European MDR Transition Timelines and Strategies

How to determine the best MDR transition strategy for your medical device



Author:
Ronald Boumans, MsC
EMERGO
Senior Global Regulatory Consultant
rboumans@emergogroup.com

November 2016

EMERGO

This white paper is based on the compromise text as published on 15 June 2016. The final version, expected in the first quarter of 2017, may have differences with this version.

European regulators have published the compromise text of the long-awaited Medical Device Regulations (MDR) and provided general implementation timeframes. However, manufacturers should realize that compliance will require more than circling dates in calendars. Given the complexity of the new Regulations, affected firms should not expect a simple, straightforward transition from the current medical device directives.

This whitepaper will highlight some strategies for planning your transition. The strategy a manufacturer takes depends on the expiration dates of their CE Marking certificates, the policies of their Notified Body (NB), the availability of clinical data, and possibly the expiration dates of the devices they intend to market.

Timing the transition: what to do and when to be in line with the MDR

Consider two timelines when planning your transition from the Medical Devices Directive (MDD) or the Active Implantable Medical Devices Directive (AIMDD) to the Medical Devices Regulation (MDR): the implementation of the MDR and the implementation of EN ISO 13485:2016. You can plan these transitions once you understand the timelines with which you have to work. However, there are no easy answers. Manufacturers need to analyze many complex factors they have not dealt with before.

For Self-Certified devices, the timing issue is less complex. Manufacturers of these devices must comply at the date of application, but they can start supplying MDR compliant devices before that date. Although this may look simple, clinical data issues may still lead to problems. An early assessment of the availability, accessibility, and validity of your clinical data is highly recommended.

ISO 13485:2016 Transition by March 2019

All ISO standards typically have a three-year transition period. This would normally allow manufacturers to update their quality systems as part of the normal maintenance of their certificates, and would imply that all manufacturers must switch to ISO 13485:2016 by March 1, 2019.

However, this transition is slightly different for CE marking. The General Safety and Performance Requirements (currently known as the Essential Requirements), sections 1 and 2 require conformity with the generally acknowledged state of the art in technology, which would include any harmonized standard used. When the 2016 version of ISO 13485 is published in the Official Journal of the European Union (OJEU), it will become the EN ISO 13485 version, which can be considered the new state of the art and all devices placed on the European market have to comply with the new version.

As the Commission has a backlog in harmonization of standards (according to the Dutch standardization institute this currently involves 149 standards for the MDD, 19 for the AIMDD, and 13 for IVDD), such efforts may take some time, and Commissioners may decide to synchronize harmonization with the three-year ISO transition period.

Emergo still sees CE Marked devices with ISO 13485:2003 certificates. If the MDR puts more pressure on NBs as expected, they will in turn persuade manufacturers to take care of this step in parallel with their next surveillance audit, or simultaneously with a recertification. Therefore, we do expect NBs will allow time for compliance after publication of EN ISO 13485:2016 in the OJEU. However, a manufacturer is expected to transition to ISO 13485:2016 before March 2019. Also, this situation is not likely to cause a hunt by the Competent Authorities for manufacturers with “old” certificates, as the change to ISO 13485:2016 would not suddenly create a public health risk. Therefore manufacturers will have some room to plan the switch to the new ISO quality system standard.

The timelines for the MDR are more complex:	
Date of Entry	Expected in Q2 2017 (20 days after anticipated publication in OJEU)
Period between Date of Entry and Date of Application	NBs may issue certificates under the MDD or AIMDD with a maximum validity of five years
Six months after Date of Entry	NBs may apply for MDR designation
Date of Application	Occurs three years after Date of Entry, expected to be Q2 2020
Two years after Date of Application	Certificates issued in accordance with Annex 4 of AIMDD and Annex IV of MDD (EC-type verifications) that have not yet expired will become void
Four years after Date of Application	Other certificates issued under current Directives that have not yet expired will become void
Five years after Date of Application	Devices that were CE Marked under the MDD or AIMDD may no longer be marketed or put into service in Europe

Sources: MDR, Emergo

Clinical data

One of the most critical changes to the MDR concerns clinical data. If you expect to have sufficient clinical data for the transition, you can consider going for early certification. If it looks like you first need to conduct extensive clinical investigations, your transition will take longer. Under the Directives, you can conduct post-market clinical follow-up (PMCF) studies that could provide you with this vital clinical evidence. You must analyze your current clinical evidence and how to close any gaps in order to decide on your transition strategy.

General safety and performance requirements

There is a major obstacle for companies aiming for an early switch to the MDR. Annex I of the MDR contains the "General Safety and Performance Requirements," which are similar to the Essential Requirements of Annex I of the MDD. Currently there are no harmonized standards or Common Specifications available, and there are no timelines as to when they will be published. This makes it difficult to verify compliance with the Requirements. Whatever the manufacturer is planning to do, switching to the MDR has to wait until the harmonized standards and/or Common Specifications are published.

Notified Body designation

European medical device market observers anticipate that there will be about 30 to 40 NBs that will remain active once the MDR is in place; a few of these entities will operate as large and possibly more expensive "broad scope" organizations, and the rest will have a more specialized focus. TEAM-NB has published a list of their members and their intentions. Other NBs may also plan to be designated under the MDR, but that information is currently not available. In order to plan your transition you must also make sure you are using an NB that will be able to assess your types of devices.

The Commission's designating teams can probably process 15-20 NBs per year, and NBs can only apply for designation six months after the date of entry. The designation process is expected to take at least 12 months, which would leave at best 18 months to finish the certification process before the date of application. The order in which Notified Bodies will be designated and audited is not clear. Article 33.11 of the MDR allows NBs to perform their activities only after they have been designated. However, they may decide to perform "gap analysis" audits and assessments in anticipation of their designation and perform the formal verification once they are designated. Even then, you have to wait for your NB to be designated before your MDR certificates are issued, and that may take until close to the end of the transition period.

Notified Bodies may also present an arrangement to use current audit results for extending or renewing current certificates to perform a gap analysis regarding the MDR. Current information – confirmed by the European Commission in documents used in the Eudamed working group on Registration – indicates NBs will remain designated for the MDD after they have been designated for the MDR. This offers more flexibility to manufacturers in planning their switch in certification.

Certificate expiration date

Devices CE Marked under MDD or AIMDD certificates can be placed on the market as long as these certificates are valid. Stock in warehouses of distributors or at health institutions can be made available or put into service until five years after the date of application. This allows for these "old" stocks to be sold out. By creating extra stock in the warehouses of independent distributors, it is possible to bridge a situation where no certificate is available. There are two situations where a manufacturer may decide to use this option:

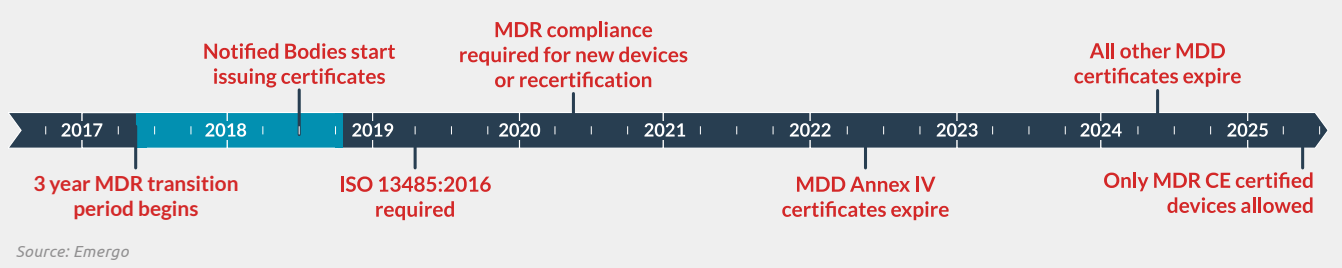
1. The manufacturer plans to introduce a new device but expects a gap between the expiration date of the old certificate and the introduction of the new device.
2. When tracking the process of getting certified under the MDR, the firm becomes aware of serious delays that may lead to an interruption in the continuity of care.

Both options are used to keep current users supplied, but the first option is driven by commercial motives; the second pertains to a public health interest.

Medical device manufacturers can utilize four basic strategies for the transition:

1. Certify under the MDR as soon as possible.
2. Remain certified under the MDD or AIMDD as long as possible, possibly until 2024.
3. Plan this switch around the date of application.
4. Go for a mixed approach with some devices certified early, others very late and the rest somewhere in between.

Option 1 – Get MDR certified as soon as possible



Source: Emergo

If your NB is able to facilitate either the "gap analysis" option or a real certification, and you have sufficient clinical evidence, you can go for the as-soon-as-possible option. This option is especially recommended if your device design will soon change significantly or you want to place a new device on the market. You will know about the continuity of your business early in the transition and if there is a waiting list at your NB, you will be at the front of the line.

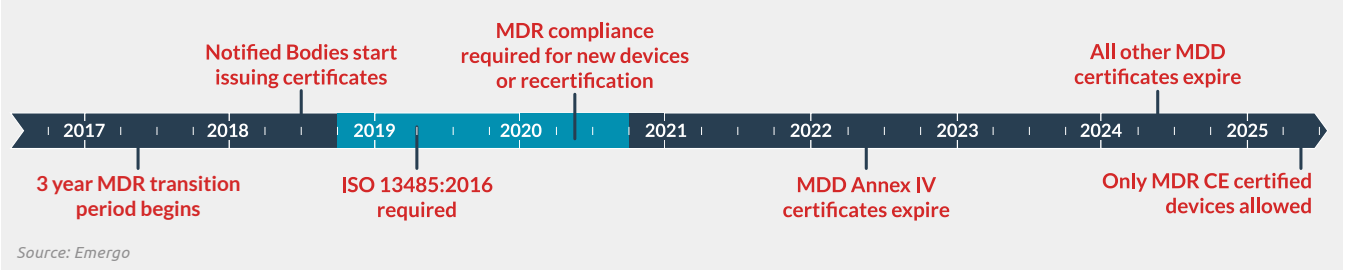
This route allows you to transition to the ISO 13485:2016 standard simultaneously. The exact timing will also depend on the expiration dates of your certificates and your possibilities to meet the new requirements. There is still one uncertainty to address: can you stay with your current NB, or do you have to change? You can only know this after your NB has committed itself, and you only have certainty once they obtain designation or formally announce they will no longer be active in this field.

Manufacturers of devices that are currently Class I self-certified, but will be in a higher risk class under the MDR, should consider the early option. They must comply after the date of application, which means they need Notified Body involvement. Therefore they can't risk delays due to capacity problems with their NB around the date of application. Article 94.3a may appear to leave an option open, but this is only intended to allow selling out "old" stocks during the five-year period for devices that were legally placed on the market before the date of application.

Option 1 is recommended if you:

- ☑ Have sufficient clinical evidence for your device
- ☑ Have CE now and expect to make design changes in the next few years
- ☑ Are introducing a new device
- ☑ Want to transition to ISO 13485:2016 simultaneously
- ☑ Know your device is currently Class I self-certified
- ☑ Know your product is currently not considered a medical device, but will be under the MDR

Option 2 – Get certified just in time



Source: Emergo

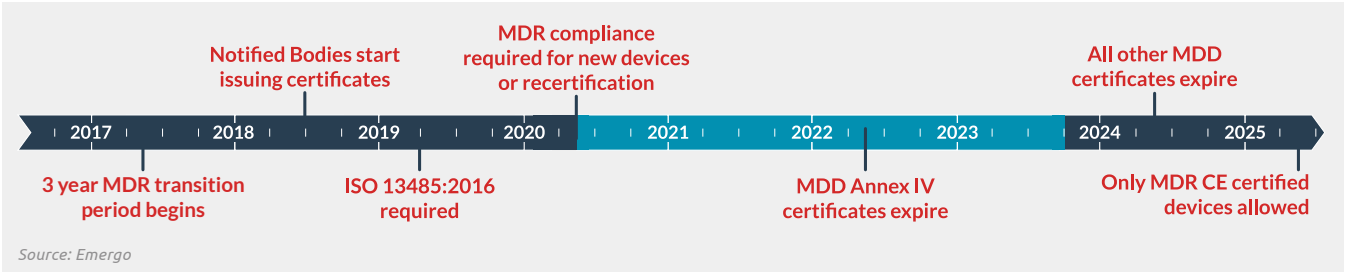
If you plan to introduce new devices between 2019 and 2021, and you expect to have sufficient clinical data, you may want to certify under the MDR around the date of application. This path also applies if it is not possible to extend your certificates for more than two years after the date of application. You may be able to synchronize the switch to ISO 13485:2016 with your MDR certificate. This option mixes some of the advantages of the previous options with their disadvantages:

1. You will be recertified for the MDR by a Notified Body that was designated. You will have only one certification procedure to go through, which cuts costs. But this will have to happen during a period when NBs are dealing with huge workloads.
2. You will probably be among the first generation of manufacturers to undergo MDR certification. As this is a complex set of requirements, you may suffer from imperfections.
3. You may make good use of this time to update your clinical data by performing PMCF studies under the current legislation, but that will only help for identical, or practically identical, devices.
4. You will probably have sufficient time to make the switch, yet you will not join at the end of the line. This option provides a relatively smooth transition, without major risks to the continuity of your business.

Option 2 is recommended if you:

- ☑ Plan to introduce new devices between 2019 and 2021
- ☑ Have sufficient clinical evidence
- ☑ Follow Annex IV of the MDD or AIMDD
- ☑ Expect your Notified Body will remain active in medical devices
- ☑ Don't mind being among the first companies to undergo MDR certification

Option 3 – Get MDR certified as late as possible



Source: Emergo

If you do not expect any major design or production changes for your device, it is not necessary to fully update your certificate. In that case you may choose to keep your device under the MDD as long as possible. Your switch to the new requirements will come when Notified Bodies, Competent Authorities, the MDCG, and all other parties have more experience with the new Regulations. It will give you a lot of time to generate clinical data for your current devices, although this may not be useful for a new device.

You need to plan your next recertification carefully, because you will need certificates that carry your device as far as possible beyond the date of application. There are five risks you should bear in mind:

1. Your recertification will have to take place shortly before the date of application, which will be a high workload period for your Notified Body.
2. You will have to switch to ISO 13485:2016 before switching to the MDR, and this requires such changes to your quality system that a new CE Marking certificate would be appropriate. An early gap analysis will help establish this risk and its consequences.
3. You will be at the back of the line, and NBs may be flooded with work. You may get stuck with outdated certificates before your new certification.
4. You will know which Notified Bodies will be in business, but you may have to change your Notified Body before switching your certificate. It is possible that your Notified Body will not be around for a recertification under the Directives.
5. Be aware that in article 94.2, the four extra years allowed for MDD certificates may be adapted in the final version of the MDR. The status and tasks of NBs designated for the MDD after the date of application is not clear.

Option 3 is recommended if you:

☑ Have CE now but do NOT expect to make design changes in next few years

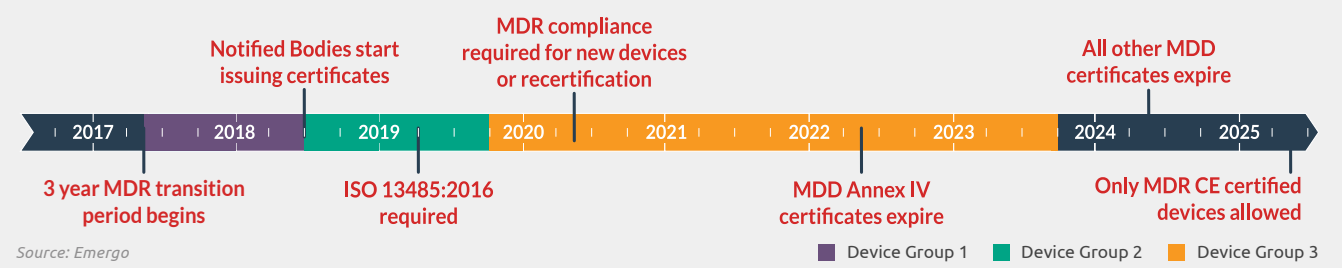
☑ Need more time to gather clinical data needed for existing CE devices

☑ Don't expect the classification of your device will change

☑ Can't risk being pushed to the "back of the line" by your Notified Body

☑ Are unsure whether you will be changing Notified Bodies

Option 4 – Take a mixed approach



Expect manufacturers with a wide range of devices to take a mixed approach to the MDR transition. They can time the switch for each device or device family separately, accounting for the current expiration of their certificates, expectations regarding the development of new devices, and the risk they want to take regarding the continuity of their business. They should time the switch to ISO 13485:2016 relatively early in the process because this will reduce the risk of problems with that switch after the MDR application date.

Option 4 is recommended if you:

- ☑ Need to transition a wide variety of devices and do not have internal bandwidth to tackle them all at once
- ☑ Have a mix of devices, some with excellent clinical evidence, others that need more data
- ☑ Are introducing new products in the next few years and working on recertification of existing legacy devices

Conclusion

Timing the switch to the MDR and ISO 13485:2016 depends on a company's strategy, product mix, the current state of certification, the availability of harmonized standards and/or Common Specifications and clinical data, and the policy and accreditation of the firm's Notified Body. There are no simple answers to what would be best. An early analysis, possibly with your NB, is necessary.

This conundrum has been thrown at industry by regulators that may not fully understand the complexity of placing devices on the European market. However, companies that manage to solve this riddle are more likely to be the strong players in the next decade. The game is on in this new level playing field!

To Learn More...

Learn more about the European MDR changes

If you enjoyed this white paper, we know you will like this white paper outlining the major QMS changes introduced in ISO 13485:2016. We discuss specific changes, how to prepare for the new standard, recertification requirements and deadlines, and much more.

DOWNLOAD PDF

Need help with CE Marking?

Emergo helps medical device companies with regulatory compliance and market access in Europe and worldwide. Here's how we can help:

- Technical File/Design Dossier compilation and review
- ISO 13485:2016 certification and audits
- European Authorized Representation

LEARN MORE

About the Author

Ronald Boumans, MsC is Senior Regulatory Consultant at Emergo's office in The Hague. He previously served as Inspector of Medical Technology at the Dutch Healthcare Inspectorate (IGZ), and his areas of expertise include European medical device legislation, Competent Authority supervision, and CE Marking requirements.