Are you ready for the new EU Regulations on Medical Devices and *in vitro* diagnostics?

qarad
European Regulatory Services

CPSL
Language Services

Content

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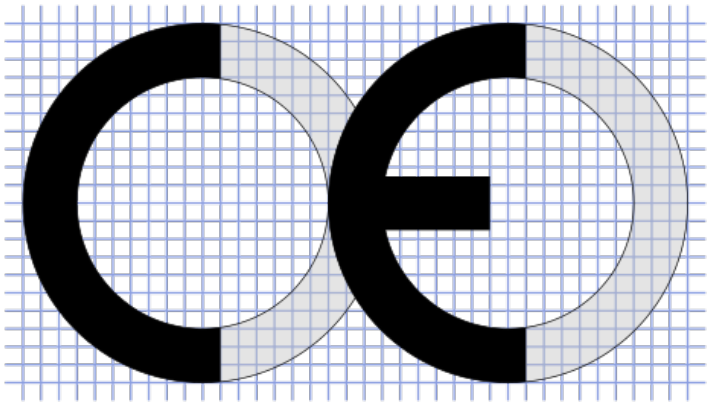
Currently medical devices and *in vitro* diagnostics are subject to the trinity of long-standing directives—Medical Device Directive (MDD), *In Vitro* Diagnostic Medical Devices Directive (IVDD), and the Active Implantable Medical Device Directive (AIMD). However, one of the most recent European regulatory overhauls in the life science industry was the publication of the new EU medical device and *in vitro* diagnostic medical device regulations. These regulations will affect the device manufacturers but also any party that is a part of the supply chain or providing service activities. The regulatory changes are driven by a need to strengthen the regulatory platform, standardize and harmonize information and create a safer environment for patients and users.

1. The Regulations

May 5th, 2017 Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (MDR) together with Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices (IVDR) was published in the Official Journal of the European Commission. These Regulations entered into force May 25th, 2017 with a three-year and five-year transitional period, respectively making them mandatory as of May 25th, 2020 and 2022. The MDR and IVDR aim to improve product transparency and traceability and create a less complex trading environment between EU member states by regulating the market with clearer rules.



Despite the three-year and five-year transition window, there is a sense of urgency to plan and prepare now to remain compliant and competitive in the marketplace. It is important for companies operating in this industry to create company-wide awareness and gain stakeholder buy-in, to assess the impact of these changes on their portfolio including current and future revenue streams, and to prioritize organisational efforts on internal processes impacting operations and getting a product to market.

2. European Market Access

Manufacturers intending to place their devices on the market in the European Union (EU) need to comply with the relevant EU regulations to lawfully do so. The CE marking of their product is the legal demonstration that the company and their devices have met the relevant regulatory requirements.

A device's intended use defines its regulatory life and will have to be clearly established prior to determining its correct classification and conformity assessment route.

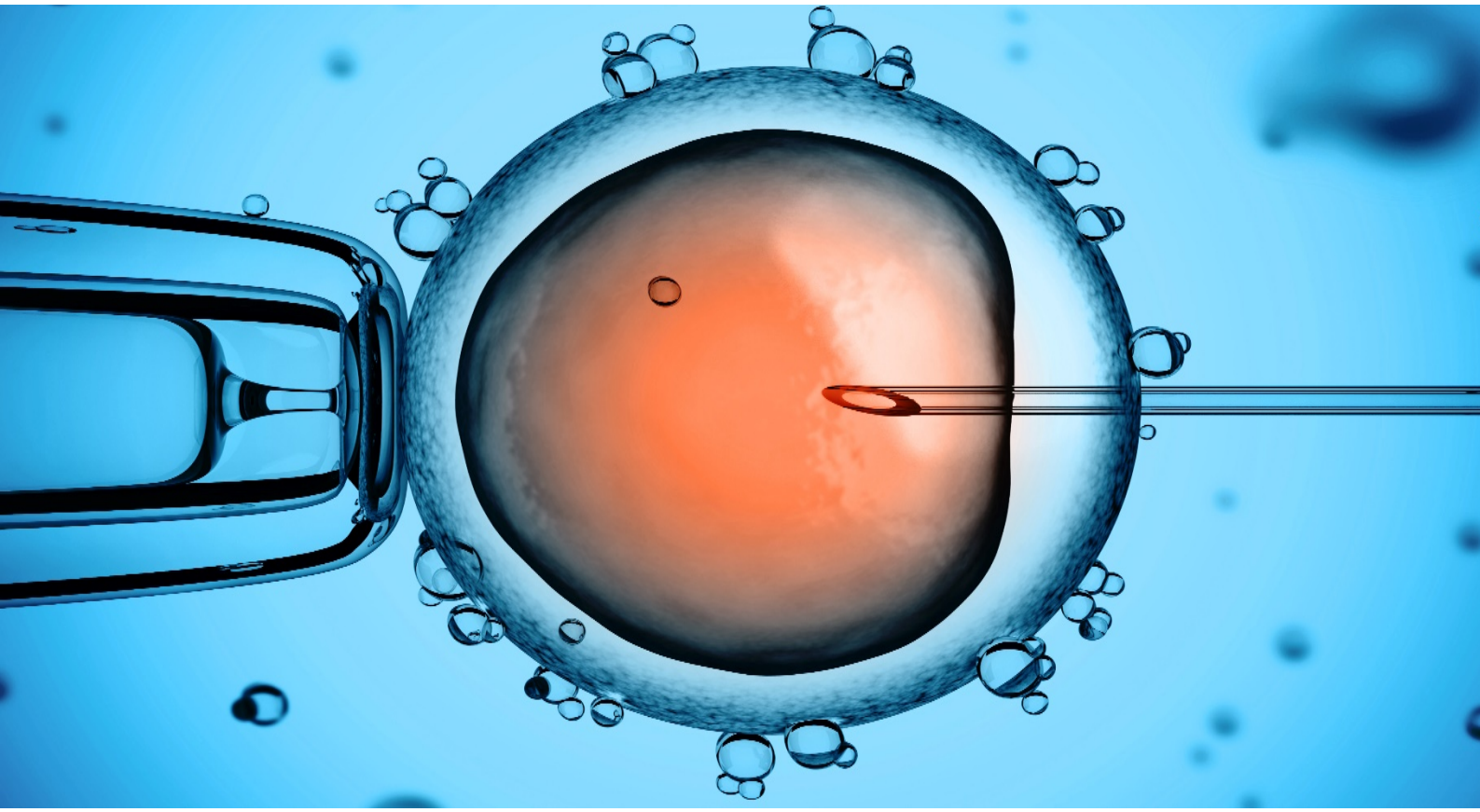
The pre-market steps to take will consist of:

- First, determining which EU Regulation applies – i.e. medical device (EU 2017/745) or IVD medical device (EU 2017/746).
- Second, in defining the class of the devices – i.e. class I, IIa, IIb or III for medical devices or A, B, C or D for IVDs.
- Then, quality system implementation and drawing up of all required documentation.
- Finally, when applicable, in appointing a notified body that would audit all relevant documentation (i.a. quality management system, post-marketing surveillance system, technical file etc.) and would issue a conformity certificate depending on the assessment route chosen. A positive assessment permits a device to being marketed in any country of the European Economic Area.

After establishing the correct classification and conformity assessment route, the companies will need to review their technical files to see if there are any gaps versus the requirements.

In case the company finds that there are product claims which are not substantiated by objective data, then the company must decide if such claims are worth keeping (triggering the need to invest time/resources and money to generate such data) or whether they will have to be dropped. In extreme situations the gaps (lack of evidence supporting the product claims) can be so big that the company may have to decide whether the financial effort involved in bringing the product to a full IVDR or MDR compliance is financially viable or not.

All keeping in mind that there is a "no grandfathering" rule, all devices must undergo the process of registration under the IVD or MD Regulations regardless of how many years they have been placed on the market.



3. 7 steps to the CE Mark

1. Change management: Familiarise yourselves with the European Regulations. You should gain an in-depth understanding of the EU Regulations and the obligations imposed on you to ensure you are compliant.

2. Gap Assessment: Perform a gap assessment of your current technical documentation, risk management and quality system versus the new regulatory requirements.

3. Define & Implement Remediation Plan: Define the remediation plan to close the gaps identified in the previous step and implement these. Actions can include creating new technical documentation, establishing a new risk management system, modify and translate IFUs and labels, modify and elaborate the quality management system and select a Notified Body to work with.

4. Mandate European Authorised Representative: A sole EU Authorised Representative per generic device group must be contractually mandated.

5. Conformity Assessment Product and QMS: Follow the applicable conformity assessment route for your product and Quality Management System (QMS) to obtain the necessary certificates if applicable.

6. Affix CE mark and Draw up DoC: Upon completion of the conformity assessment the manufacturer must affix the CE mark to the product and draw-up the Declaration of Conformity (DoC).

7. Notify Competent Authority: The final step before you can lawfully place your product on the EU market is, when no notified body is required, notifying the competent authority of your product.

Qarad can assist and support in all of the above 7 areas.

4. Language Requirements

The European Union is a union of diversity; the co-existence of many different languages symbolizes this. Currently there are **24 official EU languages** and all Europeans have a right to obtain information in a language they understand. This inevitably puts more strain on manufacturers wanting to access the EU market.

The **MDR** and **IVDR** are clear: to lawfully place a device on the EU market the information to be supplied with the device (consisting of the label and **Instructions For Use (IFU)**) must be provided in the official Union language(s) determined by the Member States in which the device will be made available to the user or patient. In addition, a company must maintain all Instructions For Use, thus all language versions, on the company website, when this is available. The location of the website is to be stated on the product label.

Country Language Requirements for which CPSL can offer assistance		
Country	**Language(s)**	**Notes**
Austria	German	National language requirement.
Belgium	Dutch, French, German	Any one of these, as required by the professional user, and all three for patient use.
Denmark	Danish	
Finland	Finnish, Swedish	Information accompanying the device must he in Finnish, Swedish or English, unless the information takes the form of generally known directions or warning symbols. Information intended for users or patients to ensure the safe use of the device must be in Finnish and Swedish.
France	French	National language requirement.
Germany	German	Other EU languages may be used for non-safety data.
Great Britain	English	English must be used on label. Insert may be in any EU language as long as it is stated on the label.
Greece	Greek	National language requirement.
Ireland	English	National language requirement.
Italy	Italian	National language requirement.
Luxembourg	French, German, Luxembourgish, English	English accepted for professional use; patient information must be in French, German and Luxembourgish.
Netherlands	Dutch	English can be used for professional use, but must be negotiated beforehand.
Portugal	Portuguese	National language requirement.
Spain	Spanish	National language requirement.
Sweden	Swedish	English can be used for professional use, but must be negotiated beforehand.

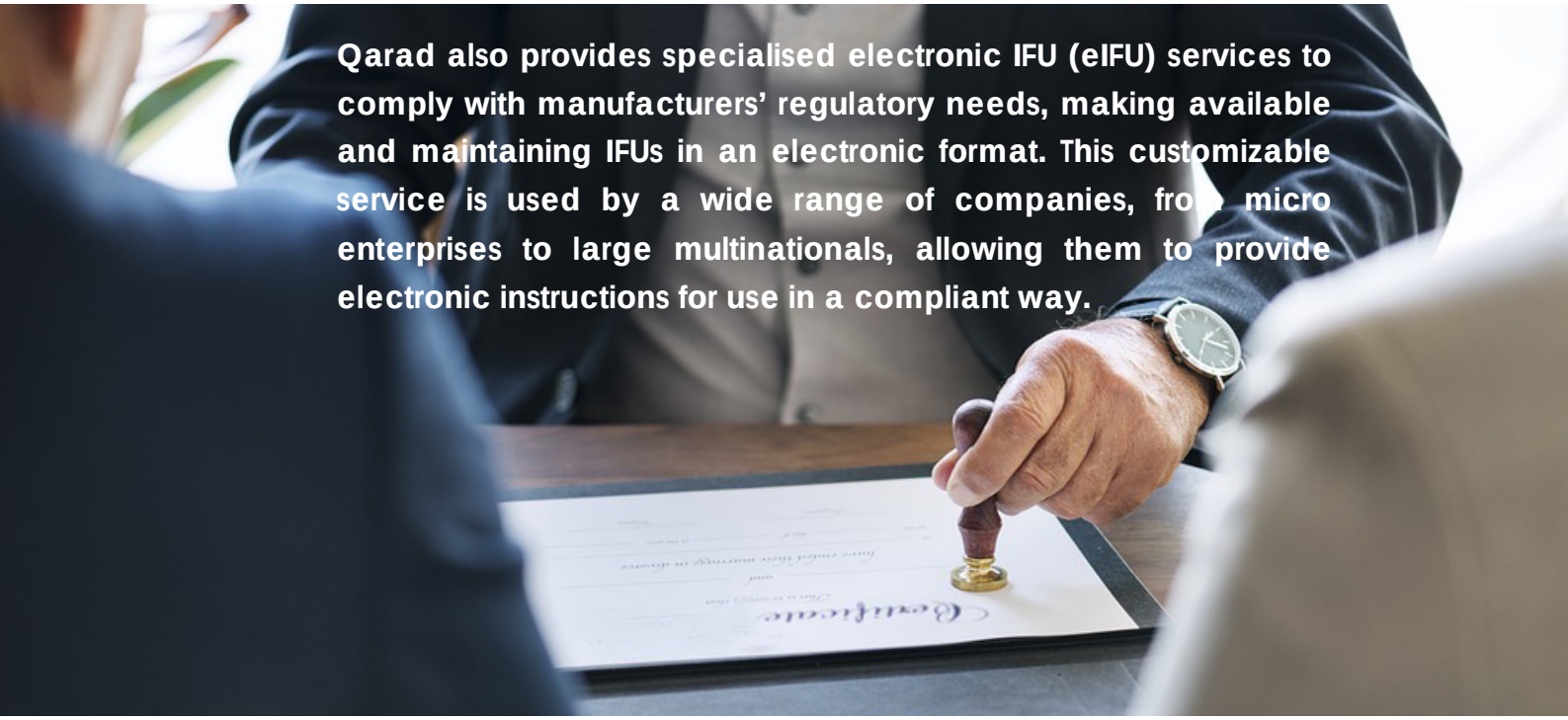
CPSL can assist and support in all of the needed languages such as the above examples' requirements.

5. Who is Qarad?

Qarad, is an **ISO 13485:2016** certified international consulting company specialised in European regulations and quality system implementations for the medical device (MD) and *in vitro* diagnostic (IVD) industry. Qarad facilitates market introduction by effectively assisting manufacturers in meeting regulatory requirements and the implementation of a compliant quality management system.

The Qarad regulatory and quality service offering ranges from high level strategic advice to hands-on support and includes in depth training, consulting, technical file review or compilation, performance evaluations and more. Qarad also functions as the designated Authorized Representative (AR) for a vast array of IVD/MD companies around the globe, that do not have a registered place of business in Europe, including for manufacturers of highly regulated assays.

Qarad's principal consultants each have more than 30 years of experience in the IVD/MD industry, in Regulatory Affairs and Quality Assurance functions giving them a wealth of experience. Through participation as a stakeholder to the European Commission's IVD Technical Group, they are at the forefront of regulatory developments.



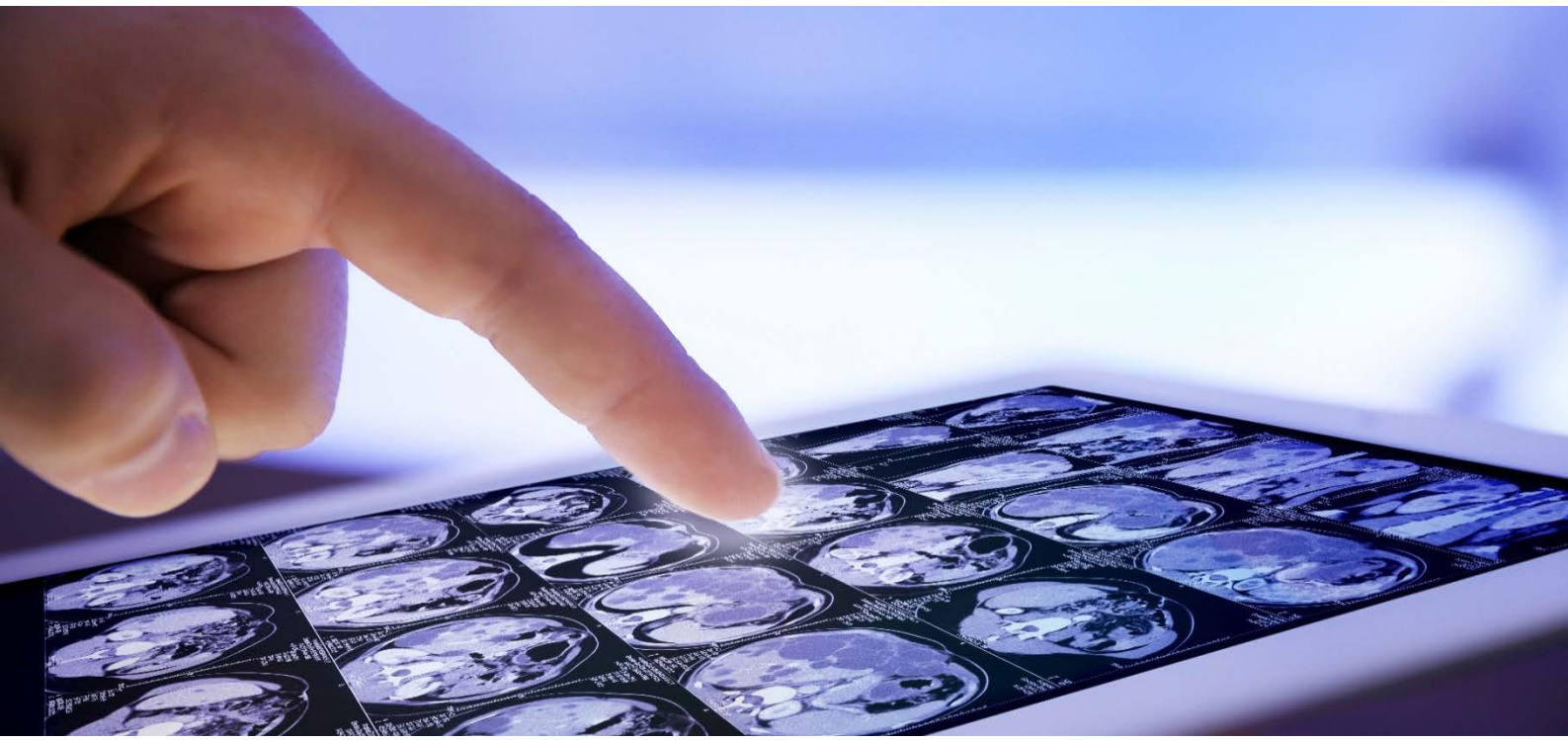
Qarad also provides specialised electronic IFU (eIFU) services to comply with manufacturers' regulatory needs, making available and maintaining IFUs in an electronic format. This customizable service is used by a wide range of companies, from micro enterprises to large multinationals, allowing them to provide electronic instructions for use in a compliant way.

6. CPSL: your partner for experienced translation and language services

CE marking of IVD products for Europe is a complex task. Added to this, there can be confusion over how translation requirements are related to the CE Mark. When going through the process to obtain the CE mark, it is imperative to partner up with the right Language Service Provider (LSP). Manufacturers need to ensure that their localisation partner fully understands the implications of all these regulations and the entire process and is therefore capable of close collaboration regarding how to implement the changes that each company decides are relevant for their products. LSP's are capable of providing general direction regarding language requirements for different markets. Supply chain transparency and risk management will mean that manufacturers will need to be able to rely on LSP's that can demonstrate robust quality methodologies.

With over 50 years' experience, helping hundreds of clients across the globe to market their devices outside their native markets, CPSL is a triple certified LSP with presence in Europe (Spain, Germany, UK) and USA (Boston). As a long-serving translation partner for medical companies and having translated close to 80 million words in multiple languages in the past few years, our credentials come from:

- **Quality certifications.** This is key. CPSL is one of a select few language service providers with 3 ISO quality certificates, **ISO9001, ISO13485 and ISO17100.**
- **Experience**. CPSL has been building on its knowledge and processes in the industry since its inception in 1963. We have the know-how to ensure accuracy and how to stay abreast of applicable changes.
- **Use of Industry-leading technologies.** Used to process our clients' work; translation memories and glossaries guarantee consistency and regulatory compliance.
- **Linguists**. Our global teams are carefully selected and vetted with demonstrated experience in life sciences and diagnostics.
- **References**. Join more than 120 industry-leading clients at CPSL including Abbott, Bayer, Bio-Rad Laboratories, EKF Diagnostics, Greiner Bio-One, Hologic, Huntleigh Healthcare, Oxford Instruments and Trinity BioTech.
- **What & which Languages.** CPSL works with regulatory information, Patient Information Leaflets, packaging, labelling, case report forms, working instructions, safety sheets and study protocols. We also work on many software, documentation, marketing and website localisation projects, depending on clients' needs, into 30+ languages.



Qarad and **CPSL** offer independent but complimentary services at different stages of the process for registering and marketing products in Europe in the required languages. For questions on our services please contact:

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