CONFORMITY ASSESSMENT PROGRAM FOR PERSONAL PROTECTIVE EQUIPMENT ACCORDING TO THE REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2016/425

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1. SUBJECT AND SCOPE OF THE PROGRAM.

1.1 Conformity assessment of products according to the Regulation of the European Parliament and of the Council (EU) 2016/425

The program defines the rules and procedures for the conformity assessment of products for compliance with Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC. The program applies to the conformity assessment of personal protective equipment for the following groups of products:

- Equipment providing protection for the chest and groin
- Equipment providing foot, leg and anti-slip protection
- Equipment providing general body protection (clothing)
- Equipment providing protection for hands and arms against chemical agents
- Equipment providing head protection
- Equipment providing protection against cold [> -50 °C] (clothing)
- Equipment providing protection against cold [cold > -50 °C], [extreme cold <-50 °C] (clothing)
- Equipment providing protection against heat [< 100 °C and > 100 °C fire and flame] (head)
- Equipment providing protection against heat [> 100 °C and fire and flame] (clothing)
- Equipment providing protection against heat [Heat < 100 °C], [Heat > 100 °C and fire and flame] (hands, arms)
- Equipment providing respiratory system protection
- Equipment to prevent drowning and assist with buoyancy
- Equipment protecting against electric shock (hands, arms)
- Equipment protecting against falls from height
- Equipment protecting against biological agents (hands, arms)
- Equipment for protection against hazards (hands, arms)
- Equipment that provides head protection against the risks resulting from sports activities
- Equipment providing general body protection (clothing) against chemicals
- Equipment providing general body protection (clothing) against the risks resulting from sporting activities
- Equipment protecting against substances and mixtures that are hazardous to health
- Specialized areas of competence: Firemen suits
- Specialized areas of competence: protective equipment for diving
- Specialized areas of competence: diving suits

1.2 Scope of application of the program

Conformity assessment program PCW-01/PPER of the Bureau of Products and Persons Certification, Polski Rejestr Statków S.A. (PRS S.A.) concerns the assessment of conformity with the requirements specified in standards or other normative documents.

Certificates of conformity are issued for all products covered by this certification program.

The following documents are an integral part of the program:

- PCW-01 System of Certification of Products and Persons - General Principles,

- Principles for the Use of Product and Person Certification Marks.

2. DETAILS

Conformity assessment - a process, carried out on the basis of notification by the government of the Republic of Poland to the European Commission, aimed at confirming compliance with the requirements of European Union regulations/directives and issuing appropriate certificates or other documents of conformity specified in the regulations/directives.

Certificate - a document issued by a notified body (PRS S.A.) confirming that the product, product design or product manufacturing process complies with the requirements.

Non-conformity (N) - failure to meet a requirement.

Omission in the described product quality assurance system or failure to meet one or more of the requirements of EU Regulation 2016/425, or finding a situation that raises serious doubts about the ability of the organization's product quality assurance system to achieve its intended results.

Observation (O) - an observation made by the auditor related to opportunities for improvement of the management system (area of improvement), for which the organization is recommended to take preventive or other improvement actions.

3. DESCRIPTION OF THE PROCEEDINGS

3.1 Start of the conformity assessment process

Upon receipt of an order, the Manager of the Certification of Products and Persons Bureau (CW) reviews it and appoints an expert to carry it out, according to the program.

The technical documentation of the product together with the order is given by the CW Manager to the expert, and the documentation of the quality system together with a copy of the order - to the auditor (together with a copy of the order, if it is a person other than the expert). The appointed expert checks whether the scope of the documentation meets the requirements of the regulation and confirms the acceptance of the order in accordance with the program, at the same time informing the auditor of the need to supplement any deficiencies. Before starting the process, the expert/auditor prepares an Evaluation Plan. In planning the evaluation, he takes into account the results of the evaluation of the review of the submitted documentation. The plan includes information on the personnel assigned to carry out each evaluation activity, as well as the individual elements of the evaluation, such as design and documentation review, sampling, testing, inspection and audit (Form.8/PCW-01).

NOTE:

1. *The following conformity assessment modules apply to security measures:*

Lp.	*Product group*	*Conformity assessment modules due to the categories of risks against which the PPE is intended to protect users*
1	Equipment providing protection for the chest and groin	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D

2	Equipment providing foot, leg and anti-slip protection	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
3	Equipment providing general body protection (clothing)	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
4	Equipment providing protection for hands and arms against chemical agents	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
5	Equipment providing head protection	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
6	Equipment providing protection against cold [> -50 °C] (clothing)	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
7	Equipment providing protection against cold [cold > -50 °C], [extreme cold <-50 °C] (clothing)	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
8	Equipment providing protection against heat [< 100 °C and > 100 °C fire and flame] (head)	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
9	Equipment providing protection against heat [> 100 °C and fire and flame] (clothing)	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
10	Equipment providing protection against heat [Heat < 100 °C], [Heat > 100 °C and fire and flame] (hands, arms)	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
11	Equipment providing respiratory system protection	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
12	Equipment to prevent drowning and assist with buoyancy	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
13	Equipment protecting against electric shock (hands, arms)	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
14	Equipment protecting against falls from height	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
15	Equipment protecting against biological agents (hands, arms)	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
16	Equipment for protection against hazards (hands, arms)	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
17	Equipment that provides head protection against the risks resulting from sports activities	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
18	Equipment providing general body protection (clothing) against chemicals	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
19	Equipment providing general body protection (clothing) against the risks resulting from sporting activities	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
20	Equipment protecting against substances and mixtures that are hazardous to health	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
21	Specialized areas of competence: Firemen suits	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D

22	Specialized areas of competence: protective equipment for diving	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D
23	Specialized areas of competence: diving suits	Appendix V Module B Appendix VII Module C2 Appendix VIII Module D

Table No. 1 - Conformity assessment modules due to the categories of hazards against which the PPE is intended to protect users.

2. *Assessment of products according to modules B and C2 is carried out by - an expert, according to module D - an auditor.*

3. *If PRS S.A. has a person who is at the same time an expert in the products that are the subject of the order and a quality systems auditor, then in the case of conformity assessment of products according to B+D modules, the whole process, if possible, is carried out by one person.*

3.2 Conformity assessment according to module B (EU type-examination)

3.2.1 The expert shall consider and approve the technical documentation in accordance with Instruction ICW-02 and the test program for compliance with the essential requirements given in Regulation (EU) 2016/425 of the European Parliament and of the Council and the requirements of applicable harmonized standards and/or other reference documents. If harmonized standards have not been applied, or have been applied only partially, or if there are no such standards, the expert shall verify that the essential requirements given in Regulation (EU) 2016/425 and other reference documents have been met.

3.2.2 Next, the expert evaluates the design of the PPE by checking
whether the PPE is made in accordance with the technical documentation and whether it can be used as intended.

After approval of the documentation and evaluation of the design, type tests are carried out according to the approved program by:

- laboratory/testing station with which PRS S.A. has entered into a cooperation agreement, and/or
- manufacturer's laboratory/testing station, if specialized tests cannot be carried out in PRS S.A. laboratory and laboratories cooperating with PRS S.A., if accepted by PRS S.A. in the given scope.

3.2.3 In the case of outsourcing samples, the expert prepares an order for the CW Manager, after approval of the order for external testing, it is approved and signed by the DC Director.

3.2.4 The expert supervises the tests, a detailed report of which is made by the laboratory / test station performing the tests.

3.2.5 From the supervision of type tests, the expert prepares a report on Form Form.9/PCW-01, in which he states whether the product meets the essential requirements of Regulation (EU) 2016/425, the requirements of the applicable harmonized standards and other reference documents, and makes a conclusion on the possibility of issuing an EU type test certificate, with justification. In the application, he shall give the name and address of the principal and manufacturer, as well as data that enable the product in question to be uniquely identified. The expert shall attach to the report the approved technical documentation and the test report.

3.2.6 The expert's report is accepted by the CW Manager, who makes the decision on issuing, or refusing to issue, an EU type-examination certificate. In the absence of the CW Manager's competence in a particular process, or in the case where the CW Manager performed the assessment in a particular process, the decision to issue or not to issue a document of compliance with the Regulation is carried out by a designated expert with the appropriate qualifications (see Attachment 1/PCW-01/PPER).

3.2.7 The expert prepares an EU type-examination certificate (on form.7/PCW-01/PPER for products of hazard categories I and II as defined in Annex I of Regulation (EU) 2016/425, and for hazard category III on - form.8/ PCW-01/PPER), or a letter informing the manufacturer or its authorized representative of the refusal to issue the certificate, including the reasons for the refusal.

3.2.8 The EU Type Testing Certificate is signed by the DC Director, after prior approval by the CW Manager (confirmed by his signature on a copy of the certificate).

3.2.9 In the case of refusal to issue an EU Type-Examination Certificate, a letter informing of this is signed by the DC Director.

3.3 Conformity assessment according to module D (conformity to type based on quality assurance of the production process)

3.3.1 The auditor shall evaluate the documentation of the quality management system for compliance with the requirements set forth in Annex VIII of Regulation (EU) 2016/425, for the manufacture of products subject to conformity assessment.

3.3.2 From the evaluation of documents, the auditor prepares a report (Form. 1/PCW-01/PPER), which is sent to the manufacturer.

3.3.3 In case of a positive result of the document evaluation, together with the document evaluation report, the auditor sends the Audit Plan (Form. 2/ PCW-01/PPER) in which he determines the objectives, scope and criteria of the audit. The audit time is determined on the basis of Exhibit 5/PCW-01/PPER.

> ***NOTE:***
> *It is not planned to develop an audit program, since the scopes of certification, intermediate and renewal audits differ slightly and are very limited in relation to the requirements of ISO 9001, as they relate only to the quality assurance of the production process, the requirements for which are defined in detail in Regulation (EU) 2016/425. If the auditor does not have experience in evaluating the technology of a product, an expert also participates in the audit.*

3.3.4 The auditor then conducts an audit of the production process quality assurance system according to the agreed Audit Plan.

3.3.5 In the event of an emergency situation, the Auditor, in consultation with the CW Manager, may take steps to use Information and Communication Technology (ICT - eng. Information and Communication Technology) to conduct an Audit at the Organization.

3.3.6 The auditor of the CW Office may conduct an audit by means of information and communication technology ("ICT") only with the use and application of documents such as:

- IAF MD 4:2018 - IAF mandatory document on the use of information and communication technology ("ICT") for audits/assessments,
- IAF ID 12:2015 - Principles of remote evaluation

3.3.7 Before deciding to conduct an audit using information and communication technology ("ICT"), the Lead Auditor should send a questionnaire (Form. 1/COVID-19/PCW-01) to the organization for completion and return to the Lead Auditor.

3.3.8 The lead auditor, on the basis of the received Questionnaire and information obtained from the organization, conducts a risk analysis as to whether there are any obstacles to conducting the audit in accordance with the appointment of the audit team. This analysis should be documented on Form Form. 2/COVID-19/PCW-01.

3.3.9 As a result of the risk analysis, the lead auditor recommends the following decisions:

- Planning a completely remote audit,

- Increase in remote audit time - provide the proposed number of hours of remote audit,
- Performing the audit in accordance with the appointment - without deviating from the standard procedure,
- postponement of the audit until the threat has ceased (in agreement with the Organization).

The risk analysis shall be sent immediately to the CW Office, which shall amend the appointment of the audit team if necessary. The CW Office shall immediately send the revised appointment to all members of the audit team and inform the Organization of the decisions made.

3.3.10 In the event of a change in the audit execution method resulting from the risk analysis performed, the Lead Auditor shall amend the audit plan accordingly.

3.3.11 Certification audit

The purpose of the audit is to assess the implementation, including effectiveness, of the customer's quality assurance system for the production process. It should be conducted at the customer's location where production of the certified product takes place. It should include at least:

- Information and evidence of compliance with all requirements of Regulation (EU) 2016/425 for Module D,
- quality objectives and organizational structure, responsibilities and authority of management in the field of product quality,
- production process, quality control and quality assurance techniques, as well as the processes and systematic measures that will be used,
- checking activities and tests that are carried out before, during and after production, and the frequency with which they will be carried out,
- Quality assurance documentation such as inspection reports, test data and calibration data, and qualification reports of production workers, etc..,
- the means of monitoring the process of achieving the desired quality of the product and the effective operation of the quality control system.

NOTES:

Due to the much smaller scope of the audit of the quality of production of certified products, described in detail in Module D of Regulation (EU) 2016/425, than, for example, the scope of the audit of the entire ISO 9001 standard, it is not envisaged to conduct the audit of the initial certification in two stages. The customer's system is initially evaluated at the auditor's premises on the basis of the documentation provided, and any doubts are clarified with the customer by correspondence.

3.3.11.1 Opening meeting

3.3.11.2 The auditor meets with the management and designated personnel of the organization in an opening meeting, the purpose of which is:

- Introduce the participants, including a presentation of their roles,
- Confirmation of the audit plan (type, scope of audit, objectives and criteria),
- Confirmation of the scope of certification,
- Confirm proper work safety, emergency and security procedures for the audit team,
- Confirmation of formal communication between the audit team and the organization,
- Confirm the availability of resources and equipment necessary for the audit team,
- Confirmation of the availability, role and identity of guides and observers, the method of reporting, including the grading of audit findings,

- Information about the conditions under which the audit may be interrupted,
- Confirm confidentiality issues, including those related to the protection of the organization's personal data,
- Confirm that the lead auditor together with the audit team, representing the certification body, are responsible for the audit and should reign over the implementation of the audit plan,
- Confirmation of the status of the findings of the previous audit, if applicable, the methods and procedures used to conduct the audit based on sampling,
- Confirmation of the language of the audit, if applicable,
- Confirmation that during the audit the organization will be informed about the progress of the audit and any objections, the opportunity to ask questions,
- Agreeing on other matters conditioning the smooth conduct of the audit,
- Agreeing on a date for the closing meeting.

3.3.11.3 Communicating during the audit

If the available audit evidence indicates that the audit objectives cannot be achieved or indicates the existence of an immediate and significant risk (e.g., safety), the auditor should present it to the client and, if possible, to the certification body for appropriate action. These actions may include reconfirming or revising the audit plan, changing the objectives or scope of the audit, or terminating the audit. The auditor should present the results of the action taken to the certification body.

The auditor, together with the client, should review any needed change in the scope of the audit that may arise as a result of on-site audit activities, and submit these changes to the certification body.

3.3.11.4 Observers and guides

The presence and justification for the attendance of observers during audit activities should be agreed by the certification body with the client before the audit is conducted. Each auditor should be accompanied by a guide, unless otherwise agreed between the lead auditor and the client. Guides are assigned to the audit team to facilitate the audit. The audit team should ensure that observers do not influence or interfere with the conduct or outcome of the audit.

3.3.11.5 Collecting and verifying information

During the audit, information related to the objectives, scope and criteria of the audit should be collected through appropriate sampling and verified to provide audit evidence.

Information collection methods should include, but not be limited to:

- Conversations,
- Observation of processes and activities,
- Review of documentation and records,
- Research.

3.3.11.6 The auditor also verifies that:

– the manufacturer has affixed the CE mark and the identification number of PRS S.A. as a notified body to each piece of the product that conforms to the product type described in the EU Type-Examination Certificate. The product marked with elements such as:

(a) type name,

(b) batch/batch number or other identifying information,

(c) details of the manufacturer: its name, registered trade name or registered trademark, and postal address,

(d) data of the importer: his name, registered trade name or registered trademark, and postal address (if applicable),

(e) for Category III PPE, the identification number of the notified body participating in the procedure set out in Annex VII or VIII of Regulation 2016/425

(f) CE marking, the marking must be: visible, legible and permanent.
If it is impossible to label the goods, all information must be placed on the packaging and in the documents accompanying the PPE,

– manufacturer has prepared a written declaration of conformity for the type of product, and whether it keeps it
at the disposal of national authorities. The retention period should be specified in
documentation of the production quality assurance system and be at least 10 years after the PPE is placed on the market,

– the production quality assurance system documentation specifies that the EU type-examination certificate
and approved technical documentation are to be kept for at least 10 years after the
placing the PPE on the market. Requirements for.
Technical documentation (Annex III) e.g:

(a) a full description of the PPE and its intended use,

(b) assessment of the risk against which the PPE is intended to protect,

(c) a list of essential health and safety requirements that apply to PPE,

d) design and manufacturing drawings and diagrams of PPE and their components, e) descriptions and explanations necessary to understand the drawings and diagrams,

(f) references to the harmonized standards referred to in Article 14, which were applied to the design and manufacture of the PPE. In the case of partial application of harmonized standards, the documentation shall specify the parts that were applied,

(g) where harmonized standards have not been applied or have been applied only partially, descriptions of other technical specifications that have been used to meet the applicable essential health and safety requirements,

(h) the results of design calculations, inspections and tests conducted to verify the compliance of the PPE with the applicable essential health and safety requirements,

(i) test reports conducted to verify the compliance of the PPE with the applicable essential health and safety requirements and, where applicable, to determine the appropriate class of protection,

(j) a description of the measures used by the manufacturer during the production of the PPE to ensure that the manufactured PPE complies with the design specifications;

(k) a copy of the manufacturer's instructions and information specified in item. 1.4 of Annex II.

– As part of the system, each piece of PPE should be evaluated and tested to verification of compliance with the relevant essential requirements.

The auditor who audits the production quality assurance system evaluates the various elements of this system, and in particular checks that the system ensures that the manufactured PPE conforms to its approved design.

– Whenever the manufacturer intends to make changes to the previously approved quality control system, it must notify the body that issued the approval opinion. The unit checks the proposed changes and then decides whether the revised quality control system meets the relevant requirements. The body notifies the manufacturer of its decision. The notification should include the conclusions of the evaluation and the reasoned decision resulting from the evaluation.

3.3.11.7 Audit records are made on the Questionnaire for certification/intermediate/renewal audit of the production process quality assurance system (module D) according to Regulation (EU) 2016/425 - Form. 3/ PCW-01/PPER.

NOTES:

Appearing in the audit forms and the Audit Plan, the audit number is in the form: CW/PPER/xxx/Czz/yyyy, where:

xxx - anticipated or assigned number of the Certificate of Conformity to Type based on quality assurance of the EU production process (Module D),

C - certification audit, interchangeably with P (intermadiate audit), S (special audit), O (renewal audit),

zz - the number of the next audit in a given company,

*yyyy - the year of the audit***.**

3.3.11.8 Observations and nonconformities found during the audit shall be recorded on the Audit Findings List (Form. 4/ PCW-01/PPER) and presented to the auditee at the closing meeting. Observations show areas for improvement, but should not be recommendations proposing or suggesting specific solutions to take preventive or other improvement actions. Nonconformities obligate corrective and/or corrective actions.

3.3.11.9 Closing meeting

A formal closing meeting should be conducted with the client's management and, if appropriate, with those responsible for the audited functions or processes. The purpose of the closing meeting is to present the audit findings including a recommendation for certification. Nonconformities should be presented in such a way that they are understood, and a time frame for addressing them should be agreed upon.

The closing meeting should also include the following:

– instructing the customer that the audit evidence was gathered from exemplary information; thereby introducing an element of uncertainty,

– method and timeframe regarding reporting, including any grading of audit findings,

– the process of dealing with nonconformities by the certification body, including any consequences with regard to the client's certification status,

– A timeframe for the customer regarding the submission of a corrective action plan and corrective actions for any nonconformities found during the audit,

– Post-audit activities carried out by the certification body,

– Information on the processes for handling complaints and appeals.

3.3.11.10 Within 7 days from the end of the audit, the auditor shall prepare an audit report (Form. 5/ PCW-01/PPER).

3.3.11.11 The audit documentation is evaluated by the CW Manager, who makes a decision on issuing or refusing to issue a certificate of conformity to type based on the quality assurance of the production process (on form form.9/PCW-01/PPER). In case of lack of competence of the CW Manager in a given process or in case the CW Manager performed the assessment in a given process, the decision to issue or not to issue the document of conformity with the regulation is carried out by a designated expert with appropriate qualifications (see Attachment 1/PCW-01/PPER).

3.3.11.12 The certificate of conformity to type based on quality assurance of the production process is signed by the DC Director after prior approval by the CW Manager (confirmed by his signature on a copy of the certificate).

3.3.11.13 In the case of refusal to issue a certificate, a letter informing of the refusal, including the reasons, is signed by the DC Director.

3.3.11.14 The documents referred to in 3.3.5.11 and 3.3.5.12 sent to the manufacturer shall be accompanied by an audit report.

NOTE:

Intermediate and renewal audits are carried out in a manner analogous to that described in 3.3.5, taking into account the specifics of these audits.

3.3.11.15 Supervision of the production quality assurance system is carried out through audits in supervision.

3.3.12 Intermediate audits are conducted once a year. Audits for renewal of the Certificate of Conformity to Type based on quality assurance of the production process shall be carried out no earlier than 60 days and no later than 30 days before the expiration of the certificate after prior receipt of the application for certification.

3.3.13 Independently of the supervision of the production process quality assurance system referred to in 3.3.5, unannounced visits to the manufacturer may be carried out (this is decided by the CW Manager) to verify that the system is functioning properly. The auditor conducting the visit shall prepare a visit report. The visit report, after approval by the CW Manager, is submitted to the manufacturer.

3.3.14 If the manufacturer holds a quality management system certificate for compliance with ISO 9001, issued by the PRS S.A. Products and Persons Certification Bureau, the conformity assessment process for conformity with Module D, specified in points from 3.3.5, may be simplified, whereby the subject of the certification audit is at least the production process of the products subject to conformity assessment, as well as inspections and tests before, during and after their production, and in addition subject to inspection in the Audit Questionnaire (Form 3/PCW-01/PPER), in the items "Verification of recognized product".

3.3.15 If the manufacturer has a quality management system certificate for compliance with ISO 9001, issued by another accredited certification body, the possible possibility of simplifying the conformity assessment process for compliance with Module D is subject to separate consideration and decision of the CW Manager in each case.

3.4 Conformity assessment according to module C2 (conformity to type based on internal control production and supervised product inspections at random intervals)

3.4.1 Product inspections to verify the uniformity of production and the conformity of the PPE with the type described in the EU type-examination certificate and the applicable essential health and safety requirements shall be carried out at least once a year, at random intervals, and shall include:

- evaluation of the conformity of products with the standard/specification and the tested type, according to the principles set forth in 3.4.3,
- assessment of production heterogeneity, according to the principles set forth in 3.4.4.

3.4.2 The designated expert shall verify that the products under supervision have an EU Type-Examination Certificate. In addition, he/she shall determine the harmonized standards/technical specifications within the scope of supervision.

3.4.3 Annual evaluation of the final product

3.4.3.1 The expert, or his designee, shall take appropriate samples of finished PPE at the location agreed with the manufacturer, according to item A.2 of the Questionnaire for Annual Supervision of PPE (Form. 6/ PCW-01/PPER). Samples should be taken randomly from available batches. The samples should be representative of the entire range of products to be inspected.

3.4.3.2 Subsequently, tests specified in harmonized standards or necessary to demonstrate compliance with the essential requirements given in Regulation (EU) 2016/425 shall be carried out in the laboratory mentioned in 3.2.2.

3.4.3.3 In case of difficulties related to the conformity assessment of tested samples of PPE, for which the EU Type-Examination Certificate was issued by another notified body, the expert shall contact this body.

3.4.4 Annual assessment of production heterogeneity

3.4.4.1 The expert recognizes cases of production inhomogeneity, by one of the following means, based on a written agreement with the manufacturer, at his choice:

- through annual inspection of the manufacturing process and test records, at the site where at least final assembly is carried out,
- through an annual audit of the production process, at the site where at least final assembly is carried out,
- Evaluation of one large sample of products,
- evaluation of several smaller samples during the year (based on information on production volumes).

3.4.5 Records of the supervision carried out are made by the expert on the Questionnaire for annual supervision of personal protective equipment (Form. 6/ PCW-01/PPER).

3.4.6 If the tested PPE does not conform to the type specified in the EU Type-Examination Certificate or does not meet the essential requirements, or the production is not homogeneous, the expert shall describe the non-conformities and present conclusions in Part C of the Form questionnaire. 6/ PCW-01/PPER.

3.4.7 Supervision documentation is evaluated and a decision is made in the process by the CW Manager. Based on this, a Certificate of Conformity to Type is prepared based on internal production control and supervised inspections of the product at random intervals (Module C2) on Form Form. 10/ PCW-01/PPER, which is signed by the DC Director and forwarded to the manufacturer. In the absence of the CW Manager's competence in a particular process or in the case where the CW Manager performed the evaluation in a particular process, the decision to issue or not to issue a document of compliance with the regulation is carried out by a designated expert with appropriate qualifications (see Attachment 1/PCW-01/PPER).

3.4.7.1 The information referred to in 3.4.6 is forwarded by the Head of DC to the authority that notified PRS S.A.. The letter notifying this is signed by the DC Director.

3.4.8 When manufacturing, importing or sourcing all Category III PPE products, bear in mind that they are subject to Regulation (EU) 2016/425 of the European Parliament and of the Council of March 9, 2016 on personal protective equipment. Accordingly, these products must be CE marked and undergo a conformity assessment procedure.

3.5 Final provisions

3.5.1 The maximum validity period of the certificate for Module B is 5 years.

3.5.2 The validity period of the certificate for Module D is 3 years.

3.5.3 The validity period of the certificate for the C2 module is 1 year.

3.5.4 Certificates (on Form.7/PCW-01/PPER and Form.8/PCW-01/PPER) and (Form.10/PCW-01/PPER) issued as a result of successful completion of the conformity assessment process shall be numbered as follows:

Organizational unit symbol / PPER / Sequence number in a given month for Regulation (EU) 2016/425 / Month / Year of issue (for example, CW/PPER/1/05/2019).

3.5.5 Not later than 5 days after the issuance of the certificate (Form.7/PCW-01/PPER or Form.8/PCW-01/PPER) or (Form.10/PCW-01/PPER), the expert/auditor shall complete the List of

Certificates of PPE according to Regulation (EU) 2016/425 (in Polish and in English) and save it on the web resource in the directory \\nascen01\CW\Lists of certificates issued for each. Directives. A copy of the certificate is placed in the folder "List of certificates ...". The expert updates the list in the folder. Once a month, the CW Manager or his/her designee shall post on the PRS S.A. website an updated list of certificates, marked with the date of editing.

4. RECORDS

4.1 Records created as a result of the implementation of this program are stored in the CW Archives in hard copy and/or placed on the CW server in electronic form in accordance with "PCW-01 System for Certification of Products and Persons - General Rules" and instruction ICW-02.

4.2 Copies of certificates and reports are kept at CW.

4.3 The storage period for the records referred to in 3.1 and 3.2 is at least 10 years after the manufacture of the last product.

5. FORMS

Form No.	Form name
Form. 1/ PCW-01/PPER	Report on the evaluation of the documents of the quality assurance system of the production process
Form. 2/ PCW-01/PPER	Audit plan according to module D of EU regulation 2016/425
Form. 3/PCW-01/PPER	Certification/intermediate/renewal audit questionnaire production process quality assurance system (module D) according to Regulation (EU) 2016/425 (PPER)
Form. 4/PCW-01/PPER	List of audit findings
Form. 5/PCW-01/PPER	Production process quality assurance system audit report (module D)
Form. 6/PCW-01/PPER	Questionnaire for annual supervision of personal protective equipment
Form. 7/PCW-01/PPER	EU type-examination certificate (module B) (hazard category II)
Form. 8/PCW-01/PPER	EU type-examination certificate (module B) (hazard category III)
Form. 9/PCW-01/PPER	CONFORMITY TO TYPE CERTIFICATE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS (MODULE D)
Form. 10/PCW-01/PPER	CONFORMITY TO TYPE CERTIFICATE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (Module C2)
Form. 11/PCW-01/PPER	ANNEX TO THE EU QUALITY ASSURANCE CERTIFICATE OF THE PRODUCTION PROCESS (MODULE D)
Form. 9/PCW-01	Survey report

6. ANNOUNCEMENTS

Annexes introduced by the program:

- *Annex 1/PCW-01/PPER - List of personnel authorized to take actions in certification processes,*
- *Annex 2/PCW-01/PPER - PRS S.A. regulations applicable to the conformity assessment of products according to Regulation (EU) 2016/425 (PPER),*
- *Annex 3/PCW-01/PPER - RECOMMENDATIONS, Horizontal Recommendation for Use sheets (RfUs),*
- *Annex 4/PCW-01/PPER - RECOMMENDATIONS, Vertical Recommendation for Use sheets (RfUs),*
- *Annex 5/PCW-01/PPER - Determination of audit time.*
- *Annex 6/PCW-01/PPER - List of activities carried out within the flexible scope of accreditation No. AC 114.*

7. RELATED DOCUMENTS

Instruction ICW-02 - Instruction for consideration and approval of technical documentation.

Relevant documents related to this program include recommendations developed by the NB PPER Notified Bodies Working Group, the so-called *Recommendations for Use*.

In addition, the reference documents may be the manufacturer's factory standards/technical conditions after their prior approval by PRS S.A..