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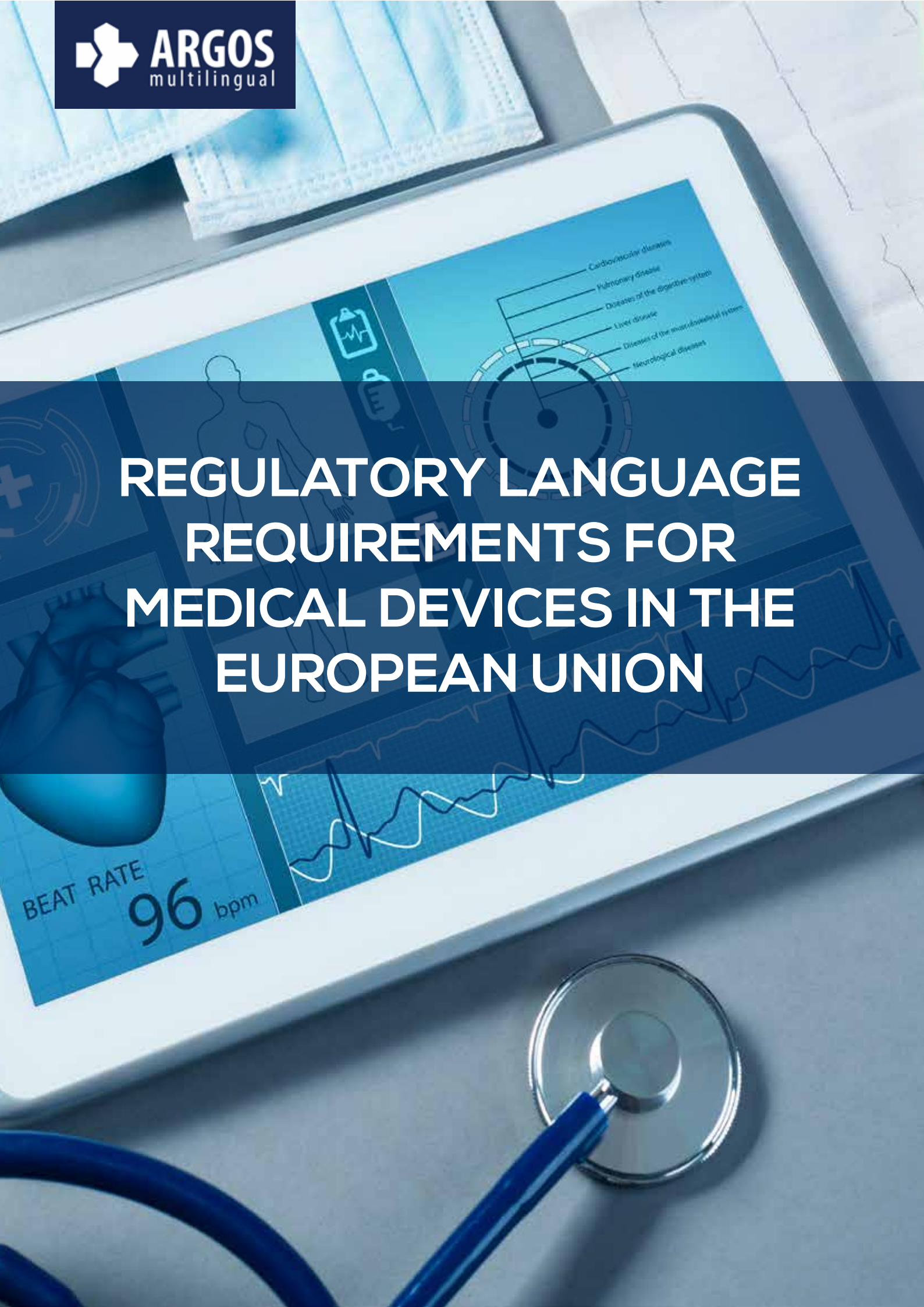

REGULATORY LANGUAGE REQUIREMENTS FOR MEDICAL DEVICES IN THE EUROPEAN UNION

Argos Multilingual is a global language service provider experienced in dealing with localization needs during regulatory changes in our client's industries.

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INTRODUCTION

Maintaining a competitive advantage in the medical device industry involves a global product strategy that recognizes the importance of the European market. Estimated at 30% of the global medical device market, the European market poses increasing regulatory challenges for manufacturers. Regulations controlling the manufacturing, marketing, and usage of medical devices in the EU are forcing manufacturers to incorporate language translation and localization into global development strategies, as individual member states demand product information in the languages of local users. Medical device manufacturers are likely to be well aware of the recent Medical Devices Regulation (EU 2017/745) and In Vitro Diagnostic Medical Devices Regulation (EU 2017/746). These regulations replace a host of existing regulations, directives, and commission decisions - some of which are nearly 30 years old.

The Medical Devices and Active Implantable Medical Devices directives were introduced in 1990, followed eight years later by the In Vitro Medical Device directive, which brought in vitro devices into line with other medical devices already regulated by the EU. The directives clearly outlined regulations regarding the manufacturing, importing, and marketing of devices, ensuring that only safe and effective products were sold in the European market.

The original regulation virtually eliminated the costly regulations imposed by individual member states by introducing the CE mark to Medical Device markets. This helped transform medical device manufacturing, as compliance with standards set out within the legislation meant that manufacturers were able to apply the CE mark to their products.

CE MARK: A PASSPORT TO THE EU

An abbreviation of the French phrase “Conformité Européenne,” the CE mark indicates that the medical device manufacturer has conformed to all obligations set forth by the new European regulations. Affixing this multinational standardized mark to a product gives any global manufacturer a “passport” to freely distribute their products within the European Union, without additional quality testing or approvals.

The CE mark was intended to further promote the establishment of a single market where the free movement of goods, people, services, and capital are ensured, removing bureaucracy while also providing stronger regulations for smaller countries. Critically, it also created language compliance requirements that would come with a cost for manufacturers. Regardless of regulatory harmonization across member states, participating countries naturally wish to preserve their national cultures and languages by requiring product information in their own local languages.

OFFICIAL LANGUAGES IN THE EU

Depending on the extent of the product's presence in the European Union, there are currently up to 24 languages required for translations:

Member State	Official Language(s)
Austria	German
Belgium	Dutch, French & German
Bulgaria	Bulgarian
Croatia	Croatian
Cyprus	Greek
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	Irish* & English
Italy	Italian
Latvia	Latvian
Lithuania	Lithuanian
Luxemborg	French & German
Malta	English & Maltese
Netherlands	Dutch
Poland	Polish
Portugal	Portuguese
Romania	Romanian
Slovakia	Slovak
Slovenia	Slovenian
Spain	Spanish
Sweden	Swedish
United Kingdom	English

**Irish temporarily derogated as working language until January 2022.*

EU ENLARGEMENT – MORE TRANSLATION REQUIREMENTS?

While Brexit has hogged most of the recent EU headlines, the EU has long sought to integrate other free-market liberal democracies. The most recent countries to join are Bulgaria and Romania in 2007, and Croatia in 2013. Current EU membership candidates include Albania, Macedonia, Montenegro, Serbia, and Turkey, while other Balkan nations like Bosnia and Herzegovina and Kosovo are potential future candidates. If these nations are under the EU umbrella, the official language set of the EU will also grow.

In addition to the EU Member States, the European Free Trade Association (EFTA) acts as a "midday regulatory shadow" to the EU so that Iceland, Liechtenstein, Norway, and Switzerland can enforce the CE mark across their markets, increasing the potential number of languages for translation.

The 2017 MDR and IVDR continue to enable a multilingual approach to selling devices across the EU by delegating the decision as to which languages are needed for each territory to the competent authorities in each member state.

MDR AND IVDR – EVEN MORE TRANSLATION?

The new MDR and IVDR apply progressive regulatory requirements to medical devices and their accessories depending on the classified risk. While the previous system was list-based, the new regulation defines a series of rules that consider devices' risk to patients, their function, and their intended use. According to Annex VIII of the MDR and Annex VII of the IVDR, a risk matrix determines whether conformity assessments can be carried out internally for certain low risk devices (like tongue depressors, disposable gloves, or specific IVD reagents) or whether they need to be assessed by a notified body.

By general consensus, the regulations will result in an increase to the number of devices requiring a third-party notified body to independently certify compliance before a manufacturer can use the CE mark. This is also likely to result in significant changes to technical documents and additional translations when a product has been reclassified.

DOCUMENTATION TRANSLATION REQUIREMENTS

One of the key developments related to the new regime is the creation of EUDAMED, a database for all medical devices sold to European markets. EUDAMED will be made available in all official languages, and it aims to enable the fast, transparent identification and tracking of every medical device in the EU (including post-market investigation data and performance studies) through the registration of unique device identifiers (UDIs). Manufacturers also need to include a UDI on every product label, meaning that their label designs need to be altered to reflect the new requirements. This requires planning, as label space may already be in short supply.

One of the benefits of the new system is that once a manufacturer's products have been assigned a UDI and the relevant information has been supplied to EUDAMED, device registration is done at the EU single market level, making multiple national level registrations a thing of the past.

Depending on marketing and distribution objectives, some products may require translation into as many as 24 languages. What's more, there can be more than 20 pieces of information required for each product label or IFU depending on the classification. As with the earlier regulatory framework, competent authorities will determine what device information will need to be translated.

EXPORTING AMERICAN MEDICAL DEVICES

Medical devices that are already marketed legally in the United States may now be exported globally without prior notification or approval, but they must still follow federal Food, Drug, and Cosmetic Act (FD&C) provisions – meaning that manufacturers may still need to request an export permit letter or export certificate.

Given that the new MDR and IVDR introduce controversial new responsibilities for stakeholders such as notified bodies, importers, distributors, and authorized representatives, manufacturers may also find that they are asked to supply proof of product status as regulated by the FDA. To help meet this need, manufacturers whose products will be exported from the US can request an export certificate containing information about a product's regulatory or marketing status from the FDA.

GLOBAL HARMONIZATION AND INTERNATIONAL QUALITY STANDARDS

In 1998, as part of the New Transatlantic Agreement (NTA), the United States and the European Union introduced the Mutual Recognition Agreement (MRA), which recognized the regulatory standards of the respective economic bodies (the FDA's quality system requirements in North America and the ISO in the EU). Since then, both quality systems have made considerable efforts to synchronize their requirements further, increasing the common ground between the two. While the earlier regulations referred specifically to ISO 9001, the new regulations no longer stipulate a compulsory ISO standard. That said, ISO 13485:2016 is generally recognized as the industry standard for medical devices in the EU, and, while a manufacturer's certification body can provide more detailed advice, ISO 13485 is likely to be a reliably compatible system for the new MDR and IVDR.

It is also worth mentioning that the ISO 13485 standard explicitly requires the effective selection and control of tasks performed by third parties. By ensuring that their supply chain is ISO 13845 certified, manufacturers can reduce their exposure to risk. Argos Multilingual is proud to be one of a small number of langauge service providers who are already certified to the ISO 13845:2016 standard.

REGULATORY LANGUAGE REQUIREMENTS AND THE EU

Working closely with a translation and localization vendor that specializes in medical language services and is ISO registered is an important step in mastering the ever-changing international regulatory process. The choice of translation provider helps guarantee that translations are accurate, consistent, and technically correct.

Language service providers (LSPs) should be able to provide documented processes that involve native-speaking linguists who have expertise in both translation and the medical device industry. To deliver consistency, quality, and reduced costs, the LSP should also integrate terminology management and computer-assisted translation solutions with its team of human linguists. As we mentioned earlier, manufacturers can reduce their exposure to supply-chain risk by selecting a LSP certified to ISO 13845:2016.

It is important to recognize the difference between vendors who are actually certified and those who only present themselves as ISO "compliant." The difference is as significant as a medical device manufacturer "promising" the compliance with the respective directives and not physically displaying a CE mark. In the eyes of government regulatory agencies, an ISO-certified language service provider is equivalent to having an in-house translation and localization department with approved processes that may be audited at any time.

Argos Multilingual has been ISO certified since 2003 and we are used to continually monitoring output, calculating deviations, and introducing continuous improvement measures to minimize risk and errors.

We are certified to ISO 9001:2015, ISO 17100:2015, ISO 13485:2016, and ISO 27001:2013.

All current certificates can be viewed on our website.

CONCLUSION

Complex and ever-changing international regulations controlling the marketing and usage of medical devices are forcing manufacturers to incorporate language translation and localization into global development strategies. The EU currently requires that all product information be in the official language of the local users, and that includes more regulations and official languages as the EU continues to grow. A simultaneous global release of medical devices involving up to 24 languages in Europe alone makes this issue as critical as the intended purpose of the medical device. Medical device manufacturers can cost-effectively market their products globally while satisfying international regulatory requirements by partnering with a qualified language service provider in the very early stages of product development. The right language partner can turn what may now appear as a chaos of regulatory requirements into a successful international product release.

ABOUT ARGOS MULTILINGUAL

Argos Multilingual is a global language solutions provider with experience in the life sciences, industrial manufacturing, and software/hardware industries. Our business is built on three core values - quality at source, a partnership approach, and technology agnostic solutions. We are committed to giving you freedom of choice while providing customized strategies to fit your business needs, and we are ISO 9001, ISO 17100, EN ISO 13485, and ISO 27001 certified. With production centers in Krakow, Poland and Colorado, USA, we provide value through dedicated customer service and subject matter expertise in your industry.

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