

**State scientific research institute Center for Physical Sciences and Technology
Department of Textile Technologies
Laboratory for Testing and Certification of Textiles– Notified body No.1401**

Personal protective equipment – protective clothing

RULES OF CERTIFICATION

According to the requirements of Regulation (EU) 2016/425

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Formulated:	Approved by:
Expert of Certification group	Head of Notified Body
Rasa Verbienė	Vitalija Rubežienė

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1. Introduction

Notified Body 1401 - Department of Textile Technologies Laboratory for Testing and Certification of Textiles of SRI Center for Physical Sciences and Technology (hereinafter in the text - Notified Body), carries out the certification of II and III category of personal protective equipment (PPE) – protective clothing, according to the requirements of the Regulation (EU) 2016/425 of the European Parliament and of the Council (hereinafter in the text -Regulation (EU) 2016/425).

The certification procedures for protective clothing shall be carried out in accordance with the following certification scheme:

- Application of the requirements of annexes V and VII to Regulation (EU) 2016/425:
 - For II category of PPE, Annex V “EU type-examination (module B)“ shall be applied;
 - For III category of PPE Annex V “EU type-examination (module B)“ and Annex VII „Conformity to type based on internal production control plus supervised product inspections at random intervals (Module C2)“ shall be applied;
- Application of the harmonized and specific standards;
- Application of the recommendations of the Horizontal Committee of Notified Bodies for the European Personal Protective Equipment and VG 5 of the Vertical Group for the Coordination of Notified Bodies.

2. Certification of protective clothing of II category

2.1. The Notified Body shall certify in accordance with the requirements of Regulation (EU) 2016/425 the following groups of protective clothing:

Group of protective clothing	Requirements of harmonized / specific standards for the group of protective clothing	
	Reference	Title
Clothing to protect against atmospheric conditions that are not of an extreme nature	LST EN 343:2019*	Protective clothing - Protection against rain
High-visibility clothing	LST EN ISO 20471:2013, LST EN ISO 20471:2013/A1:2017	High visibility clothing - Test methods and requirements
Protective clothing for use in welding and allied processes	LST EN ISO 11611:2015	Protective clothing for use in welding and allied processes
Clothing to protect against heat and flame (< 100 °C)	LST EN ISO 11612:2015	Protective clothing - Clothing to protect against heat and flame - Minimum performance
Electrostatic dissipative protective clothing	LST EN 1149-5:2018	Protective clothing - Electrostatic properties - Part 5: Material performance and design

* - Protective clothing against atmospheric conditions that are not extreme (EN 343:2019) is classified as category I according to Annex I of Regulation (EU) 2016/425. The conformity assessment - an EU-type examination (module B), for this clothing group is carried out only together with another clothing group of category II or III falling in to the area of activity of the Notified Body.

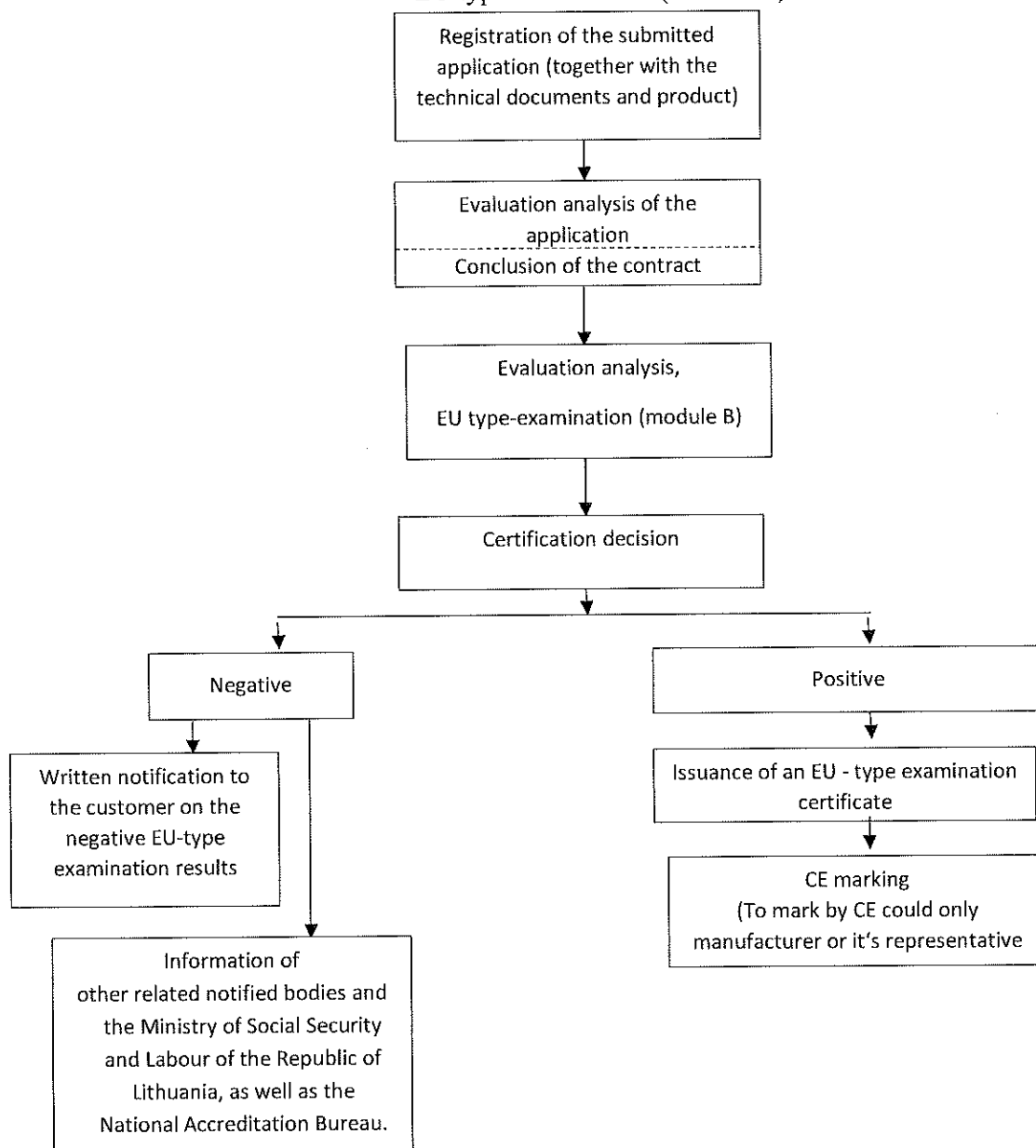
2.2. The process of certification

2.2.1. The course of the certification scheme

Notified Body shall carry out the certification procedures for protective clothing of II category in accordance with the requirements of Annex V "EU-type examination (Module B)" to Regulation (EU) 2016/425.

The course of the certification scheme is presented below.

The course of the certification scheme of PPE of II category
EU type-examination (module B)



Note:

Duration of the certification process

After signing the contract, receiving all the technical documents and performing the necessary tests, the certification documents shall be executed within a maximum of 10 working days.

2.2.2. Registration of the submitted application

An application for the certification (EU type examination) may be submitted to the Notified Body by the manufacturer of the protective clothing (hereinafter - clothing) of the Republic of Lithuania and foreign companies or their authorized representatives established in the European Union and having received a written authorization from the manufacturer to act on his behalf according to the requirements of Regulation (EU) 2016/425. An Application form is presented at SRI Center for Physical Sciences and Technology website: <https://www.ftmc.lt/>

The manufacturer or his authorized representative (hereinafter referred to as the "customer") may apply for EU type-examination of the same clothing model to only one notified body.

Together with the application, the customer shall submit the technical documents specified in the application, one model of the clothing and samples of the materials used in sewing the clothing. The quantity of clothing and materials shall be adjusted before the contract is concluded, according to the number of tests to be carried out.

The customer may submit technical documents in Lithuanian, English or Russian languages.

The application shall be registered if it is duly completed and all the technical documents and clothing models specified therein have been submitted.

2.2.3. Evaluation analysis of the application

After the registration of the application in the Notified Body, an evaluation of the application shall be carried out with the aim to identify the possibilities to meet the needs of the customer. The appropriateness of the technical documents provided by the customer shall be analysed, the required tests foreseen - whether the tests will be carried out at the Department of Textile Physical-Chemical Testing or in other subcontracted accredited laboratories selected by the Notified Body, also the time limit for the certification process and the costs of the intended work shall be calculated. During this analysis, all the issues shall be discussed with the customer. Upon completion of the analysis, the protocol of the application evaluation analysis shall be sent to the customer for the final approval.

2.2.4. Conclusion of a certification contract

Upon receipt of the application analysis protocol signed by the customer, a draft contract for the EU-type examination of the submitted clothing shall be prepared and sent to the customer for approval. In addition to all the issues that were agreed during the evaluation of the application, the contract shall include the following obligations of the customer:

- to fulfil the requirements of certification, including the implementation of relevant changes, when notified by the Executor (Notified Body);
- to ensure that the certified product continues to meet its requirements;
- to inform the Executor about the date when the garment, to which EU type certificate is issued, is placed on the market, about modifications of the garment, that may affect the compliance with the essential health and safety requirements or the indicated garment usage conditions, within 5 days after accomplished fact;
- to indicate harmonized/special standard indicated in agreement when referring to a certified garment in the media;
- to indicate, in the label of the garment and in user instruction accompanying the product, the harmonized/special standard and pictograms in accordance with this standard indicated in agreement;
- to facilitate the handling of complaints, keep records of all complaints related to compliance with the certification requirements and provide these records to the Executor when requested;

- do not use garment certificate in such a manner as to bring the Executor into disrespect and do not make any statements related to the garment certification that the Executor may consider misleading or unauthorized;
- to submit an application for the extension of the certificate to the Executor at least 6 months prior to the expiry date of the certificate;
- do not use any promotional material related to the certification upon the expiry of the certificate, as well as upon the suspension or repeal of the certificate by the Notified Body;
- when providing copies of the certification documents to their customers, the documents must be provided in full volume.

The contract shall also specify the obligations of the Notified Body: not to publish, disseminate the results of certification works, as well as not to use them for purposes not covered by this contract without the written agreement of the customer, also to perform certification in a qualified manner and ensure confidentiality.

Once the contract between the Notified Body and the customer has been signed, the certification process is started.

If it becomes necessary to make changes in the contract, it shall be agreed with the customer.

2.2.5. EU type-examination (module B)

After concluding of the contract, an EU-type examination shall be launched.

The EU-type examination shall be carried out in accordance with the following work stages:

- the technical documents provided by the customer shall be examined and evaluated;
- the design of the clothing model and its compliance with the essential health and safety requirements of Regulation (EU) 2016/425 and the relevant harmonized / specific standards shall be investigated;
- the necessary testing of the materials shall be performed in the Department of textile Physical-Chemical Testing and / or in subcontracted accredited laboratories of the Notified Body;
- the results of material tests obtained shall be evaluated;
- the evaluation analysis of the work stages shall be performed.

2.2.6. Certification decision, issuance or refusal of an EU-type examination certificate

Following the positive results of all stages of the certification work and the performance of the assessment analysis, the Notified Body shall decide to issue the EU-type examination certificate. The certificate shall be valid for 5 years. The certificate shall be accompanied by the EU-type examination report describing the tested clothing model, its purpose, the data provided by the customer on the materials used and justifying compliance of the tested clothing model and submitted technical documentation with the relevant requirements of Regulation (EU) 2016/425 and harmonized / specific standards.

If negative results shall be obtained and a decision shall be taken not to issue an EU-type examination certificate, the Notified Body shall provide the customer in written form with the detailed reasons for such refusal on the basis of the results of the tests. In accordance with the requirements of Regulation (EU) 2016/425, if a certificate is refused, the Notified Body must inform about it other related notified bodies and the Ministry of Social Security and Labour of the Republic of Lithuania, as well as the National Accreditation Bureau.

2.2.7. CE marking

Once an EU-type examination certificate has been issued by the Notified Body, it must be CE marked by the manufacturer before the clothing is placed on the market.

2.2.8. Duration of the certification process

After signing the contract, receiving all the technical document, performing the necessary tests and certification decision, the certification documents shall be executed within a maximum of 10 working days.

3. Certification of protective clothing of III category

3.1. The Notified Body shall certify the following groups of protective clothing in accordance with the requirements of Annex V (Module B) and Annex VII (Module C2) of Regulation (EU) 2016/425.

Group of protective clothing	Requirements of harmonized / specific standards for the group of protective clothing	
	Reference	Title
Protective equipment (protective clothing) against chemical substances and mixtures which are hazardous to health	LST EN 14605:2005+A1:2009	Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])
	LST EN ISO 13982-1:2005 su keitiniu LST EN ISO 13982-1:2005/A1:2011	Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing)
	LST EN 13034:2005+A1:2009	Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)
Protective equipment (protective clothing) against harmful biological agents	LST EN 14126:2004+AC:2005	Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
	<p><u>Note.</u></p> <p>LST EN 14126:2004+AC:2005 should be applied only in conjunction with another harmonized standard for the relevant type of protective clothing:</p> <p>for 3-B ir 4-B types - LST EN 14126:2004+AC:2005, LST EN 14605:2005+A1:2009</p> <p>for 5-B type - LST EN 14126:2004+AC:2005, LST EN ISO 13982-1:2005 with amendment LST EN ISO 13982-1:2005/A1:2011</p> <p>for 6-B type - LST EN 14126:2004+AC:2005, LST EN 13034:2005+A1:2009</p>	

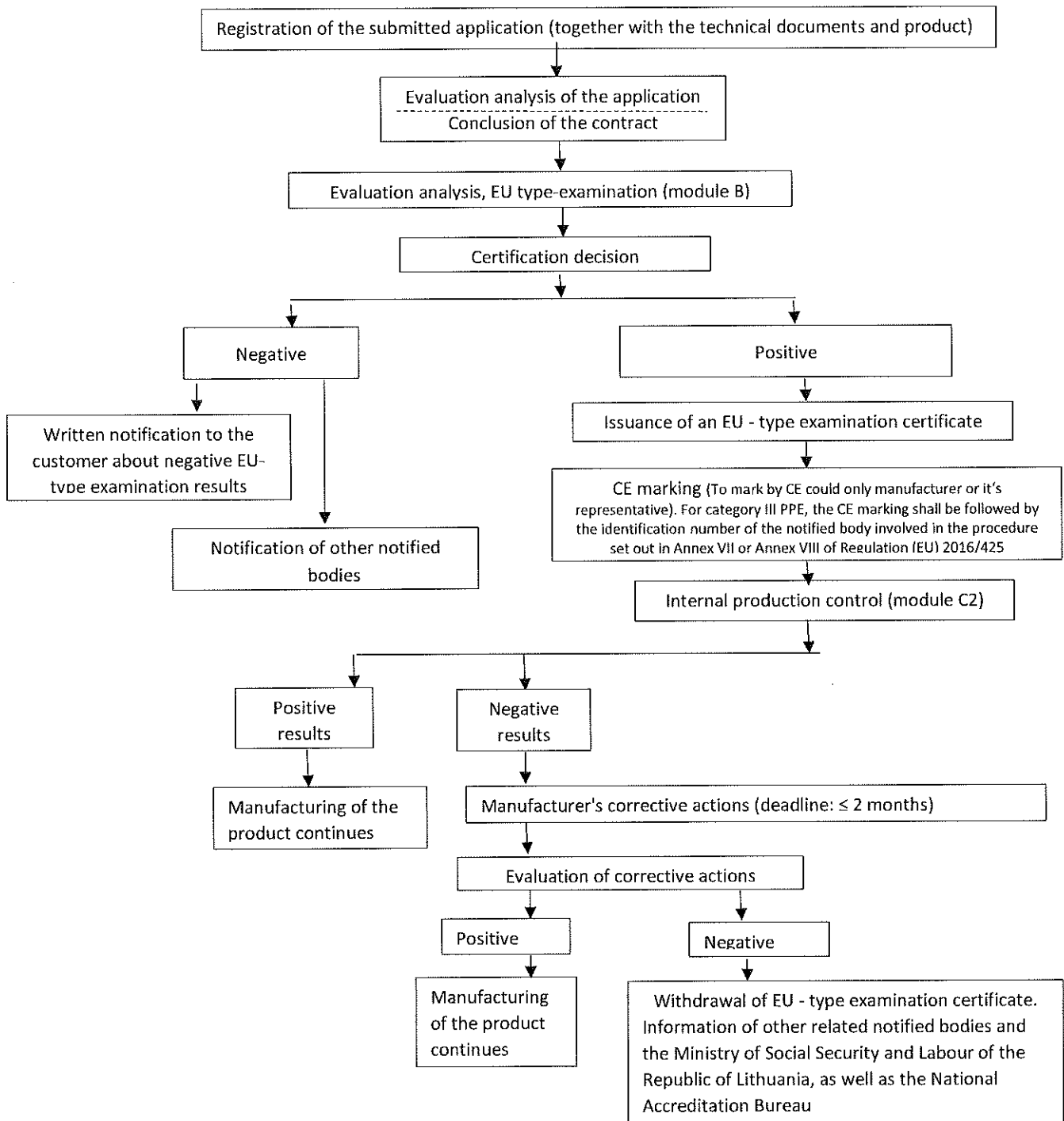
3.2. The process of certification

3.2.1. The course of the certification scheme

The Notified Body shall carry out certification procedures of Category III PPE in accordance with the requirements of Annex V “EU-type examination (Module B)” and Annex VII “Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2)” of Regulation (EU) 2016/425.

The course of the certification scheme is presented below.

The course of the certification scheme of PPE of III category
 EU type-examination (module B) and internal production control (module C2)



Note:

Duration of the certification process

After signing the contract, receiving all the technical documents and performing the necessary tests, the certification documents shall be executed within a maximum of 10 working days.

3.2.2. Registration of the submitted application

See. 2.2.2.

3.2.3. Evaluation analysis of the application

See 2.2.3.

3.2.4. Conclusion of a certification contract

Upon receipt of the application analysis protocol signed by the customer, a draft contract for the EU-type examination of the submitted clothing and internal production control by inspecting the clothing at random intervals shall be prepared and sent to the customer for approval. The customer shall be informed that after the EU type-examination certificate has been issued, he must apply to the Notified Body (not necessarily the one that issued the EU-type examination certificate) for the internal control of the certified protective clothing before placing it on the market.

If the customer decides that the certified clothing will be supervised by this Notified Body, then in addition to all the issues that were agreed during the analysis of the application evaluation, the contract shall also include the following obligations of the customer:

- to fulfil the requirements of certification, including the implementation of relevant changes, when notified by the Executor (Notified Body);
- to ensure that the certified garment continues to meet the requirements;
- to inform the Executor about the date when the garment, to which EU type certificate is issued, is placed on the market, about modifications of the garment, that may affect the compliance with the essential health and safety requirements or the indicated garment usage conditions, within 5 days after accomplished fact;
- to indicate harmonized/special standard indicated in agreement when referring to a certified garment in the media;
- to indicate, in the label of the garment and in user instruction accompanying the product, the harmonized/special standard and pictograms in accordance with this standard indicated in agreement;
- to facilitate the handling of complaints, keep records of all complaints related to compliance with the certification requirements and provide these records to the Executor when requested;
- do not use garment certificate in such a manner as to bring the Executor into disrespect and do not make any statements related to the garment certification that the Executor may consider misleading or unauthorized;
- to submit an application for the extension of the certificate to the Executor at least 6 months prior to the expiry date of the certificate;
- do not use any promotional material related to the certification upon the expiry of the certificate, as well as upon the suspension or repeal of the certificate by the Notified Body;
- when providing copies of the certification documents to others, the documents must be provided in full volume.

Before placing certified garments on the market, the Customer shall also undertake:

(if the Executor will inspect the products)

- to submit to the Executor - Notified Body 1401 an Application (according to Annex 2 of the agreement) for internal production control by product inspection according to module C2 of Regulation (EU) 2016/425;
- to make all the necessary arrangements for the inspection of the products, including examination of the relevant documents and records;

- to create conditions for the assessment groups of the Lithuanian National Accreditation Bureau to assess the effectiveness of the certification group in performance of conformity assessment activities at the place where the manufacturer is located;
- to mark each individual unit of PPE that conforms to the model described in the EU-type examination certificate and the applicable requirements of Regulation (EU) 2016/425 with the CE mark and to indicate the number of the Notified Body that performed the EU-type examination - No. 1401;
- to withdraw the CE marking of products, indicating the number of the Notified Body that carried out the EU-type examination, in case of suspension or revocation of the certificate by the Notified Body;
- to inform immediately about the changes in the contact address and place of production.

If the customer shall decide to choose another Notified body to carry out the inspection of the certified clothing, this shall be stated in the contract and the customer shall inform the Notified Body when and to which Notified body it has applied for the inspection of the clothing. If the customer shall not provide this information within one year after the issuance of the EU type examination certificate, the issued certificate shall be cancelled and other related Notified bodies and the Ministry of Social Security and Labour of the Republic of Lithuania shall be informed in accordance with the requirements of Regulation (EU) 2016/425. The National Accreditation Bureau shall also be informed.

The certification contract shall also specify the obligations of the Notified Body: not to publish, disseminate the results of certification works, as well as not to use them for purposes not covered by this contract without the written agreement of the customer, to certification and clothing maintenance work, ensure the confidentiality of the results and other data related to the customer.

The contract shall be accompanied by an application form for internal production control of clothing in accordance with module C2 of Regulation (EU) 2016/425.

Once the contract between the Notified Body and the customer has been signed, the certification process is started.

If it becomes necessary to make changes in the contract, it shall be agreed with the customer.

3.2.5. EU type-examination (module B)

See. 2.2.5.

3.2.6. Certification decision, issuance or refusal of an EU-type examination certificate

See. 2.2.6.

3.2.7. CE marking

Once an EU-type examination certificate has been issued by a Notified Body, it must be CE marked by the manufacturer before the clothing is placed on the market. The CE marking shall include the identification number of the Notified Body, i.e. No. 1401.

3.2.8. Duration of the certification process (EU - type examination)

After signing the contract, receiving all the technical documents and performing the necessary tests, the certification documents shall be executed within a maximum of 10 working days.

3.2.9. Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2)

When concluding a contract with the customer for the EU-type examination of protective clothing of category III, the clothing inspection procedures and their implementation shall also be discussed.

Before placing the clothing for which an EU-type examination certificate has been issued on the market, the customer shall provide the Notified Body with an application for the examination of the clothing at random intervals. An Application form is presented at SRI Center for Physical Sciences and Technology website: <https://www.ftmc.lt>.

The procedure of protective clothing inspection shall be the following:

- the application submitted by the customer for the inspection of certified clothing at random intervals shall be registered and analysed;
- an inspection plan shall be scheduled (for the period of validity of the EU-type examination certificate, i.e. 5 years);
- the clothing shall be inspected in accordance to the method chosen by the Notified Body, i.e. in one year, the conformity of production is inspected, the conformity of the clothing to the clothing model described in the EU-type examination certificate is evaluated in another years, the relevant tests for these procedures shall be carried out. For the inspection, the tests shall be selected in such a way that, throughout the entire period (5 years), the certified clothing would undergo all the essential tests confirming the compliance with the applicable essential health and safety requirements;
- an annual inspection report shall be prepared.

Other annual inspections shall be carried out in the same way, except that the customer does not need to apply for an inspection, and the Notified Body shall contact the customer (while the relevant clothing is being manufactured) to carry out checks at least once a year, at random intervals determined by the Notified body.

If the examinations and tests shall reveal that the production is not even or that the certified clothing does not confirm to the clothing model described in the EU-type examination certificate or to the applicable essential health and safety requirements, the Notified Body may allow the customer to take corrective actions not longer then 2 months upon completion of which, the institution shall re-evaluate the clothing.

If according to the nature and significance of the identified non-conformities it is not possible to carry out corrective actions or the customer refuses to take corrective actions, the EU type examination certificate shall be cancelled and the institution that notified the Notified Body - Ministry of Social Security and Labour of the Republic of Lithuania and other related Notified Bodies shall be informed about it. The National Accreditation Bureau shall also be informed.

If the customer, to whom the EU-type examination certificate for the protective clothing of category III was issued, is not engaged in the manufacturing activities for a period of time (e.g. more than 1 year), he must inform the Notified Body accordingly. In this case, internal production control shall not be performed, but the EU-type examination certificate shall remain valid (it shall not be cancelled). When the customer shall inform that production is being started or renewed, the Notified Body shall carry out clothing inspections (internal production control). The clothing may be placed on the market while production is under internal control.

4. Complaints and appeals

The customer dissatisfied with the activities of the Notified Body, may provide the complaint in a free form (e.g. an official document). The complaint should be accompanied by the documents or substantiated arguments proving the validity of the complaint. Complaints shall be registered in the complaint register at the Notified Body. Only complaints received within one month of the certification action has been carried out, and which is the subject of the complaint, shall be considered. The Notified Body shall be responsible for the impartial, independent and objective examination of the complaint. The deadline for dealing with the complaint shall be 2 weeks after the date of complaint submission.

An appeal against a decision relating to the certification of protective clothing shall be submitted to the Appeals Commission of the Department of Textile Technologies of the SRI Center for Physical Sciences and Technology (Demokratu str. 53, Kaunas). The customer shall be notified about the date and time of the Commission meeting in which the appeal shall be analysed. After the meeting, the Commission shall notify the customer in a written form about the results and decisions taken.

If the customer is not satisfied with the conclusion of the complaint or investigation of the appeal, he may also apply to an independent body, such as the National Accreditation Bureau (T.Kosciuškos g. 30, Vilnius).