Are you ready for the new Medical Devices Regulation?

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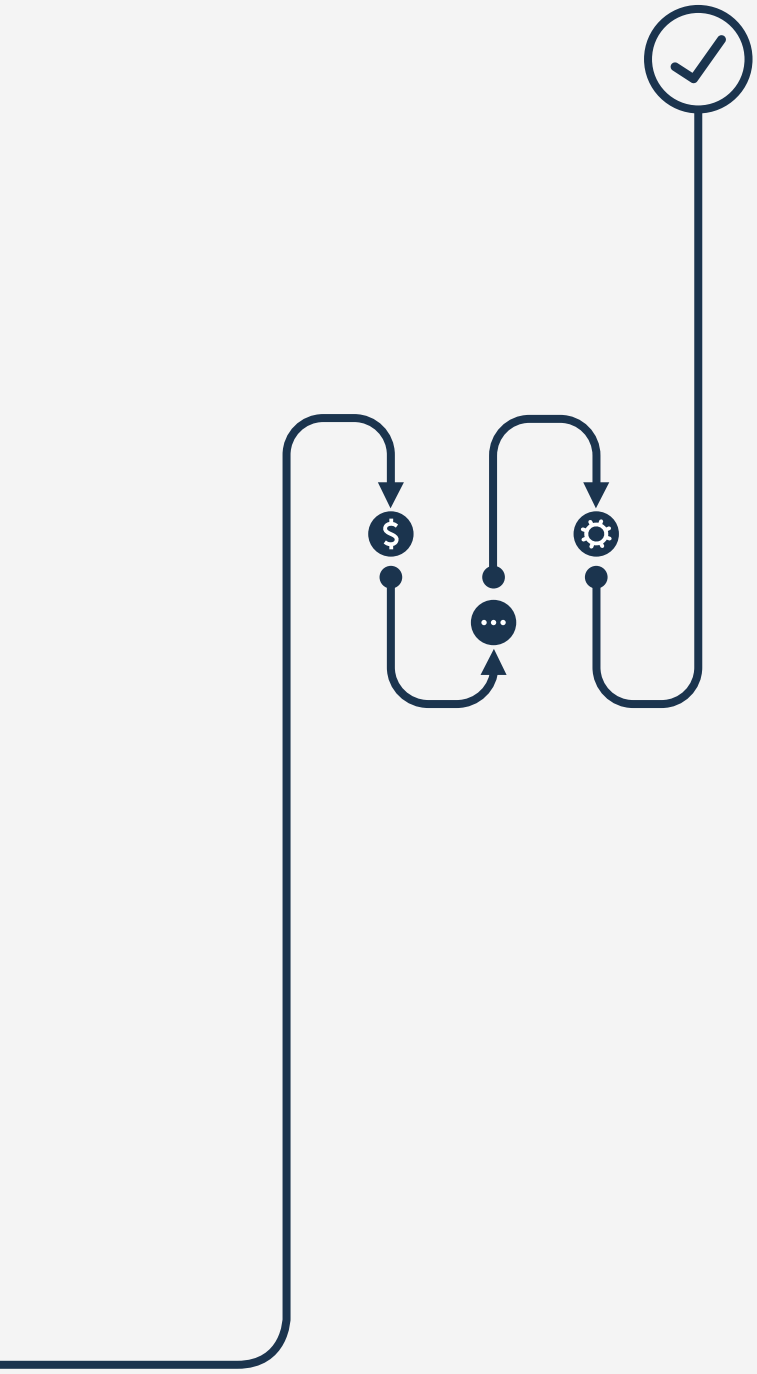
New regulations, which were signed off in June 2016, will affect all devices manufacturers looking to sell products in the EU, with stricter requirements being introduced in order for these products to be approved.

Here we provide some essential information about the new Medical and In-vitro Device Regulations, and what it means for those involved in medical devices development.

On June 27th 2016, the final drafts of the Medical Device Regulations (MDR) and In-vitro Medical Device Regulations (IVDR) were made public and they are expected to be adopted and enter into force in Q2 of 2017.

The transition period will be three years for the MDR and five years for the IVDR, meaning that the dates of application (DOA) will be Q2 2020 and Q2 2022, respectively.

However, this does not mean that there are three (or five) years to prepare for this. There are some major changes, so it is essential for medical devices manufacturers to engage management in the process now, so that money and resource can be available to support and implement the new device regulations.



Redesignation of Notified Bodies

Under the regulations, all Notified Bodies (NBs) will need to be redesignated. The NBs can start to apply for this redesignation in October 2017 – six months into the transition period. It could take 12-24 months for the redesignation evaluation, as it is a new process and more bodies are involved in assessing, so there is potential for MDR certificates not to be available from the redesignated NBs until as late as Q4 2019.

There is also an issue regarding the availability of NBs. There will be fewer NBs and many are already overwhelmed with the extra work required from the 'unannounced audits' program. The number of NBs is falling and the expertise is being switched to other CE Marking projects (Conformité Européenne or European conformity). This is already causing delays in reviews and certifications. It is essential that diagnostic medical devices manufacturers establish a good relationship with their NB now to ensure that they are not 'forgotten', to reduce the possibility of their products being pushed to the back of the evaluation queue – this is especially important for devices companies with only one or two products.

We should also not be surprised to see NBs push up their costs for devices approval certification, as the extra work involved in the assessment will need to be recouped.

So, if the approval process takes longer and there is a potential for a higher cost, medical devices companies need to start looking at their cash flows now as product release may be delayed, which in turn could cause some loss of faith from customers requiring the approved medical devices.

Do products that are already on the market need reassessment?

All products need to be re-assessed under the regulation, even if they are already on the market. Any current CE Mark will no longer be valid after a specified time period.

Article 102.2, paragraph 1 of the new regulations, states that certificates issued under 93/42/EEC before the MDR entry into force (Q2 2017) will remain valid as per certificate, so if your current certificate (pre Q2 2017) expires in Q4 2020 it will remain valid until then.

Paragraph 2 of that same article (120.2) states that:

- Certificates issued after MDR entry into force (Q2 2017) under directive 93/42/EEC will remain valid for a maximum of five years but will expire, at the latest, four years after DOA (Q2 2020). If you get a CE Mark certification for a product during the transition period under 93/42/EEC in Q3 2019 it would usually be valid for a maximum of five years taking you through to Q3 2024; however, as DOA is Q2 2020 and MDR only allows a certificate to be valid for four years after DOA, it will actually expire in Q2 2024.
- For products placed on the market before MDR DOA (Q2 2020) under directive 93/42/EEC, these may continue to be made available on the market or put into service five years after DOA according to article 120.4.

So a strategic decision needs to be made by the manufacturer, depending on the validity of the current certificate: do you renew now, under the current directive, or go straight to the new MDR when the certificate needs renewing?

Classification changes

There are some changes in classification under the new MDR. It is essential for a manufacturer to check whether any product has been reclassified or up-classified and, if so, think about whether the current method of conformance for the product is still valid. If not, perhaps this is an opportunity to look at sales to see whether they justify the cost of bringing the product into conformance with the MDR – especially important if new data are going to be required.

For IVDs, there have been major changes in classification which will result in a shift from a system where currently 20% of IVDs need NB intervention, to a system where 80% will require such intervention. This is why the longer transition of five years is absolutely essential.

What about the technical documentation?

Prior to the MDR and IVDR, there was no set way of providing the data to NBs and each company produced technical files which were slightly different. Annex II of the MDR is much more specific regarding content and format of technical files and it is a little different from that which we are used to. In addition, the Essential Requirements are now termed General Safety and Performance Requirements, so at a minimum this will require a rewording of all compliance checklists (Annex I). Even if everything else is acceptable in the file, the rewording will take time and needs to be planned for. Another big change, which will also take time to enact, is the requirement for the labels and Instructions for Use (IFU) to be included in all languages where the product is to be, or is envisaged to be, sold.

From a business point of view it is likely that all product or product family files will need some conversion. It is important to consider how long this will take and to identify which staff will do this.

Clinical Evidence

A key part of the new regulations are the much more stringent clinical evidence requirements which will undoubtedly result in more clinical investigations being needed, although there are some exceptions for products such as dental fillings and sutures (see article MDR 61.6). There are also increased restrictions on filing via the literature route. The MDR definition of 'equivalence' from Annex XIV, Part A, paragraph 3 can be summarized as follows:

- Technical, biological and clinical characteristics shall be similar to such an extent that there would be no clinically significant difference in the clinical performance and safety of the device.
- Considerations of equivalence must always be based on proper scientific justification.
- Manufacturers must be able to clearly demonstrate that they have sufficient levels of access to the data on devices to which they are claiming equivalence in order to justify that claimed equivalence.

The MDR goes on to say that it might not be necessary for a manufacturer to conduct a clinical investigation to demonstrate equivalence to an already marketed product, not manufactured by themself, provided that the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis, and the original clinical investigation has been performed in compliance with the requirements of the MDR and the manufacturer of the second device provides proof of this to the NB.

Manufacturers need to ensure the clinical data that they have are still valid. Is the literature route still appropriate for their product? Do they need to complete more clinical studies? Do they need to get outside help to analyze the clinical data they have? Completing clinical studies is a costly and lengthy process; can this be done in house, or would using a Clinical Research Organization (CRO) ultimately save costs?

What's Changed in Vigilance and Post Marketing Surveillance?

MDR Chapter VII is about developing a robust and proactive post market surveillance system. The reporting timeline has been reduced from 30 to 15 days for serious incidents and the MDR leaves provision for an act to establish new electronic vigilance reporting forms with product problem and adverse event codes (Article 92). This could increase pressure on vigilance departments, so thought should be given to outsourcing this function.

A new requirement of article 86 is that of a Periodic Safety Update Report (PSUR) for all devices with those in class IIb or III needing annual reporting and other classes two yearly.

What else is new?

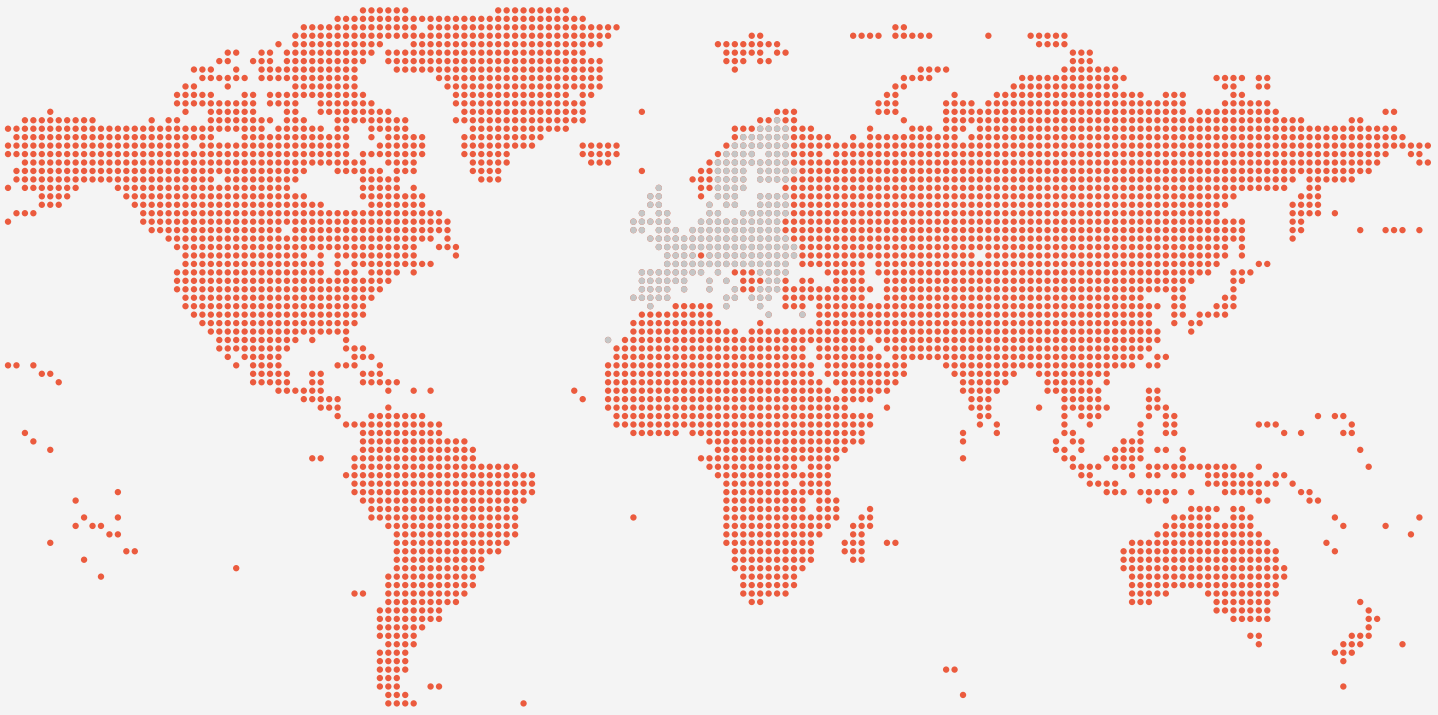
Unique Device Identification (UDI) is coming to the EU. It is hoped this will be much like the U.S. system, but there will be an EU specific database which could have different data requirements. It is not known when the database will be available at present.

There are new requirements for labels, aside from the need to add the UDI, and these are detailed in the MDR Annex I section 23. It will be important to plan for this to ensure a healthy label stock is maintained – enough new labels when required and not too many old labels to discard.

Distributors and importers are now regulated under the MDR and the Authorized Representative role is much more clearly defined. They all become 'economic operators' and all, bar the distributor, need a single registration number (SRN) under MDR article 31. All of these individuals will require training, and communication will need to be exceptional, to avoid conflicts with regard to product on the market.

And finally, what about outside of the EU?

Some manufacturers have registrations in the rest of world (ROW) that are linked to the CE Marked product. An audit needs to be carried out to see which registrations rely on what data and then a transition plan needs to be in place.



In conclusion

Although there are three/five years for transition, manufacturers need to develop a plan as soon as is practical to ensure MDR compliance. A CRO can help with this, and other tasks such as clinical review of data, technical file updates, clinical investigations and vigilance requirements and notified body liaison. Finally, manufacturers need to engage senior management early so that a team can be developed and resource and cost implications can be understood from the outset.

Want more advice on how the Medical Devices Directive affects you?

At INC Research, we can provide medical devices regulatory consulting services to help you get your product approved. We have a dedicated business group focusing solely in this area, so you can benefit from their knowledge to guide you from concept to marketing.

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