

Certification Agreement

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1 Introduction

This document consolidates all the requirements of each management system certification scheme run by the Company. It is a requirement that the Certificate Holder, 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, Newbridge 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 for Management Systems under standard and regulations.

- ISO 9001:2015 Quality Management Systems Requirement
- ISO 13485: 2016 Medical Device- Quality management systems requirement for regulatory purposes
- The Medical device Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)
- The General Product Safety Regulations 2005 (SI 2005 No 1803)

4 Definitions

Certificate Holder – An organisation (legal entity) in one or 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 Certificate Holder and appropriate identification of manufacturing location always appears on the Product label without exception. Certificates are always issued in the name of the Certificate Holder(s) but may be primarily identified as either the Applicant or Certificate Holder depending on the certification scheme.

Note: this does not exclude an agent of a Certificate Holder or designer of the equipment from applying for certification. However, any subsequent Certificate will be issued in the name of the Certificate Holder, irrespective of the owner of 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.

Activity, Product or Service – the output of the Certificate Holder

Note: The certification holder shall comply with the statutory and regulatory requirements applicable to the safety and performance of the medical devices. The maintenance and evaluation of legal compliance is the responsibility of the client organization.

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

5 General

The Certificate Holder shall additionally comply with the relevant sections of the following documents amended from time to time by the issuing authority. These documents describe the certification evaluation rules and procedures. On request, the Certificate Holder shall assist the Company with its duties and responsibilities prescribed in relation to Certificates issued in the name of the Certificate Holder.

ACCREDITATION LOGO & SYMBOLS - The National Accreditation Logo and Symbols: Conditions for Use by UKAS and UKAS Accredited Organisations (February 2024). In particular, Appendix B Requirements and National Accreditation Symbols for certification bodies and their certified clients. ([https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/727923/UKAS Accreditation Logos June18 final.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/727923/UKAS_Accreditation_Logos_June18_final.pdf))

ISO/IEC 17021-1:2015 Conformity Assessment - Requirements for bodies providing audit and certification of management systems – Part 1: Requirements

6 Ownership

All Certificates are the property of the Company and shall be returned and withdrawn from circulation on request. On request, the Certificate Holder 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 Certificate Holder 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 Surveillance

On request, the Certificate Holder shall allow the Company (and its representatives) access to its premises and where relevant, the Certificate Holder'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 Certificate Holder will be informed about observers in advance. Charges will be levied for the cost of all surveillance.

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

8 Changes or Pending Changes Affecting the Management System

The Certificate Holder 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:

- Changes to the organisation, its ownership and/or its structure,
- Significant changes in personnel (significant increase or decrease in staff) and/or changes in personnel that directly affect the management system (for example, senior management, quality manager, senior technical staff)
- Change of address
- Changes to the business that affects the scope of the certification and/or changes to the business that are required to be covered by the scope of the certification.
- Significant amendments to the management system and/or its processes

The Company shall advise the Certificate Holder should the change/s, in the opinion of the Company, require further assessment and certification.

9 Complaints to the Certificate Holder

The Certificate Holder 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 Certificate Holder 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 Certificate Holder shall handle these deficiencies in accordance with the requirements in sections on “Non-Conformities and Manufacturing Defects” and “Pending Changes” in this Agreement.

10 Payment

The Certificate Holder 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.

11 Misuse of Marks

The Certificate Holder shall not use the name of the Company or its Certificates, or its marks or registration references, such as UKAS registration number, in a misleading manner.



The Certificate Holder 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.

12 Permitted Use of Marks

Certificate Holders 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. Where the UKAS logo is displayed in the Certificate then its use is governed by, and the Certificate Holder shall comply with, documentation published by UKAS. Advice can be obtained from the Company or refer to www.ukas.com.

13 Use of Management System Certification Mark

The Company certification mark for management system certification is as follows:

	
<p>Without UKAS logo</p> <p>XXXXXXXX to be replaced by CML certificate number.</p> <p>For use by certificate holders without accredited certificate (no UKAS mark appears on the ISO 9001 certificate)</p> <p>May be used on vehicles, buildings, and flags by certificate holders with or without accredited certificate</p>	<p>With UKAS logo</p> <p>XXXXXXXX to be replaced by CML certificate number.</p> <p>For use by certificate holders with accredited certificate (UKAS mark appears on the ISO 9001/or ISO 13485 certificates)</p> <p>Not permitted for use on vehicles, buildings, or flags</p> <p>When printed on an unfolded portion of stationery sized no greater than A4, this logo shall be displayed in a size no larger than 30 mm high. On larger portions of unfolded stationery, the size may be proportionately increased.</p>

These marks shall not be used on products or associated documentation.

A statement may be used on product packaging or accompanying information, but without the use of either the certification body mark or the UKAS accreditation logo. Product packaging is defined as being that which can be removed without the product disintegrating or being damaged. Accompanying information is considered as separately available or easily detachable. Note: type labels or identification plates are considered as part of the product and are not included in this section. The statement shall in no way imply that the product, process, or service is certified by this means. The statement shall include reference to:

- Identification (e.g., brand or name) of the certified client
- The type of management system (e.g., quality, environment) and the applicable standard
- The certification body issuing the certificate.

14 Misrepresentation

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

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

15 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. Reduction or extension would normally be covered by the issue of an amendment to the Certificate. Public information would include the issue number and date of latest issue to the Certificate.

Suspension of a Certificate is normally initiated by the Company where resolution of compliance issues is 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 the business covered by the scope of the Certificate.

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 failure to implement corrective action in a timely manner; failure to cooperate in relevant investigations or reasonable requests for information or failure to provide documentation for repeat 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 Management System. 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 such that compliance cannot be assessed; other management system shortcomings; 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 complaints procedure.

The quality System Certification validity check information is included on UKAS website via this link: <https://certcheck.ukas.com/> and will show the status of each Certificate, withdrawn (cancelled), current or suspended.

16 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 Certificate Holder 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 Certificate Holder, address, and website are maintained on public registers dependent on the applicable scheme requirements.

17 Impartiality

The Company is required to maintain impartiality in relation to certification decisions. The Certificate Holder 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.

18 Complaints and Appeal

Complaints about the company and appeals against decisions made by Eurofins CML must be made in writing and, in the case of appeals, within 21 days of receipt of the Eurofins CML decision. Address your complaint or appeal to the Managing Director. Once your complaint / appeal has been received, the Managing Director will notify you of the detail of the applicable complaints and appeals procedure, including the resolution and escalation procedure.

Agreed by (Client Name)	Agreed by Eurofins E&E CML Limited
Print Name	Print Name
Position held	Position held
Signature	Signature
Date	Date