Certification Agreement

Contents

1 Introduction 2
2 The Company 2
3 Agreement 2
4 Definitions 2
5 General 3
6 Ownership 3
7 Surveillance 4
8 Audit Day Calculations for ISO 13485:2016 and UKCA 4
9 Changes or Pending Changes Affecting the Management System 5
10 Complaints to the Certificate Holder 5
11 Payment 6
12 Misuse of Marks 6
13 Permitted Use of Marks 6
14 Use of Management System Certification Mark 7
15 Misrepresentation 8
16 Refusal, Suspension, Withdrawal (Cancellation) or Reduction and Extension of scope. 8
17 Confidentiality 9
18 Impartiality 9
19 Complaints and Appeal 9
20 Unannounced Audits: 10
21 Audit Requirements: 10
22 Agreement 11

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 clients 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 or failure to respond to requests for compliance.

3 Agreement

This agreement applies to all Certificates issued by the Company for Management Systems under the following 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)

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 (September 2021). In particular, Appendix B Requirements and National Accreditation Symbols for certification bodies and their certified clients. www.ukas.com

In addition, the requirements of the use of the UKCA marking must be adhered to where the medical device is certified under the MHRA scheme. The use of these marks can be found is Using the UKCA marking - GOV.UK (www.gov.uk)

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

8 Audit Day Calculations for ISO 13485:2016 and UKCA

The audit days are defined as per the requirements of IAF MD9 - Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485) and Annex D; audit days are set based upon number of employees at each facility to be certified. These audit days may vary per certification cycle based upon any audit findings and their severity and risk to the certification and any changes to certification; for example extension or reduction to scope.

This initial agreement has been issued based upon the information supplied at the time of application and will be re-issued if any scope or site changes are required.

Company Name			
Location 1		Location 2 or critical location (if applicable)	
Employees at Location		Employees at Location	
Site Scope		Site Scope	
Initial audit days		Initial audit days	
Surveillance 1		Surveillance 1	
Surveillance 2		Surveillance 2	
Surveillance 3 (UKCA)		Surveillance 3 (UKCA)	

Surveillance 4 (UKCA)		Surveillance 4 (UKCA)	
Surveillance 5 (UKCA)		Surveillance 5 (UKCA)	
Certification Renewal		Certification Renewal	
Unannounced audit			
Technical File information (UKCA)			
Number of Technical Files held by the organisation		Classification of Device 1	
		Classification of Device 2	
Technical File review days (File 1)		Technical File review days (File 2)	

9 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 manger, 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.

10 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

11 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.

12 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 and/or UKCA 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.

13 Permitted Use of Marks

Certificate Holders are permitted to use the Management System Certification Marks (see section 14) if any, and references to the Certificate number as displayed in the Certificate on any marketing material or website or on the product (or packaging).

The Eurofins E&E CML Ltd name or logo shall only be used in association with the relevant Certificate number. Where the UKAS logo is displayed on the Certificate then its use is governed by, documentation published by UKAS, and the Certificate Holder shall comply with the advice which can be obtained from the Company or refer to www.ukas.com and Using the UKCA marking - GOV.UK (www.gov.uk).

14 Use of Management System Certification Mark

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

<table>
<tr>
<td> 
</td>
<td> 
</td>
</tr>
<tr>
<td>Without UKAS logo

XXXXXXXX to be replaced by Eurofins E&E CML certificate number

For use by certificate holders without accredited certificate (no UKAS mark appears on the ISO 9001 certificate)

May be used on vehicles, buildings, and flags by certificate holders with or without accredited certificate</td>
<td>With UKAS logo

XXXXXXXX to be replaced by Eurofins E&E CML certificate number

For use by certificate holders with accredited certificate (UKAS mark appears on the ISO 9001/or ISO 13485 certificates)

Not permitted for use on vehicles, buildings, or flags

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.</td>
</tr>
<tr>
<td> 
</td>
<td>Rules for using the UKCA Mark

You must sign a ‘declaration of conformity’ before you can place the UKCA mark on your Medical Device product.

An identification number for an Approved Body needs to be placed below the UKCA mark if it has been involved in the conformity assessment

You must make sure that:

If you reduce or enlarge the size of your marking, the letters forming the UKCA marking must be in proportion to the version set out below

The UKCA marking is at least 5mm in height unless a different minimum dimension is specified in the relevant legislation

The UKCA marking is easily visible, legible, and indelible.</td>
</tr>
</table>

The UKAS or MHRA marks or logos 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

15 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.

16 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 public register of Certificates will show the status of each Certificate, withdrawn (cancelled), current or suspended.

17 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.

18 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.

19 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.

20 Unannounced Audits:

It is a requirement of this Certification Agreement that the Approved Body will pay unannounced visits to the manufacturer and associated critical suppliers (if applicable), as part of the 5-year certification cycle for UK MDR.

At the time of such visits, the Approved Body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly, and that the production conforms to the requirements of the Medical Device Regulation 2002.

In addition, if a major non-conformance has been raised against the organisation's certification(s) this could be followed up by an unannounced visit. This is on the basis that the controls of the quality management system, subcontractors or suppliers do not meet the certification or regulatory requirements.

If the organisation refuses entry, then the relevant certificates could be suspended.

If the matter of refusal is resolved, then a re-planned job will need to be created.

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 unannounced audits are available on request. The decision to initiate and repeat unannounced audits is at the sole discretion of the Eurofins E&E CML Ltd based on reasonable grounds.

21 Audit Requirements:

The Accreditation Body UKAS and the Regulatory Approvals Agency the MHRA can on occasion request to attend the manufacture/ certification holder's premises as part of an observed or witnessed audit.

It is a requirement of this certification agreement that access must be granted to the applicable Accreditation Bodies and Regulatory Bodies when requested, these organisations can request to witness any part of the certification activities and by signing this agreement any documents or records requested, during the observed audit must be presented to the requester.

22 Agreement

In signing the agreement of Eurofins E&E CML Limited, the applicant attests that:

The rights to any certificate issued shall rest with the certificate holder stated.

They have the authority to represent, submit the request, agree terms on behalf of the applicant.

Agreed by Organisation requiring certification:

Signed By

Position held

Date

Agreed by Eurofins E&E CML Ltd

Signed By

Position held

Date