# Application for EU Type-Examination of a Personal Protective Equipment in accordance with Regulation (EU) 2016/425

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| **Company (applicant):** | |

**hereby applies to RISE Research Institutes of Sweden AB, as Notified Body, in accordance with the PPE-regulation (EU) 2016/425 Annex V for the product(s) registered below**

**The application concerns:**

☐ New certificate

☐ Revision of certificate No.:*

☐ Renewal of certificate No. (extension of validity time):*

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| Type of Product | |
| Model/type/ identification | |
| Description, intended use etc. | |
| Designed according to: | |
| - the harmonized European Standard: | |
| or | |
| - the following specification: | |

*If it is a revision/renewal of an certificate issued according to the directive, the revision/renewal will be issued according to the new regulation, if nothing else is specified. Please have this in mind when updating the technical file.

**Please attach to this application:**

- for a new certificate
  A technical file (see page 4 for guidance)

- for revision of an existing certificate:
  Please describe the reason for revision and if applicable suggested changes. This can be presented in an appendix.
  Also apply the new/revised technical documentation.

- for renewal of a certificate:
  - Copies of the current technical file including product drawings and photographs, product marking and the information supplied by the manufacturer
  - Data from the controls and tests facilities that have been used
  - For category III products: Status of Article 11/Module C2/Module D (e.g report(s) from the latest surveillance activity)
  - One sample of the product

**The application shall be sent to:**

- by e-mail: certifiering@ri.se , or
- your contact person at RISE: firstname.secondname@ri.se, or
- by mail to: RISE Certification, Product Certification, Box 857, SE-501 15 Borås, Sweden,

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**The applicant confirms:**
**For a new certificate**

- That no application for EU Type-Examination for this product has been sent to any other Notified Body.
- That the applicant/manufacturer will keep him/her self informed about any restrictions of the validity of referred standards and if necessary adjust the product in order to adapt the changed requirements.
- That the applicant/manufacturer has taken the basic health and safety requirements stated in annex II of Regulation (EU) 2016/425 in consideration. (A complete statement shall be added in the case where a harmonized standard has not been applied)
- That the applicant/manufacturer, for every market where the product is to be placed, arranges that the information to the user is presented in the official language valid in the actual country.
- That those parts of the product coming into contact with the users skin are free from substances which can course allergy, skin irritation or unhealthy.
- That the applicant/manufacturer during the validity period of the certificate will not make any changes at all of the product, without first contacting RISE:
- That the applicant/manufacturer will draw up a declaration of conformity according to annex IX of regulation (EU) 2016/425 and keep it available.
- That the applicant/manufacturer as the certificate holder allows RISE to publish issued certificates, in listings over certified products.

**For revision of a certificate:**

- That there has be no other changes to the product, since the last revision of the certificate, than those which are applied for in this application
- That no part of the product does contain any substances at levels that are known, or suspected to adversely affect user hygiene or health
- That there has been no changes in the state of the art, that could affect the PPE, in means that it not longer fulfills the essential requirements of the regulation.

**For renewal of a certificate:**

- That the company's name and address is still the same
- That the production process is still the same
- That there has be no changes to the product, since the last revision of the certificate,
- That no part of the product does contain any substances at levels that are known, or suspected to adversely affect user hygiene or health
- That there has been no changes in the state of the art, that could affect the PPE, in means that it not longer fulfills the essential requirements of the regulation.

**In the case that the product is of category III, the manufactured products/the manufacturing process shall be put under surveillance of a Notified Body in accordance with annex VII or VIII of the regulation (EU) 2016/425**

The Manufacturer already has an agreement with a Notified Body regarding surveillance
☐ Yes ☐ No

If no, the Manufacturer is interested signing up an agreement with RISE about surveillance
☐ Yes ☐ No

_____
Place, date and signature of the person representing the company

_____
Clarification/name of the person representing the company

Information about the applicant is to be filled out on the next page



**RISE – Research Institutes of Sweden AB**
**RISE Certification**
Box 857, 501 15 Borås
Tfn: +46 (0)10-516 50 00
E-post: certifiering@ri.se Internet: www.ri.se

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***Information about the applicant***

☐ Manufacturer ☐ Authorised representative

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| Company name: | |
| Full postal address: | |
| Invoice address (if other than above) | |
| Visiting address: | |
| Org./VAT No.: | |
| Phone company: | |
| E-mail company: | |
| Internet (www): | |
| Contact person: | |
| Phone contact person: | |
| E-mail contact person: | |
| Manufacturing places: | |

***Information about the manufacturer*** (if other than applicant):

| | |
|---|---|
| Company name: | |
| Full postal address: | |
| Visiting address: | |
| Org./VAT No.: | |
| Phone company: | |
| E-mail company: | |
| Internet (www): | |
| Contact person: | |
| Phone contact person: | |
| E-mail contact person: | |
| Other information | |

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**Technical documentation to be applied with the application**

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| 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) and of the operation of the PPE; | |
| (f) the references of the harmonised 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 harmonised standards, the documentation shall specify the parts which have been applied; | |
| (g) where harmonised 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. | |

**This is an extract of annex III to the regulation (EU)2016/425**