

**VUTCH s.r.o., Rybníky 954/10, 011 68 Žilina, Slovak Republic**  
**Notified Body No. 3020**  
**Authorized Body SKTC-182**

**Certification Body Certifying Products**

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## **GUIDANCE**

on EU Type - examination and conformity assessment of  
**personal protective equipment**

in accordance with the Regulation (EU) 2016/425 of the European Parliament  
and of the Council from 9th March 2016 on personal protective equipment and  
on repeal of the Directive of the Council 89/686/EEC

Worked out by: Ing. Kamila Huljaková

Checked by: Ing. Karol Andreutti, PhD.

Approved by: Pavol Kopečný, MBA

Žilina, 04.12.2023

# 1 INTRODUCTION

These instructions are intended as a guide for the manufacturers, importers and distributors of the personal protective equipment (PPE) who submit an application to perform EU Type - examination, conformity assessment of a product type sample and issue EU Type - examination certificate according to the Regulation (EU) No. 2016/425 of the European Parliament and of the Council from 9th March 2016 on personal protective equipment and on repeal of the Directive of the Council 89/686/EEC.

VUTCH is the Authorized Body SKTC-182 in accordance with the Decision No. UNMS/03716/2023-801 – 013896/2023 from 09.10.2023 and the Notified Body No. 3020 listed in the NANDO information system on the website (<https://webgate.ec.europa.eu/single-market-compliance-space/#/notified-bodies/notifications/1004581?organizationVersion=1>), where the following defined range of activities for these groups of personal protective equipment is indicated:

- equipment providing general body protection (clothing);
- equipment providing protection of hands and arms;
- equipment providing protection against cold [cold > -50 °C], [extreme cold < -50 °C];
- equipment providing protection against heat [> 100 °C and fire and flame];
- equipment providing protection against heat [heat < 100 °C], [heat > 100 °C and flame];
- protective equipment against electric shock;
- protective equipment for protection against hand chain saws;
- protective equipment against mechanical risks;
- protective equipment against substances and compounds dangerous to health;
- specialized areas of competence: Firemen clothing;
- specialized areas of competence: High-visibility clothing;
- specialized areas of competence: Protective clothing designed for use in potentially explosive atmospheres.

## **Procedures/modules of conformity assessment:**

- EU Type - examination (Module B) according to the Annex No. 5 to the Regulation (EU) No. 2016/425 of the European Parliament and of the Council
- EC quality control system for the final product based on internal production control and supervised product checks at random intervals (Module C2) according to the Annex No. 7 to the Regulation (EU) No.2016/425 of the European Parliament and of the Council

**The Notified Body is entitled:**

- a) when carrying out conformity assessment of a determined product to consult the technical documentation relating to the conformity assessment of the determined product and to enter manufacturing premises, storage premises and business premises of the person whom it carries out the conformity assessment of the determined product and the premises of its suppliers or subcontractors;
- b) when finding that essential requirements or corresponding harmonized technical standards or other specifications have not been applied by the manufacturer it is entitled to require the manufacturer to take appropriate corrective action and refuse to issue a conformity assessment output document to the manufacturer;
- c) issue a conformity assessment output document and to stamp the conformity assessment output document;
- d) require the manufacturer to take immediately appropriate corrective action and, if necessary, suspend validity of the conformity assessment output document or cancel the conformity assessment output document if he finds after issue of the conformity assessment output document that the determined product does not meet the basic requirements.

## **2 APPLICATION PROCEDURE**

1. The applicant will bring personally or send by post to the Notified Body No. 3020:
  - a) application (application form is available on [www.vutch.sk](http://www.vutch.sk));
  - b) an attachment to the application stating exactly purpose of use of the PPE and harmonized standards, which the PPE has to meet;
  - c) technical documentation to the PPE elaborated in accordance with the Regulation (EU) No.2016/425 of the European Parliament and of the Council, Annex III;
  - d) necessary number of product samples for laboratory tests according to the instructions of the NB;
  - e) photo of the PPE and/or a drawing of the product on an electronic medium;
  - f) instructions for use of the product and other information for the user ( in accordance with the Regulation (EU) No.2016/425 of the European Parliament and of the Council and relevant harmonized standard).
2. The Notified Body will examine the completeness and appropriateness of the attached technical documentation and product type samples. In case of incompleteness of the documentation and/or product type samples the Notified Body will ask the applicant to complete them and/or remove the deficiency.
3. On the base of the technical documentation, harmonized standards and purpose of use of the PPE the Notified Body will decide about the scope of necessary tests and will send a quote for approval.
4. After approval of completeness and appropriateness of the documentation and product type samples the Notified Body will prepare and send a draft contract for execution of

the EU Type – examination and conformity assessment of a product type sample and issue of the EU Type - examination certificate to the applicant for approval.

5. After agreement of the contract, the applicant will pay the advance payment on the basis of a sent advance invoice by its due date.
6. The Notified Body will start to perform the ordered works after settlement of the advance invoice. The Notified Body will elaborate documentation on conformity assessment after completion of the works and send it to the applicant and if the PPE meets the basic requirements for safety and health protection it will issue EU Type - examination certificate to the applicant. Period of validity of the issued certificate does not exceed 5 years. At the same time, a final invoice for the works performed is sent.
7. If the PPE does not meet the basic applicable requirements for safety and health protection, the Notified Body will refuse to issue EU Type - examination certificate and informs the applicant about it in writing, stating the detailed reasons for its rejection.

### 3 CONCLUSION

These instructions are intended to guide the manufacturer/importer/distributor upon contact with the Notified Body and do not exhaust the full text of the Regulation (EU) No. 2016/425 of the European Parliament and of the Council from 9th March 2016 on personal protective equipment and on repeal of the Directive of the Council 89/686/EEC.

Therefore, it is necessary for each manufacturer to become familiar with full wording of the mentioned document.

Contact address of the Notified Body No. 3020:

**VUTCH s.r.o.**  
**Rybníky 954/10**  
**011 68 ŽILINA**  
**Slovak Republic**

Contact persons authorized to act on behalf of the Notified Body 3020:

**Name: Ing. Kamila Huljaková   Pavol Kopečný, MBA   Ing. Karol Andreutti, PhD.**

**Position: Head of the NB                      CEO of the company                      deputy head of the NB**

**Phone: +42141/72 32 857, +42141/76 45 519**

**e-mail: [huljakova@vutch.sk](mailto:huljakova@vutch.sk)                      [pavol.kopecny@vutch.sk](mailto:pavol.kopecny@vutch.sk)                      [karol.andreutti@vutch.sk](mailto:karol.andreutti@vutch.sk)**