

1. General and Scope

1.1 These General Terms & Conditions for PPE Certification (“GT&C”) govern all PPE certification services provided by CCQS Certification Services Limited (“CCQS”) to any applicant (“Applicant”) under the PPE Regulation (EU) 2016/425, including but not limited to:

- **Module B** - EU Type-Examination
- **Module C2** - Conformity to Type based on Internal Production Control plus Supervised Product Checks at Random Intervals, and
- **Module D** - Conformity to Type based on Quality Assurance of the Production Process

1.2 The GT&C apply together with the specific written offer, order form, contract or similar document signed by both parties that sets out project-specific details (the “Individual Contract”). The GT&C and the Individual Contract together form the Agreement between CCQS and the Applicant.

1.3 In case of conflict between the GT&C and the Individual Contract, the provisions of the Individual Contract shall prevail *only* with respect to commercial terms expressly deviating from the GT&C. For all other matters, the GT&C prevail.

2. Parties and Representation

2.1 CCQS Certification Services Limited, Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin 15, D15 AKK1, Ireland, is an EU Notified Body, number 2834, appointed by the Government of Ireland.

2.2 Unless otherwise agreed in writing, all payments under an Individual Contract shall be made to the bank account indicated in that Individual Contract.

2.3 Certification decisions are made only by CCQS personnel or persons formally authorised by CCQS and under CCQS’s control.

3. Exclusion of Applicant’s Terms

3.1 Any general terms and conditions of business of the Applicant, including purchasing or procurement terms, are hereby expressly excluded and shall not apply to the Agreement.

3.2 The Applicant’s terms and conditions will not become part of the Agreement even if CCQS does not expressly object to them in individual cases.

4. Certification Services - General Provisions

4.1 The Individual Contract specifies the PPE product(s), model(s), brand name(s), manufacturing location(s), and the type(s) of services requested (initial certification, OBM/re-branding, extension, re-issue, renewal, or transfer from another Notified Body), as well as the applicable EU legislation and standards.

4.2 CCQS has the right to determine:

- The range and quantity of samples;
- The test plan; and
- The laboratory(ies) that shall carry out the required testing for EU Type-Examination (Module B) and any subsequent testing.

4.3 The Applicant shall supply the agreed samples and a complete Technical File in English. CCQS will verify that the samples correspond to the description in the Technical File and then submit the samples to the nominated test laboratory.

4.4 CCQS will assess the product, test reports and Technical File for conformity with the requirements of PPE Regulation (EU) 2016/425, applicable standards, and/or other relevant technical specifications. If non-conformities are identified, the Applicant will be informed and requested to correct them.

4.5 Test reports produced before the Agreement was concluded may be accepted by CCQS if:

- They meet the criteria in the CCQS QMS procedure on external testing, and
 - It is clearly possible to correlate the product in the test report with the samples presented for certification.
- CCQS has sole discretion to decide whether test reports are acceptable. If test reports are not acceptable, new testing will be required.

4.6 Where the Applicant changes the product design, structural materials, production mode, production supervision mode, production location, product use information, or product brand name(s), the Applicant must promptly and truthfully inform CCQS. CCQS has the absolute right to decide which additional information, documents or supplementary tests are necessary to verify that the product remains in conformity with the relevant requirements.

4.7 Any changes must be presented in an updated Technical File. Where supplementary testing is required, the Applicant shall provide the necessary samples to the agreed laboratory at its own expense.

4.8 If CCQS decides that the product remains in conformity with the applicable requirements, CCQS may extend or reissue an existing certificate, or issue a new certificate, as appropriate. The Technical File must be updated to include new test reports and modified specifications or documents.

4.9 Changed products must not be placed on the market until CCQS has extended or reissued the relevant certificate.

4.10 If CCQS determines that the product cannot be brought into conformity, CCQS will issue a refusal notification. CCQS may have a legal duty to inform the relevant Notifying Authority and other PPE Notified Bodies of such refusal in accordance with PPE Regulation (EU) 2016/425.

4.11 If serious problems with product conformity are found in production, the Applicant shall cease placing that product on the EU market and may be required to recall products already placed on the market. In such cases, CCQS may suspend or withdraw the relevant certificate(s) as set out in Articles 8, 9 and 10 below and shall notify the relevant authorities and other Notified Bodies as appropriate.

4.12 The Applicant shall maintain complete files and records for all products and/or systems certified by CCQS for at least ten (10) years after the last production of the product concerned (or the last unit of a series-manufactured product).

4.13 The Applicant acknowledges that standards, regulations and directives are revised from time to time. There is no guarantee that a certificate remains valid beyond its date of issue if the requirements for conformity have changed. CCQS will inform the Applicant of changes that affect compliance of the product; in all other cases CCQS will endeavour to inform Applicants of important changes in requirements.

5. Rights and Obligations of the Applicant (General)

5.1 The Applicant shall submit all information and documentation required for certification in accordance with the relevant standards and CCQS instructions, allowing sufficient time for planning and performing the assessments.

5.2 The Applicant shall appoint one or more contact persons or audit representatives, as appropriate, to support CCQS in performing the agreed services and to act as the Applicant’s primary contact.

5.3 The Applicant shall:

- Record and retain all customer complaints regarding certified products or processes in relation to the certification requirements;
- Take appropriate measures to address such complaints; and
- Document the actions taken and make these records available to CCQS upon request.

5.4 The Applicant undertakes:

- To fulfil all certification requirements at all times, including implementing required changes;
- Shall maintain product conformity in accordance with the technical files and the PPE Regulation (EU) 2016/425; and
- To operate any underlying management system continuously and effectively throughout the validity of the certification.

5.5 The Applicant undertakes to comply with relevant certification and accreditation regulations, to cooperate with supervision and inspections by certification supervision authorities, and to provide truthful and relevant information in response to inquiries or during investigations.

5.6 The Applicant shall provide all requested files and documents in English within the agreed time. If the Applicant delays or fails to provide accurate or complete information, the Applicant shall, in addition to the original agreed fees, bear the costs of any additional work incurred.

5.7 For Category III PPE, the Applicant must not place the product bearing the CE marking on the EU market until:

- A Module B EU Type-Examination certificate has been issued; and
- An initial assessment has been carried out to Module C2 or Module D (whether by CCQS or another Notified Body).

If CCQS is not responsible for monitoring production control (Module C2 or D), the Applicant shall formally notify CCQS of any contract with another Notified Body for such monitoring.

5.8 If the Applicant is unable to bring the product and its documentation into conformity with the relevant Directives and Regulations, the Applicant is not permitted, under EU law, to present that same product to another EU Notified Body for conformity assessment without prior written approval of CCQS.

5.9 The Applicant shall make all necessary arrangements so that CCQS can provide both the initial assessment and the ongoing assessment of production. These arrangements include, but are not limited to, providing:

- Documentation and records,
- Access to relevant products, locations and personnel, and
- Access to relevant sub-contractors as CCQS deems necessary.

5.10 The Applicant shall permit, upon reasonable request, the participation of observers (e.g. from accreditation bodies or authorities) in certification activities.

5.11 The Applicant shall:

- Make necessary arrangements for investigating complaints relating to product compliance,
- Take such actions as are necessary to rectify any problems found so that only compliant products are placed on the market, and
- Document all such actions.

If these actions lead to the withdrawal of a product from the market, whether required by Market Surveillance authorities or by the Applicant’s own organisation, the Applicant shall notify CCQS without delay and provide further information on request (e.g. corrective actions).

6. Rights and Obligations of CCQS (General)

6.1 CCQS will clearly define for the Applicant, within a reasonable time after commencement of the Agreement and as work progresses, what is required to proceed with the assessment for certification.

6.2 CCQS will assess the product, production control and documentation for conformity with PPE Regulation (EU) 2016/425 and applicable harmonised standards and will inform the Applicant of any non-compliances identified.

6.3 CCQS will clearly state what documentation, samples and testing are required for assessment.

6.4 CCQS has the absolute right to determine whether test reports produced by the Applicant or by external test facilities are acceptable for certification purposes.

6.5 Issuing an EU Type-Examination certificate or a positive production control supervision report is conditional on the product and associated documentation being found to meet the relevant requirements. CCQS has the absolute right to refuse to issue or to withdraw certificates or positive reports for products that do not conform.

6.6 CCQS shall provide the Applicant with a copy of the finally approved Technical File or relevant certification documentation.

6.7 CCQS employees and personnel formally authorised under CCQS’s control shall be independent and impartial, and technically competent for the work undertaken, in accordance with ISO 17065:2012 and CCQS’s accreditation as a Notified Body.

7. Module B - EU Type-Examination

7.1 Module B services involve EU Type-Examination in accordance with PPE Regulation (EU) 2016/425 and applicable harmonised standards.

7.2 The Applicant declares in the Individual Contract that no application for Module B EU Type-Examination of the same product has been presented to any other Notified Body, unless explicitly disclosed and permitted by CCQS.

7.3 In the event of serious non-conformity of products already produced, CCQS may suspend or withdraw the relevant Module B certificate(s) and notify the relevant authorities and other Notified Bodies in accordance with the PPE Regulation.

8. Module C2 - Supervision of Production Control

8.1 Where Module C2 services are included in the Individual Contract, CCQS shall conduct supervision of production control as required by PPE Regulation (EU) 2016/425.

8.2 While Module C2 is an annual sample selection assessment, the Module C2 certification cycle under the Agreement is typically three (3) years from the completion of the initial Module C2 assessment. This is to ensure that all aspects of the standard(s) and product range have been included. Maintenance of Module C2 certification depends on satisfactory completion of the agreed annual sampling and testing.

8.3 Following completion of Module B Type-Examination, if Module C2 has been chosen this must be completed before the product can be placed on the EU market. The Applicant may not continue to place the product on the EU market unless it has a current Factory Production Control (FPC) monitoring contract with a Notified Body.

8.4 CCQS and the Applicant will agree when sampling and monitoring of production control will begin. Sampling is, by nature, random and therefore a fixed date cannot be stated at the start of the Agreement, but CCQS shall provide sufficient time for preparation.

8.5 Module C2 monitoring of production control shall be carried out:

- Prior to placing the product on the EU market and only after the Module B certificate has been issued; and
- Thereafter on an annual basis for the duration of the contract, provided that requirements continue to be met unless otherwise notified.

8.6 After successful pre-market sampling for Module C2, the next visit will normally be approximately six (6) months later and thereafter annually. Samples will be taken to ensure:

- Conformity to type as represented by the Module B Type test; and
- An assessment of homogeneity based on suitable sampling (single clause multi-item, or product family basis where appropriate).

8.7 Samples may be taken from the manufacturing plant and/or from other points in the supply chain.

8.8 Any required testing will be carried out in accordance with a test plan provided by CCQS and will be subject to a separate contract between the Applicant and the testing laboratory. All such testing costs are borne by the Applicant.

8.9 The Applicant must give CCQS auditors and assessors free access to all production facilities, production control records and relevant test facilities related to the PPE being monitored and allow the taking of any samples required during sampling.

8.10 If samples are found not to conform or if other evidence shows inadequate production control, CCQS may:

- Take further samples, and/or
- Make further audit visits to the manufacturing location, which may result in additional charges to the Applicant.

8.11 If serious conformity problems are found in production, CCQS will suspend the relevant Module B and Module C2 certificate(s). If the Applicant cannot promptly rectify the problems and continues or intends to continue placing the product on the EU market, CCQS will withdraw the relevant certificate(s) and notify the appropriate authorities and other Notified Bodies.

8.12 CCQS will provide the Applicant with a report of its findings within four (4) working weeks of sample collection.

8.13 If the Applicant refuses to allow the Module C2 assessment to be carried out within a complete one-year cycle or does not allow planning of the assessment within ninety (90) days of the end of the assessment year, CCQS has the right to suspend or withdraw any issued certificate. All fees already paid are non-refundable.

8.14 The Applicant shall notify CCQS of any change of Notified Body for FPC monitoring at least three (3) months before the planned date of a Module C2 assessment. If the Applicant provides notice less than three months before that date, the Applicant remains liable for the costs of the planned assessment. This also applies where CCQS has already issued the Module B certificate and the Applicant notifies CCQS fewer than six (6) weeks before the planned assessment date.

9. Module D - Quality Assurance of the Production Process

9.1 Where Module D services are included in the Individual Contract, CCQS shall perform audits of the Applicant’s quality assurance of the production process in accordance with PPE Regulation (EU) 2016/425.

9.2 The Applicant declares in the Individual Contract that no application for Module D supervision of production control of the same product has been presented to any other Notified Body, unless explicitly disclosed and permitted by CCQS.

9.3 Module D assessments normally follow a three-year cycle consisting of:

- An initial assessment (two stages: Stage 1 document/system review and Stage 2 on-site assessment); and
- Two surveillance assessments (annual or as agreed).

9.4 After the three-year cycle, a Module D re-assessment audit is required if the Applicant wishes to continue certification. The re-assessment and subsequent surveillance assessments form the start of the next three-year cycle, subject to a renewed Individual Contract.

9.5 CCQS auditors carry out:

- Stage 1: review of the company’s basic compliance with the PPE Regulation (usually off-site, but may be on-site on request); and
- Stage 2: initial on-site assessment of production control.

Only after satisfactory completion of the initial assessment (including any required corrective actions) may production commence and product be placed on the EU market.

9.6 The Applicant must give CCQS auditors free access to all production facilities, production control records and test facilities related to the PPE being monitored.

9.7 CCQS will provide the Applicant with a report of audit findings within four (4) working weeks of the date of each audit.

9.8 If audit evidence indicates inadequate production control, CCQS may decide to carry out further audits at the manufacturing location, which may incur additional charges to the Applicant.

9.9 If serious conformity problems are found in products produced, CCQS will suspend the relevant Module B and Module D certificate(s). If the Applicant cannot promptly rectify the problems and continues or intends to continue placing the product on the EU market, CCQS will withdraw the relevant certificate(s) and notify the appropriate authorities and other Notified Bodies.

9.10 CCQS normally accepts up to ninety (90) days for the closure of nonconformities, but may reduce this timeframe based on the significance of the findings. If this timeframe is exceeded, certification may be refused or, if already granted, suspended or withdrawn.

9.11 The Applicant shall notify CCQS of any change of Notified Body for FPC monitoring at least three (3) months before the planned date of a Module D assessment. If notified later, the Applicant remains liable for the costs of the planned assessment and associated fees. This also applies where CCQS has already issued the Module B certificate and the Applicant notifies CCQS fewer than six (6) weeks before the planned assessment date.

9.12 A current production supervision contract with a Notified Body is required for the Applicant to continue placing the product on the EU market.

10. Use of Certificates and Certification Marks

10.1 If the agreed certification procedure is successfully completed, CCQS will issue the corresponding certificate(s) to the Applicant. The certificate(s) shall be valid for the period defined in the Agreement, subject to continued fulfilment of the applicable requirements.

10.2 Upon issuance of a certificate, the Applicant is granted a simple, non-exclusive, non-transferable right to use the certification mark and certificate during the defined period of validity. This includes referring to the certification in communication media such as documents, manuals and advertising materials.

10.3 Certificates remain the property of CCQS and may be withdrawn at any time if CCQS has reason to believe that the product is no longer in conformity with the applicable requirements. CCQS is required to notify relevant authorities and other PPE Notified Bodies if a certificate is withdrawn or refused.

10.4 The right to use the certificate and any certification mark is limited exclusively to the parts of the Applicant's organisation and the scope described in the certificate. Use beyond the stated scope is prohibited.

10.5 The Applicant undertakes to use the certificate and certification mark only to make statements about the organisation or parts thereof that are accurate and consistent with the certification granted.

10.6 The Applicant shall not adjust, alter or translate the certificate in any manner whatsoever.

10.7 The right of use expires if the Applicant no longer holds a valid certificate, in particular if:

- The period of validity has expired; or
- Required surveillance or re-assessment audits have not been carried out.

10.8 The right of use also expires with immediate effect, without the need for separate termination, if the Applicant uses the certificate or certification mark in violation of these GT&C or other terms of the Agreement. CCQS reserves the right to claim damages.

10.9 The right of use ends upon ordinary termination taking effect, or immediately in the event of justified extraordinary termination for good cause or where maintenance of the certificate is prohibited by administrative regulation or court order.

10.10 If a certificate is suspended or withdrawn, the Applicant shall not use or refer to the certificate. In case of withdrawal, the Applicant shall return the original certificate to CCQS within seven (7) working days from the date of withdrawal.

10.11 The Applicant shall:

- Keep records of the use of the certificate in its business dealings;
- Permit CCQS to monitor proper use of the certificate and marks, including by random sampling; and
- Inform CCQS immediately if it discovers that any third party is improperly using its certificate.

10.12 Certificates may be extended or reissued conditional on the product continuing to meet the requirements of the applicable Regulation and standards current at the time of re-issue.

11. Intellectual Property

11.1 Each party remains the sole owner of its intellectual property and rights existing prior to the Agreement, including, without limitation, CCQS’s rules, protocols, templates for certificates, reports and checklists.

11.2 CCQS is entitled to use, for the purposes of its own certification activities, any know-how acquired in the course of performing its work under the Agreement. CCQS may use information received or generated under the Agreement in aggregated, anonymised form for certification and related activities.

11.3 CCQS holds all intellectual property rights, including copyright, to the certificates and technical documents it issues to the Applicant. The Applicant holds a restricted, non-transferable, worldwide, royalty-free licence to use any valid certificate in accordance with these GT&C and applicable requirements.

11.4 The Applicant may provide deliverables (including certificates) or parts thereof to third parties only without altering the content, context or original language of the deliverables.

12. Indemnification and Liability

12.1 If the Applicant, its legal representative or its employees:

- Fail to provide truthful and accurate information, documents and/or data as required by CCQS, or
- Misuse any CCQS certificate in any form,

The Applicant shall compensate CCQS in an amount of not less than three (3) times and not more than five (5) times the total contract value specified in the relevant Individual Contract(s).

12.2 The time limit for filing claims is subject to the statute of limitations prescribed by applicable law.

12.3 The Applicant shall indemnify and hold CCQS harmless from any costs and expenses which CCQS may incur due to requests made by public authorities, courts, counterparties or other stakeholders in connection with or arising from the work performed under the Agreement.

12.4 The indemnities above apply irrespective of how relevant claims, damages, losses or expenses arise and regardless of whether they arise under contract, tort (including negligence), strict liability or otherwise, except to the extent they are caused by:

- (i) CCQS’s intentional and wilful act or omission with the intent to inflict damage or injury; or
- (ii) any circumstances in which CCQS may not lawfully limit its liability under the applicable law.

13. Confidentiality

13.1 Each party agrees to keep confidential any information received from the other party in the course of the Agreement which, by its nature or circumstances, is reasonably considered confidential to the disclosing party.

13.2 The receiving party shall treat such information with reasonable care and diligence and shall not disclose it to third parties without the disclosing party’s prior written consent, except as permitted under this Article.

13.3 The confidentiality obligations do not apply to information that:

- Is required to be disclosed to accreditation bodies, certification scheme owners, competent courts, governmental agencies or other public authorities in accordance with applicable law, court order or public regulation; or
- Was known to the receiving party prior to disclosure by the other party, or is obtained from a third party without any confidentiality obligation; or
- Becomes generally available in the public domain through no act or omission of the receiving party.

13.4 CCQS will maintain any samples provided under secure storage and will not pass them to third parties without the Applicant’s consent, except where required by law or by a competent authority.

13.5 The confidentiality obligations in this Article survive completion of the work or termination of the Agreement and remain in effect for as long as the relevant information can reasonably be deemed confidential.

14. Term and Termination

14.1 The Agreement enters into force on the date the last of the two parties signs the Individual Contract and remains in force until completion of the contracted work and any related certificate validity periods, unless terminated earlier in accordance with this Article.

14.2 Any party proposing to terminate the Agreement may do so by giving at least thirty (30) working days’ written notice to the other party. Termination becomes effective upon mutual agreement, without prejudice to any accrued rights or obligations.

14.3 Either party may terminate the Agreement by written notice with immediate effect if

- The other party commits a material breach and fails to remedy it within ten (10) working days after receiving written notice; or
- The other party becomes insolvent, is unable to pay its debts as they fall due, is subject to bankruptcy proceedings, receivership, dissolution, liquidation, winding-up, or otherwise discontinues its business.

14.4 If the Applicant cannot bring the product and documentation into a condition suitable for certification within one (1) year from the commencement of the Agreement, CCQS may terminate the Agreement without the Applicant’s consent.

14.5 CCQS is entitled to terminate the Agreement without notice for important reasons, including but not limited to:

- The Applicant’s failure to promptly notify CCQS of changes or indications of changes in the organisation relevant for certification;
- Misuse of a certificate and/or certification mark, or use contrary to the Agreement; or
- Failure to comply with the time periods scheduled by CCQS for audits or service provision (e.g. surveillance audits), such that withdrawal of the certificate is necessary.

14.6 Termination of the Agreement does not relieve the Applicant of its obligation to pay fees incurred or due for work already performed or for costs that CCQS cannot reasonably avoid.

15. Complaints and Appeals

15.1 Complaints regarding CCQS’s activities shall be submitted in writing to CCQS.

15.2 If a complaint is found justified, CCQS shall take appropriate measures.

15.3 If a complaint is considered unfounded, CCQS will inform the complainant and invite comments within ten (10) calendar days. If no amicable solution can be reached, the parties may agree to arbitration or pursue other legal remedies, as appropriate.

15.4 Appeals concerning certification decisions shall follow the CCQS Appeals procedure as set out in CCQS’s Quality Management System and applicable accreditation rules.

16. Governing Law, Disputes and Language

16.1 The Agreement, including these GT&C and all Individual Contracts, is governed by and shall be construed in accordance with the laws of Ireland, without regard to conflict of law principles.

16.2 In the event of any dispute arising out of or in connection with the Agreement, the parties shall endeavour to settle the dispute amicably. Failing such settlement, disputes shall be handled through arbitration or courts as may be agreed or required by applicable law, without prejudice to the right of any authority to intervene where required.