**Initial order** **Extension** **Renovation** **Supervised product check**

**NOTIFIED BODY NR 2766**

**Accepted CTV Proposal / Quotation (reference nr):**

**Information related to the Manufacturer:**

|  |  |
| --- | --- |
| Name: | |
| Address: | |
| Postal Code: | Email: |
| Vat Number: | Phone Number: |

**OR**

**Information related to the Authorised Representative:**

|  |  |
| --- | --- |
| Name: | |
| Address: | |
| Postal Code: | Email: |
| Vat Number: | Phone Number: |

**Initial application for EU type examination for the following Personal Protective Equipment (PPE):**

|  |  |
| --- | --- |
| PPE Manufacturing Plant: |  |
| PPE Description: |  |
| Model Reference: |  |
| Certification Standard(s): |  |
| PPE Category (I, II or III): |  |
| Country(ies) where will be marketed: |  |

**For Renovation / Extension requests:**

|  |  |
| --- | --- |
| EU type examination certificate Nr: |  |
| Expiration date of the certificate |  |

**Notes:**

1. In addition to the documentation referred bellow, should the manufacturer attached to this application for EU type examination a written declaration that the same application has not been lodged with any other notified body [(b) Annex V of Regulation (EU) 2016/425 of 9 March 2016].
2. PPE samples should be representative of the production.
3. For PPE produced in series, where each item is adapted to fit an individual user, should be delivered samples that are representative of the range of different users and for the PPE produced as a single unit to fit, which considers the specific needs of a particular user needs, should be given a basic model.
4. CTV may request further specimens if needed for carrying out the test programme.
5. CTV subcontracts specific tests to verify the conformity of PPE, the customer approves by signing this form.
6. If the PPE is category III the manufacturer should indicate to CTV the date of 1st production and the appropriate lot size.
7. If the request is a supervised product check and another notified body has issued the certificate, the application must be accompanied with the technical documentation of the PPE and the certificate copy.
8. The EU type examination certificate expires if:
9. the period of validity shown on the certificate has expired. The validity of the EU type examination certificate is five years.
10. the manufacturer terminates the contract (informing CTV in writing to this effect).
11. The manufacturer is declared bankrupt or in case of insolvency proceedings against him.
12. In the case of category III PPE, the monitoring can be carried out by Module C2 (internal production control and supervised product control at random intervals - Annex VII) or Module D (quality assurance of the production process - Annex VIII) in accordance with Regulation (EU) 2016/425 of the European Parliament and of the Council of March 9, 2016. CTV only monitors in accordance with Module C2.

**Technical documentation and specimens shall include at least the following elements** (Annex III, Regulation (EU) 2016/425 of 9 March 2016):

* 1. A complete description of the PPE and of its intended use.
  2. An assessment of the risks against which the PPE is intended to protect.
  3. A list of the essential health and safety requirements that are applicable to the PPE.
  4. Design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits.
  5. 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.
  6. The references of the harmonised standards 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.
  7. 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.
  8. 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,
  9. The reports of 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.
  10. 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.
  11. A copy of the manufacturer's instructions and information set out in point 1.4 of Annex II in the Regulation.
  12. 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.
  13. 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.

**Note**: The request must be accompanied by an appropriate number of specimens of the model to be approved.

**General principles of the CE marking** (Article 30 of Regulation (EU) No 765/2008 of 9 July 2008):

1. The CE marking shall be affixed only by the manufacturer or his authorised representative.
2. The CE marking as presented in Annex II shall be affixed only to products to which its affixing is provided for by specific Community harmonisation legislation and shall not be affixed to any other product.
3. By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set out in the relevant Community harmonisation legislation providing for its affixing.
4. The CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant Community harmonisation legislation providing for its affixing.
5. The affixing to a product of markings, signs or inscriptions, which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. Any other marking may be affixed to the product if the visibility, legibility and meaning of the CE marking is not thereby impaired.
6. Without prejudice to Article 41, Member States shall ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

**It is Manufacturer or authorised representative duty:**

* 1. States that the request for EU type examination was only requested to CTV.
  2. Commits that the products for which have been issued EU type examination certificates are produced according to the same specifications of the samples examined by CTV.
  3. Commits to inform CTV if contact address and production sites/premises changes.
  4. Inform CTV that holds the technical documentation concerning the EU type examination certificate of all changes to the approved type and all changes of the technical documentation that could affect the conformity of PPE with the health and safety essential requirements applicable or certificate validity conditions. Such modifications require additional approval, as an amendment to the original EU type examination certificate.
  5. Ensure that the PPE continues to meet the essential health and safety requirements applicable to the current state of the art.
  6. Make the manufacturer instructions precisely, comprehensibly and at least in the official language (s) of the Member State of destination.
  7. Commits to request CTV to review the EU type examination certificate in any of the following situations:

1. In case of modification of the approved type, referred to in point 4.
2. In the case of state of the art amendment, referred to in point 5.
3. At the earliest 12 months and at the latest 6 months, before the certificate validity term.
   1. If not met the conditions referred to in subparagraphs a) and b) of point 7 must be applied a simplified review process. The manufacturer shall provide the following to CTV:
4. Its name and address, and the EU type examination certificate identification data.
5. Confirmation that the approved type changes were not made as referred the point 4, also in relation to materials, sub-components or sub-groups or the relevant harmonised standards or other technical specifications.
6. Confirmation that the state of the art referred to in point 5 has not changed,
7. If not yet provided, copies of drawings and photographs of the current product, product labeling and information provided by the manufacturer,
8. For Category III products if the supervised product check at random intervals is provided by CTV (in the 1st production and annually) in accordance with Annex VII of the Regulation.
   1. Makes all necessary arrangements for the conduct of the evaluation and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and client's subcontractors.
   2. If CTV confirms that there were no changes to the approved type referred to in point 4 or state of the art changes referred in point 5 shall be applied the simplified revision procedure. In these cases, CTV must renew the EU type examination certificate.
   3. Keep a record of all complaints made known to it relating to compliance with certification requirements and makes these records available to CTV when requested, and:
9. Take appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification.
10. Document the actions taken.
11. Makes all necessary arrangements for investigation of complaints.
    1. Should not use its product certification in such manner as to bring the certification body into disrepute and does not make any statement regarding its product certification that CTV may consider misleading or unauthorised.
    2. Upon suspension, withdrawal, or termination of certification, the client discontinues its use of all advertising matter that contains any reference thereto, and takes action as required by the certification scheme (e.g. the return of certification documents) and takes any other required measure.
    3. During the period of suspension or cancellation, the manufacturer shall be prohibited from selling the product with EC type-examination certificate. The manufacturer must also notify all customers affected by suspension or cancellation of product certification.
    4. If the manufacturer provides copies of the certification documents to others, the documents shall be reproduced in their entirety.
    5. The suspension or cancellation of certificates shall be published on the CTV website and communicated to the notifying authority.
    6. Always comply with the certification requirements including the implementation of appropriate changes when these are communicated by CTV.
    7. Authorise the participation of observers to comply with the obligations of CTV as a certification body. It aims the evaluation of CTV and not the manufacturer.
    8. Inform CTV, without delay, of matters that may affect its ability to conform to the certification requirements. This shall include changes in: the legal, commercial, organizational status or ownership.
    9. Complies with the requirements of the certification body or those specified by the certification scheme in making reference to its product certification in communication media such as documents, brochures or advertising.
    10. Comply with any other requirements that may be prescribed in the certification scheme regarding the use of conformity marks and for product information.
    11. When original manufacturer to offer their product to one or more companies who wish to sell the product as their own “Own Brand Certificates”. The conditions which must fulfill before the granting of certification for an own brand product:
12. The original manufacturer to hold a valid EU type-examination certificate and if category III, to provide evidence of current supervision of product at random intervals.
13. Written agreement to be submitted to CTV, signed by both parties (original manufacturer and own brand manufacturer).

**Manufacturer or authorised representative commitment of conformity to type based on internal production control** (Annex IV and VI of the Regulation (EU) 2016/425, of 9 March 2016)**:**

1. The manufacturer or authorised representative ensures and declares under his sole responsibility that the PPE concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.
2. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid: manufacturing, apposition of CE marking, drawing up a written EU declaration of conformity described in Annex IX this Regulation.
3. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured PPE with the technical documentation of the product and / or the type describe in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.
4. The manufacturer or authorised representative shall affix the CE marking to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.
5. The manufacturer or authorised representative shall keep at the disposal of the national authorities for 10 years after the PPE has been placed on the marked, the EU type examination certificate, a written EU declaration of conformity and technical documentation for PPE model.

**It is CTV duty:**

* 1. Examine the technical documentation to evaluate the adequacy of technical design of PPE. Introducing such exam, there is no need to consider paragraph j) from Annex III of the Regulation.
  2. Be responsible, for the management of all information obtained or created during the performance of certification activities. In compliance with Regulation (EU) 2016/425 of 9 March 2016 CTV places into the public domain the following information: name of the manufacturer/ authorised representative; product identification and technical specifications.
  3. Aside from the manufacturer/authorised representative public information, all other information handled by CTV is treated as confidential and whenever it is necessary to disclose or publish additional information, CTV should request authorisation from the manufacturer/authorised representative. If CTV is required by law or authorised by contractual arrangements to release confidential information, the client or person concerned shall, unless prohibited by law, be notified of the information provided. Information about the client obtained from sources other than the client shall be treated as confidential.
  4. For the PPE produced in series, where each item is customized according to a determined user, to examine the description of measures to determine their suitability.
  5. For the PPE produced as a single unit and customized according to a determined user, to examine the instructions of the PPE manufacture, based on the original approved model to evaluate its adequacy.
  6. Verify if the exemplar was produced according to the technical documentation and identify the conceived elements according with the harmonised standards, as well as elements which conception is in conformity with other relevant technical specifications.
  7. Subcontract the necessary tests to verify, if the manufacturer had chosen to apply solutions according to the relevant harmonised standards, these were correctly applied.
  8. Subcontract the necessary tests to verify if, in case of non-application of the solutions according to the relevant harmonised standards, the adopted solutions by the manufacturer, including the ones in other technical specifications applied, are compliant with the essential health and safety applicable requirements and were correctly applied.
  9. Carry out checking on PPE manufactured. Such checks shall be carried out at random, at least once a year.
  10. Faced with renewal request if CTV verify that there was a change in the state of art, should examine the type of PPE and, if necessary, considering the changes made, carry out all the relevant tests to ensure that the approved type continues to meet the applicable essential health and safety requirements. If CTV consider that the approved type continues to meet the requirements, must renew the EU type examination certificate. It should also ensure that the review process is completed before the expiration date of the EU type examination certificate.
  11. Ensure the manufacturer the right to file a claim and/or appeal ([link](https://www.ctv-certificacao.pt/portaldadenuncia)).

**I confirm that I have read and accept the *Terms and Conditions* of application certification and agreed to the proposal.**

|  |  |
| --- | --- |
| **Company** | **CTV** |
| Date: | Date: |
| Signature and Stamp: | Signature and Stamp: |