



# Guide

## How to change your Notified Body to GMED in 8 steps

**August, 2019**

**Document property of GMED**

- **The process for all certifications**
  - **CE Marking, ISO 13485, ISO 9001 -**
  - (Including Class III applications, excluding EC verification and batch release)**

Are you considering changing your Notified Body (NB) for the purpose of placing your medical devices on the market?

Within the constantly changing regulatory framework and in view of uncertainties regarding the future of certain Notified Bodies, more and more companies are requesting the transfer of their certificates to a reliable Notified Body.

Each process for the transfer of Notified Body is different. A guide has been specially designed for this purpose describing the various stages which make up the NB transfer process to GMED.

In this guide, you will find the various steps of the Notified Body change and the list of elements requested to be eligible at 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:

- E-mail at [medical.gmed@lne-gmed.com](mailto:medical.gmed@lne-gmed.com)
- Telephone on +33 (0) 1 40 43 3700

to provide you with any assistance you may need.

### **Pre-requisites:**

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

- The certificate is valid and has at least 14 months until expiry as of your transfer application date.
- 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 Notified Body.
- The certificate was issued by a Notified Body whose accreditation has not been suspended and will be not 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 GMED and the NB that issued your current certificate.
- Reports made by the issuing Notified Body are all in your ownership and are available in English and/or French. 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.

## • Detailed process of transfer to GMED



## • Frequently asked questions

N°	Question	Answer
1	Why change Notified Body?	<p>With continuously changing legislation and ever more pressing client expectations, the choice of Notified 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.</p> <p>GMED, a Notified Body with particular expertise in the medical devices field for over 20 years, is able to provide you with the support you require to improve your regulatory practices and to enhance the quality of your products and services.</p>
2	What is the best moment in the certification cycle to transfer your certificates to GMED?	<p>You may change Notified Body at any time, provided all the pre-requisites are complied with. Few notified bodies try to prevent such a move, but you should check your current certification contract regarding any notice periods.</p> <p>We recommend that you take such steps at least 14 months prior to the expiry date of your certificate.</p>
3	Can I change the scope on transfer?	<p>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.</p>
4	Can I break my contract in mid-cycle?	<p>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.</p>
5	Will I be penalised by my Notified Body if I break my contract mid-cycle?	<p>Every contract imposes specific terms of cancellation; please examine your own contract.</p>
6	Do I have to undergo a new initial audit?	<p>If your application fulfils the pre-requisite conditions, GMED will continue with the current certification cycle.</p> <p>Otherwise, or in accordance with the conclusions of the certification committee(s), GMED will propose a new certification cycle.</p>

N°	Question	Answer
7	How long does the transfer process last?	<p>From the first contact, and according to the number of concerned standards or regulations, the number of devices concerned by the EC marking and their class, a schedule of realization of the corresponding services will be proposed to you.</p> <p>The various chronological stages of the transfer are:</p> <ul style="list-style-type: none"> <li>- Check of the eligibility of your request</li> <li>- One or several documentary reviews of transfer,</li> <li>- Opinion of the selection panel and decision of certification</li> <li>- Issue of one or several certificates</li> <li>- Continuation of the cycle of audit and the evaluation</li> </ul>
8	How much will it cost me?	<p>The rate to change a notified 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 EC mark and their classes. Please contact us to obtain our offer.</p>
9	When must I inform my current Notified Body of the transfer?	<p>When you are taken on by GMED, 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, GMED and your former Notified Body. Your former Notified Body will be informed via this process. However, you must forward to GMED a registered letter with acknowledgement of receipt announcing the cancellation of the contract with your former Notified Body (cancellation date to be agreed with your GMED Certification Project Manager).</p>
10	Does a documentary or on-site transfer audit take place?	<p>Our transfer process systematically includes a documentary audit. Once completed, and assuming approval is given by the certification committee, we will automatically continue with your audit cycle.</p> <p>Should approval not be given, an on-site audit may be required and/or a documentary review.</p>

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 Notified Body and the marking issued by the new Notified 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 referential concerned by the Notified Body change: Voluntary certification as ISO 9001 or ISO 13485 and/or EC mark according medical device regulation. Please contact us to obtain the corresponding list of documents requested.
13	When can I affix the GMED 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 GMED number 0459.

## FOR MORE INFORMATION

<p><b>In Europe:</b>            1, rue Gaston Boissier            75015 Paris • France            +33 (0)1 40 43 37 00  <a href="http://www.gmed.fr">www.gmed.fr</a>  <a href="mailto:medical.gmed@lne-gmed.com">medical.gmed@lne-gmed.com</a></p>	<p><b>In the United States:</b>            6550 Rock Spring Drive, Suite 280,            Bethesda, MD 20817 • USA            +1 (301) 495-0477  <a href="http://www.LNE-america.com">www.LNE-america.com</a>  <a href="mailto:gmedna@lne-gmed.com">gmedna@lne-gmed.com</a></p>
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