



LATAK-D.049-02/03.2024

Regulations on the arrangement of accreditation activities for inspection bodies performing electrical safety and functional testing of active II a, II b, III class medical devices.

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The document text may be translated into other languages. The text in Latvian is considered the base text.

Additional Information

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1. Introduction

This document specifies additional procedures for inspection bodies conducting electrical safety and functional tests on active II a, II b, and III class medical devices in accordance with the requirements set forth in Annex 2 of the Regulation of the Cabinet of Ministers No. 461 "Medical Device Regulations" of August 15, 2023 (hereafter referred to as Regulation No. 461), or the requirements stipulated by the respective medical device manufacturer, for accrediting the applied scope.

2. Data Format

The accreditation scope must be submitted electronically to the "Latvian National Accreditation Bureau" (hereafter - LATAK) in a format such as a Microsoft Word file, signed by the head of the inspection body, to the email address pasts@latak.gov.lv.

3. Data Layout in Tables

When defining the accreditation scope, inspected objects (types of medical devices) are separately identified, whose inspections are conducted according to Annex 2 of Regulation No. 461, and inspected objects whose test parameters and limits are set by the conformity assessment body according to the medical device manufacturers' documentation. The following information layout must be adhered to when entering data into the table (see Appendix):

3.1 Electrical safety and functional testing of active II a, II b, and III class medical devices according to the requirements specified in Annex 2 of Regulation No. 461

1. *Column: **Inspection object*** - specifies the relevant active II a, II b, and III class medical devices from the list in Annex 2 of Regulation No. 461

Example:

Defibrillators, external cardiac pacemakers, infant incubators

Note: Point 57 of Regulation No. 461 stipulates that "A medical device is subjected to the relevant electrical safety and functional tests mentioned in Annex 2 of these regulations once a year if at least one of the following conditions exists: 57.1. the active IIa, IIb, and III class device is not marked with the CE marking; 57.2. there is no available medical device documentation on the manufacturer-defined electrical safety or functional tests or their intervals; 57.3. services of the medical device manufacturer, authorized representative, or manufacturer's representative (distributor) are not available in Latvia."

The inspection bodies must perform the electrical safety and functional tests of the mentioned medical devices in accordance with the requirements specified in Annex 2 of Regulation No. 461; thus, the test parameters and criteria for the respective devices are not indicated in the accreditation scope documentation.

2. *Column: **Inspection Area*** - Indicates the type of inspection for the inspected object (in this case, an object in operation)

Example:

Electrical safety and functional inspection of objects in operation

3. *Column:* Title of Normative Technical Documentation and/or Name of Methods and Procedures - The first cell should state the applicable legislative act and its annex (Regulation No. 461, Annex 2) and the second cell should state the name, identification, and approval date of the methodology approved by the inspection institution.

Example:

*Cabinet of Ministers Regulation No. 461 of 15 August 2023, "Medical Devices Regulations", Annex 2
"Method of Electrical Safety and Functional Testing for Medical Devices", MIEF-01-2017, approved on 02.12.2023.*

3.2. Electrical safety and functional testing of active II a, II b, and III class medical devices according to the test parameters and criteria specified by the respective medical device manufacturer

1. *Column: Inspection Object* - Specifies the respective active II a, II b, and III class medical devices from the list in Annex 2 of Regulation No. 461 or other II a, II b, and III class medical devices not included in Annex 2 of Regulation No. 461. For each medical device, all electrical safety and functional testing parameters and criteria (limit values) that the institution is competent to test are indicated.

Example:

External cardiac pacemaker:

Assessed parameter for electrical safety and functional testing, compliance criterion

Cardiotocograph:

Assessed parameter for electrical safety and functional testing, compliance criterion

Note: Article 56 of Regulation No. 461 specifies that "Technical surveillance of medical devices is a set of measures determined by the manufacturer regarding the electrical safety and functional tests to be performed during the operation of the specific medical device, respecting all the manufacturer-defined compliance criteria (limit values), according to the manufacturer's specified timelines and scope, as well as after each use, maintenance, and repair procedure that may affect the device's technical parameters. [...]". Given the above, in the first column of the accreditation scope documentation for the respective medical device, the inspection institution must specify those electrical safety and functional testing parameters and criteria (limit values) which it is capable of testing.

1. *Column: Inspection Area* - Indicates the type of inspection for the inspected object (in this case, an object in operation)

Example:

Electrical safety and functional inspection of objects in operation

2. **Column: Title of Normative Technical Documentation and/or Name of Methods and Procedures** - The first cell indicates the applicable legislative act - Regulation No. 689, and the second cell states the name, identification, and approval date of the methodology approved by the inspection institution.

Example:

Cabinet of Ministers Regulation No. 461 of 15 August 2023, "Medical Devices Regulations" "Method of Electrical Safety and Functional Testing for Medical Devices", MIEF-01-2017, approved on 02.12.2023.

Note: Article 56 of Regulation No. 461 specifies that "The aforementioned technical surveillance does not apply to Class I devices, inactive devices, and implantable devices." Therefore, in the regulated accreditation scope documentation, the first column – Inspection Object – does not list these medical devices.

If it is reasonable and to avoid repetition with each type of medical device, the parameters and criteria for electrical safety tests can be delineated as a separate object.

Register of Changes Made

Version	Change Content	Date
01	New document	04.2018
02	Deleted reference to LATAK document D.025 Reference made to the Regulations of the Cabinet of Ministers No. 461 of August 15, 2023, "Medical Devices Regulations" Specified LATAK email address	03.2024



Appendix

Inspection Object	Inspection Area	Normative-Technical Documentation Title or Methods and Procedures
1	2	3
Defibrillators; external cardiac pacemakers; infant incubators	Electrical safety and functional inspection of objects in operation.	The Regulations of the Cabinet of Ministers No. 461 of August 15, 2023, "Medical Devices Regulations" Annex 2 "Method of Electrical Safety and Functional Testing for Medical Devices", MIEF-01-2017, approved on 02.12.2023.
External cardiac pacemaker: Electrical safety test parameter, criterion Functional test parameter, criterion	Electrical safety and functional inspection of objects in operation.	The Regulations of the Cabinet of Ministers No. 461 of August 15, 2023, "Medical Devices Regulations"
Cardiotocograph: Electrical safety test parameter, criterion Functional test parameter, criterion		"Method of Electrical Safety and Functional Testing for Medical Devices", MIEF-01-2017, approved on 02.12.2023.