

# **Notified Body 2369**

# Application for EU Type Examination and Conformity assessment of Personal Protective Equipment according to Regulation (EU) 2016/425

Fill out CB (date, name, signature) Review date: Registration date: Registration number: 1. Applicant Address: Banking connection ID No: ..... Name and address of the bank: account number: ..... Authorized person Contact person Name: Name: ..... Position: Position: ..... Telephone: Telephone: ..... E – mail: ..... Website: 2. Product Type of product (Model): ..... Manufacturer (if different from applicant): (Name, Address, Country) Place of manufacturing (if different from applicant): (Address) The applicant asks the NOTIFIED BODY 2369 to realize following activities: EU-Type examination - Annex V Regulation (Module B) \* Conformity to type based on internal production control plus supervised product checks at random intervals - Annex VII (Module C2) 4. Technical requirements Technical requirements (technical regulation or standard) under which conformity of product type samples is to be assessed:

Note: \* For category III PPE, it is required to choose module C2 together with the module B. In a separate module B, it is not possible to affix the CE marking with the number of the notified body to the product(s). The Notified body no. 2369 does not perform the assessment according to the module D.

## 5. Accompanying documentation for the application

Specification	Document ID and Date
Product specifications and product variants with photo	
Material sheets of materials used on the product with manufacturer's indication	
Test results – test reports and final reports	
Technical documentation as required by Annex III Regulation	

#### 6. Declaration of the applicant:

The development of the product as a type is finished and all data and technical documentation presented in this conformity assessment application are complete and they represent product state on the date of the submission of this application. We hereby declare that we have not asked any other notified body for conformity assessment of the product and have been the Testing and Certification Regulation recognized and acknowledged.

## After obtaining the certificate, the applicant undertakes:

- always to fulfil the certification requirements, including implementing appropriate changes when they are communicated by the certification body,
- if the certification applies to ongoing production, the certified product continues to fulfil the product requirements,
- to make all necessary arrangements for:
- 1) the conduct of the evaluation and surveillance (if required), including provision for examining documentation and records, and access to relevant equipment, location(s), area (s), personnel, and applicant's subcontractors,
- 2) investigate of complaints,
- 3) the participation of observers, if applicable,
- to make claims regarding certification consistent with the scope of certification,
- do not to use its product certification in such a manner as to bring the certification body into disrepute and do not to make any statement regarding its product certification that the certification body may consider misleading or unauthorized,
- upon suspension, withdrawal, or termination of certification do not to use of all advertising matter that contains any reference thereto
  and to take action as required by the certification scheme (e.g. the return of certification documents) and to take any other required
  measure.
- to provide copies of the certification documents to others, the documents shall be reproduced in their entirety or specified in the certification scheme,
- in making reference to its product certification in communications media such as documents, brochures or advertising, to comply with the requirements of the certification body or as specified by the certification scheme,
- to comply with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product,
- to keep records of all complaints made known to it relating to the compliance with the certification requirements and to make these records available to the certification body when requested, and to take appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with requirements for certification and to document the actions taken,
- to inform the certification body, without delay, of changes that may affect its ability to conform with the certification requirements.

#### After obtaining the certificate, the applicant has the right:

- in case of disagreement with the decision of the certification body to submit an appeal in writing to the address of CB, VIPO a.s. Partizanske within 15 days of submitting the decision to the applicant. A complaint as an expression of dissatisfaction other than in an appeal may be made by any person or organization. Both the complaint and the appeal must contain the date of submission, the subject, the name, the address and the signature of the person lodging the complaint or appeal. Their records are performed by the head of the CB, who is obliged to respond in writing within 30 days.

#### 7. Duties of applicant

Submit documents needed for conformity assessment as stated in point 5 in Slovak, Czech or English language, in case of test reports also German language is accepted. Documentation in other language can be accepted after mutual agreement. Enable sampling or submit the product sample so that the conformity assessment can be completed in a given time. Provide the cooperation during the conformity assessment in the scope required by the Notified Body. In case of an application for conformity assessment of a product according to module C2, supply a copy of the EU-type examination certificate.

# 8. Applicant's consent \*

Tests can be carried out in a subcontracting manner, in accredited or non-accredited regime, the list of providers of outsourced services is available on the website of VIPO a. s.. The applicant has been notified and agrees that the tests are carried out in abovementioned manner, eventually a written objection can be raised by the applicant:

yes		no	
9. Trade-legal relations An application initialed responsibility of the certification by	d by both parties for certification activities is considered body and its client.	legally enforceable and takes into account the	
Place and date	Name of authorized person	Signature and stamp	
Fill out CB			
Pagistration number	Amount	Amount of sample:	

Note: \* choose one of the options

and date of receipt of the sample:

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