

<b>PFI</b>	PRÜF- UND FORSCHUNGSINSTITUT PIRMASENS E.V. - ZERTIFIZIERUNGSSTELLE -			<b>9.6.5.2</b>
		<b>PROD</b>	SYST	PRÄQ   ETI
<b>Restriction / suspension / withdrawal of certification for product certifications</b>		Revision		<b>004</b>
		Freigabe		2023-05-30

Where significant non-conformities with certification requirements are identified as a result of surveillance or otherwise, appropriate actions will be considered and decided upon. This may include evaluations, assessments and decisions to find solutions to the suspensions. Appropriate actions may include limiting, suspending and/or withdrawing certifications until the non-conformities are resolved. If the appropriate measures include evaluation, assessment or a certification decision, the requirements for these processes must be complied with.

## 1. Certification restriction

The scope of certification may be restricted at the request of the certified organisation or by the certification body of the PFI if it becomes apparent during certification or surveillance that the conditions required for the granting of certification are not met in the entire area of validity applied for.

The restriction leads to a reissue of the certificate. The original certificate must be returned to the certification body without delay.

## 2. Certifications shall be suspended, if

(a) reasons subsequently become known which, had they been known at the time of the decision to grant certification, would have led to a refusal of certification, or

(b) a product no longer complies with the essential requirements of Directive 89/686/EEC/Regulation (EU) 2016/425, 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.

(c) a product is not or no longer covered by the original assessment basis (e.g. directive/regulation, standard) or has been erroneously assigned to an incorrect assessment basis or an incorrect class according to the directive/regulation.

(d) for PPE in category III, product control or production control is not enabled from the applicant's side.

(e) defects or deviations are found 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.

(f) the certified client itself has requested a suspension; or

(g) the PFI certification body has not been able to verify or confirm the implementation of satisfactory corrective actions, including root cause actions to prevent reoccurrence, for all non-conformities; or

(h) the certified client is in any other way in breach of the established rules or is not in compliance with the contractual obligations but there is an expectation that the certified client will be able to effectively address the identified non-conformities within the foreseeable future (maximum 3 months).

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The decision to suspend certification gives the certified client a reasonable period of time within which to allow a reassessment.

If the problems that led to the suspension have not been resolved within this period (this also applies in the case that the suspension was requested by the certified client), this leads to the withdrawal or limitation of the scope of the certification.

During the suspension of the certification, all advertising with the certification must be discontinued.

**3. Certifications shall be withdrawn, if**

(a) requirements for the product are not fulfilled; or

(b) there are reasons for suspending certification and there is no expectation that the certified client will be able to effectively remedy the identified non-conformities in the foreseeable future; or

(c) the prerequisites for the granting of certification (e.g. also due to failure to meet deadlines in the event of suspension of certification) are no longer fulfilled, or

(d) there has been or will be a serious breach of the requirements or the contractual provisions, or

(e) requirements have not been fulfilled even after an appropriate period of grace has been granted; or

(f) violations of applicable law are proven which are related to the certified products or

(g) the client voluntarily requests the cancellation of the certification. In this case, the withdrawal of the certification does not constitute a sanction.

**4.** The decision on the restriction, suspension or withdrawal of certifications is taken by the top management of the certification body in consultation with the responsible certifier. The top management of the certification body appoints a person to inform the client of the suspension. At the same time, the client shall be informed of the measures necessary to end the suspension and to restore certification for products in conformity with the certification scheme. This shall include any further action required by the certification scheme. This person shall have the necessary competence and knowledge to perform this task.

**5.** The PFI certification body shall maintain lists of certifications granted or withdrawn, which shall include at least for each certified product, labelling, the marketer, applicable normative documents, scope and geographical location (e.g. city and country).

Information on issued certificates shall be provided upon justified request. Notifications of suspended and withdrawn certifications shall be made immediately to the competent authorities. Publication is waived due to the possibility of misuse of the data by third parties.

In the event of restriction and withdrawal of certification, the client is obliged to return the certificates to the certification body. In the event of restriction, the certificate shall be reissued.

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## 6. Reinstatement of certificates

When certification is reinstated after suspension, all changes to formal certification documents, public information (including regulatory authority), authorisations to use marks are made to ensure that all references to certification of the product are again present.

Where certification can only be restored on the condition of scope limitation, any necessary changes will be made to formal certification documents, public information (including the regulatory body) and authorisations to use marks. This ensures that clients are clearly informed of the limited scope of certification, which is clearly described in the certification documentation and public information.