



eurofins



Certification Agreement

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1 Introduction

This document consolidates all the requirements of each certification scheme run by the Company. It is a requirement that the Manufacturer, in whose name the certificate is issued, agrees to these terms before the issue of each certificate and at other times when notified of updates to this document by the Company.

2 The Company

The Company is Eurofins E&E CML Limited trading as CML, whose registered office is Unit 1 Newport Business Park, New Port Road, Ellesmere Port CH65 4LZ

It is a private limited company funded by its shareholders

Fees charged to client are determined on a project by project basis, directly proportional to the estimated time taken to complete a given task plus consumable material cost. The service is provided on a non-discriminatory basis without pre-qualification of clients. Exceptions to this include but are not limited to repeated or extended delays in payment or non-payment of fees, unreasonable or repeated delays in the supply of samples or certification information, any form of abuse or attempted bribery towards Company staff or its other clients, misuse of certificates, logos and marks, failure to respond to requests for compliance.

3 Agreement

This agreement applies to all Certificates issued by the Company under the following:

ATEX Directive 94/9/EC and 2014/34EU

IECEX certification schemes

The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulation 2016 (SI 2016 No. 1107, as amended)

UKCA Radio Equipment Regulations 2017 S.I. 2017/1206

UKCA Personal protective equipment Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (Regulation 2016/425)

UKCA Machinery: The Supply of Machinery (Safety) Regulations 2008 as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

UKAS Accreditation 8175

- EU Type examination Certificate (Conformity assessment Module B)
- EC type-examination
- Quality Assurance Notification Certificate Annex IV Production QA and Annex VII Product QA,
- Certificate of Conformity Annex V Product Verification
- Type-examination Certificate Annex VIII Type Examination Certificate
- Certificate of Conformity Annex IX Unit Verification
- IECEX Certificate of Conformity
- IECEX Unit Verification
- UK Type examination Certificate, Schedule 3A Part 1, UK Type Examination Certificate or Type Examination Certificate (UKAB)



- Certificate of Conformity (Unit Verification) Noise regulations Schedule 10 (Annex VII)
- UK Quality Assurance certificate associated with UKCA regulations.
 - Radio Equipment regulations, Schedule 4 (Module H)
 - PPE Module C, C2, D
 - Machinery Annex X, Part 10 of Schedule 2),
- Quality Assurance Notification Certificate, Schedule 3A Part 2, Production QA and Schedule 3A Part 5, Product QA
- Certificate of Conformity, Schedule 3A Part 3, Product Verification
- Type-examination Certificate, Schedule 3A Part 6, Type Examination Certificate (non-UKAB)
- Certificate of Conformity, Schedule 3A Part 7, Unit Verification
- Any other certificate or document stating compliance with or identified as issued under these regulations listed.

4 Definitions

Manufacturer – An organisation (legal entity) in one more locations that carries out or controls such stages in the manufacture, assessment, handling and storage of a Product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection. The Manufacturer and appropriate identification of manufacturing location always appears on the product label without exception. Certificates are always issued in the name of the Manufacturer (s) but may be primarily identified as either the Applicant or Manufacturer depending on the certification scheme. Note that this does not exclude and agent of a Manufacturer or designer of the equipment from applying for certification. Any subsequent certificate however will be issued in the name of the Manufacturer irrespective of the owner of the part or all of the design or intellectual property. The Company shall always assume that the agent or designer has protected their rights by appropriate means.

Product – the equipment, system, component or assembly that is the subject of the Certificate

Certificate – A statement in paper or electronic form, issued under the authority of the Company that attests the compliance of a Product with stated certification scheme(s) and/or requirements of relevant normative documents.

5 General

The Manufacturer shall additionally comply with the relevant sections of the following documents that apply to the certification scheme, as amended from time to time by the issuing authority.

- BEIS Accreditation Logo and Symbols: Conditions for Use by UKAS and UKAS Accredited Organisations (February 2017) as amended. In particular, Appendix B Requirements and National Accreditation Symbols for certification bodies and the certified clients.
- Directive 2014/34/EU – Equipment and protective systems intended for use in potentially explosive atmospheres
- SI 2016 No. 1107 (as amended) – The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulation 2016
- UKCA Radio Equipment Regulations 2017 S.I. 2017/1206
- UKCA Personal protective equipment Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (Regulation 2016/425)



- UKCA Machinery: The Supply of Machinery (Safety) Regulations 2008 as amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.
- The “Blue Guide” on the implementation of EU product rules 2016. 5.4.2016
- EN/ISO/IEC 17065:2012 Conformity Assessment - Requirements for bodies certifying products, processes and services
- EN/ISO/IEC 17025:2017 General Requirements for the competence of testing and calibration bodies
- Guidance document on the ATEX Directive Transition from 94/9/EC to 2014/34/EU and with reference to the Guidelines On The Application Of Directive 94/9/EC Of The European Parliament And The Council Of 23 March 1994 On The Approximation Of The Laws Of The Member States Concerning Equipment And Protective Systems Intended For Use In Potentially Explosive Atmospheres.- 4th edition Sept 2012 updated December 2013.
- ATEX 2014/34/EU Guidelines
- IECEx 01 IECEx – Basic Rules
- IECEx 02 – Rules of Procedure

These documents describe the certification evaluation rules and procedures. On request, the Manufacturer shall assist the Company with its duties and responsibilities prescribed in relation to Certificates issued in the name of the Manufacturer.

6 Ownership

All Certificates are the property of the Company and shall be returned and withdrawn from circulation on request. On request the Manufacturer shall also cease to use References to Certificates, the Company and UKAS or other regulatory body in its literature, communications, website or other marketing material. The copyright belongs to the Company. The Manufacturer is permitted to copy the certificate but only in its entirety while the public register of certificates show that the certificate status is current or valid.

7 Conditions of Certification

The Manufacturer shall always fulfil the requirements stated on any Certificate and shall manufacture the product defined in the certificate without modification.

8 Special Conditions for Safe Use

The Manufacturer shall ensure that purchasers and users of the Certified Product are informed about in special conditions for safe use stated on any Certificate.

9 Non-conformities and Manufacturing defects

The Manufacturer shall monitor and immediately declare to the Company certified product manufacturing non-conformities and defects to the Company and implement required changes to certified products and controlled drawings as a result of a review by the Company. The Company may charge for this review. The Manufacturer shall cooperate fully and openly with any investigation by the Company. The review may include recommendation for recall of products at the Manufacturer's expense.

The Manufacturer shall immediately implement action required to correct non-conformities found during surveillance audits or as requested by the Company.

The Manufacturer shall communicate with its clients on request by the Company informing them about changes to the Product, amendments to its Certificate, its use, maintenance, or recall.



The Manufacturer shall not without consultation with the Company, modify the Product after manufacture to correct a manufacturing defect, or other fault or oversight in order to bring Products “back into compliance with the Certificate”.

The manufacturer shall also notify the Company immediately of any situation where a certified product could lead to a potential hazard. For products approved against US or Canadian standards this includes electrical safety hazards.

10 Monitoring Normative Documents

The Manufacturer shall routinely monitor normative documents and technical standards controlling marking, construction and production and promptly implement significant changes to certified products or approved certification drawings. Significant changes to the product and associated drawings and documentation shall be verified by the Company through the issue of a variation to the Certificate.

11 Surveillance

On request, the Manufacturer shall allow the Company (and its representatives) access to its premises and where relevant, the Manufacturer’s subcontractors for the purpose of routine, announced and unannounced surveillance of manufacture or product investigation. The Company may also be accompanied by observers representing regulatory bodies. The Manufacturer will be informed about observers in advance. Charges will be levied for the cost of all surveillance.

The Manufacturer shall not unreasonably deny access to the manufacturing location, relevant information or documentation for the purposes of any surveillance and shall at all times accompany auditors outside normal office environments. The costs and frequency of surveillance are available on request. The decision to initiate and repeat announced or unannounced surveillance is at the sole discretion of the Company based on reasonable grounds.

The manufacturer shall implement, without delay, any corrective or preventive actions required by the certification body to address audit actions.

12 Sample Availability

The Manufacturer shall provide additional product samples for testing on request to facilitate in the surveillance or investigation of the product manufacture.

13 Pending Changes or Updates to Product or Certification Scheme

The Manufacturer shall inform the Company about any pending changes to the certified Product design or relevant manufacturing system. The Manufacturer shall apply for a variation to the Certificate should the change to the design, or system controlling manufacture, in the opinion of the Company, require further assessment and certification. The application for a variation shall include at least a detailed written description of the changes, a declaration that no further changes will be made and two copies of the original certified drawing(s) – one unmodified and one marked-up clearly identifying the proposed changes.

The Manufacturer shall implement any actions notified to them by the Company as a result of changes to certification scheme requirements or applicable standards. The Manufacturer shall cooperate with the Company in verifying the implementation of any actions.



The Manufacturer shall appoint a person or persons responsible for liaison with the Company under this section. Refer to EN ISO/IEC 80079-34:2011 clause 5.5.1 Responsibility and Authority

14 Complaints to the Manufacturer

The Manufacturer is required to keep a record of all complaints and their resolution in relation to the certified product. This record shall be made available to the Company on request. The Manufacturer shall document and take appropriate action with respect to such complaints and any deficiencies found in the product or manufacturing system that affect compliance with the requirements for certification. The Manufacturer shall handle these deficiencies in accordance with the requirements in sections on “Non-Conformities and Manufacturing Defects” and “Pending Changes” in this Agreement

15 Payment

The Manufacturer shall pay or arrange for payment of all fees and outstanding debts owed to the Company. Non-payment of debts will lead to suspension of Certification or refusal to Certify.

16 Organisation Changes

The Manufacturer shall inform the Company of a change in its ownership or control. The Company at its sole discretion may suspend the Certificate until it is satisfied the requirement of the Certification Scheme continue to be met.

The Manufacturer shall inform the Company without delay of a change that may affect its ability to conform to the certification requirements. Such changes include but are not limited to:

Change of organisation and management (key managerial, decision-making, or technical staff)

Change of contact address or manufacturing location

Major, substantial and material changes to the quality management system affecting certification

Change of supplier of significant components or assemblies affecting certification

17 Misuse of Marks

The Manufacturer shall not use the name of the Company or its Certificates, or its marks or registration references such as notified body identification number in a misleading manner.

The Manufacturer shall not make references to the name of the Company in publicity material, articles, papers, social media, website or other literature or communication without express permission other than as provided in this agreement.

18 Permitted Use of Marks

Manufacturers are permitted to use the Company Certification marks, if any, and references to the Certificate number as displayed in the Certificate on any publicity material or website or on the Product (or packaging). The Company name or logo shall only be used in association with the relevant Certificate number. The Company notified body identification number may only be used in as prescribed on the Certificate or approved certification drawings. Where the UKAS logo is displayed in the Certificate then its use is governed by, and the Manufacturer



shall comply with, documentation published by UKAS. Advice can be obtained from the Company or refer to www.ukas.com.

19 Misrepresentation

The Manufacturer shall only make claims regarding certified products that are consistent with its Certificate and the certification scheme. The Manufacturer shall not use its product Certificate in a manner that is likely or does bring the Company into disrepute. The Manufacturer shall not make any statement about the product Certificate that the Company at its sole discretion considers misleading or unauthorised.

Upon Suspension, Withdrawal or Reduction of certification the Manufacturer shall cease to use or remove or amend inaccurate references to the certificate and certification scheme and Company or accreditation marks in any media.

20 Refusal, Suspension, Withdrawal (Cancellation) or Reduction and Extension of scope.

Reduction of a certificate scope is either at the request of the client or as required by the Company. For example, the reduction of number of products in a range or reduced function or vice versa. Reduction or extension would normally be covered by the issue of a Variation appended to the certificate. Public information would include the number and date of latest Variation to the certificate

Suspension of a certificate is normally initiated by the Company where resolution of compliance issues or technical updates are required that have not yet been completed. Certificates would normally be reinstated after corrective action has been undertaken. Certificates may also be suspended due to non-payment of any debt. Certificates may be voluntarily suspended due to cessation of manufacture.

Withdrawal (Cancellation) of a certificate is an enforcement action by the Company for failure to satisfactorily comply with enforcement communication issued by the Company. For example but not limited to non-compliance with the conditions of certificate issue or failure to implement corrective action in a timely manner, failure to cooperate in relevant investigations or reasonable requests for information or failure to provide samples and documentation for repeat testing and evaluation. Once a certificate is withdrawn, reinstatement is not possible. A new application for certification would be required.

Refusal of a certificate is the decision by the Company not to certify a product. This decision can be made at any time and may be based on but not limited to the following, inability to comply with any clause of the applicable standards, failure to provide required sufficient information or samples such that compliance cannot be assessed, test failure, production management system short-comings, non-payment for services. The Company will make a written statement of its reasons for refusing certification. The Applicant may appeal this decision, using the complaint procedure.

The public register of certificates will show the status of each certificate, withdrawn (cancelled), current or suspended.

The Company shall inform the relevant authorities (notifying authority in the case of notified body activities) of the refusal, restriction, suspension or withdrawal of certificates.



21 Confidentiality

The Company will keep all communication, documentation and contractual information confidential. This information will not be released to any third-party unless as required by law (in this case the Manufacturer will be informed of the disclosure unless the Company is prohibited to do so by law) or regulatory body governing the scheme. Information may be transmitted to outsource agents or contractors for the purposes of assessment, surveillance or maintenance of the applicable Certification scheme. All outsource agents and staff are covered by similar confidentiality requirements. The existence of an issued certificate, its amendments, validity status, issue date, the Product name and type, the name of the Manufacturer, address, website and are maintained on public registers dependent on the applicable scheme requirements.

22 Impartiality

The Company is required to maintain impartiality in relation to certification decisions. The Manufacturer shall not engage in activities that are intended to influence the outcome of any certification decision, for example, but not limited to subjecting the Company staff, associates, agents, directors, committee members and contractors to any form of direct or indirect bribery, abuse, harassment, threats, blackmail, intimidation or bullying.

23 Complaints about the Company

If the Manufacturer has cause to complain about the certification service received from the Company, they should write to the Managing Director at the Company's operating address. Details of the applicable complaint procedure, its resolution and escalation will be provided on receipt of any written complaint.