Certification rules for the testing and certification of personal protective equipment (PPE) according to Regulation (EU) 2016/425 and

1. General / Scope / Basics

Personal protective equipment may only be placed on the market in the European Union if it complies with the requirements of Regulation (EU) 2016/425 on personal protective equipment (PPE).

The Regulation distinguishes between 3 categories of PPE, which are subject to different procedures for certifying conformity with the Regulation, in particular with the essential health and safety requirements set out in Annex II to the Regulation.

PPE falls at least under category II, according to which an EU type examination is obligatory in accordance with Annex V of the Regulation.

Special PPE intended to protect against lethal hazards or serious, irreversible damage to health (e.g. firefighting footwear, footwear for work on low-voltage installations, foundry boots) must, in addition to the EU type examination, be inspected in accordance with module C2 or module D of the Regulation.

Type testing and inspection of PPE must be carried out by approved testing bodies (Notified Bodies).

According to section 5 of the PSG (§ 20 to 23), voluntary GS mark recognition is also possible for technical work equipment and ready-to-use articles. For PPE, this is only possible in categories I and II of the Ordinance. In addition to a type test, an inspection of the production site and annual product monitoring are also necessary for this.

2. Certification process

Application
The applicant submits the corresponding application documents with associated documentation, as well as samples of the intended products, to the certification body of the PFI Pirmasens. In addition, it is possible to submit already existing test reports on the PPE or parts thereof.

Application assessment
On the basis of the application documents, the technical documentation, the product samples and any available test reports, the certification body determines the scope of the type examination to verify conformity with the ordinance. If available, harmonised standards are used for the verification of the products. Additionally submitted test reports on the PPE or parts thereof are checked for usability for certification.

Assignment of the inspection body
A consecutive order number from the IT data system is determined for the order received. The samples received are photographed and the evaluation plan FB 9.5.200 is filled in. The scope of the examination determined in the course of the examination of the application is entered in this plan. This evaluation plan is attached to the products to be tested. The order marked in this way is handed over to the testing laboratory. The test order is thus officially issued.

Evaluation
The PFI certification body assesses the test results for conformity with Regulation (EU) 2016/425. As far as possible, the assessment is based on the statutory presumption of conformity with harmonised standards and rules of the relevant European bodies.

If individual parameters of the harmonised standards are not met, retesting of improved products is possible, whereby the retesting may also include the control of other parameters that have been influenced.

In case of repeated deficiencies or non-achievement of the requirements, the EU type examination for this type is refused. Other certification bodies and the ZLS are informed of this by the PFI.

EU Type Examination Certificate
In case of a positive assessment result, the certification body of the PFI Pirmasens issues the EU type examination certificate for the personal protective equipment. The EU type examination certificate is valid for 5 years.

An extension of the EU type examination certificate for another 5 years is possible. For this purpose, a review of the conformity of the products with the Regulation and with the original type examination is necessary.

Retention samples
The samples required to ensure traceability can be kept either at the certification body or at the client's premises.

3. Surveillance (Category III)

In addition to the type examination for category II (e.g.: procedure under 3.1), the manufacturer concludes a contract with the certification body of the PFI either for product surveillance (according to module C2 of the Regulation) or for surveillance of production (according to module D of the Regulation).

Foreign EU type certificate
If an EU type examination of another approved body is available, the certification body of the PFI shall carry out a check for correctness and plausibility, whereby details shall be coordinated with the external approved body if necessary.

Product surveillance according to Annex VII (Module C2) of the Regulation
The applicant concludes a product surveillance contract with the certification body of the PFI after passing the type examination.

Within the framework of the product surveillance contract, the manufacturer agrees that the certification body of the PFI may take samples on site or instruct the certificate holder to send it samples from the current production.

Exact details of the rights and obligations are regulated in the separate contract.

The validity of the EU-type examination certificate is linked to the duration of the product surveillance contract.

EC quality assurance system with surveillance according to Annex VIII (Module D) of the Regulation
After passing the type examination, the applicant concludes a contract for the inspection of the quality assurance system with surveillance with the certification body of the PFI. Within the scope of production monitoring, the manufacturer agrees that the certification body is granted all rights necessary for monitoring.

Exact details of the rights and obligations are regulated in the separate contract.

The validity of the EU type-examination certificate is linked to the duration of the surveillance contract.

4. Withdrawal or restriction of the EU type-examination certificate

The certification body may withdraw or restrict a type examination certificate in particular if a product no longer fulfils the essential requirements of the ordinance, standards or other criteria, so that the user, operator or third parties are exposed to not inconsiderable risks, or which does not fulfil the intended purpose stated by the manufacturer and these deficiencies are not remedied within a reasonable period of time. And / or a product is not or no longer covered by the original assessment basis (e.g. regulation, standard) or was erroneously assigned to an incorrect assessment basis or an incorrect category according to the regulation.

For category III products
- product monitoring or production monitoring is not enabled on the part of the applicant.
- Defects or deviations are detected in the course of product monitoring or monitoring of the quality assurance system,
- Products do not conform to the type or essential requirements of the certified product/system are not (or no longer) fulfilled and these defects are not remedied within a reasonable period of time..

5. GS mark

In addition to the EU type examination for PPE products of category II, an additional GS mark recognition can be carried out. GS mark recognition is also possible for non-PPE.

Mandatory activities for the GS mark are:
- Tests of the product properties
- Initial factory inspection with sampling
- Regular production monitoring (usually annually)
- Market observation

It is also possible to obtain a GS mark recognition for a batch-related production (e.g. certain number of pieces, certain production period, ...).

Testing of product characteristics PPE
In addition to the type examination according to the EU regulation, all national requirements regarding health and harmlessness (ZEK documents) must be complied with in order to be awarded the GS mark.

In particular, more extensive requirements for certain pollutants must be met here.

Testing of the product characteristics of non-PPE
Safety-relevant tests as well as the national requirements regarding health and harmlessness (ZEK documents) are carried out on non-PPE. In particular, further requirements for certain pollutants must be met here.

Factory tour
The purpose of the initial factory inspection is to determine whether the applicant has introduced and applies a suitable quality assurance system with self-monitoring of its production processes. The certification body of the PFI Pirmasens (if necessary also with an auditor commissioned by it) carries out the initial inspection and prepares a written report on it. The basis for the assessment of the initial factory inspection is Annex A of the ZEK Basic Decision ZEK GB2006-01 or corresponding successor documents..

FB 9.5.204 *Questionnaire for GS factory tour*
FB 9.5.205 *Inspection report for GS factory tour*
FB 9.5.206 *Overview of examinations and check-ups*
FB 9.5.207 *Sampling form*
FB 9.5.208 *Evaluation form*

Monitoring the production
After the initial factory inspection, the production must be monitored. As a rule, this is carried out by means of recurring or batch-related factory inspections, pre-shipment inspections, product sampling from production or from the manufacturer's warehouse, at least once a year, or more frequently if required. The procedure to be carried out in each case is agreed between the PFI certification body and the certificate holder.

In the event of a positive result of the scheduled surveillance measure, the certificate holder receives a written confirmation.

In the event of a negative result of the scheduled monitoring measures, the further procedure and the corrective measures shall be coordinated with the certificate holder.

FB 9.5.205 *Inspection report for GS factory tour*

	FB 9.5.206	*Overview of examinations and check-ups*
	FB 9.5.207	*Sampling form*
	FB 9.5.208	*Evaluation form*

GS certificate
After the product has been tested and the initial factory inspection has been successfully completed and the documents have been checked for plasibility, the PFI certification body issues a GS certificate. The certificate is valid for a maximum of 5 years. The certificate is only valid in conjunction with the successfully completed factory inspections.

A certificate renewal is possible.

Withdrawal of the GS certificate
In addition to the criteria mentioned in point 2.3, the PFI certification body may withdraw or revoke the GS certificate without notice or with notice, in particular if:

The monitoring measures on the part of the certificate holder are not enabled.

Within the scope of the surveillance measures, defects or deviations are detected, products do not conform to the type or essential prerequisites of the certified product/system are not (or are no longer) fulfilled and these defects are not remedied within a reasonable period of time. The exact measures are listed in Section D of ZEK Decision 2006-01.

The notification of the withdrawal of the GS certificate shall be made to the relevant supervising bodies.