

**CERTIFICATION AGREEMENT**  
OB-CO-02

Notified Body

**ZVD d.o.o., Pot k izviru 6, 1260 Ljubljana-Polje, Slovenia (NB 1493):**

**1 General**

- 1.1 By signing the Application Form (OB-CO-01), the applicant (hereafter the “Client”) accepts this Certification Agreement as a legally binding contract between ZVD d.o.o. (hereafter “ZVD”) and the Client.
- 1.2 EU Type Examination procedures will not be carried out for any Client until a fully completed and signed Application Form (OB-CO-01) has been received by ZVD.

**2 Client Responsibilities**

- 2.1 Undertakes to pay all agreed fees and costs charged in conjunction with this application.
- 2.2 Informs ZVD, without delay, of any changes that may affect its ability to conform with the certification requirements, including changes significantly affecting the product’s design or specification, or changes in the standards to which compliance of the product is relevant, or in the case of any other information indicating that the product may no longer comply with the requirements of the certification scheme.

NOTE: Examples of changes may include the following:

- the legal, commercial, organisational status or ownership,
- modifications to the product or the production method,
- contact address and manufacturing sites,
- major changes to the quality management system.

Where changes have taken place, the Client shall not release CE-marked products until the appropriate changes to the certified product, as agreed by ZVD and the Client, have been implemented.

The decision on whether a change requires additional evaluation, testing, review or a new certification decision is taken by the Certification Body in accordance with OP-CO-01 and the applicable certification scheme.

- 2.3 Keeps records of all complaints relating to compliance with certification requirements and takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification. All actions shall be documented.
- 2.4 Where product certification applies to on-going production, the certified product shall continue to fulfil the requirements of the product certification (e.g. levels or classifications achieved as part of the certification process).
- 2.5 The Client shall take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and tests, ensures the homogeneity of production and the conformity of PPE with the type described in the EU Type Examination Certificate and with the relevant basic requirements of the Regulation (EU) 2016/425.
- 2.6 Ensures that any claims regarding certified products are consistent with the scope of product certification with respect to the identification of:
- a) the product, for which the certification is granted;
  - b) the applicable certification scheme; and,
  - c) the standard(s) and other normative document(s) (including date of publication) to which the product(s) have been judged to comply.
- 2.7 Does not use its product certification in such a manner as to bring ZVD into disrepute and does not make any statement regarding its product certification that ZVD may consider misleading or unauthorised.
- 2.8 If the Client provides copies of the certification documents to others, the documents shall be reproduced in their entirety.
- 2.9 **Reference to the certificate may be made only by including:**
- name of the certificate holder,
  - name of the Certification Body / Notified Body (ZVD d.o.o., NB 1493),
  - certificate number,
  - product brand and type/model,
  - the applicable certification scheme and standard(s) (including edition/year), where relevant,
  - and only during the validity of the certificate and within its scope.

When referring to the certificate, the certificate holder shall ensure that the certificate is mentioned only in relation to products covered by that certificate.

- 2.10 In the event of suspension, withdrawal or termination of certification, the Client shall immediately cease all use of the certificate and any reference to certification, CE marking and the Notified Body number 1493 in relation to the affected products. This includes the removal of such references from products, packaging, instructions for use, technical documentation, websites and all publicity material.
- 2.11 When making reference to its product certification in communication media such as documents, brochures or advertising, the Client shall comply with the requirements of ZVD and/or as specified by the applicable certification scheme.

- 2.12 That the Client complies 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. These being:
- Any reference to CE marking and to ZVD as the Notified Body in publicity material (including internet, brochures and advertisements) shall relate only to products for which certification has been granted and shall not be misleading. If there is any doubt regarding the intended use, the Client shall consult ZVD prior to publication.
  - The minimum height of the CE mark must be no less than 5 mm and shall only be increased in proportion.
  - The CE or other mark may not be used in any way that may be interpreted as misleading nor shall the client make any misleading statements regarding its certification
  - Use of the Notified Body number 1493 in connection with CE marking shall be in accordance with applicable legislation and the applicable certification scheme. The number 1493 may be used only in relation to products covered by a valid certificate issued by ZVD.
  - Upon suspension or withdrawal of certification, the Client shall immediately discontinue any reference to certification, CE marking and the Notified Body number 1493 for the affected products, as directed by ZVD.
  - Where the scope of certification has been reduced, the Client shall amend all publicity and documentation so that references to certification are limited strictly to the reduced scope.
- 2.13 Uses certification only to indicate that products are certified and in conformity with specified standards.
- 2.14 Shall confirm that the samples submitted for any testing required as part of the certification process shall be representative of the product to be certified in respect of all its characteristics taken together, and be made from production tools and assembling methods used for the production run.

### **3 ZVD Responsibilities**

- 3.1 Shall inform the Client of any changes that may affect the validity of the product certification.
- 3.2 After confirming the acceptance of the application, the ZVD Assessor shall discuss and agree with the Client the responsibilities for carrying out the various tasks according to the requirements of Annex II of Regulation EU 2016/425.
- 3.3 Shall carry out the certification process against an agreed product standard(s) or specification(s) where possible. The normal route shall be to use the appropriate European Harmonised standard. However, other standards or technical specifications may be used where harmonised standards do not exist, where this is deemed necessary then it shall be by mutual agreement with the Client. Whichever option is chosen it shall satisfy all the relevant requirements of the EU Regulation. This shall also include appropriate test data to demonstrate that the materials used to construct the products do not contain substances that may cause harm and that they are in compliance with the current requirements of all applicable product standards.
- 3.4 ZVD shall retain records and copies of technical files related to certification activities for at least 10 years after completion of the certification process, and in accordance with applicable legal and accreditation requirements. Records shall be made available to surveillance authorities upon request.
- 3.5 Where re issue or an extension of an existing certificate is requested, the Assessor shall send the Client an application form (OB-CO-01) for completion and return. On return of the completed application form, the Assessor shall make a decision on whether reduced Certification Procedures may be undertaken and shall document the decision.
- 3.6 Where ZVD becomes aware that a registered Client has misused a certificate, schedule, logo or accreditation mark, the Client shall be required to ensure that the misuse is rectified. Incorrect references to the certification system or misleading use of information found in advertisements, catalogues etc. shall be dealt with through suitable means including corrective action, publication of the transgression and, if necessary, legal action.
- 3.7 Suspension, termination and withdrawal of certificates
- Where a certificate is suspended, terminated or withdrawn then the Client has the right to appeal. The appeal shall be received in writing, by the Head of Certification (e-mail: info@zvd.si) on ZVD, within eight days of the Client having been informed of the suspension, withdrawal or termination of the certificate.
  - The first instance decision on an appeal is taken by the Management Board (UO) of the Certification Body.
  - A second instance appeal may be submitted to the Director of ZVD d.o.o.; the Director's decision concludes the internal appeal process of the Certification Body.
  - Where an appeal is successful, reimbursement of the Client's justified costs may be decided by ZVD d.o.o.
  - Suspension of certificates
    - A Client's EU Type Examination Certificate may be suspended for the following reasons:
      - Contravention of ZVD's rules and regulations relating to product certification;
  - ZVD shall inform the Client in writing that their certificate has been suspended, the reason(s) for the suspension and the actions required to reinstate the certificate.
  - If product certification is reinstated after suspension, ZVD shall make all necessary modifications to formal product certification documents, public information, authorisations for use of marks, etc., in order to ensure all appropriate indications exist that the product continues to be certified.
  - If a decision to reduce the scope of product certification is made as a condition of reinstatement, ZVD shall make all necessary modifications to formal product certification documents, public information, authorisations for use of marks, etc., in order to ensure the reduced scope of product certification is clearly communicated to the Client and clearly specified in product certification documentation and public information.

- Withdrawal or termination of certificates
- A certificate shall be withdrawn or terminated if:
  - it is found that the product design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable EU Regulation.
  - The Client fails to settle their financial obligations to ZVD,
  - The Client fails to effectively implement the actions agreed following the suspension of a certificate,
  - Actions taken by the Client in the course of their business activities that would bring ZVD and / or the Product Certification Scheme into disrepute,
  - The Client does not wish to continue with certification,
  - The Client goes out of business.
  - ZVD shall inform the Client in writing that their certificate has been withdrawn or terminated, the reason(s) for the withdrawal or termination and any actions required.
  - ZVD shall inform the appropriate notifying authority when a Client's certificate has been withdrawn or terminated.

### 3.8 Confidentiality

- The results of Product Certification activities shall be treated by ZVD as confidential. Results obtained shall only be passed to third parties with the permission of the Client that originally commissioned it, with the exception of requests from enforcement and surveillance authorities.

### 3.9 Complaints and Appeals

- Upon receipt of a complaint or an appeal which relates to product certification activities, the Head of Certification on ZVD or their nominated deputy shall deal with it in accordance with OP-CO-01 and ZVD's complaints and appeals procedure.
- Where the complaint or appeal relates to the on-going conformity of a product certified by ZVD, it is possible that any agreed remedial actions may involve recalling non-compliant products in which case ZVD shall require documented evidence of such a recall.
- ZVD shall only accept written appeals received within eight days of the Client being informed of the decision that gave rise to the appeal.

## 4 ZVD Requirements

### 4.1 Any test reports submitted to ZVD in support of EU type examination shall meet the following criteria:

- a) Test reports used for certification shall be relevant to the product submitted for certification and shall be based on the edition of the referenced standard(s) applicable at the time of evaluation. The test reports shall relate to a sample that is identical, in all relevant aspects, to the product that is the subject of certification. Where necessary to confirm relevance or equivalence, the Certification Body may request additional information, clarification, samples or testing;
- b) Where not undertaken by ZVD, all testing and reporting shall be carried out by a laboratory considered as being competent to conduct the work. Accreditation of a laboratory to EN ISO/IEC 17025 for the work undertaken will be taken as evidence of competence;
- c) Reports shall contain where possible the following information:
  - (i) sample references given in any test report shall be the same as those detailed in the technical file,
  - (ii) scanned or copied versions of a report may not be acceptable, in which case ZVD shall request that an original hard copy is provided,
  - (iii) reference to the manufacturer and manufacturing site(s),
  - (iv) identification of the organisation and personnel responsible for the test,
  - (v) identification of the product(s) in accordance with the relevant technical specification,
  - (vi) date(s) samples were received and the date(s) testing was undertaken,
  - (vii) details of samples received and the sampling procedure if applicable,
  - (viii) testing methods and procedures used according to the relevant technical specification,
  - (ix) the results of all testing carried out, including analysis of these where relevant,
  - (x) registration number of the Notified Body (when relevant),
  - (xi) signature of the person authorised to sign such test reports;
- d) The Test Report shall include results for all relevant requirements of the applicable harmonised standard(s) (or other specified technical specification) to enable ZVD to determine conformity.

4.2 Copies of all Test Reports used as part of the certification process should be sent to ZVD. Copies of Test Reports that form part of any on-going monitoring procedure should be retained by the manufacturer and made available to ZVD upon request.

4.3 All test reports submitted as part of the certification process shall, where applicable, include information relating to the use of uncertainty of measurement. When evaluating the suitability of results and reports ZVD will, where applicable to safety critical aspects of the product, take uncertainty of measurement into account on a worst case basis. ZVD reserves the right to reject reports where the uncertainty of measurement cannot be determined for those tests/properties deemed by ZVD to be safety critical.

4.4 Where a technical file is required as part of the certification process then it shall include at least all elements from Annex III – Technical documentation for PPE from Regulation (EU) 2016/425.

4.5 Clients are required to retain the EU Declaration of Conformity and related product documentation for at least the period required by applicable legislation.

4.6 ZVD reserves the right to request additional supporting documentation including further testing, where the certification process becomes protracted.