  1) artificial respiration control according to the volume at the set respiration volume of 500 ml, inspiratory time/expiratory time ratio of 1:2, end-expiratory pressure 5 hPa, breathing frequency 10 times per minute;  2) artificial respiration control according to the volume at the set respiration volume of 300 ml, inspiratory time/expiratory time ratio of 1:2, end-expiratory pressure 5 hPa, breathing frequency 20 times per minute;  3) artificial respiration control according to the pressure at the set respiratory pressure which exceeds the end-respiratory pressure by 20 hPa, inspiratory time/expiratory time ratio of 1:2, end-expiratory pressure 5 hPa, breathing frequency 20 times per minute. |
| 1.7. | Values of the set and indicated end-expiratory pressure | Accuracy of the value indicated by the built-in quantifier: ≤ ±(2 hPa + 4 % of the measured value) |
| 1.8. | Values of the set and indicated respiration volume | Accuracy of the value indicated by the built-in quantifier: ≤ ±(4 ml + 15 % of the measured value) |
| 1.9. | Values of the set breathing frequency | ≤ ±1 time per min |
| 1.10. | Set and indicated oxygen concentration (if such is intended) | ≤ ±5 % | Measurements are performed in the volume control mode at the set respiration volume of 500 ml, inspiratory time/expiratory time ratio of 1:2, end-expiratory pressure 5 hPa.  If an external gas concentration monitor is used, oxygen concentration is evaluated on the basis of its indications and its identification data are indicated on the title page of the inspection protocol (manufacturer, name, serial number).  Inspection is performed at the following set oxygen concentrations: 21, 40, 60, 100 % |

6. Inspection of the following parameters shall be performed in relation to the medical devices for pressure chamber therapy, i.e. hyperbaric chambers and other devices for the use of increased or intermittent pressure for more than half of the body:

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| --- | --- | --- | --- |
| Table 6 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the protection (if such is intended) functions provided by the manufacturer against incorrect use of the device | Conforms / Does not conform | Mechanical protection against accidental turning-off of the device is inspected |
| 1.3. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| 1.4. | Conformity of audible and visual alerts (if such are intended) | Conforms / Does not conform | It is inspected whether audible and visual alerts are in working order |
| 1.5. | Pressure increase rate | > 0.8 bar/min and < 3.0 bar/min | Inspection is performed at maximum compression speed |
| 1.6. | Pressure reduction time | > 40 sec and < 80 sec | The time in which pressure drops to 2 bar is measured at the set pressure of 4 bar |
| 1.7. | Pressure stability | ≤ ±5 % | Inspection is performed at maximum intended pressure after stabilisation of the pressure mode |
| 1.8. | Internal temperature | < +7 °C and > –5 °C from the ambient temperature | Inspection is performed by comparing the measured temperature with the measured ambient temperature at the maximum set pressure after stabilisation of the pressure mode |

7. Inspection of the following parameters shall be performed in relation to cryosurgery, cryotherapy, and hypothermia devices:

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| Table 7 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| 1.3. | Conformity of audible and visual alerts (if such are intended) | Conforms / Does not conform | It is inspected whether audible and visual alerts are in working order |
| 1.4. | Conformity of the protection (if such is intended) functions provided by the manufacturer against incorrect use of the device | Conforms / Does not conform | Mechanical protection against accidental turning-off of the device is inspected |
| 1.5. | Conformity of the temperature of a hypothermia device with the selected temperature | ≤ ±1 °C | Measurements are performed at the following set temperatures:  –33.5 °C;  –37 °C.  Measurements at each setting are performed for at least 20 minutes after stabilisation of the temperature |
| 1.6. | Conformity of the minimum temperature and the functions of the devices restricting it | < –2 °C | Measurements are performed at the minimum available temperature |
| 1.7. | Maintaining of the working temperature of the instrument of the cryosurgery and cryotherapy device | ≤ –2 °C for cryotherapy devices  ≤ –20 °C or ≤ –50 °C depending on configuration of the cryosurgery device  or at values which are indicated in the technical documentation of the manufacturer | Measurements are performed for corresponding available temperature settings (depending on the configuration of the device) according to the instructions of the manufacturer |

8. Inspection of the following parameters shall be performed in relation to neonatal incubators:

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| Table 8 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| 1.3. | Conformity of audible and visual alerts | Conforms / Does not conform | In performing inspection, values of parameters outside the permissible limits are reached |
| 1.4. | Accuracy of the relative air humidity indicating device | ≤ ±10 % for stationary incubators  ≤ ±15 % for portable incubators | Measurements are performed by placing the humidity meter in the centre of the incubator chamber, at the set temperature of 36 °C |
| 1.5. | Accuracy of the temperature indicating device of the incubator | ≤ ±0.8 % for stationary incubators  ≤ ±1.0 % for portable incubators | Measurements are performed at the set temperature of 36 °C at the conditions of the stationary temperature mode (average temperature in the incubator chamber within at least an hour does not change by more than 1 °C). The set temperature is compared to the average temperature of the incubator at the centre of the chamber.  The measuring instrument ensures accuracy of ±0.05 °C in the temperature range from 20 °C to 40 °C |
| 1.6. | Conformity of regulation accuracy of the incubator temperature | ≤ ±1.5 °C | Measurements are performed at the set temperature of 36 °C at the conditions of the stationary temperature mode (average temperature in the incubator chamber within at least an hour does not change by more than 1 °C) |

9. Inspection of the following parameters shall be performed in relation to infrared neonatal radiant warmers, electrically heated beds/mattresses, and other body heating devices:

|  |  |  |  |
| --- | --- | --- | --- |
| Table 9 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| **1. Common group parameters** | | | |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| **2. Electrically heated beds/mattresses and other body heating devices** | | | |
| 2.1. | Conformity of the temperature with the selected temperature | ≤ ±1.5 °C | Measurements are performed after lighting of the temperature stabilisation indicator at the set temperature values which conform to:  1) the minimum value;  2) the maximum value;  3) 50 % of the maximum value of the range.  If it is technically not possible to set any of the abovementioned temperature values, a note is made and the nearest possible setting is used.  Measurements at each setting are performed for at least 20 minutes after lighting of the temperature stabilisation indicator.  The means for measuring the temperature must ensure accuracy of ±0.1 °C |
| 2.2. | Conformity of the temperature maintenance stability | ≤ ±1.0 °C |
| **3. Infrared neonatal radiant warmers** | | | |
| 3.1. | Conformity of the condition of the infant temperature sensor | Conforms / Does not conform | Visual inspection is performed and it is detected whether the temperature sensor has damages and whether it is in working order |
| 3.2. | Conformity of audible and visual alerts | Conforms / Does not conform | It is inspected whether audible and visual alerts are in working order |
| 3.3. | Conformity of the accuracy of temperature sensor measurements | ≤ ±0.3 °C | Measurements are performed at the set temperature of 36 °C. Indications of the infant temperature sensor on the display of the warmer are compared to indications of the reference meter.  The means for measuring the temperature ensures accuracy of ±0.05 °C |
| 3.4. | Conformity of the operation of the radiant device in the temperature control mode, using the infant temperature sensor | ≤ ±0.5 °C | Measurements are performed at the set temperature of 36 °C after stabilisation of temperature with the mattress being in horizontal position.  For evaluating the conformity of the operation of the radiant device, the infant temperature sensor is attached to the upper surface of the aluminium disk placed in the centre of the mattress. The set temperature of the radiant device is compared to the indications obtained from the infant temperature sensor.  An aluminium disk with the following parameters is used:  coating of non-reflective black colour;  mass 500 ± 10 g;  diameter 100 ± 2 mm;  borehole with the diameter of 5 mm and length of 50 ± 2 mm |

10. Inspection of the following parameters shall be performed in relation to the medical devices which are intended for the observation of vital physiological parameters with the nature of variations causing immediate danger to the patient –vital signs monitors:

|  |  |  |  |
| --- | --- | --- | --- |
| Table 10 | Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| 1.3. | Conformity of the working condition of electrodes for patients | Conforms / Does not conform | Visual inspection is performed and it is detected whether the working surface of electrodes for patients and the electrode wires for patients have damages which affect the operation of the device |
| 1.4. | Conformity of audible and visual alerts | Conforms / Does not conform | Inspection is performed by exceeding the set alert limit values |
| 1.5. | Conformity of the functions of the autonomous electricity source (if intended) | > 30 min | Inspection is performed with fully charged battery by disconnecting the device from the grid.  If the battery of the device can be changed, the identification data of the battery shall be indicated in the inspection protocol.  If the possibility of using a battery that can be changed is intended for the device but the device is being used without it, it shall be indicated unmistakably on the title page of the inspection protocol |
| 1.6. | Conformity of accuracy of the non-invasive blood pressure measuring device (if such is intended) | ≤ ±5 mmHg | Inspection is performed at the following pressure values set in the patient simulator or non-invasive blood pressure simulator:  1) SYS 120 mmHg;  2) SYS 180 mmHg or 200 mmHg |
| 1.7. | Conformity of accuracy of measuring the electrocardioscopy signal pulse frequency | ≤ ±5 beats per minute | Measurements are performed at the following pulse value of a patient-simulating ECG signal: 60, 120, 180 beats per minute |

11. Inspection of the following parameters shall be performed in relation to steam sterilisers, i.e. disinfection devices and sterilisation devices with elevated pressure:

|  |  |  |  |
| --- | --- | --- | --- |
| Table 11 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| 1.3. | Conformity of audible and visual alerts (if such are intended) | Conforms / Does not conform | It is inspected whether audible and visual alerts are in working order |
| 1.4. | Inspection of a built-in temperature meter | ≤ ±1 °C | A programme of the disinfection device or autoclave is used for inspection according to the requirements of the commissioning party |
| 1.5. | Readings of a built-in pressure meter (for autoclaves) | ≤ ±0.05 bar |
| 1.6. | Conformity of temperature with the nominal temperature of the programme to be used in the sterilisation stage (for autoclaves) | +4 °C |
| 1.7. | Conformity of the operation of registration devices (if such are intended) | Conforms / Does not conform | It is inspected whether it is possible to obtain a print-out describing the sterilisation/disinfection cycle as a result of the sterilisation cycle |

12. Inspection of the following parameters shall be performed in relation to devices for warming fluids to be administered into blood circulation and hot-air sterilisers:

|  |  |  |  |
| --- | --- | --- | --- |
| Table 12 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| 1.3. | Temperature control test (if such is applicable) | Average temperature ≤ ±5 °C from the set temperature for sterilisers  Average temperature ≤ ±1 °C from the set temperature for devices for warming fluids to be administered into blood circulation | Inspection is performed at 180 °C for sterilisers and at 37 °C for devices for warming fluids to be administered into blood circulation.  If it is not possible to set any of the abovementioned temperature values, if changing of the settings is not technically possible or changing of the settings of the device may affect the quality of medical services, a note is made and the nearest possible setting is used |

13. Inspection of the following parameters shall be performed in relation to diagnostic ultrasound devices:

|  |  |  |  |
| --- | --- | --- | --- |
| Table 13 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction, functions of control and indicating devices | Conforms / Does not conform | Device is visually inspected from the outside, i.e. the body, connections, functions of the control and indication elements |
| 1.2. | Inspection of axial resolution of probes | ≤ ±1 mm of the basic value for probes with the frequency > 4 MHz  ≤ ±2 mm of the basic value for probes with the frequency > 4 MHz | Inspection is performed in a mode suitable for each probe |
| 1.3. | Inspection of lateral resolution of probes | < ±1.5 mm of the basic value | Inspection is performed in a mode suitable for each probe |
| 1.4. | Inspection of measurement accuracy of probe distances on a horizontal plane | ≤ ±3 mm error or ≤ ±3 % difference, the largest one is applied | Inspection is performed in a mode suitable for each probe |
| 1.5. | Inspection of measurement accuracy of probe distances on a vertical plane | ≤ ±2 mm error or ≤ ±2 % < 2 mm difference, the largest one is applied | Inspection is performed in a mode suitable for each probe |
| 1.6. | Inspection of the capacity to display test objects of various sizes of probes (blind spot inspection) | ≤ ±4 mm for probes with the frequency ≥ 7 MHz  ≤ ±7 mm for probes with the frequency 3÷7 MHz  ≤ ±10 mm for probes with the frequency ≤ 3 MHz | Inspection is performed in a mode suitable for each probe |

14. Inspection of the following parameters shall be performed in relation to physiotherapy ultrasound devices with the operating frequency from 0.5 MHz to 5 MHz:

|  |  |  |  |
| --- | --- | --- | --- |
| Table 14 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| 1.3. | Condition of the mechanical construction of probes and cables of probes | Conforms / Does not conform | Visual inspection is performed and it is detected whether the working surface of probes, body, and cables of probes have damages which affect the operation of the device |
| 1.4. | Supply accuracy of the set power | ≤ ±20 % | Inspection is performed for each probe in such mode which ensures maximum output power.  Identification data of all probes (manufacturer, name, type, and serial number) and inspection mode are indicated in the inspection protocol |

15. Inspection of the following parameters shall be performed in relation to spirometry devices:

|  |  |  |  |
| --- | --- | --- | --- |
| Table 15 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the pipe and body of a spirometer have damages which affect the operation of the device |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| 1.3. | Conformity of the functions of registration devices | Conforms / Does not conform | Visual inspection is performed and it is detected whether the registration devices are in working order.  It is inspected whether the graph or print-out is clearly visible |
| 1.4. | Conformity of accuracy of the measured volume | ≤ ±3.5 % | Measurements are performed in room temperature and with humidity  from 20 to 80 RH.  Temperature and humidity values are indicated in the inspection protocol |
| 1.5. | Conformity of accuracy of the measured flow | ≤ ±3.5 % |

16. Inspection of the following parameters shall be performed in relation to magnetic resonance imaging (MRI) devices:

|  |  |  |  |
| --- | --- | --- | --- |
| Table 16 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| 1.2. | Conformity of homogeneity of the magnetic field | ≤ 5 ppm | Inspection is performed according to the “ACR MRI Accreditation Program” documentation |
| 1.3. | Inspection of impedance matching | ±2 mm |
| 1.4. | Conformity of high-contract object resolution | ≤ 1 mm |
| 1.5. | Inspection of low-contrast image resolution | MRI up to 3T: ≥ 9  MRI 3T: ≥ 37 |
| 1.6. | Inspection of signal doubling | ≤ 0.025 |
| 1.7. | Conformity of homogeneity of the image intensity | MRI up to 3T: ≥ 87.5 %  MRI 3T: 82.0 % |
| 1.8. | Conformity of accuracy of the incision depth | 5.0 ± 0.7 mm |
| 1.9. | Conformity of accuracy of the incision position | ≤ 5 mm |

17. Inspection of the following parameters shall be performed in relation to UV therapy devices and neonatal phototherapy devices with a UV radiation component:

|  |  |  |  |
| --- | --- | --- | --- |
| Table 17 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection of the functions of the control and indicating elements is performed, ensuring functional inspection of other parameters |
| 1.3. | Conformity of the set radiation power intensity (W/m2 or mW/cm2) | ≤ ±25 % | Measurement is performed at the maximum radiation power.  Measurements of the radiation power intensity are performed within the wavelength range stipulated by the manufacturer.  The distance of the source of radiation from the detection device is determined according to the instructions for use.  If the instructions for use are not available, measurements are performed within one of the following distances: 10, 50, or 100 cm.  The distance used in the measurements is presented in the inspection protocol |

18. Inspection of the following parameters shall be performed in relation to electrocardiographs:

|  |  |  |  |
| --- | --- | --- | --- |
| Table 18 | **Technical parameters of medical devices, their minimum conformity criteria, and conditions of measurements in testing and evaluation of functions** | | |
| No. | Parameter to be evaluated | Conformity criterion1 | Conditions of measurements |
| 1.1. | Conformity of external construction | Conforms / Does not conform | Visual inspection is performed and it is detected whether the body of the device has damages which affect the operation or safe use of the device |
| 1.2. | Conformity of the functions of control and indicating devices | Conforms / Does not conform | Visual inspection is performed and it is detected whether the control devices and indicating devices are in working order |
| 1.3. | Conformity of the working condition of electrodes for patients | Conforms / Does not conform | Visual inspection is performed and it is detected whether the working surface of electrodes for patients and the electrode wires for patients have damages which affect the operation of the device |
| 1.4. | Conformity of the functions of registration devices | Conforms / Does not conform | Visual inspection is performed and it is detected whether heart rate registering devices are in working order, whether the print-out is clearly visible |
| 1.5. | Presentation accuracy of the ECG signal interval in the print-out | ≤ ±10 % | Measurements are performed at the printing speed of 25 mm/sec and simulating ECG signal pulse frequencies: 60, 120, 180 beats per minute, distance between R wave of the QRS complex in the ECG signal is evaluated |
| 1.6. | Accuracy of the signal range in the print-out | ≤ ±10 % | Measurements are performed at simulating 1mV signal with the frequency of 60 impulses/min, range of the signal obtained is evaluated at the enhancement factor of 10 mm/mV set in the device |

Note.

1If the parameter to be evaluated does not conform to the conformity criterion brought forward and another conformity criterion or reference to a standard to which the parameter to be evaluated conforms is indicated in the documentation of the manufacturer of the device submitted by the medical treatment institution, the inspection protocol shall also include an indication on the conformity of the parameter with the reference to the relevant documentation, indicating its name, number, version, and year.

**Annex 3**

Cabinet Regulation No. 461

15 August 2023

**Signal Report of the Vigilance System of a Medical Treatment Institution on an Incident Related to a 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 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 submitter of the report) |
| Address of the branch of the medical treatment institution (which is represented by the submitter of the report) (*where 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 submitter of the report) |

**2. Information on the medical device (hereinafter – the MD)**

|  |  |
| --- | --- |
| Name of the MD | |
| Make of the MD | |
| Purpose of use of the MD (*please specify the purpose of use specified by the manufacturer of the device*) | |
| Classification class of the MD (*mark as appropriate*): | |
| ▢ I | |
| ▢ IIa | |
| ▢ IIb | |
| ▢ III | |
| ▢ implantable MD | |
| ▢ active implantable MD | |
| ▢ custom-made MD | |
| ▢ unknown | |
| Catalogue number (REF) | |
| Serial number (SN) of the MD | |
| Lot or batch number (LOT) of the MD | |
| CE marking | ▢ yes ▢ no ▢ unknown |
| Has the MD been preserved? | ▢ yes ▢ no ▢ partially |
| Is the MD available for inspection? | ▢ yes ▢ no ▢ partially |
| Is the packaging of the MD available for inspection? | ▢ yes ▢ no ▢ partially |
| Current location of the MD (*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*) | |
| Date of manufacture of the MD (*if known*) | |
| Term of validity of the MD (*if known*) | |

**3. Manufacturer of the MD**

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

**4. Authorised representative of the manufacturer of the MD 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 MD/supplier of the MD/pharmacy/marketing facility where the device was acquired**

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

**6. Information on the incident**

|  |
| --- |
| Date of the incident |
| Consequences of the incident: |
| ▢ serious health impairments |
| ▢ potentially 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 MD to the incident: ▢ definitely ▢ possible ▢ difficult to say |
| Is there information on similar incidents with this MD? ▢ yes ▢ no |
| Description of the possible defect of the MD |
| Has a signal report been sent to the manufacturer of the MD, its authorised representative and/or distributor? ▢ yes ▢ no |
| Signal report has been sent (*mark if the answer to the previous question is “yes”*): |
| ▢ manufacturer |
| ▢ authorised representative |
| ▢ 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 MD*) |
| 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 MD suspected? ▢ yes ▢ no |

Documents attached in annex (*please, attach the documents at the disposal of the reporter or their copies: copies of the documents certifying the quality of the medical device (for example, EC declarations of conformity, certificate 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 (where 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

|  |
| --- |
|  |

|  |  |
| --- | --- |
| 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.

**Annex 4**

Cabinet Regulation No. 461

15 August 2023

**Signal Report of the Vigilance System of a Natural Person on an Incident Related to a Medical Device1, 2**

|  |  |
| --- | --- |
| 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 medical 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 medical device (hereinafter – the MD)**

|  |  |
| --- | --- |
| Name of the MD | |
| Make of the MD | |
| Purpose of use of the MD *(please specify the purpose of use indicated by the manufacturer of the device)* | |
| Catalogue number (REF) of the MD | |
| Serial number (SN) of the MD | |
| Lot or batch number (LOT) of the MD | |
| CE marking | ▢ yes ▢ no ▢ unknown |
| Has the MD been preserved? | ▢ yes ▢ no ▢ partially |
| Is the MD available for inspection? | ▢ yes ▢ no ▢ partially |
| Is the packaging of the MD available for inspection? | ▢ yes ▢ no ▢ partially |
| Current location of the MD (*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*) | |
| Date of manufacture of the MD (*if known*) | |
| Term of validity of the MD (*if known*) | |

**4. Manufacturer of the MD**

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

**5. Authorised representative of the manufacturer of the MD 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 MD/supplier of the MD/pharmacy/marketing facility where the device was acquired**

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

**7. Information on the incident**

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

Documents attached in annex (*please, attach the documents at the disposal of the submitter of the signal report or their copies: copies of the instructions for use, images of the packaging and marking (where 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 submitter of the signal report 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 signal report shall be submitted by the person who is using the medical device independently or upon instructions of a medical practitioner or by his or her representative.

3The 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 5**

Cabinet Regulation No. 461

15 August 2023

**Labelling on the Prohibition of Reuse**

1. Labelling on the prohibition of reuse shall consist of a circle with a strike-through digit “2” in the middle thereof:

A black and white symbol

Description automatically generated

2. If the labelling is scaled down or enlarged, the ratio visible in its graphic image shall be conformed to.

3. The labelling may not be smaller than 5 mm.

4. The requirement referred to in Paragraph 3 of this Annex need not be conformed to in relation to small medical devices.