How to Select or Change Your European Notified Body

Things to consider before choosing your medical device CE Marking auditing and certification partner.



Author
Jaap Laufer, MD, PharmD
EMERGO
Vice President, of Regulatory and Clinical Affairs
jlaufer@emergogroup.com

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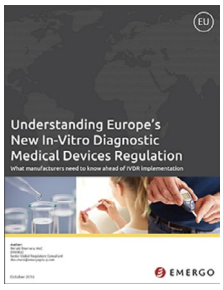
What Is a Notified Body (NB)?

The selection of a Notified Body is a crucial step for obtaining CE Marking and registering your medical device for sale in the European Union. This article will cover key considerations for medical device manufacturers during their search for a suitable Notified Body, as well as what to do if and when it becomes opportune to find a new Notified Body.

Note: *we will discuss the upcoming Medical Devices Regulations (MDRs). Even though the MDR and IVDR (In Vitro Diagnostic Regulations) have not been finalized at the release of this article, we expect the sections and paragraphs pertinent to Notified Bodies will not change materially. If a significant change vis a vis the current MDD is anticipated, we will highlight it.*

A Notified Body (NB) is an accredited organization recognized by the European Union to audit quality management systems to an applicable standard (such as ISO 13485). They also review medical device Technical Files or Design Dossiers to ensure they comply with Directives such as the MDD 93/42/EEC, AIMD 90/385/EEC, and IVDD 98/79/EC. If the manufacturer passes the QMS audit and the device review process, the chosen NB issues a certificate verifying the company's compliance with applicable EU laws and regulations. Notified Body involvement is required to obtain a CE certificate of compliance for all devices (except for Class I non-sterile or non-measuring) and combination products with both medical device and pharmaceutical characteristics, if the Principal Intended Action does not place it in the remit of the Medicinal Products Directive (MPD).

Most medical device manufacturers looking to enter the European market are required to hire a Notified Body (NB) as part of their commercialization and compliance processes. Specifically, manufacturers of Class I Sterile and/or Measuring, IIa, IIb, or III devices must meet this requirement; manufacturers of active implantable devices must also hire NBs for CE certification. This requirement will stay virtually unchanged under the MDR except for Class I reusable surgically invasive devices that will get a similar status as Class I – sterile and measuring. Manufacturers of IVDs currently in Annex II List A or List B and self-tests are also required to hire a NB. This will change significantly under the new In Vitro Diagnostic Regulation (IVDR), with the vast majority of IVD manufacturers required to use a NB.



Learn more about Europe's IVDR

Download our new white paper Understanding Europe's New In Vitro Diagnostic Medical Devices Regulation for details about the change in classification and conformity assessment procedures for IVDs.

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Notified Body vs. Registrar

Before discussing NB selection further, we should distinguish between the terms "Notified Body" and "Registrar." These terms are often used interchangeably in the US, but they are not the same: NBs are authorized to conduct ISO 13485 quality system audits *and* issue CE certificates, while Registrars are authorized *only* to conduct ISO 13485 audits, *not* issue CE certificates. Many companies have found out the hard way that their Registrars charge considerable fees for ISO 13485 audits but are unable to issue this essential CE certificate.

In 2014, there were over 70 NBs available. Since then, three factors conspired to rapidly reduce their number:

- In the wake of the PIP scandal, the EU Commission (COM) formulated an action plan to increase the monitoring of notified body performance, notably with respect to their competence versus their scope. The tool for the supranational surveillance of NBs is the dreaded Joint Audit Team (JAT), which comprises at least two auditors from different Member States, a COM observer, and sometimes a representative of the national NBs' association. The resulting non-compliance observations drove a number of NBs out of existence, as implementing of the remedial actions proved to be too costly.
- In other cases, the inability to hire adequate staff to remedy the observed lack of competence, the absence of a regular "unannounced audit" program, or other major faults drove the fusion of two NBs, or the takeover of one. In many cases, such a planned fusion enabled a reasonably well-controlled management of Certificates (see below).
- The new MDRs demand a re-notification of all NBs under the new regime. Even those NBs currently operating "under the radar" will be scrutinized and some may not survive. Also, the re-notification process will be prolonged due to the lack of competent auditors within the CAs that constitute the JAT. We have seen a number of NBs backing out pre-emptively for this reason.
- Finally, there is the ill-defined area of semi-obliteration of a NB, where they demonstrate inability to comply with mandatory audit schedules. Emergo has seen a fair number of these situations, often early indications that a NB is on its way out.

For quite obvious reasons, a company wishes to ensure optimal reliability in its choice of a NB. Over the last year we have interviewed and tried to assess the actual and probable future scopes of a number of NBs. While this is no guarantee of survival or a timely certification, the most widely known and largest NBs for medical devices in Europe include: British Standards Institute (BSI), DEKRA, LNA-GMed, LRQA and TUV PS. Smaller, reputable NBs operate in Europe as well, and may also warrant consideration during a NB search. But, as explained below, an abundance of caution befits this pivotal selection.

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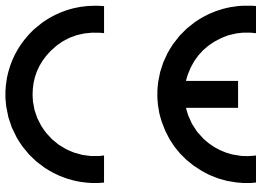
Considerations for an Effective NB Selection

Evaluating NB partners should involve much more than cursory pricing considerations or accidental proximity. You will have to employ the NB's services for years to come, so adequate service levels and a good understanding of your products and the market locations are crucial factors. Low pricing is actually becoming obsolete, for reasons explained before: demand is steeply increasing while supply is significantly reduced. In addition, a longer review time due to unavailable reviewers at a smaller NB could negate any price difference.

Below are some high-level recommendations for conducting an effective NB search:

- **Where are you based?** Consider all your locations and their importance for certification. Make sure your NB has a strong presence close to the location that is likely to be audited the most.
- **Consider your future plans.** Do they include expansion into other markets such as Canada, Brazil or Japan? Not all European NBs operate on an international level. If you intend to go global, NBs that can support certification and registration in multiple markets will make better candidates. In addition, not all NBs have MDSAP capabilities (see below).
- **Beware of "partners."** Smaller NBs or Registrars that have partnered with NBs to offer CE services may say they can support you in markets beyond the EU. But ask whether the Registrar or NB actually has a presence in those other markets or has instead formed a partnership with other firms in those countries. Dealing with both your Registrar or your European NB, and its partner in another market means two hands in the cookie jar—which leads to more expenses and potential management problems. If your business plan calls for (near) global presence, selecting a NB with a global reach may be more expensive, but is usually worth the extra cost.



- **Bigger is usually better—but not always.** Depending on the company's business goals, having a large brand-name NB associated with your device can have a direct impact on your ability to secure new contracts with overseas firms. People pay more attention to—and pay more for—established brands. In addition, larger NBs have the ability to withstand challenges by national competent authorities (NCAs) and the re-notification JAT in the case of classification disputes and compliance related issues. On the other hand, some mid-sized European NBs can offer faster, less expensive services for manufacturers whose business plans are focused primarily on the EU and whose products do not represent significant challenges. Finally, some mid-size NBs offer specialized scopes, which may speed up certification.
- **Identify your service needs.** Make sure the NB you choose can provide the service you require now, as well as provide services for future products and markets. Does the NB respond to your calls and emails fast enough? How long will it take the NB to conduct your QMS audit, review your Technical File or Design Dossier, and issue your CE Marking certificate? Many NBs in Europe use contract auditors and their ability to control contractors' schedules can be limited. In addition, the use of contractors will be limited under the MDRs. These are all important issues that can be difficult to ascertain during your NB selection process. Ask for non-competitor references, and call them. If a NB is unable to perform its audits as scheduled, this should prompt a quick review of its continued suitability for your company.
- **Extra fees.** Nobody likes to be surprised by extra fees. Before making your NB selection, ask the NB if it charges any special administrative, renewal or address change fees if these are not clearly defined in their proposal. Who bears the cost if the NB reneges on its obligatory audit schedule, your certificate lapses, or you have to suspend sales? How much would it cost to get extra copies of your CE certificate? Once you sign your NB contract and have gone through the certification process, you will have no choice but to pay those fees—better to know about them now rather than later.
- **Experience.** If possible, select an NB that has experience with your medical device. Ask the NB you are considering whether it has experience with your specific device type—especially if you manufacturer a Class IIb or III higher-risk device.

Are All Notified Bodies Equally Qualified?

Theoretically, all Notified Bodies are equally qualified. But consider this: Medical Devices Directive 93/42/EEC lays out criteria for Notified Bodies, particularly in Annex XI. Lately, the European Commission has taken measures to strongly enforce the consistency of the designation and monitoring of NBs by EU member states, including but not limited to the JAT enforcement mentioned above. In addition, relevant regulations have been issued to address the inequalities and create a level playing ground for NBs. *Always verify* whether your preferred or actual NB is still in good standing, especially for the product and classification you are seeking to CE mark. If in doubt, Emergo can inquire on an anonymous basis for you.

The Notified Body Code of Conduct (CoC) is another factor to consider. The CoC is a semi-voluntary initiative developed to reassure manufacturers that all CE certifications and quality system audits performed by NB signatories fully comply with European Medical Device Directives. Have the NBs you're considering signed on to the Code? If the NB did not sign the CoC, then it cannot be a Member of Team NB, the "trade association" of NBs. That does not bode well for its future.

Reviewing proposals from Notified Bodies

Once you've narrowed your list of possible NB partners and received proposals from two or three of them, you'll see that prices vary. Your price quote depends on several factors: your company size, number of locations, complexity of operations, availability of auditors, device classification and complexity, and the NB's prior experience with your device type. These factors significantly affect the number of audit days at your site and the time needed to review your Technical File or Design Dossier.

NB price quotes usually include charges for your registration audit as well as annual or semi-annual surveillance audits, depending on your preference. Travel costs are another consideration and are not usually included in quotes. Ask up front about your auditor's location because you do not want to be surprised to learn you have to fly your auditor from Europe to your inspection site in the United States.

In general, larger NBs charge higher fees than smaller ones because they have more overhead, and bear higher costs for maintaining their accreditation from their governing Competent Authorities. Furthermore, auditors for larger NBs need extensive training to maintain their knowledge of European regulations as well as those in Japan, Canada, Australia, and/or other markets where they are active.

If a NB is certified to participate in the MDSAP quality system program, they may charge higher fees for the QMS certification. A larger NB also has more clout when a problem has been identified by a NCA and tends to have more in-house device knowledge. It usually pays off to have Emergo screen an offer by a NB, unless you feel confident in your choice. Finally, it is essential to adequately asses the viability and future of your preferred or actual NB.

Switching Notified Bodies

Relationships do not always work out, even in the medical device industry. If you are stuck with a Notified Body that is unresponsive, offers poor customer service, or is unsatisfactory in other ways, you *do have the option* of replacing your NB. Typical reasons for changing NB include:

- **Consolidation or divestment:** When a medical device manufacturer is divested or subsumed by another company that may have another NB, it may actually be a good time to consider switching to the same NB.
- **Acquisition of product lines:** When a device manufacturer acquires a line of products with CE Marking through a different NB, it may make more business sense for the acquiring company to switch its entire product line over to that NB for greater efficiency or regulatory compliance purposes.
- **Lack of global reach:** In cases where a manufacturer wants to expand into another market, two or three Australia, Brazil, Japan, or the United States, but its NB does not offer ISO 13485:2016 certification in accordance with the requirements in these markets, that manufacturer would be better served by a NB that can support such expansion plans.
- **Poor customer service:** Lengthy review delays and response times from your NB can cause frustration and disrupt sales. Although responsiveness and review times should be defined at the beginning of your NB relationship, agreed-upon communication and support levels sometimes are not met. The situation is far worse when the NB is incapable of keeping its mandatory time frame for surveillance or re-certification audits. Unfortunately, Emergo has experience with manufacturers who did not pay proper attention to such a deficient performance, often with costly consequences.
- **Involuntary change of NB:** Some NBs have lost their notification and can no longer provide certification and auditing services, in which cases manufacturers must seek out new NB partners in an emergency mode. This situation has become so serious that several CAs have issued publicly available remedial actions.

Logistical Considerations

Before beginning the process of switching Notified Bodies, you should consider the logistical requirements of doing so described in the European Commission's Notified Body Operational Group (NBOG) Guidance 2006-1. First and foremost, manufacturers are not permitted to have two applications outstanding with two separate NBs.

You should also draw up a contract and quality plan for all three parties involved in the switch—you, your current NB, and your prospective NB—clearly delineating all changes and spelling out issues, including:

- Date of invalidity of existing certifications
- Dates that new certificates are needed
- Duties to inform
- Duties to label
- Responsibilities, timelines, property rights, and costs

You should also plan a phase-out period of no more than six months for device labeling and marketing materials that bear your old NB's information. All labeling changes must also be documented and correlated with specific production or batch numbers.

These processes can require significant effort on the manufacturer's part; thoroughness and attention to detail are crucial to avoiding costly mistakes.

The selection of a NB suitable to your needs is one of the most critical business decisions a company has to make. Emergo can help if you feel uncertain, need to effect a change, or simply wish to obtain an independent, objective reference to your prospective choice.

Learn More...

Learn more about Notified Bodies and the MDR

If you enjoyed this white paper, we know you will like our in-depth white paper about transition timelines and strategies for Europe's new Medical Device Regulation. We discuss compliance deadlines, Notified Body recertification, transitioning to ISO 13485:2016, transition steps, and much more.

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- Device classification and assessment
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About the Author

Jaap Laufer, MD, PharmD is Vice President of Regulatory & Clinical Affairs at Emergo. Dr. Laufer has over 30 years of experience in the medical device and pharmaceuticals industries. He previously held executive and senior regulatory positions at Pfizer, Abbott Laboratories, LipoMatrix, and others. His areas of expertise include a vast array of mostly implant and higher classed products, ISO and FDA QSR audits, and clinical study approvals and compliance. He holds a PharmD in Pharmacy from the University of Groningen and is an MD from the Medical School of the University of Nijmegen, both in The Netherlands. Dr. Laufer is a member of the Medical Devices Expert Group to the EU Commission and teaches at the University of Southern California in Los Angeles, USA.