PROCEDURE 16.108.002

Application for EU type-examination

CONTENTS

1 Scope

Describing the method to fill in the Application form for EU type-examination and the minimum information to be provided by the Client.

2 Applicability

This procedure is applicable whenever a Client applies for EU type-examination.

3 Reference documentation

For the activities included in this procedure reference is made to the 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.16.108.2.001 "Application for EU type-examination".

4 Method of execution

4.1 Informal application

The Client (manufacturer or representative) who wishes to provide a new device with EU type-examination Certificate shall make a first enquiry to Dolomiticert for a preliminary estimate. Such enquiry shall be made by sending the data collection form M.108.2.002.XX by email or fax.
It should be addressed to Dolomiticert's Sales Office, which will make a preliminary analysis. The preliminary analysis will lead to:

- Rejection of the enquiry due to the fact that the type of device does not come into the EU type-examination plan applied by Dolomiticert. The Sales Office will send a communication of rejection, explaining the reasons, by email or fax.
- Preliminary acceptance of the application, after which the Sales Office will send the Client a quotation and form M.16.108.2.001 - Application for EU type-examination.

4.2 Filling in the Application for EU type-examination

When s/he receives the form "Application for EU type-examination", the Client must fill in all the sections applicable to her/him.

4.2.1 Page 1
The fields on page 1 are to be filled in by Dolomiticert. The Client must print page 1 on his own letterhead paper.

4.2.2 Page 2 – Identification Data – Manufacturer
It is obligatory for the Client to fill in all the fields described below.

- Company name;
  - Client's complete designation, including the business name;
- Legal Headquarters;
  - Full address, including post/zip code, number, and country in which the Client's registered office is located;
- Operative Headquarters;
  - Full address, including post/zip code, number and country in which the Client's facilities are located, if this is different from the registered office;
- Legal Representative;
  - name and surname of the person legally representing the Client; this may be the General Manager, Managing Director or other;
- Telephone;
  - telephone number of the Client's registered office;
- Fax;
  - fax number for the Client's registered office;
- Company Contact Person;
  - name and surname of the contact person(s) who deal(s) with and manage(s) EU type-examination procedures and contacts with Dolomiticert on behalf of the Client;
- Role;
  - position held by the contact person(s) in the Client's company;
- Telephone;
  - telephone number for calling the company contact person(s);
- Fax;
  - fax number for communicating with the company contact person(s);
- E-@ MAIL;
  - email address of the company contact person(s);
- Manufacturing Unit;
  - denomination and business name of the production unit which actually produces and/or assembles the device for which EU type-examination is required;
    Note: if there are a number of manufacturing 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;
  - telephone number for the manufacturing unit.

4.2.3 Page 2 – Identification Data – Authorized Representative or Legal Representative in the European Union.
If the Client appoints an Authorized Representative or Legal Representative (both must reside in the European Union), the Client must provide all the following information:

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

If the Client appoints an Authorized Representative or Legal Representative established in the European Union, a copy of the letter of appointment must be attached to the Application for EU type-examination. The letter of appointment must clearly indicate the duties which the Authorized Representative or Legal Representative established in the European Union must perform on behalf of the Client.

4.2.4 Page 2 – Identification Data – Product – Basic model

This section is used by the Client to identify and describe the basic or reference model of the equipment for which EU type-examination is sought. The Client must fill in the following fields, in detail:

- Type of PPE;
  - type of personal protection equipment:
    - Head protection devices;
    - Hands and arms protection devices;
    - Personal protection equipment against falls from a height for work and mountaineering;
    - Body protection devices for sports and work;
    - Feet and legs protection devices;
    - etc.
- Field of application;
  - intended use, including the protection class for which the device is designed, together with any variants;
    - e.g. industrial safety helmet:
      - safety helmet with increased protection capacities by optional requirements: very low temperature, very high temperature, electrical properties, lateral deformation.
    - e.g. protective gloves for motorcycle riders:
      - motorcycle gloves that protect the user against mechanical wounds.

        - e.g. mountaineering harness – type C:
            - Mountaineering and climbing harness that maintains a conscious body in sitting position.
        - e.g. motorcyclists' protective clothing against mechanical impacts – shoulder protector – type "S"
        - e.g. safety footwear:
            - the footwear protects against: penetration, electrical properties, hostile environments (hot or cold insulation), water penetration, cut and gives protection to metatarsus and ankle.
        - etc.
- Trade-mark;
    - brand or trademark on the device (may appear on the packing, manufacturer's information notice or device);
- Identification code/Model name;
    - univocal code, name or whatever else the Client uses to identify the device;
- Reference standards;
    - harmonized European standards or technical specifications used to assess conformity;
        - e.g. EN 397:2012 + A1:2012;
        - e.g. EN 13594:2017;
        - e.g. EN 12277:2015;
        - e.g. EN 1621-1:2012;
        - e.g. EN 20345:2012;
        - etc.
- Certifications in existence;
    - Mention, depending on the case, EC type-examination Certificates or EU type-examination Certificates already obtained by the device, indicating type number or ID code, date of issue and variations made by filling in the new Application for EU type-examination;
        - e.g.: EU type-examination Certificate number XXX issued on YYY by Dolomiticert Scrl for shoulder protector – type S – denominated ZZZ. This Application for EU type-examination takes into consideration the following changes made …
- PPE category;
    - indicate the device category (class). Definition of the category must comply with the instructions foreseen by Regulation (EU) 2016/425. For the field of application to which this procedure refers, the categories admitted are II and III.

4.2.5 Page 2 – Product – Variants

This section is used by the Client to identify and describe variants to the basic model, if applicable, for which EU type-examination is required. The Client must fill in the following fields, in detail:

- Variants of the basic model;
    - indicate whether variants will be produced requiring EU type-examination and how many, together with the basic model, clearly showing the differences between the variants;
- Identification code;

- univocal code, name or other identification used by the Client to distinguish each of the device variants.

4.2.6 Pages 3, 4 and 5 – Contract

Pages 3, 4 and 5 of the Application for EU type-examination contain the standard contract provided by Dolomiticert and necessary for accepting the application. The contract gives a detailed description of the obligations for both the Client and Dolomiticert.

The Client must complete the parts relating to her/him with:

- Client's name and business name;
  - page 3, below the words "and the Client (hereinafter called "the Applicant")" on the dotted line;
- Client's registered office;
  - page 3, following the word "Legal Headquarter" on the dotted line;
- name and surname of the legal representative;
  - page 3, following the word "Legal Representative" on the dotted line;
- name of device model for which the Client requires EU type-examination;
  - page 3, following the word "Model" on the dotted line;
- type of device for which the Client requires Product EU type-examination;
  - page 3, following the word "Protective equipment:", on the dotted line.

4.2.7 Pages 2, 3, 4 and 5 – Header

In the header on second, third, fourth and fifth pages of the Application for EU type-examination the Client must fill in the fields as follows:

- name;
  - Client's name and business name on the word <Manufacturer>;
- type of device;
  - following the words "Application for EU type-examination – Equipment" write on the dotted line the type of equipment to which the Application for EU type-examination applies;
    - e.g. mountaineering harness;
    - e.g. motorcycling gloves;
    - e.g. shoulder protector – type "S";
    - etc.
- model code or name;
  - following the word "Model:" write on the dotted line the univocal code, name or other used by the Client to identify the device.

4.3 Signing and forwarding the Application for EU type-examination

When the Application for EU type-examination has been filled in, the Client, as legal representative or person appointed by her/him, will sign the document, adding the date to the fields on the second and fifth pages and forward a copy to Dolomiticert together with the Technical Documentation and test pieces for initial tests.

5. Responsibility

The Client is responsible for all the steps involved in filling in the Application for EU type-examination. Dolomiticert's sales office and certifying office have the task of checking that the Application for EU type-examination has been properly filled in, requiring the Client to make any necessary corrections.

6. Quality Control Registration

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

7. Enclosures

Application for EU type-examination form M.16.108.2.001.