RULES OF LNE-GMED UK CERTIFICATION

Revision: 4

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1 THE CUSTOMER JOURNEY

The benefits to certification with an accredited conformity assessment body (CAB) are:

- Working with a CAB who is independently verified as competent and impartial;
- Confidence that there are established processes in place to manage the certification at all stages;
- Reassurance that there are processes to support and resolve areas of concern.

The usual steps to certification involve:

1.1 Pre-application

- A client enquiry to UKenquiries@lne-gmed.com initiates the process, or the enquiry can be passed internally from GMED or LNE;
- Collection of information from the manufacturer;
- Information analysis;
- Quote preparation and issuance.

1.2 Conformity assessment application

- Quote and contract signature;
- Application file submission by the manufacturer;
- Application file review.

1.3 Conformity assessment activities

- Planning and preparation for assessment activities;
- Assessment activities completion, including any special procedures or testing needed;
- Interim report issuance to the company;
- Action plan submission by the company, if needed;
- Action plan analysis;
- Report finalization and communication to the company.

1.4 Certification decision

- A certificate recommendation is made to independent, LNE-GMED UK decision makers;
- The certificate decision is made;
- The certificate decision is communicated to the client;
- Where a positive decision has been made, the certificate(s) are issued.

1.5 Post-certification company surveillance

- Surveillance activities, such as audits or technical document sampling;
- Control activities, such as 'for cause' unannounced visits or vigilance follow ups;
- Recertification at the prescribed interval.

2 TYPES OF AUDIT OFFERED BY LNE-GMED UK

The following types of audit are offered – some are unique to the scheme. Clients should contact their account handler or use the UKenquiries@lne-gmed.com mailbox for more detailed scheme information.

Pre-assessments: A readiness review, sometimes called a diagnostic audit – not available for all schemes, e.g. UKCA medical. Please note that undertaking this type of audit will prevent UKCA certification for 3 years.

Transfer audits: When a client wishes to move from another conformity assessment body or approved body, to LNE-GMED UK.

Initial audits: Typically split into stage 1 (documentation review) and stage 2 (implementation and effectiveness). Usually at least the stage 2 will be on-site unless extraordinary conditions are identified.

Surveillance: A typically annual review of a selection of processes and their effectiveness.

Renewal: A recertification audit typically covering all processes and leaving to the issue of a new certificate. For most schemes this occurs three yearly, but for UKCA this can be 5 yearly and type tests may be valid for longer.

Extension to scope: An audit to add additional products or processes to the certificate scope.

Close of major non-conformity: A visit conducted typically within 12 weeks of the visit that raised the nonconformity, to demonstrate that the systems have re-established compliance.

Transition audits: Audits intended to monitor the clients progress to revised normative requirements.

3 CERTIFICATION STATUS

3.1 Valid certification

After initial certification, renewing certification or expanding certification, a certification review will be conducted prior to making a decision to grant certification if:

- the appropriate duration audit has been conducted;
- the information obtained during the audit supports certificate validity;
- all major nonconformities have been closed out, and;
- the plan for correction and corrective action for all outstanding minor nonconformities have been reviewed and accepted.

For maintaining certification, the client shall continue to satisfy the requirements of the management system, regulatory or product standard applicable and LNE-GMED UK Terms of Service.

Valid certificates can be verified using the certificate database: https://lne-gmed.com/client-directory-search or by sending an enquiry to the UKenquiries@lne-gmed.com mailbox.

3.2 Refusing, suspending or withdrawing certification

Reasons for refusing, withdrawing, suspending, or narrowing the scope of a certificate by LNE-GMED UK are as follows:

- Non-compliance with contractual requirements,
- Management system is not compliant with scheme or legal requirements,
- Defined corrective actions have not been implemented after a certificate suspension,
- Refusal of the holder to undergo a surveillance or renewal audit within the timeframe set by LNE-GMED UK or its subcontractors,
- Failure of holder to honour its financial commitments,
- Use of any part of the LNE Group services in such a way that may be misleading or bring the Group into disrepute,
- Request for a cancellation of certification by the entity
- The client ceases to provide part of the services or products within the scope of certification.

LNE-GMED UK then formally notifies the holder of the suspension, reduction of scope or withdrawal by recorded delivery letter or similar arrangement such as email with attachment and mandatory receiving notice, indicating, in the first case, the terms and conditions of the lifting of the suspension, in particular the corrective measures to be taken and the suspension time established by LNE-GMED UK. Upon suspension, the client management system certification is temporarily invalid, and the client may not use certification logos or display their certificate. LNE-GMED UK or its subcontractor undertakes the verifications necessary to restore the certification, typically suspension should not exceed six months. Where applicable, suspension is lifted, and certification is back into force and the holder is notified. Should certification be withdrawn, the client must immediately cease use of all certification logos and certificates. For some schemes, this may preclude any further products being placed on the market e.g. UKCA Marking

3.3 Customer feedback: Complaints, Appeals and Compliments

Complaints and appeals can be registered with LNE-GMED UK by sending a summary of the issue, together with any relevant report or project reference numbers to UKcustomerfeedback@lne-gmed.com

3.3.1 Appeal

An appeal is a protest against an outcome of an audit or certificate decision. It must be submitted within 15 days of the receipt of the item under appeal, e.g. receipt of a non-conformity during the closing meeting, or receipt of a certificate decision. Appeals after that date will not be considered.

LNE-GMED UK will allocate an individual who is independent of the audit or decision to investigate the concern.

The concern will be acknowledged within 5 working days of receipt and investigated within 30 working days. This process may take longer if the issue is particularly complex or involves other partner organisations with whom other certifications are held.

Additional information may be requested to support the concerns identified. After the investigation, a letter summarising the outcome will be sent to the customer advising them of any further actions or next steps. The outcome of the appeal is final.

3.3.2 Complaint

A complaint is an expression of dissatisfaction with an element of the service provided by LNE-GMED UK. The concern will be acknowledged within 5 working days of receipt and investigated impartially within 30 working days. This process may take longer if the issue is particularly complex or involves other partner organisations with whom other certifications are held.

3.3.3 Compliments

Clients may use this communication medium to register their satisfaction with the service delivered. Positive feedbacks will be passed back to the individuals concerned.

4 RULES FOR USING SPECIFIC MARKS OR LOGOS

4.1 Rules for using the UKCA image

In most cases, you must apply the UKCA marking to the product itself or to the packaging. In some cases, it may be placed on the manuals or on other supporting literature. This will vary depending on the specific regulations that apply to the product.

The UKCA marking must be clearly visible and legible when you affix it to the product. If this is not possible, you must attach it to the packaging (if any) or accompanying documents.

UKCA markings must only be placed on a product by you as the manufacturer or your authorised representative (where permitted in the relevant legislation).

When affixing the UKCA marking, you take full responsibility for your product's conformity with the requirements of the relevant legislation.

You must only use the UKCA marking to demonstrate conformity with the relevant UK legislation.

You must not place any marking or sign that may misconstrue the meaning or form of the UKCA marking to third parties.

You must not attach other markings on the product which affect the visibility, legibility or meaning of the UKCA marking.

The UKCA marking cannot be placed on products unless there is a specific requirement to do so in the legislation.

A product may have additional markings and marks, as long as they:

- fulfil a different function from that of the UKCA marking;
- are not likely to cause confusion with the UKCA marking;
- do not reduce the legibility and visibility of the UKCA marking.

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.

The UKCA marking can take different forms (for example, the colour does not have to be solid), as long as it remains visible, legible and maintains the required proportions.
Note: The UKCA mark does not belong to LNE-GMED UK. Please visit the UK Government website for more information.

4.2 LNE-GMED UK Marks and Logo

4.2.1 LNE-GMED UK Logo

The LNE-GMED UK logo is registered in accordance with UK law. No-one aside from LNE-GMED UK is entitled to use this logo except by displaying and sharing reports and certificates that may contain this logo by design.

4.2.2 LNE-GMED UK Mark

The rules for the use of the mark are laid out in the Appendix.

Using this mark demonstrates to the certified client's customers that they have used an accredited conformity assessment body to assess their processes and systems in an impartial and consistent manner. This aims to provide a level of assurance that such systems:

- conform to specified requirements, for example, ISO 13485;
- are capable of consistently achieving its stated policy and objectives;
- are effectively implemented.

4.2.3 Use of the mark – graphic rules

A company whose quality system has been certified by LNE-GMED UK may use the mark only in accordance with the Graphical Charter

4.2.4 Products or services covered by the mark

Voluntary quality management system audits of organisations involved in one or more stages of the life-cycle, including design, development, production, storage, distribution, installation, servicing or decommissioning of: non-active medical devices; active medical devices; active implantable medical devices; in-vitro diagnostic medical devices, or associated activities.

4.2.5 Misuse of the mark

LNE-GMED UK reserves the right to withdraw authorization to use the mark if a certified company or entity fails to respect the rules set out above. A decision to withdraw authorization may be made at any time and will take immediate effect. Under certain circumstances LNE-GMED UK may also suspend or revoke

the company's certification. If authorization to use the mark is withdrawn, the company concerned must take all necessary steps to remove the mark from all media within a maximum period of one month. Any misuse of the mark, whether by the entity entitled to use it or by a third party, entitles LNE to bring the legal action it deems appropriate, in accordance with the legislation in force.

4.2.6 Application of the rules

These rules form part of the company's contractual obligations when it submits an application for certification.

4.3 Accreditation marks

Holders of certificates issued by UKAS accredited certification bodies may use the appropriate national accreditation symbol in accordance with the requirements of this publication on stationery and publicity material or other items relevant to their certification. The national accreditation symbol(s) shall always be used in conjunction with the logo/mark of the certification body or certification scheme (see below). Holders of accredited certificates may use the logo/mark of the certification body or certification scheme without the accreditation symbol.

Further information can be found at:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022081/guidance-ukas-accreditation-logo-and-symbols-v2.pdf

4.4 Use of marks from different parts of the LNE-GMED Group

If you have an accredited certification from another part of the LNE-GMED group that is covered by the COFRAC accreditation, rules for the use of using LNE and GMED marks can be found here:

LNE:

https://www.lne.fr/sites/default/files/bloc-telecharger/regles-usages-marques-certification-LNE.pdf

GMED:

https://lne-gmed.com/wp-content/uploads/2022/07/CERTIFICATION-RULES-G-MED-720-DM-0501-1a-rev9.pdf

APPENDIX

LNE-GMED UK CERTIFICATION GUARANTEE MARKS FOR MANAGEMENT SYSTEMS

PURPOSE

The purpose of this document is to define:

- the terms and conditions of reference to LNE-GMED UK certification for management systems and LNE-GMED UK certification of products, processes and services,
- the rules of use and reproduction of the associated LNE-GMED UK CERTIFICATION guarantee marks.

The LNE-GMED UK CERTIFICATION marks are represented as follows:

Use of the LNE-GMED UK CERTIFICATION mark, as presented above, is reserved for LNE-GMED UK.

This graphic representation will be supplemented by a range name corresponding to the activity of the company (e.g. Healthcare) and by a reference to an LNE-GMED UK certification reference system e.g. ISO 13485.

The certified entity must comply with all the elements of the graphic charter of the LNE-GMED UK Certification mark for the range corresponding to its activity, which will be sent to it by file as soon as certification is granted.

The characteristics of the management systems, processes, products and services covered by the LNE-GMED UK CERTIFICATION guarantee marks appear in each certification rules. All LNE-GMED UK certification rules are available on the website lne-gmed.com, in particular on the «QMS Certification» page available at the following address: lne-gmed.com/certification/iso

GENERAL PROVISIONS

The legal entity meeting the conditions set out in these Rules of use may benefit from the use of the LNE-GMED UK CERTIFICATION guarantee marks.

The company may refer to the LNE-GMED UK certification from the day on which it is notified of this certification by LNE-GMED UK and for as long as the certificate remains valid.

It is contractually committed to comply with these rules whenever it makes reference to this certification.

References shall never be ambiguous concerning the scope of certification (site, activities, covered processes, products or services) or the kind of certification.

Reference to LNE-GMED UK certification should be made either by producing the current certificate in its entirety or by explicitly referring to this certification, possibly with the use of the mark according to the requirements defined below.

For products, processes and services certification, clarifications can be specified in the LNE-GMED UK certification rules.

Statements on LNE-GMED UK certification shall be consistent with the certificate issued by LNE-GMED UK.

The way in which LNE-GMED UK checks the characteristics of management systems, processes, products and services and monitors the use of the trademarks for LNE-GMED UK CERTIFICATION is described in each certification rules. All LNE-GMED UK certification rules are available on the lne-gmed.com website.

REFERENCE TO LNE-GMED UK CERTIFICATION

When referring to the certification, the company shall meet the following requirements:

- comply with LNE-GMED UK's requirements when making reference to its certification status in communication media, such as websites, brochures or advertising and other documents,
- do not make or permit any misleading statements regarding its certification,
- do not use or permit the use of a certification document, in whole or in part in a misleading manner,
- upon withdrawal of its certification, cease all advertising which refers to its certified status,
- stop referring in any way whatsoever to LNE-GMED UK certification in case of suspension,
- modify any advertisement if the scope of certification is reduced,
- do not allow any reference to the certification of its management system which would imply that a product, service or process is certified by the LNE-GMED UK,
- do not imply that the certification applies to activities, sites, products, processes or services that are not covered by the certification scope,
- do not use its certification in such a manner that would bring LNE-GMED UK's reputation and / or the certification system into disrepute and thus compromise public confidence.

The right to use the marks LNE-GMED UK CERTIFICATION granted to the certified entity shall not be transmitted to a third party, either free of charge or in return for payment.

USE OF LNE CERTIFICATION GUARANTEE MARKS OR TEXTUAL REFERENCE TO LNE CERTIFICATION ON THE COMPANY'S VARIOUS MEDIA

General rules

Compliance with LNE-GMED UK's graphical charter

Reproduction of the mark must comply with the model defined in the graphical charter of the LNE-GMED UK CERTIFICATION marks.

Communication medium (Marketing and promotional merchandise are excluded)

The company may, in particular, reproduce the mark or text reference to LNE-GMED UK certification, on administrative, business and promotional documents, brochures, websites, emails, letterheads specific to the certified site, within the limits defined below:

- It must always appear with the company's trading name and the name of the site(s), products, processes, services covered by the certification.
- If the site concerned operates in other activities in addition to those covered by the certification, this field should be specified by indicating the activities covered, as specified in the certificate or by a brief description of these activities, to be defined on request by the LNE-GMED UK.
- If the company has several sites, at least one of which is not covered by the certification, only the sites involved in the field covered by the certificate can refer to LNE-GMED UK certification or use the mark.
- When the documents and communication media of the certified entity feature a trademark or refer to membership of a group/ grouping/network, the inclusion of the guarantee marks must not imply, for example through the positioning or dimensions of the logos, that the certification is associated with the trademark of the entire group/grouping/network.
- Any possible confusion with other products, processes or services, particularly with non- certified, should not exist.

Specifications for LNE-GMED UK certification - Management systems

The certificate number issued by LNE-GMED UK must be added next to the mark.

It is acceptable to refer to the certification in compliance with the principles of clarity and transparency, in particular on the scope of certification (entities, sites, activities, or process covered), on the type of management system and the applicable standard and in referring to LNE-GMED UK, the body that granted certification.

There should be no risk of confusion about the beneficiary of certification or the scope of the certification.

Reports or certificates issued by the certified entity

When testing or calibration or inspection activities are covered by the certification, reports or certificates issued by the entity as part of its activities are considered as products and, as such, the certification mark shall not be applied on these documents. However, an unambiguous textual reference may be allowed.

Products and labels affixed to the product

The mark or an accompanying text reference to the certification shall not be used on a product nor labels affixed to the product nor in any other way that may be interpreted as denoting product conformity.

Product packaging and accompanying information

The mark cannot be affixed to it.

A reference to the certification can be made on the product packaging or in the accompanying document if and only if:

- The product concerned is covered by the scope of the certification held by the entity.
- The reference includes:
  - the name and address of the certified site,
  - the type of management system and the applicable standard,
  - the name of LNE-GMED UK, entity issuing the certification.
- The statement does not imply that the product, service or process is certified by LNE-GMED UK.

These various elements must be visible simultaneously, on the same page, regardless of medium or document used.

Improper use of the LNE-GMED UK marks

Any improper use of marks or improper reference to LNE-GMED UK CERTIFICATION is subject to prosecution in accordance with current UK regulations regarding false advertising and intellectual property.

In the event of non-compliance with this document, LNE-GMED UK reserves the right to withdraw the right to use the mark at any time and may pursue sanctions through to suspension or withdrawal of certification.

The decision to withdraw the right to use the mark must be implemented immediately. All necessary measures must be taken to remove the mark from any medium within a maximum of 3 months.

Any delay in implementing this measure or any improper use of the Mark, whether by a holder or a third party, shall entitle LNE-GMED UK to institute any legal proceedings that it considers appropriate, in the framework of applicable legislation.

Ownership of the Guarantee marks

The owner of the LNE-GMED UK CERTIFICATION marks is the LABORATOIRE NATIONAL DE METROLOGIE ET D'ESSAIS, a public industrial and commercial establishment, 1 rue Gaston Boissier, 75015 PARIS.

The goods and services covered by the LNE-GMED UK CERTIFICATION marks are listed in Appendix of this document.

In accordance with UK law, LNE-GMED UK declares to be a legal entity that is neither a manufacturer, importer nor seller of the products or services.

LNE-GMED UK is UKAS accredited. Accreditation numbers and corresponding certificate schedules are available on https://certcheck.ukas.com/

Application

The present rules are applicable as from the date on which they were signed. They supersede all previous revision of the Specific rules for use of the LNE-GMED UK guarantee marks LNE-GMED UK CERTIFICATION for management systems.

The LNE-GMED UK CERTIFICATION guarantee marks are registered at the INPI (French National Institute of Industrial Property) as well as the rules of use.
These rules of use are approved and revised by the Quality and Accreditation Director of LNE-GMED UK.