CERTIFICATION AGREEMENT
OB-CO-02

Notified Body

ZVD d.o.o., Chengdujska cesta 25, 1260 Ljubljana-Polje, Slovenia (NB 1493):

1 General

1.1 By signing the Application Form (OB-CO-02), the applicant (hereafter known as the 'Client') shall accept the application and Certification Agreement as a legally binding contract between ZVD d.o.o. (hereafter referred as ZVD) and the applicant as stated in the Applicant For EU Type Examination (OB-CO-01).

1.2 EU Type Examination work will not be carried out for any Client until a fully completed and signed Application Form (and Certification Agreement) 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,
- organisation and management (e.g. key managerial or technical staff),
- 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.

2.3 Where applicable, to provide access to certified products for surveillance activities.

2.4 Where product certification applies to on-going production, the certified product shall continue to fulfill the requirements of the product certification (e.g. levels or classifications achieved as part of the certification process).

2.5 Makes all necessary arrangements for:

a) the conduct of the evaluation and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and the Client's subcontractors;
b) the investigation of complaints;
c) the participation of observers, if applicable.

2.6 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 PPE Regulation.

2.7 Ensures that any claims regarding certified products are consistent with the scope of product certification with respect to the identification of:

a) the product(s), process (es) or services(s) 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); process(es) or service(s) has been judged to comply.

2.8 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.

2.9 That upon suspension, withdrawal, or termination of certification, the Client discontinues its use of all advertising matter that contains any reference thereto and takes action as required by the certification scheme (e.g. the return of certification documents) and takes any other required measure.

2.10 That if the Client provides copies of the certification documents to others, the documents shall be reproduced in their entirety.

2.11 That in making reference to its product certification in communication media such as documents, brochures or advertising, the Client complies with the requirements of ZVD or as specified by the 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:

2.12.1 The CE Mark can only be applied to stationery and publicity material which relates to the products for which certification has been granted. This can include the internet, brochures, advertisements etc. We would advise any Client to contact us prior to printing if there is any doubt regarding the intended use. The misuse of the CE or other marks could result in the issue of a requirement to withdraw offending items.

2.12.2 Where possible the minimum height of the CE mark must be no less than 5 mm and shall only be increased in proportion.

2.12.3 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

2.12.4 The use of ZVD's Notified Body number after the CE mark is restricted to those products defined as complex design, it however may be used on user information of all certified products as a means of identifying ZVD as the type approval body and or article 11 body.

2.12.5 Upon suspension or withdrawal of its certification, The Client shall discontinue its use of the CE mark as directed by ZVD and shall amends all advertising matter when the scope of registration has been reduced. The Client shall ensure that the CE or other marks are not used in such a manner that would bring ZVD into disrepute and lose public trust.

2.13 Uses certification only to indicate that products are certified as being 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.

2.15 Retains a record of all non-conformities and complaints relating to certification requirements of the certified product(s) and makes these records available to ZVD when requested, and:

a) takes appropriate action with respect to such complaints about any deficiencies found in products that affect compliance with the requirements for certification;

b) documents the action taken.

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 responsibility 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 including any amending directives or regulations. 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 as well as the current version of Annex XVII of the EU REACH Regulation (1907/2006).

3.4 ZVD shall retain copies of technical files for a minimum of 10 years after the product is last placed on the market and/or the EU Type Examination certificate is cancelled or withdrawn, whichever comes sooner. These shall be made available to the Surveillance Authorities upon demand.

3.5 Where re issue of an existing certificate is requested, the Assessor shall send the Client an appropriate application form 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 an extension to an existing certificate is requested, the Assessor shall send the Client an appropriate application form for completion and return.

3.7 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 by suitable means including corrective action, publication of the transgression and, if necessary, legal action.

3.8 Suspension, termination and withdrawal of certificates

3.8.1 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 Product Certification Manager, within twenty one working days of the Client having being informed of the intention to suspend, withdraw or terminate the certificate.

3.8.2 The outcome of an appeal shall be final and binding on both parties and no counter claim by either party shall be accepted. Where an appeal is successful, the Clients costs may be reimbursed at the discretion of the Product Certification Coordination Committee.

3.8.3 Suspension of certificates

3.8.3.1 A Clients EU Type Examination Certificate may be suspended for the following reasons:

- Contravention of ZVD's rules and regulations relating to product certification;
- Where effective corrective action is not implemented within an agreed timescale against a major non-compliance found during a surveillance visit.
- Where significant non homogeneity is highlighted during on-going surveillance.

3.8.3.2 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.

3.8.3.3 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.

3.8.3.4 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.

3.8.4 Withdrawal or termination of certificates

3.8.4.1 A certificate shall be withdrawn or terminated if:

- it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer
- comply with the requirements of the 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.

3.8.4.2 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.

3.8.4.3 ZVD shall inform the appropriate notifying authority when a Client's certificate has been withdrawn or terminated.

3.9 Confidentiality

3.9.1 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.

3.10 Complaints and Appeals

3.10.1 Upon receipt of a complaint or an appeal which relates to product certification activities, the ZVD Product Certification Coordinator or Manager or their nominated deputy shall deal with it in accordance with ZVD's complaints and appeals procedure.

3.10.2 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.

3.10.3 Complainants raising issues regarding a) products not being CE-marked when they should be or b) EU Type Examination certificates issued by other Notified Bodies shall be directed to the appropriate enforcement authority.

3.10.4 ZVD shall only accept written appeals received within twenty-one days of the client being informed of the decision that gave rise to the appeal.

3.10.5 Full details of the ZVD Complaints and Appeals procedure are available on request.

4 ZVD Requirements

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

a) The report shall be dated no earlier than 24 months before the date of the signature on the ZVD application form. Reports older than 24 months will be rejected; in some cases ZVD may accept reports that are more than 24 months old if the client is able to provide additional supporting documentation, such as more recent check test data;

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 ISO 17025 by a National Accreditation Body that is recognised by UKAS (see ILAC website) for the work undertaken will be taken as evidence of competence as long as it can also demonstrate that it has knowledge of, and access to, any appropriate recommendation for use sheets and guidance papers endorsed by the European Commission In the absence of such accreditation, a report will be accepted only when competence has been demonstrated to the satisfaction of ZVD, via an audit visit and, where judged necessary, check testing. Note, in either case if the laboratory is not a European Notified Body, ZVD may commission limited check testing on safety critical properties;

c) Innocuousness test data which has been requested in addition to that required by the main European Harmonised Standard or performance specification. These additional innocuousness tests (i.e. not detailed in the product standard) need not be carried out by ZVD or an ISO 17025 accredited facility but it will be necessary to submit actual test data (declarations of conformity are not acceptable).

d) 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 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;

e) The Test Report shall indicate compliance of the product(s) with the relevant clauses of the harmonised standard (s).

4.2 Copies of all Test Reports used as part of the certification process must 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 on 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 Certificate of Conformity (or a copy of it) for a minimum of 10 years after the product to which it relates is last placed on the market.

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