RULES OF LNE-GMED UK CERTIFICATION

Revision: 1

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LNE-GMED UK Ltd. • Suite A, First Floor East Wing, focus 31 - Mark Road - Hemel Hempstead - Hertfordshire - HP2 7BW - United Kingdom • lne-gmed.com

1 THE CUSTOMER JOURNEY

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, eg UKCA medical.

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.

Some schemes require the use of the certificate number on documentation or products. This should be used exactly as it appears on the certificate.

Valid certificates can be verified 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 marks 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 marks and certificates.

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, eg 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

There are no authorised certification marks associated with non-medical products at this time.

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 certification of a management system by LNE-GMED UK also indicates that the product, service or process is certified by LNE-GMED UK.

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 Group

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

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

https://lne-gmed.com/wp-content/uploads/2020/01/CERTIFICATION-RULES-G-MED-720-DM-0501-1a-der_.pdf