



# Certificate re-examination or renewal procedure

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As you know, one of the major changes introduced by Regulation 2016/425 concerns the period of validity of EU type-examination certificates.

Regulation (EU)-2016-425 on personal protective equipment defines:

- The period of validity of a certificate at a maximum of 5 years (Annex V, paragraph 6.1).
- The procedures to be implemented for renewing certificates that have reached the end of their validity (Annex V, paragraph 7.4.c).

The regulation states:

"The manufacturer shall request the notified body to carry out the re-examination of the EU type-examination certificate at the latest before the expiry date of the certificate. In order for the notified body to be able to carry out its tasks, the manufacturer shall submit its application no earlier than 12 months and no later than 6 months before the expiry date of the EU type-examination certificate."

Since April 2018, as a manufacturer of PPE (gloves, footwear, clothing), CTC has issued you with EU type-examination certificates (certificates). It is therefore necessary for CTC to explain the procedures that are implemented and in particular when your certificate reaches the end of its validity.

## Procedures for the re-examination of certificates

The procedure applied depends on several parameters:

- PPE category (III fatal or irreversible risks module C2 or D, II intermediate risks module B)
- Changes in legislation (categorisation decision by the European Commission, instructions issued by the notifying Member State, etc.)
- Developments in standardisation (new standards, revision, harmonisation, changes in the levels of risk covered, changes in the state of the art, etc.)
- Any changes made by the manufacturer to the PPE.

Depending on the situation, and in accordance with the regulations, CTC has put in place several certificate re-examination procedures which are detailed in the following pages of this document.

## What is the deadline for submitting applications for the renewal of an expiring certificate?

In accordance with § 7.4 of Annex V of the Regulation, the manufacturer must submit his request for re-examination no earlier than 12 months and no later than 6 months before the expiry date of the certificate.

On a case-by-case basis and depending on the resources and time required to assess the re-examination request and issue the renewed certificate, CTC may agree to process a renewal request submitted between 0 and 6 months before the expiry date. In this case, CTC will not be able to commit to issuing the renewed certificate before the expiry date of the current certificate.

If the renewed certificate is issued after the expiry date, the manufacturer is not authorised to place its PPE on the European Union market for the period between the expiry date of the initial certificate and the certificate renewal date.

Any renewal application submitted after the expiry date of the certificate will be rejected. The manufacturer will have to submit a new application for certification, which will result in a new certificate number.

## For how many years are renewed certificates valid?

When CTC issues a renewed certificate, the validity of the new certificate is given by the initial date of end of validity plus 5 years. It is not necessary to wait until the end of the initial certificate before issuing the renewed document.

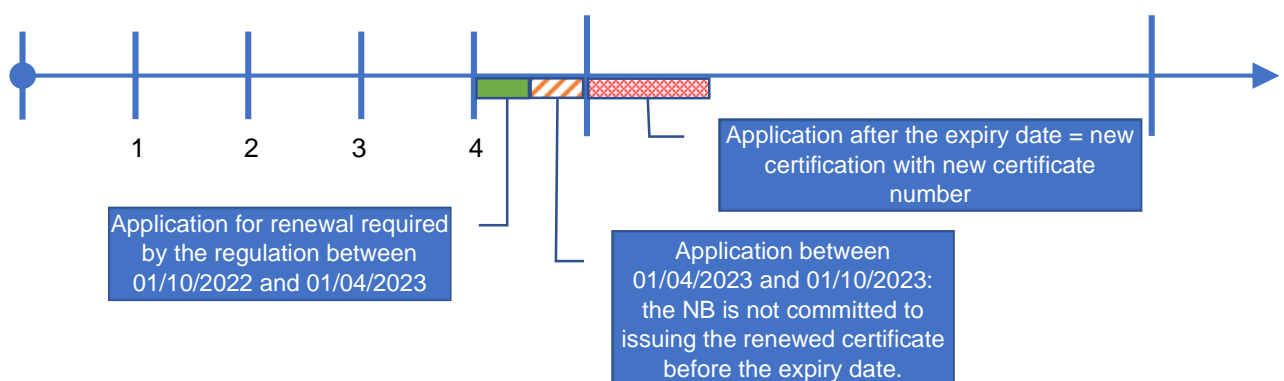
Example:

- A certificate was issued on 01/10/2018. It must be renewed before 01/10/2023.
- The manufacturer must make the application between 01/10/2022 and 01/04/2023. The manufacturer places its application on 15/11/2022. The new certificate will be ready 3 months later, on 15/02/2023.
- The validity of the renewed certificate will be extended until 01/10/2028.

Issuance of the  
initial certificate  
on 01/10/2018

Initial date of end of  
validity: 01/10/2023

Extended date of end  
of validity: 01/10/2028



## Initiate the re-examination for certificate renewal

It is the manufacturer's responsibility to keep the list of his CE certified products up to date and to initiate the re-examination procedure with the notified body that issued the certificates according to the validity dates of its certificates.



## Request for re-examination of an expiring certificate without modification of the product and without modification of the state of the art

This situation corresponds to the following conditions:

- The certificate expires in 6 to 12 months.
- No change to the standards used for the initial certificate.
- No changes have been made to the PPE (only a reduction in the size range is acceptable).

This situation corresponds to the simplified re-examination procedure described in paragraph 7.6 of Annex V of Regulation 2016/425.

### **The simplified review procedure is as follows:**

1. The manufacturer analyses its collection and identifies the products concerned.
2. The manufacturer completes and signs Doc474.
3. At the earliest 12 months and at the latest 6 months before the expiry date of the EU type examination certificate, the manufacturer sends his renewal application including:
  - Doc474 completed and signed.
  - The indexed instructions for use if they have not been generated from the questionnaire.
4. CTC registers the renewal application.
5. CTC assesses the application and completes an assessment report based on the technical file to ensure that:
  - The standards used to assess the product are still applicable.
  - The PPE is identical (manufacturer's declaration).
6. Once all the conditions have been met, CTC generates a new TAA with the same number as the previous one, but with the words "Renewal date" and a validity date extended by 5 years compared with the initial validity date.

<i>Note: Validity of test reports: Test reports remain valid regardless of their date of issue.</i>
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### **Request for re-examination of a certificate following modification of the product or its protective performance, or following a change in the state of the art (revision of the harmonised standard).**

Other situations may arise, but they will not be like a renewal under the simplified procedure:

- The standards framework has changed (2 distinct situations)
  - ✓ The standard used for the original certification no longer gives a presumption of conformity. It therefore becomes necessary to apply the new harmonised standard when renewing the certificate.
  - ✓ The standard used at the time of the original certification still gives presumption of conformity, but there has been a published revision of the standard since the date of issue of the certificate and the manufacturer wishes to apply it to his product.
- The manufacturer wishes to change his product: increase the size range, change certain components, change the performance levels, add a performance, etc.

This case corresponds to the re-examination procedure described in paragraph 7.5 of Annex V of Regulation 2016/425.

#### **Procedure of re-examination:**

1. The manufacturer analyses its collection and identifies the products concerned.
2. The manufacturer identifies the tests required by the revision of the harmonised standard(s) or by the modification of the product. At this stage, the manufacturer may request a pre-expertise from CTC to draw up this list. The CTC laboratories send the manufacturer a quote for the tests to be carried out.
3. The manufacturer arranges for the tests to be carried out.
4. The manufacturer sends his request for re-examination to CTC, including:
  - The Manufacturer attestation for revision (Doc343), completed and signed,
  - The questionnaire (in the event of changes to the standards, you will need to request the corresponding version of the questionnaire) or the updated technical file,
  - A copy of the new reports,
  - The indexed and updated instruction leaflet, if issued by you,
  - A sample of the product if it has been modified.
5. CTC registers the re-examination application.
6. CTC evaluates the certification file and completes an evaluation report to ensure that the product continues to meet the applicable essential health and safety requirements, considering the changes made.
7. When all requirements are met, CTC generates a new certificate with the same number as the previous one but with the mention "Date of revision".
8. Certificate validity date:
  - a. If the re-examination request was submitted no earlier than 12 months and no later than 6 months before the expiry date of the original certificate, then the validity date will be extended by 5 years from the original validity date.



## Certificate re-examination and renewal procedure

- b. If the re-examination request was submitted more than 12 months before the expiry date of the original certificate, then the expiry date of the revised certificate remains unchanged.

*Note: Validity of test reports:*

- *Test reports not affected by changes to standards or product modifications remain valid regardless of their date of issue.*
- *Test reports relating to requirements impacted by the normative revision(s) or by the product modification must have been issued less than 5 years ago in general and less than 3 years ago for safety and innocuousness requirements applicable to footwear.*



### Special case: publication of an amendment to the initial specific standard which does not change the state of the art

For example, as it is currently the case for EN 388:2016 and EN ISO 374-1:2016, an amendment has been published (both in 2018). However, these amendments only include editorial changes. This means that the state of the art remains strictly the same.

The procedure is as follows:

1. The manufacturer analyses its collection and identifies the products concerned.
2. The manufacturer updates:
  - The questionnaire or its own technical file to update the initial normative reference with the amendment. (For example: EN 388:2016+A1:2018)
  - The marking if necessary.
  - Updated and indexed instructions for use if not issued by CTC.
3. At the earliest 12 months and at the latest 6 months before the expiry date of the certificate, the manufacturer sends CTC his request for re-examination for renewal (Doc474) including:
  - Doc474 completed and signed, (tick the appropriate box in this case)

☒ I certify that the published amendment does not affect the state of the art. (tick this commitment only if applicable, for example EN 388/A1:2018 or EN ISO 374-1/A1:2018)
4. CTC will apply the administrative revision procedure before applying the re-examination procedure.

### Special case: request for re-examination of an OBC certificate

As the OBC certificate is closely linked to the original product certificate, the period of validity of an expiring OBC certificate can only be extended if the original model certificate is also renewed.