PREPARING TO CHANGE YOUR NOTIFIED BODY

Considerations for manufacturers transitioning to EU MDR compliance

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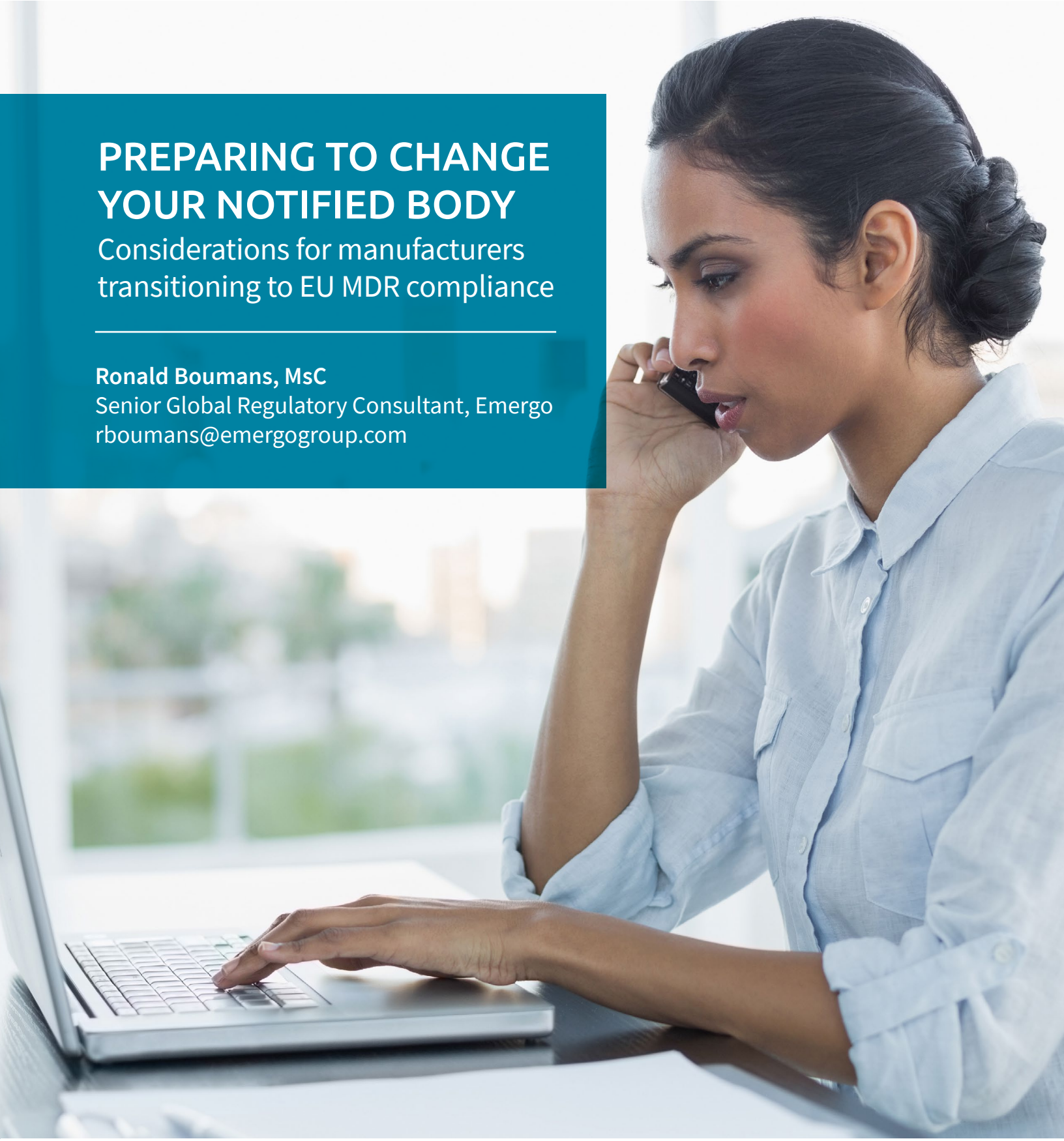

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Key points:

- Losing Notified Body (NB) support can happen to any manufacturer for a number of reasons.
- Be vigilant for early signs of departure or dysfunction of your NB.
- Carefully review your product portfolio and all technical files, and make sure your clinical data is state of the art.
- Keep your European distribution chain well stocked; this may help bridge any CE Mark certification gaps.

Note: This white paper focuses on medical devices. The situation for IVDs has its own dynamics and will be addressed in another whitepaper.

Losing your Notified Body

A manufacturer can lose its Notified Body (NB) in several ways. However, this whitepaper will focus on the scenario in which your NB reduces its scope, stops operating, or does not apply for designation under the Medical Devices Regulation (MDR 2017/745).

Political developments may also affect the position of your NB. Brexit may force NBs to leave the United Kingdom. This move could impact these organizations' scopes, as they may not be able to take all their specialists with them across the Channel. In addition, the European Union's current relationship with Turkey could impact the implementation of the Regulations under the Association Treaty, leaving Turkish NBs without the possibility of designation under the Regulations.

There are three basic scenarios for Notified Body departure and each scenario could affect the expiration timeline of your CE Mark. It is important to maintain the validity of your CE Mark so you can refer to your certificate for renewal. Otherwise, you will have to start from scratch. The three scenarios are as follows:

1. **Advanced notice:** Your NB's departure is announced well in advance. This may be the case if your NB does not apply for designation under the MDR, but remains active until all (or most) certificates have expired. In that case, you will have some time to look for your next NB and prepare for this change. Make sure none of your certificates expire before the date of application of the MDR (May 2020), as your NB may not be in a position to recertify.
2. **Announced at short notice:** The above scenario is most unlikely. Most NBs that do not want to apply for designation or that want to reduce their scope under the MDR will announce these intentions as late as possible to retain their clients for as long as possible. Manufacturers currently using such NBs may have limited time for their switch. This scenario may cause huge problems if this happens some time before May 2020 for manufacturers aiming for the so-called "grace period" for extending the expiry date of their current MDD certificates well towards 2024. It will be very difficult to have new MDD certificates issued before May 2020 from another NB. This scenario could force a manufacturer to speed up its transition to the MDR.
3. **Without warning:** In this scenario, a considerable number of manufacturers will suddenly be left without an NB backing up their devices ("orphaned manufacturers"). This has already happened and **Competent Authorities** are willing to accept certificates for a limited time (usually up to 12 months) or until they expire. However, authorities often pose additional requirements on these manufacturers. So while firms are working hard to find another NB, they must also deal with multiple requests for information from their Competent Authority.

Although it will not be easy if your NB suddenly disappears, you can anticipate these scenarios. This whitepaper will help you recognize problems with your NB and help you prepare for such events.

Early Signs of Dysfunction or Disappearance

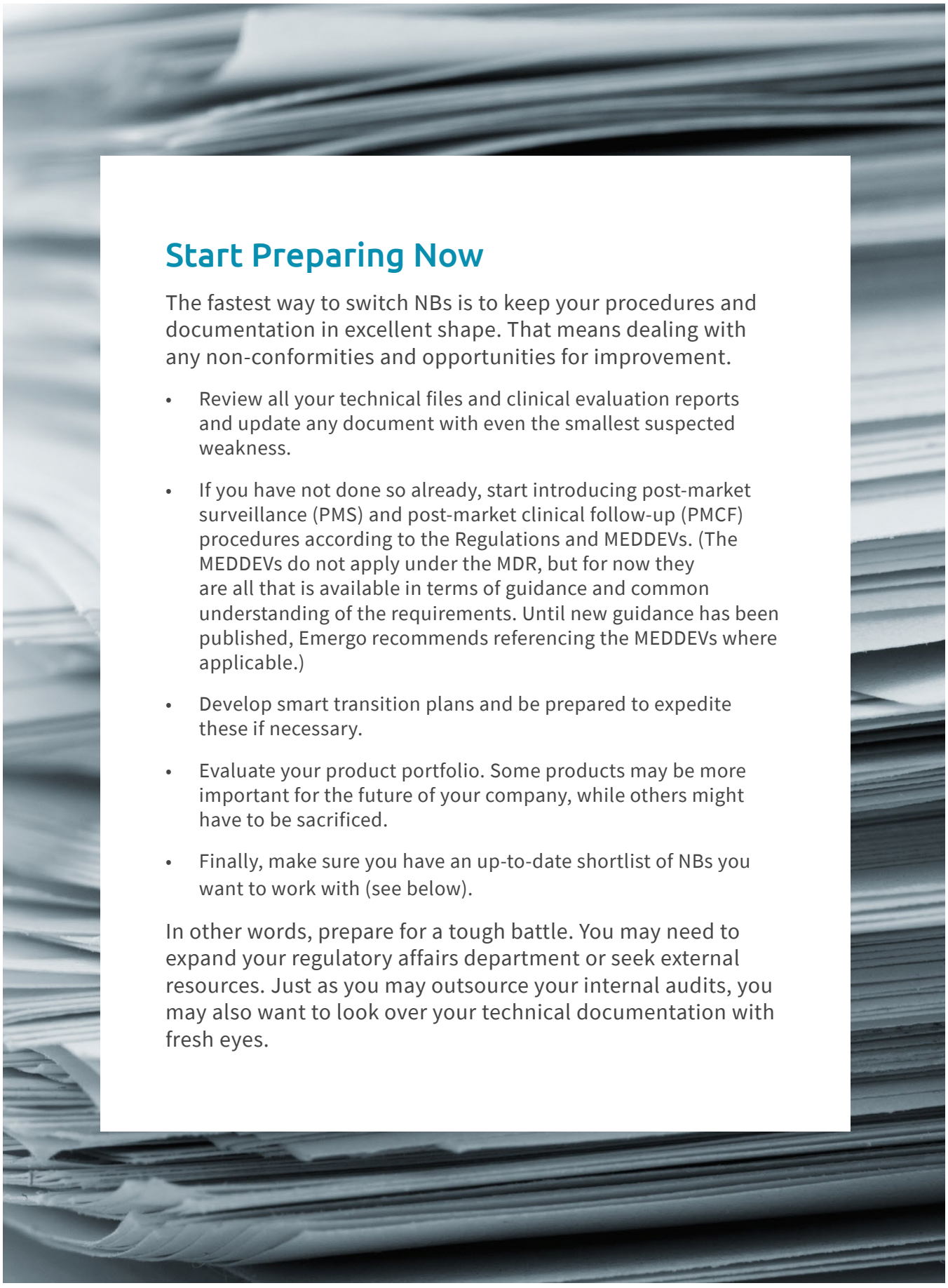
A Notified Body usually does not suddenly evaporate. Its disappearance will be gradual, with some early signs that you may notice:

- The clearest indicator is client handling: if your NB does not pick up the phone, respond to emails, timely plan audits, or significantly delays reactions, get away as soon as possible! If their clients are no longer their top priority - what is?
- When asked, your NB does not tell you it will apply for designation. Even if an NB has applied for designation but didn't pass the designation audit, the NB can still honestly say it tried. If your NB does not let you know that they are trying to remain in business, it is time to start looking for an alternative.
- Some NBs are part of larger organizations involved in certifying for other product groups apart from medical devices. You may find news about them on the financial pages. They may announce investing significantly in other parts of the organization, indicating their medical devices NB section does not have significant growth plans.

On the other hand, you may pick up some positive indications:

- If your NB is hiring extra staff and your contacts are complaining they have to spend so much time on training, you know your NB is investing in its future.
- It is possible that your NB will plainly tell you they are doing everything in their power to be designated as soon as possible and they share their intended scope with you.
- Some NBs are very open about their intentions: All 23 **TEAM-NB** members have clearly indicated they will apply for designation, even indicating their interest in designation under the In-vitro Diagnostics Regulation. Others have not been open about their intentions, although some may follow soon.

You may not be left completely in the dark, but you must read between the lines. And whatever you find, there are no guarantees. So you should still prepare for the worst.

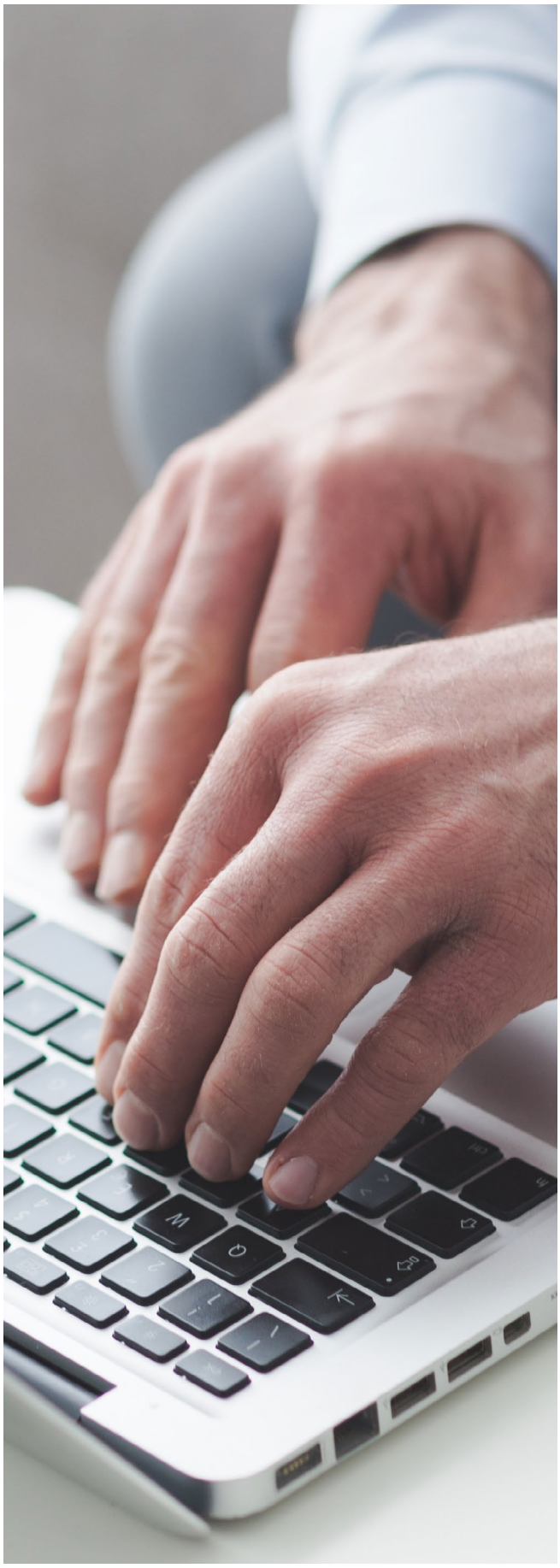


Start Preparing Now

The fastest way to switch NBs is to keep your procedures and documentation in excellent shape. That means dealing with any non-conformities and opportunities for improvement.

- Review all your technical files and clinical evaluation reports and update any document with even the smallest suspected weakness.
- If you have not done so already, start introducing post-market surveillance (PMS) and post-market clinical follow-up (PMCF) procedures according to the Regulations and MEDDEVs. (The MEDDEVs do not apply under the MDR, but for now they are all that is available in terms of guidance and common understanding of the requirements. Until new guidance has been published, Emergo recommends referencing the MEDDEVs where applicable.)
- Develop smart transition plans and be prepared to expedite these if necessary.
- Evaluate your product portfolio. Some products may be more important for the future of your company, while others might have to be sacrificed.
- Finally, make sure you have an up-to-date shortlist of NBs you want to work with (see below).

In other words, prepare for a tough battle. You may need to expand your regulatory affairs department or seek external resources. Just as you may outsource your internal audits, you may also want to look over your technical documentation with fresh eyes.



Your Notified Body May Be Leaving

As soon as you learn that your NB will end its activities, you should start enacting your emergency plan. First, figure out how much time you have until you can no longer place devices on the European market. It is important to understand that you can place devices on the market as long as your certificate is valid. Placing on the market means two things:

1. The device is no longer in your possession. Its ownership has passed to another legal entity.
2. The device is somewhere on European territory. A manufacturer based outside the EU must physically transport the device to Europe in order to have it placed on the market and have ownership of the device changed.

Once a device is legally placed on the market it can be legally distributed further. You may want to stock up your European suppliers as much as possible to bridge any gap in supply caused by a temporary gap in your certification. As part of your preparation, you should also consider which European market is the most important for you, as you may have to temporarily reduce supply in one market to stay in another market.

As a next step, you may have to choose between European public health and your business. From a patient safety perspective, you may wish to inform the market that supplies may get low so your users can stock up. However, this may drive your users to start looking for another supplier. Some Competent Authorities will have measures in place in case a group of manufacturers loses its certification. Make sure that you know the plans of the Competent Authorities that are relevant for you. Now you should have a good idea of how much time you have for your switch to a new NB.

Which Notified Body?

As you may not be the only company in this situation, good preparation may help you get to the front of the line. There is a lot you can do already. First you must figure out which NB is relevant for you. Two characteristics are absolutely crucial: scope and location.

Scope pertains to the compliance routes the NB can review (the Annexes), the products according to their NBOG codes, and the horizontal technical competence. **NANDO** provides the official list of NBs and their scopes. Be aware that NANDO is not currently up to date; these scopes should only be used as an indication. The details relevant to the MDR cannot be found there yet. Looking at the current NANDO scopes, you may be able to draft a short list of NBs. You may also want to consider the TEAM-NB members that published their intentions regarding designation under the Regulations.

The second step concerns location. You should only look for NBs with presences in the market where your head office (or your intended certificate holder) is based. Therefore, the profile will be different for a US-based company compared to one in Japan. This will further narrow your list. You should make this list now and update it regularly.

There is a next step you can use to further narrow your search. Some NBs will go for a broad scope, covering all possible product groups. These NBs may also be able to serve the most important markets. In terms of scope and presence, these organizations are the safest options. However, they may also be the busiest. There may be NBs with smaller scopes and a limited global footprint that still work for you. These specialists may be more flexible in accepting new clients. You may even have to divide your portfolio between NBs to make sure all devices are covered. Solid preparation and a good understanding of your product portfolio are crucial for these decisions.

Anticipate some rough times ahead. We may see a shake-out in industry, which is bad news for weaker companies. The better medical device manufacturers make plans and understand their priorities if they enter tough times.

What to Expect from the Authorities?

Under the MDD, some (but not all) Competent Authorities have the option to allow devices without CE Marking into their markets for "compassionate use" purposes. This is a truly complex procedure characterized by a high degree of uncertainty. In addition, this route is only applicable until the date of application of the MDR for devices certified under the current MDD.

After May 2020, Article 59 becomes available, which enables Member States to allow devices on their markets without the CE Mark. However, this will only be effective for the particular Member State that allows these devices on their territory, and it can be expected that this route will not have the capacity to process large groups of devices in a short time.

Reliable sources indicate that there might be another option in certain cases: a so-called "Plan B." However, the Member States and the European Commission are not formally endorsing it and maintain that the three years for the transition and the "grace period" of four additional years should be sufficient for all manufacturers to make the transition to the new Regulations.

Unfortunately, it is increasingly evident that the actual transition period is much less than three years because the Competent Authorities need time for the transition, and the extension of the certificates comes with strict conditions that may not be an option for all manufacturers. Last but not least, the current steep transition process for NBs—in sharp contrast to the level of oversight provided by the authorities over the last decades—creates a problem that has not been foreseen in the MDR or in the impact analysis of the MDR transition. Some industry participants and observers are demanding smarter solutions in case large groups of orphaned manufacturers form as a result of these issues.

After all, the Competent Authorities will have to explain to their citizens why medical devices meeting a medical need that are proven safe and useful may no longer be available. This interesting journey will take a while.

In Conclusion

You should carefully review the capability and willingness of your current NB to serve your company in the future. Now is the time to prepare for a forced transition to the new Regulations, if needed. Waiting will mean joining the end of the queue.

Learn More

Need help transitioning to the EU MDR? Emergo helps medical device companies with regulatory compliance and market access in Europe and other markets worldwide. Here's how we can help:

- Technical File and CER compilation and review
- European Authorized Representation
- MDR gap audits and transition consulting
- ISO 13485:2016 implementation and audits

Learn more about how we can help you with European medical device compliance at **EmergoGroup.com**.

About the Author

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