GUIDE

HOW TO CHANGE YOUR APPROVED BODY TO LNE-GMED UK IN 8 STEPS

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LNE-GMED UK property document - UKMED 0100-3 rev 0

LNE-GMED UK
LNE GROUP

TABLE OF CONTENTS

THE PROCESS FOR ALL CERTIFICATIONS: UKCA MARKING, ISO 13485
(INCLUDING CLASS III APPLICATIONS, EXCLUDING VERIFICATION AND BATCH RELEASE ROUTES)

Are you considering changing your Approved Body (AB) for the purpose of placing your medical devices on the market? Or perhaps your Certification Body (CB) for ISO 13485?

Within the constantly changing regulatory framework, more and more companies are requesting the transfer of their certificates to an Approved Body that has the experience to support their regulatory journey.

In this guide, you will find the various steps of the Approved Body change and the list of elements requested to be eligible for the transfer process. At the end of the guide, a list of frequently asked questions will help you to gain an in-depth understanding of the procedure.

Should you have any questions after reading this guide, our team is available via UKenquiries@lne-gmed.com to provide you with any assistance you may need.

1 → Pre-requisites

To ensure an optimum AB change process, please ensure that:

- The certificate is valid and has at least 14 months until expiry as of your transfer application date. Less may be possible for ISO 13485, but the more notice we have the more seamless we can make the process;
- The sites addresses will have to be the identical that those described on your current certificates at the time of the effective date of change of Approved Body;
- The UKCA certificate was issued by an Approved Body whose designation has not been suspended and will be not be suspended during the transfer period;
- The ISO 13485 certificate is issued by an IAF signatory and a certification body whose accreditation has not been suspended and will be not be suspended during the transfer period;
- The scope of the new certificate will be identical to that of the certificate being transferred;
- You provide written authorization for the communication of information between LNE-GMED UK and the AB that issued your current certificate;
- Reports made by the issuing Approved Body are all in your ownership and are available in English. These reports are audit reports, assessment reports of the conformity of the product, or the reports of competent authorities.

Other elements are prerequisites; they are determined according to your medical devices and according to their class. We are at your disposal to indicate the specific prerequisites to your devices.

II DETAILED PROCESS OF TRANSFER TO LNE-GMED UK

1
- First contact with LNE-GMED UK
- By phone / remote meeting, e-mail: UKenquiries@lne-gmed.com

2
- Complete online Application Form via supplied link
- In addition the form « Eligibility of the application for changing the Approved Body »

3
- Transmission of the « elements to provide » check list. See below for examples
- Offer submission for eligibility and transfer review, with estimate timetable for Approved Body change

4
- Receipt of your order
- Receipt of elements requested
- Assignment of your Certification Project Manager, who will support you throughout the transfer process

5
- ISO 13485 only: Completion of remote documentary review for eligibility and then transfer
- UKCA: Completion of eligibility review and QMS and technical document transfer review

6
- Communication from LNE-GMED UK about transfer decision
- Offer submission for full certification cycle
- Timetable confirmed: additional elements requested, contact with outgoing AB/CB

7
- Issuance of LNE-GMED UK certificates
- The certificate(s) will start on a date agreed with you, LNE-GMED UK and the outgoing Approved Body and will be valid until your previous certificate's expiry date

8
- Continuation of the normal audit cycle

FREQUENTLY ASKED QUESTIONS

N°	Question	Answer
1	**Why change Approved Body?**	With continuously changing legislation and ever more pressing client expectations, the choice of Approved Body is crucial in order to respond to such developments and also to ensure that you are able to place your products on the market in optimum conditions. LNE-GMED UK, an Approved Body, can call on more than 20 years of regulatory knowledge and experience from its headquarter GMED, as well as UK based staff with a combined regulatory and product knowledge of more than 60 years, including specific experience of working with UK regulators and being founding members of Team-AB.
2	**What is the best moment in the certification cycle to transfer your certificates to LNE-GMED UK?**	You may change Approved Body at any time, provided all the pre-requisites are complied with. Few Approved Bodies try to prevent such a move, but you should check your current certification contract regarding any notice periods. We recommend that you take such steps to ensure at least 14 months prior to the expiry date of your certificates.
3	**Can I change the scope on transfer?**	No, when you make a transfer the scope of the new certificate will be identical to the one already in place. However, you may extend the scope once the transfer process has been completed.
4	**Can I break my contract in mid-cycle?**	Every contract imposes specific terms of cancellation; please examine your own contract. In our experience, our new clients have not encountered any difficulties when cancelling their contract, providing the appropriate notice is given.
5	**Will I be penalised by my Approved Body if I break my contract mid-cycle?**	Every contract imposes specific terms of cancellation; please examine your own contract.
6	**Do I have to undergo a new initial audit?**	If your application fulfils the pre-requisite conditions, LNE-GMED UK will continue with the current certification cycle. Otherwise, or in accordance with the conclusions of the certification decision makers, LNE-GMED UK will propose a new certification cycle.

III FREQUENTLY ASKED QUESTIONS (continued)

N°	Question	Answer
7	**How long does the transfer process last?**	From the first contact, and according to the number of concerned standards or regulations, the number of devices concerned by the UKCA marking and their class, a schedule of the corresponding services will be proposed to you. Non-supply of requested documentation or undisclosed issues that are subsequently identified may delay the transfer.
8	**How much will it cost me?**	The rate to change an Approved Body is linked to the number of the concerned standards or regulations, sites and employees number concerned by the scope and depending of medical devices covered by the UKCA mark and their classes. Please contact us to obtain our offer.
9	**When must I inform my current Approved Body of the transfer?**	When you are taken on by LNE-GMED UK, your Certification Project Manager will advise you about this step and the appropriate timing. Once you have accepted our offer, a 3-way notification will take place between you, LNE-GMED UK and your outgoing Approved Body. However, you must forward to LNE-GMED UK a registered letter or email with acknowledgement of receipt announcing the cancellation of the contract with your former Approved Body (cancellation date to be agreed with your LNE-GMED UK Certification Project Manager).
10	**Does a documentary or on-site transfer audit take place?**	Our transfer process systematically includes a documentary audit for ISO 13485 but typically an on-site audit for UKCA QMS certificates. Technical documentation will also be reviewed remotely. Once completed, and assuming approval is given by the certification decision makers, we will automatically continue with your audit cycle. Should approval not be given, further on-site audit may be required and/or a documentary review, depending upon the issue identified.

III FREQUENTLY ASKED QUESTIONS (continued)

N°	Question	Answer
11	**What happens to my stock?**	Any stock transferred to a distributor or made available at health establishments (on hire) is considered to be on the market. In accordance with NBOG-BPG-2006-1 of 1 November 2008, the transition period between the marking issued by the former Approved Body and the marking issued by the new Approved Body should not exceed six months. However, each situation is treated on a case-by-case basis.
12	**Which documents are requested?**	During review of the transfer certain documents will be requested from you. This list is specific to the standards concerned by the Approved Body change: Voluntary certification as ISO 13485 and/or UKCA mark according medical device regulation. See example list below, but others may be requested depending upon any issue identified.
13	**When can I affix the LNE-GMED UK number?**	When you become a client you will receive technical support from a Certification Project Manager who will guide you through this step of the transfer and will agree with you a provisional date for the issue of the new certificates. This synchronisation is required to enable you to optimise your stock management and to update your internal documents. On receipt of the certificate, you may affix the LNE-GMED UK number 8521 under your UKCA mark where appropriate and in line with the rules of use.

IV DOCUMENTS TO SUPPLY

Some of these documents will be requested early on in the process in order to conduct a basic eligibility check. Once you proceed to the transfer step, additional documents will be requested. Your Certification Project Manager will keep you informed of which document you should submit.

ISO 13485 only	UKCA Marking
• Valid ISO 13485 certificate from IAF signatory; • QMS certificates of any critical subcontractors; • Description of sites and activities that are within scope of the certificate; • QMS audit reports for all visits conducted by the CAB/AB up to and including the last recertification (this may be the initial certification); • Application form; • Description of complaints received within the last 12 months and summary of measures taken; • Statement explaining the reasons for transfer; • Acceptance of the corrective actions for all open NCs; • Confirmation of closure for any major NCs; • Statement confirming that the certificate is not suspended or under threat of suspension or withdrawal; • Confirmation that you are not in legal dispute with any regulatory bodies; • Confirmation that there have been no significant changes since the last assessment; • Quality manual; • Confirmation that you are happy for the transfer to proceed and for LNE-GMED UK to contact the outgoing certification body.	Relevant documents for ISO 13485, in addition to the below list: • Valid UKCA certificates for the products under review, with a minimum of 12 months expiry; • All technical documentation reviews, including unannounced audits, scope extensions, sterilisation and clinical / performance evaluation reports, for the certification cycle in progress, including the last renewal; • If any products are not covered by the above sampling, then the last report conducted on the product in question; • The technical documentation for the products selected for sampling; • The certification for the products; • Completed eligibility questionnaire information forms / Application form; • Action plan and draft IFU/labelling and declaration of conformity demonstrating LNE-GMED UK UKCA mark/number; • PMS summary outlining date of first placing on the market, volumes sold, vigilance event history and actions taken following such incidents; • In the case of a device with materials of animal origin: evidence of consultation to Regulation (EU) No 722/2012, copies of TSE certificates, where relevant, and acceptance by the Approved Body; • In the case of devices that incorporate a medicinal substance: reports and opinions relating to the evaluation of usefulness of the substance; • In the case of Annex II list A IVDs, the final review procedure for the verification of manufactured products; • Signed tripartite agreement; • Confirmation of the cancellation of the UKCA certificate with the outgoing body at the appropriate time.

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