# PROCEDURE 16.02

# Application for EU type-examination



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|---|---|---|---|---|---|
| 1 | 08/01/2018 | First revision | Zenarolla A. | Sommariva G. | Boito L. |

## 1 Scope

To describe the method for completing the Application for EU type-examination form and the minimum information to be provided by the Applicant.

## 2 Applicability

The present procedure is applicable whenever the Applicant applies for an EU type-examination.

## 3 Reference documents

Activities included in this procedure are linked to documents listed below:

- REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC;
- UNI CEI EN 45020:2007 Standards “General terms and their definition regarding training and related activities”.
- UNI CEI 70006 Standards “General rules for a standard product certification system by an independent body”.
- EN ISO/IEC 17065:2012 Conformity assessment Requirements for bodies certifying products, processes and service;
- Form M. 8.2.005.

## 4 Implementing rules

### 4.1 Formal request

The Applicant (manufacturer or its Authorised Representative) whom intends to provide a device with an EU type-examination Certificate shall submit an enquiry to CERTOTTICA for a preliminary quotation.

Such enquiry shall be made by sending the format for data collection form M.8.2.002 or form M.8.2.003 by email or fax.

CERTOTTICA Marketing Department will conduct the preliminary analysis. This preliminary analysis might lead to:

- Rejection of the enquiry due to the fact that the device does not fall within the Certification Scheme applied by CERTOTTICA. The Marketing Department will send a communication of rejection by email or fax, explaining the reasons.
- Preliminary acceptance of the enquiry, after which the Marketing Department will provide the Applicant with quotation and the form M.8.2.005 - Application for “EU” type-examination. The Applicant is, however, free to directly access the form M.8.2.005 via web at www.certottica.it.

### 4.2 Completing the Application for EU type-examination

The Applicant shall complete the Application for EU type-examination in all its sections, where applicable.

4.2.1 Page 1

The blanks in this page must by filled in by CERTOTTICA staff. The Applicant should print page 1 on his own letterhead paper/header.

4.2.2 Page 2 – Identification Data – Manufacturer

All sections below described shall be completed by the Applicant.

- Company name;
  - Manufacturer's complete designation, including its business name;
- Legal Headquarters;
  - Full address, including post/zip code, number, and country in which the Manufacturer is located;
- Operative Headquarters;
  - Full address, including post/zip code, number and country in which the Manufacturer's facilities are located, if different from the Legal Headquarter;
- Legal Representative;
  - name and surname of the person legally representing the Manufacturer; this may be the General Manager, Managing Director or other;
- Telephone;
  - Manufacturer's Legal Headquarter telephone number;
- Fax;
  - Manufacturer's Legal Headquarter fax number;
- Company Contact Person;
  - name and surname of the contact person(s) who deal(s) with and manage(s) the EU type-examination procedure and keep contacts with CERTOTTICA on behalf of the Manufacturer;
- Role;
  - position held by the contact person(s) in the Manufacturer's Company;
- Telephone;
  - company contact person(s) telephone number;
- Fax;
  - company contact person(s) fax number;
- E-@ MAIL;
  - company contact person(s) email address;
- Manufacturing Unit;
  - Designation and business name of the production unit which actually produces and/or assembles the device covered by the Application for EU type-examination;

    Note: in case of several different production units, please list them all.
- Manufacturing Unit Headquarter;

- full address of the production unit, including post/zip code, number, and nation in which the production unit is located;

- Telephone;
  - manufacturing unit telephone number.

4.2.3 Page 2 – Identification Data – Mandatary or Authorised Representative in the Union.

Where a Manufacturer appoints a Mandatary or Authorised Representative (both must be located in the European Union) to act on his behalf, the following information shall be provided:

- Company Name;
  - complete designation of the Manufacturer's Mandatary or Authorised Representative, including the business name, if applicable;
- Legal Headquarter;
  - full address, including post/zip code, number and nation in which the Manufacturer's Mandatary or Authorised Representative is located;
- Legal Representative;
  - name and surname of the person who legally represents the Manufacturer's Mandatary or Authorised Representative;
- Company Contact Person;
  - name and surname of the person acting as company contact for the Manufacturer's Mandatary or Authorised Representative;
- Role;
  - position held by the company contact person for the Manufacturer's Mandatary or Authorised Representative;
- Telephone;
  - telephone number of the Manufacturer's Mandatary or Authorised Representative;
- Fax;
  - fax number of the Manufacturer's Mandatary or Authorised Representative;

The delegation of tasks from the manufacturer to the mandatary or Authorised Representative must be explicit and set out in writing, in particular to define the contents and limits of the representative's tasks.

The delegation, set out in writing (appointment letter), if any, shall be enclosed to the Application for EU type-examination.

4.2.4 Page 2 – Identification Data – Product – Basic model

In this section the Applicant shall clearly identify and describe the product for which the EY type-examination Certificate is sought.

In particular, following sections shall be completed:

- Type of PPE;
  - type of device and the part of the body to be protected;
    - e.g. protective spectacles:
      - Personal eye protection – Protective spectacles;
    - e.g. safety face-shield:
      - Personal eye and face protection – Protective face-shield;
    - e.g. Goggle for motorcycle riders:
      - Personal eye protection – Goggle for motorcycle and moped users;
    - e.g. mesh face screen:
      - Personal eye and face protection – Mesh face screen;
    - e.g. welder's face shield:
      - Personal eye and face protection – Welder's face shield;
    - etc.
- Field of application;
  - intended use, including the protection class for which the product is designed, together with any variants;
    - e.g. basic safety spectacle:
      - Increased robustness/basic use;
    - e.g. protective goggle resistant to high speed particles:
      - Protection against high-speed particles – Low energy impact;
    - e.g. protective goggle with oculars with filtering action (UV filters) and resistance to high speed particles:
      - Protection against optical radiations – UV filters;
      - Protection against high-speed particles – Low energy impact;
    - e.g. protective goggle with variants of oculars filtering effect (UV and sun filters for industrial use), resistance to high speed particles and misting:
      - Protection against optical radiation – UV filters (Clear oculars);
      - Protection against optical radiation – Sunglare filters for industrial use (Smoke oculars);
      - Protection against high-speed particles – Low energy impact;
      - Resistance to fogging of oculars;
    - e.g. Motorcyclist's goggle with high impact level and ocular resistant to misting:
      - Enhanced impact resistance protection level;
      - Resistance to fogging;
    - e.g. Mesh face Screen resistant to high speed particles:
      - protection against high-speed particles – Medium energy impact;

        - e.g. welder's face shield resistant to high speed particles and against melted metal and hot solids:
            - protection against high-speed particles – Low energy impact;
            - Protection against melted metal and hot solids
        - etc.
- Trade-mark;
    - brand or trademark on the product (it may appear on the packing, Users Instruction and/or on the device itself);
- Type number / Model name;
    - univocal code, name or whatever else the Applicant uses to identify the product;
- Harmonised standard / Reference Technical specifications;
    - harmonized European standards or technical specifications used for the conformity assessment procedure;
        - e.g. EN 166:2001;
        - e.g. EN 175:1997;
        - etc.
- Existing EU type-examination certificate / EC type-Examination Certificate;
    - mention any EC type-examination Certificate and/or EU type-examination Certificate already obtained for the device, and/or any related product with common aspects, indicating type number or ID code, date of issue and variations introduced by the new Application for EU type-examination;
        - e.g.: "*EC type-examination Certificate and/or EU type-examination Certificate number XXX issued on YYY by Certottica Scrl for the protective goggle model ZZZ. This Application for EU type-examination takes introduces the following changes: …*"
    - In the case of a product already certified to another manufacturer, which is required for the extension of the EU Type-Examination Certificate, the following shall be indicated: EU type-examination Certificate already obtained for the device, indicating type number or ID code, date of issue, holder of the EC type-examination and changes with respect to the product already certified;
        - eg .: "*EU type-examination Certificate number XXX issued on YYY to ZZZ by Certottica Scrl for the protective goggle denominated ZZZ. Compared to the certified product, are excluded from this request the following variants...*"
- PPE category;
    - indicate the device category. The category definition must be conducted according to Regulation UE 2016/425. For the field of application to which this procedure refers, admitted categories are II and III.

4.2.5 Page 2 – Product – Variant(s)

The Applicant will complete this section to identify and describe any variant to the basic model, if applicable, for which the EU type-examination certificate is required. In particular, following sections shall be clearly completed:

- Variant(s) of the basic model;
    - indicate whether and how many variants will be foreseen the EU type-examination, compared to the basic model, clearly showing the differences between each variant;
- Identification code(s);
    - univocal code, name or other means of identification adopted by the Applicant to differentiate each variant.

**NOTA:** A product is considered as a variant of a "basic model" PPE only if it differs on points that have no noticeable influence on the expected protective performances. This assessment shall be carried out by the Applicant.

It is responsibility of CERTOTTICA to evaluate in each case if a given PPE can be considered as a variant. In any case and, for each of the variants identified, the Applicant will provide CERTOTTICA with a detailed description indicating the differences in comparison with the basic model and the number of samples of the variants required for the conduction of additional tests;

4.2.6 Pages 3, 4 and 5 - Contract

From Page 3 to Page 5 of the Application for EU type-examination, the Contract expected by CERTOTTICA and mandatory for the acceptance and formalization of the task, has been explicated.

Such Contract offers a detailed description of all obligations of both the Applicant and CERTOTTICA.

The Applicant must complete each required information:

- Applicant's name and business name;
    - page 3, below the words "and the Company" on the word "<*Manufacturer*>";
- Applicant's Legal Headquarter;
    - page 3, on the word "<Manufacturer address>";
- name and surname of the Applicant's legal representative;
    - page 3, following the words "Legal Representative Managing Director:" on the dotted line "<…>";
- type number / model name for which the Applicant is requiring the EU type-examination;
    - page 3, following the word "Model:" on the dotted line;
- type of device for which the Applicant is requiring the EU type-examination;
    - page 3, following the words "Protective equipment:", on the word "<Type>".

4.2.7 Pages 2, 3, 4 and 5 – Header

In the header/letterhead of the second, third, fourth and fifth page of the Application for EU Certification the Applicant must complete the fields as follows:

- name;
    - complete designation of the Manufacturer on the word <Manufacturer>;
- type of device;
    - following the words “Application for EU type-examination - Equipment” write on the word “<type>” the type of equipment to which the Application for EU type-examination applies;
        - e.g. protective spectacle;
        - e.g. goggle for motorcycle and moped users;
        - e.g. welder’s hand shield;
        - etc.
- type number / model name;
    - following the word “Model:” write on the dotted line the univocal code, name or other used by the Applicant for which the EU type-examination is sought.

### 4.3 Signatures and forwarding the Application for EU type-examination

Once the Application for EU type-examination has been properly completed by the Applicant,
its legal representative or person appointed by him, will sign the Application, by including in addition on pages 2 and 5 the date of signature, and will forward a copy to CERTOTTICA together with the Technical Documentation and test samples, if required, for initial tests.

## 5. Responsibility

The Applicant is responsible for all the steps involved in completing of the Application for EU type-examination. CERTOTTICA's Marketing Department and the Assessment Manager will check the correctness of the submitted Application upon receiving it, and, if the case, will require to the Applicant the pertinent corrections.

## 6. Quality Control Registration

The Head of the Quality Management System and Certification Board Manager are responsible for registering all the submitted documents.

## 7. Annex(es)

Application for EU type-examination form M.8.2.005.