Assessment of personal protective equipment in accordance with Regulation (EU) 2016/425
Foreword

A manufacturer can apply the CE-mark on personal protective equipment after performing necessary activities as described in Regulation (EU) 2016/425.

This document contains RISE rules for assessing personal protective equipment that is covered by Regulation (EU) 2016/425. The document presents the procedures for assessment of conformity applied by RISE, acting as a notified body. The activities for certification are in line with ISO/IEC 17065. In this document, Regulation refers to the Regulation (EU) 2016/425, PPE Regulation.

Evaluation and testing are based on harmonized standards/normative documents and when these are lacking, the essential requirements in annex I of the Regulation.

The rules are revised as necessary to suit new and revised harmonized standards/normative documents. Revision may also be necessary if the Regulation changes or as a consequence of experience gained from the application of the system, within the framework of the Regulation.

This version of the rules replaces the previous version dated 2021-03-17.

Borås, December 2021

RISE Research Institutes of Sweden AB
Certification - Notified body no. 0402

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Appendix 1. List of personal protective equipment covered by RISE notification. 16
1 Scope

These rules cover procedures for assessment of personal protective equipment in accordance with Regulation (EU) 2016/425 with the aim of issuing documents that can be used as a basis for the manufacturer to apply the CE-mark. The services which RISE can offer are set out below. See also a separate appendix for a list of personal protective equipment covered by RISE notification.

Module B
EU Type-examination (annex V of the Regulation)

Module C2
Conformity to type based on internal production control plus supervised product checks at random interval (annex VII of the Regulation)

Module D
Conformity to type based on quality assurance of the production process (annex VIII of the Regulation)

For Category II-products module B is applicable.
For Category III products Module B + either module C2 or module D is required. The manufacturer chooses which combination it wants to use and, in the same manner, chooses which notified body/bodies shall perform which task.

The prerequisites for the respective modules are described in the following document in sections 2-4.
2 EU type-examination (Module B)

2.1 General
This section describes the EU type-examination (certification) of personal protective equipment, which is based on Regulation (EU) 2016/425, annex V, module B, and involves examining that the product meets the applicable requirements of the Regulation. The EU type-examination will be performed by assessment of the adequacy of the technical design of the PPE through examination of the technical documentation as well as inspection (testing) of one or more specimens representative of the production of the complete PPE.

2.2 Presumption of conformity
Equipment that is manufactured in accordance with, and complies with the requirements in harmonized standards published in the Official Journal of the European Union shall be presumed to be in conformity with the essential requirements set out in annex II of the Regulation. For equipment that only partly or not at all complies with harmonized standards, see under 2.3.1.1.1.

2.3 The assessment process

2.3.1 Application
Application for EU type-examination are to be in writing and must be accompanied by:
- the manufacturer’s name and address and, if the application is lodged by an authorised representative, his name and address as well,
- a written declaration that the application has not been submitted to another notified body,
- technical documentation (see below),
- the specimen(s) of the PPE representative of the production envisaged. RISE may request further specimens if needed for carrying out the test programme. For PPE produced in series where each item is adapted to fit an individual user, specimens shall be provided that are representative of the range of different users, and for PPE produced as a single unit to accommodate the special needs of an individual user, a basic model shall be provided,

A special application form is available on RISE website.

2.3.1.1 Technical documentation
The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the PPE with the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II. The technical documentation shall include at least the following elements:
(a) a complete description of the PPE and of its intended use;
(b) an assessment of the risks against which the PPE is intended to protect;
(c) a list of the essential health and safety requirements that are applicable to the PPE; (d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits;
(e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) of the operation of the PPE;
(f) the references of the harmonized standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonized standards, the documentation shall specify the parts which have been applied;
(g) where harmonized standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
(h) the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
(i) reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
(j) a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;
(k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
(l) for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model;
(m) for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.

All documents including drawings, product descriptions, assembly instructions, user manuals etc. shall be given a name or number and date as well as date of last revision.

2.3.1.1 Equipment not complying with a harmonized standard
In the case where the manufacturer has not applied a harmonized standard, the application shall in addition to what has been listed above, be followed by a specification which describes what the purpose with the equipment is, i.e. what the protection function is, what shall the equipment protect against. There shall also be a description over how the relevant requirements in the Regulation has been taken in consideration, (A template for this is available)

An evaluation plan will be developed. If possible the plan will be based on elements from one or several harmonized standards. The plan can also be based on evaluation plans for similar products. The plan will be communicated with the manufacturer in order to have acceptance. If an agreement about the evaluation plan can not be established, RISE can refuse the application.

2.3.2 Review of application
When reviewing the application, RISE checks that the application is complete and that the application can be handled within RISE notification. The review may mean that RISE cannot accept the assignment, which is then communicated to the manufacturer with an explanation.
If the application is accepted, the manufacturer is notified by means of a confirmation. An evaluation plan is prepared if this does not already exist. The standard applied constitutes as a rule the evaluation plan. If a subcontractor must be engaged, this is communicated to the manufacturer. The manufacturer is entitled to object to the selected subcontractor.
If this is not done with the application, the manufacturer is asked to send test samples to
the extent that the evaluation plan requires. This is stated in the rules of the harmonized
standard, if this is applied.

2.3.3 Evaluation
During the evaluation process, the product is checked to ensure it has been
manufactured in accordance with the technical data, and that it meets the requirements
that the standard or specification requires. The evaluation process includes tests and
inspections that are carried out to the extent specified by the requirements specification
and/or evaluation plan. In some cases, previous test results can be used for the
evaluation. The requirements for these tests include that they shall have been carried out
by an accredited independent testing laboratory. The evaluation also includes a review of
marking and information to the user etc.

In cases where the product and/or documentation shows deficiencies, i.e. does not meet
the requirements, the evaluation may be cancelled. The manufacturer will then be able to
send in completion to make corrections, send in missing documentation etc.

Results of the evaluation are summarised in an assessment report, which is presented to
the manufacturer. The report is confidential and may not, in full or part, be disseminated
without the manufacturer’s consent.

If the results of the evaluation show that the product and documentation meet the
requirements of the specification, the process proceeds to review and decision.

2.3.4 Review and decision
The evaluation work is reviewed, and following successful results, the process proceeds to
the decision phase. When a decision on certification has been taken, an EU type-examination
certificate is issued to the manufacturer. The certificate can be used by the manufacturer as
a part of the documentation required for issuing a declaration of conformity and to put the
CE-mark on the equipment.

2.4 EU type-examination certificate

2.4.1 Validity
EU type-examination certificates for personal protective equipment are normally issued
with a validity period of five years from the date of issue. The validity period may then be
extended for five years at a time. In the event of revision of a certificate, the original
validity period is retained.

2.4.2 Extension of validity period for the issued certificate.
Applications for extension shall made be in writing, at least 6 months before the end of the
validity period. For the application, an assessment is made of the measures required for the
extension. If no changes are made to the regulations, specifications, etc. a simplified
procedure can be applied. This means that the certificate can be renewed without any
further testing. Of course, this presumes that the product is unchanged relative to the
original certification or the latest revision. The applicant must certify that no changes have
been made. A current set of the technical documentation shall be attached (see 2.3.1.1).
If changes are planned for the product, the application shall be supplemented with details
about this. This may result in the need to conduct additional assessments and/or tests.
In this case, the manufacturer must be informed thereof and will then also receive a price
quotation for this.
2.5 Changes to certified products
Note that no changes may be made to the certified product, without this being assessed and approved by RISE. For this reason, the manufacturer must notify RISE of any planned changes to the certified product. Along with this notification, a description of the changes as well as supplementary information to the technical data must be attached. RISE will then assess what measures need to be taken in order for the certificate to remain in force after such changes have been made. The assessment may result in the need to conduct additional tests. In this case, the manufacturer is notified thereof and will then also be given a price quotation for this. If the result of the change means that the certificate is still valid, the certificate is revised with the new data.

2.6 Market access and marking, category III products
Introducing a product of category III to the market requires that in a supplement to a valid EU type-examination certificate, the manufacturer must also allow a notified body to perform any of the confirmation procedures stated in point 1.3. The manufacturer chooses the appropriate confirmation procedure to be used and the notified body that will perform each task. The CE-mark must be supplemented with the identification number of the notified body that performs this task. See more on this in section 5. See section 3 and onwards for the different procedures.
3 Conformity to type based on internal production control plus supervised product checks at random interval (Module C2)

3.1 General
The procedure entails that the manufacturer takes all necessary measures for ensuring that manufactured equipment conforms to the requirements and that RISE establishes that manufactured equipment conforms to what is stated in EU type-examination certificate. The manufacturer must have a valid EU type examination certificate for each equipment that will be included.

3.2 Application
The manufacturer applies for assessment of its equipment.
The application shall include the following:
   (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;
   (b) a written declaration that the same application has not been lodged with any other notified body;
   (c) the identification of the PPE concerned.

Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:
   (a) the technical documentation described in Annex III of the Regulation;
   (b) a copy of the EU type-examination certificate or certificates.

3.3 Product checks
RISE carry out product checks in order to verify the homogeneity of the production and the conformity of the manufactured PPE in accordance with the description in the EU type-examination certificate(s). The check will be performed at least once a year, and at random interval, decided by RISE. The first check shall be performed within a year after the EU type-examination certificate(s) is issued.

An adequate statistical sample of the equipment(s) shall be selected by RISE. The sampling can be performed at the manufacturers premises or in a warehouse or any other place where there is possible to make a sampling. The collected samples will be examined to compare them with the technical file. Appropriate tests will be carried out, using the same methods as for the type test. These tests can be carried out at RISE own laboratories or at the manufacturers premises if there is appropriate testing equipment available.

3.4 Report
RISE will issue a test report where the result of the product check is summarized. If the outcome of the test points out that the production of the equipment(s) is homogeneous, the manufacturer will be allowed to use RISE notified body number 0402 on the equipments.

3.5 Marking
See section 5.
### 3.6 Failed product checks

If the outcome of the test points out that the production of the equipment(s) is not homogeneous, or that the examined PPEs are not complying with the technical files, or with the essential health and safety requirements. RISE shall take measures, e.g. forbid the manufacturer to use RISE id number. RISE shall also inform their notifying authority.
4 Conformity to type based on quality assurance of the production process (Module D)

4.1 General
Regulation (EU) 2016/425 states two options from which manufacturers can choose for examination of type approved/certified equipment with the aim of approving them for the market. One option is the quality assurance of the production, for which the manufacturer is responsible, and which is followed up through monitoring, for which RISE is responsible. This is based on annex VIII of the Regulation, Module D. Following inspection, a report is issued with an assessment and proposed decision. Using this as a basis, a decision is taken to issue a certificate. Other conditions are listed in section 5. For Module D, the manufacturer must have a valid EU type-examination certificate for each equipment that will be included.

4.2 Application
The application for examination (certification) of the quality system shall be in writing and be accompanied by:
(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
(b) the address of the manufacturer's premises where the audits can be carried out;
(c) a written declaration that the same application has not been lodged with any other notified body;
(d) the identification of the PPE concerned;
(e) the documentation concerning the quality system.

* By manufacturer the company placing the product on the market under its name is meant.

If another body than RISE has carried out the EU type-examination, the application shall also include the following:
(a) the technical documentation of the PPE described in Annex III;
(b) a copy of the EU type-examination certificate.

The application must also state if the quality system covers all or parts of the company, or all or parts of the production. In addition it must be stated if manufacturing takes place at any other company.

4.3 Quality system requirements
The quality system shall ensure that the PPE is in conformity with the type described in the EU type-examination certificate(s) and complies with the applicable requirements of the Regulation. The requirements on the quality system are stipulated in annex VIII of the Regulation. The system shall be documented in accordance with point 3.4 below.

The manufacturer shall undertake to:
• Maintain the approved quality system to ensure its continuing suitability and effectiveness.
• Inform RISE about all changes that are planned in the quality system.
4.4 Documentation requirements
The documentation shall describe:
(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
(d) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned; and
(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

All relevant information such as quality documents and design documents shall be kept available for RISE.

4.5 Review and assessment of the quality system

4.5.1 General
During the assessment (audit), auditors and technical experts who are employed or contracted by RISE are used. At least one of the members in the audit team has experience of the product area. Auditors or technical experts may not participate in an audit if impartiality can be questioned. Companies undergoing an audit can veto an auditor without needing to state the reason why. The assessment (audit) shall be carried out where the manufacturing and/or final inspection takes place. Agreements on dates and times for assessments are normally made between the lead auditor in question and the manufacturer. The requested documentation shall be sent to the auditor in question.

4.5.2 Initial audit stage 1
The initial audit stage 1 is carried out in order to plan the initial audit stage 2 and to ensure that the management system is auditable. Review of documentation and examination of product certificates, type approvals and similar which are covered by the management system are also conducted. Following the initial audit stage 1, the total scope of the initial audit is determined. If it differs from what was stated in the original tender, a new tender is submitted. In some cases audit stage 1 has to be performed at the manufacturer premises.

4.5.3 Initial audit stage 2
Initial audit stage 2 is conducted to assess the conformity of the management system with all requirement elements in the Regulation. All departments, units, functions or similar that are covered by the audit shall be reviewed.

4.5.4 Report
An audit report containing the results, recommendation on approval and the scope of the audit is compiled for the audit. The result contains information on any deviations against requirements which emerged during the audit. Deviations are classified as major deviations, minor deviations or notes. Major deviations are serious and mean that corrective measures should be performed immediately, and should be audited through another visit by the auditors or through a document review (post audit). In the event of a risk of products which do not fulfil essential requirements reaching the market, a major deviation is always issued. Minor deviations also need to be rectified. A note is an observation which may be useful to consider, but there is no requirement for any measure.
The company should report corrective measures for deviations (major and minor) within the period stipulated in the report. The auditor checks and approves the corrective measures and sends an acceptance of measures statement to the manufacturer.

4.5.5 Post audit
In the event of major deviations from the requirements set out in the Regulation, a complementary post audit is required. This can be performed as a document review or audit on site at the company and is charged in accordance with the applicable price list.

4.5.6 Re-audit
If initial audit Stage 2 results in a large number of major deviations, an entirely new audit (stage 2) may be required.

4.6 Certificate
When corrective measures of all non-conformities, if any, are finished, reported and accepted, RISE can take a decision on approval of the quality system. As a receipt, an assessment decision (certificate) will be issued. The certificate allows the manufacturer to use RISE identification number, see section 5. The validity period of this certificate is 5 years, provided that all conditions are fulfilled.

4.7. Marking
See section 5.

4.8 Surveillance of quality system
RISE will conduct audits at regular intervals, normally once a year, and submit audit reports as described under 4.5.4 above. RISE may visit the manufacturer without notice and/or conduct/allow the conduct of testing. RISE reports results in the audit report and/or testing report.
If major deviations are found, corrective measures should be performed immediately, and should be audited through another visit by the auditors or through a document review (post audit). In the event of a risk of products which do not fulfil essential requirements reaching the market, a major deviation is always issued. Minor deviations also need to be rectified, but the manufacturer will have 6-8 weeks respite to report this. A note is an observation which may be useful to consider,

4.9 Renewal of certificate
The certificate can be renewed every fifth year. One of the conditions for renewal is that surveillance audits has been performed as scheduled and with approved result.
5 General conditions

5.1 Marking
The CE marking of personal protective equipment is carried out on the manufacturer’s responsibility. In those cases where RISE has carried out the assessment procedures according to module C2 or D, with an approved result, RISE ID number as notified body (0402) shall be placed adjoining the CE-mark. Only the products that comply with the requirements in the Regulation may be marked. Misuse of RISE ID number may lead to legal action.

5.2 Certificate
The validity of the certificate is based on continuous compliance with the conditions. Certificates are not transferable. Copies of certificates and associated documents may only be reproduced in their entirety, unless otherwise agreed with RISE

5.3 Responsibility
The certificate holder is responsible:
• to fulfil all requirements connected to the certification including notified changes in certification rules or conditions,
• to not provide any misleading information about the extent or conditions of the certification which can harm the confidence for the certification or RISE
• that CE-marked products comply with applicable requirements in the Regulation and other directives, with corresponding national provisions and the requirements specified in the certificate
RISE is responsible for:
• ensuring that all processing is carried out with the necessary care and in accordance with the procedures of RISE quality system
• the certification rules
• to inform about changes in the certification rules and conditions.

RISE has no responsibility for certified products.

5.4 Withdrawal of certificate
RISE, either definitely or permanently, can withdraw a certificate if:
• the product no longer meets the set requirements
• errors in the certificate come to light
• demands for continual examination are not met
• the internal examination shows serious shortcomings
• shortcomings in the internal examination are not remedied in the time prescribed
• there are failed results in examination testing in the regulatory examination
• the product is not suitable for its purpose or can cause injury or problems
• changes are made to legislation, regulations or similar.
• the competent authorities or coordinating body for a notified body recommends RISE to do so
• the holder has used the certificate or in connection with products that do not meet the requirements or are not covered by the certificate
• fees are not paid within the prescribed deadline, the certificate holder is subject to bankruptcy, has gone into liquidation or has transferred the business
• breach of the conditions for the certificate.

If a certificate is withdrawn, the holder shall cancel all reference to the certificate and RISE name and id.no. 0402 in his EU declaration of conformity and marking. The holder
may neither refer to the certificate or RISE in advertisements or other publications for the product in question.

5.5 Changes to products, quality systems, organisation
Changes to certified products, see 2.5.
Regarding quality systems according to modules D, changes to the quality system shall be notified to RISE. Even major organisational changes or other factors which may impact the certificate shall be notified.

5.6 Information obligation, confidentiality and access
As a notified body, RISE is in some cases obliged to reveal information on certificates to other notified bodies and competent authorities. RISE informs Swedac about issued certificates as well as refusals, restrictions, suspensions and withdrawals of certificates.

RISE keeps a register of certificate holders, certificates, certified products and certified quality systems, manufacturing sites, validity period for certificates etc. This information may be published, for example, on RISE websites. RISE may provide copies of or publish the certificates. RISE is also entitled to publicise decisions on the withdrawal of certificates and the misuse of certificates or marking. Other information is classified.

The manufacturer, or its representative, shall ensure that RISE, the control body that RISE has approved, or observers (e.g. from the accreditation body) have access to premises and documents that are needed to perform the duties described in the sections 3-4.

5.7 Revised rules
RISE reserves the right to modify these rules in order to harmonize them with standards, changes to the Regulation or rules for Notified Bodies, or as a result of experience of application of the system.

5.8 Fees
Fees are set according to agreement and shall be paid by the certificate holder. Costs for work resulting from deviations in the continuous examination shall be paid by the certificate holder. The fees for another examination shall only be paid by the certificate holder if the examination results show that the requirements of the certification regulations are not fulfilled.

Application and registration fees are normally not reimbursed when an assignment is cancelled or a certificate cannot be issued. In the case of assignments that are not estimated to be completed within a month of the acceptance date, RISE has the right to issue regular (monthly) invoices for costs to date.

5.9 Appeals
Appeals against RISE decisions shall be made in writing. Decisions on measures necessary as a result of appeals are taken by the RISE Certification board.
## Appendix 1

### List of personal protective equipment covered by RISE notification.

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<tbody>
<tr>
<td>Chest and groin protection</td>
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<tr>
<td>Eye protection</td>
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<tr>
<td>Face protection</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Foot, leg and anti-slip*</td>
<td>X</td>
<td></td>
<td>*Sport equipment *Not antislip</td>
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<tr>
<td>General body protection (clothing)</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>Hand and arm protection</td>
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<td></td>
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<tr>
<td>Head protection</td>
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<tr>
<td>Protection against heat [Heat &gt;100°C and fire and flame]</td>
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<tr>
<td>Respiratory system protection</td>
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<tr>
<td>Electric shock</td>
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<td>X*</td>
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<tr>
<td>Falls from heights</td>
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<td>X</td>
<td>X</td>
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<tr>
<td>Harmful biological agents</td>
<td>X*</td>
<td>X*</td>
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<td>Substances and mixtures which are hazardous to health</td>
<td>X</td>
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<td>Spezialized areas of competence:</td>
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<td>High visibility clothing</td>
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