



**LNE/G-MED North America, Inc.**  
*Your Global Quality Partner*



## Simply Switching your Notified Body

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Even though it may seem counterintuitive, it is quite simple to change notified bodies (NB). Manufacturers can change notified bodies when they go through a merger or acquisition with another company or the manufacturer's divestment. Sometimes, manufacturers may wish to find a notified body that offers a service that is more adapted to their needs and business plans. Regardless of the reasons, LNE/ G-MED's (a subsidiary of LNE) streamlined transfer process makes it painless for manufacturers to change notified bodies.

### Important Documents Governing Transferring Notified Bodies

There are two international documents that provide rules and guidelines for both NBs and manufacturers when switching NBs. The International Accreditation Forum (IAF)<sup>1</sup> created the *IAF Mandatory Document for the Transfer of Accreditation Certification of Management Systems*, which went into effect in 2008. According to the [Document,] it provides "...normative criteria...[and] minimum criteria for the transfer of certification."<sup>2</sup> Even though the *Document* was created for voluntary management systems certification programs, it can be used as a basis for other programs as CE Marking certification process. The *Document* lays out the minimum requirements for transferring NBs, including the accreditation of the certification body, the extent of the pre-transfer review, and requirements for the transfer process.

Dedicated to the CE Marking certification process, the Notified Body Operations Group (NBOG)<sup>3</sup> promulgated a set of [guidelines] that provide Notified bodies and manufacturers a background and outline the situations where a change may occur and the process of changing.<sup>4</sup> LNE/G-MED follows these two documents closely to better serve its clients when helping prospective clients to switch NBs.

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<sup>1</sup> According to the *Document*, "The International Accreditation Forum, Inc. (IAF) operates programs for the accreditation of bodies that provide conformity assessment services. Such accreditation facilitates trade and reduces demand for multiple certification."

<sup>2</sup> IAF MD2:2007 0.1, 0.3.

<sup>3</sup> The NBOG's objective is, "To improve the overall performance of Notified Bodies in the medical devices sector by primarily identifying and promulgating examples of best practice to be adopted by both Notified Bodies and those organisations responsible for their designation and control."

<sup>4</sup> NBOG Best Practice Guide, 2006-1.

## Reasons to Change Notified Bodies

NBOG outlines some reasons for switching notified bodies, drawing a line between situations where the change is voluntary or involuntary for the manufacturer. A voluntary change is when a manufacturer is willing to switch notified bodies, whereas an involuntary change is when the notified body can no longer provide services. Involuntary changes are those where the NB itself either loses its designation or the NB withdraws its designation from its national competent authority. In these cases, the previous NB has the duty to inform the manufacturer at the earliest possible moment of their actions and until when the manufacturer's certificates are valid. This includes cases in which a certificate may be invalid immediately as a result of the previous NB's inadequate audits.

Because the EU regulatory requirements have a direct impact on the products and the QMS processes, both keys to a manufacturer's success, a manufacturer may be fearful of changing their notified body. Switching notified bodies should not, in fact, change anything with regard to the previously-certified product, provided the notified body issued valid certificates. According to NBOG, the notified bodies must agree to the extent the old NB's identification number can be used attached to the CE marking on the product and the labeling. There is no need to re-label any existing product, as the NBOG also states that the CE marking done by one body is exclusive to those products. New or newly manufactured devices must display the new notified body's identification number (0459 for LNE/G-MED), but there should be no reason to re-label duly CE-marked devices.

## Prerequisites for Transferring Notified Bodies

Keeping in mind the safety and health purposes of the EU regulation, it is in the best interest of all parties involved to work together to figure out and find appropriate solutions on the various aspects to cover in switching NBs. The NBOG outlines some points in particular that should be discussed between the two NBs and the manufacturer:

- When the existing certificates' become void;
- The duties of the manufacturer to inform each NB of any notifications, when the transfer starts and when it is complete;
- The manufacturer's duty to work with each NB to determine when and how the manufacturer will re-label any devices that need it;
- Which party has the responsibilities regarding conformity assessment tasks and a quality system survey;
- Which party has proprietary rights of any intellectual property;
- How much transferring will cost for the manufacturer.

To transfer NBs, a manufacturer should have some documents and certificates at the ready for the new NB to validate. Additionally, there are a few more prerequisites for a manufacturer to transfer NBs. To transfer NBs, the manufacturer must have:

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- Valid certificates for the products;
- The address for the manufacturing sites, which must be the same as those on the valid certificates
- The devices must be within the same scope of the previous certificates;
- There must be no threat to the certificates, meaning the certificates must not be predicated on fixing non-conformities; and
- There is enough time to transfer the certificates.<sup>5</sup>

Sometimes, manufacturers may not be able to provide all these necessary documents. [Contact us] to talk to one of our expert technical staff for more information on how to transfer notified bodies.

### **Important Documents to Include**

When transferring NBs, the manufacturer should include in their file:

- All current cycle audit reports from the previous notified body including the report of any non-conformities and the action plan to fix any non-conformities and the EC product reports (Type examination, Design Examination)
- All appropriate EC certificates;
- A letter from the manufacturer effectuating the transfer; and
- A report of any adverse events, like customer complaints and recalls, since the last audit.

These documents give the new NB a full view of the products and QMS involved to provide manufacturers the best and most efficient transfer process. Note that the new NB may require additional assessments (like an on-site audit).

Switching notified bodies need not be a repeat of the hassle that causes manufacturers to want to switch in the first place. This is a result of LNE/G-MED's streamlined technique for transferring a manufacturer's notified body and its dedication to customer service, making transferring to a superior notified body easy and pain-free. For more information on changing notified bodies and how LNE/G-MED can help, [contact us](#) to speak to one of our expert technical team.

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<sup>5</sup> IAF MD2:2007 2.2.1.