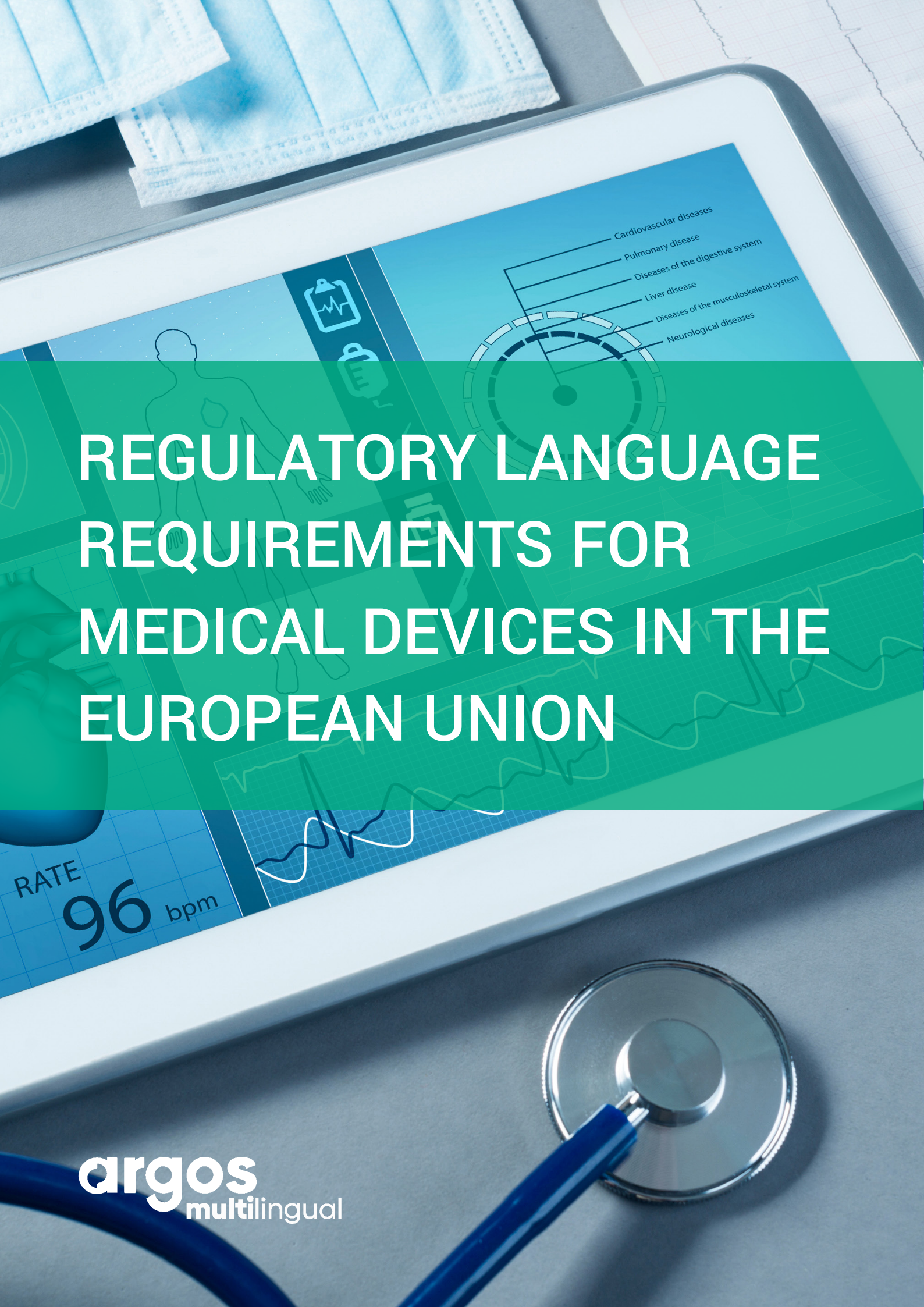


REGULATORY LANGUAGE REQUIREMENTS FOR MEDICAL DEVICES IN THE EUROPEAN UNION

argos multilingual

CONTENTS

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. Individual EU member states require product information in local languages, highlighting the essential role of language translation and localization in global development strategies. The relatively recent EU regulations Medical Devices Regulation (EU 2017/745) and In Vitro Diagnostic Medical Devices Regulation (EU 2017/746) 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 aligned in vitro devices 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 the standards in 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 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 come at 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 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. This table lists the official languages of each European country:

COUNTRY	LANGUAGE
Austria	German
Belgium	Dutch, French, German
Bulgaria	Bulgarian
Croatia	Croatian
Cyprus	Greek, Turkish
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish, Swedish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	Irish, English
Italy	Italian
Latvia	Latvian
Liechtenstein**	German
Lithuania	Lithuanian
Luxembourg	Luxembourgish, French, German
Malta	Maltese, English
Netherlands	Dutch
Norway**	Norwegian
Poland	Polish
Portugal	Portuguese
Romania	Romanian
Slovakia	Slovakian
Slovenia	Slovenian
Spain	Spanish
Sweden	Swedish
Switzerland**	French, German, Italian
United Kingdom*	English

*The UK's regulatory framework mirrors many aspects of the EU's regulations but some differences exist.
**These countries are included in the European Free Trade Association (EFTA) and are not technically part of the EU. However, through the EEA agreement, they can participate in trade with the EU with respect to medical devices and medicinal products. Several of these countries are bringing their requirements in line with the MDR so that they can continue to participate in this trade.

EU EXPANSION - MORE TRANSLATION REQUIREMENTS?

While Brexit has dominated discussions in the European sector over the past few years, the EU continues courting other free-market liberal democracies as part of its strategic direction. The most recent countries to join are Bulgaria and Romania in 2007, and Croatia in 2013. According to the European Commission, current candidate countries include Albania, Bosnia and Herzegovina, Moldova, Montenegro, North Macedonia, Serbia, Turkey, and Ukraine. As the EU's borders expand, so does its linguistic roster.

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. Switzerland, although outside the EEA, aligns with the CE mark regulations via bilateral pacts with the EU.

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 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 current 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.

Based on recent data and expert insights, there's a marked increase in devices needing independent certification from notified bodies before attaining the CE mark. This shift also suggests significant updates to technical documents will be needed, requiring additional translation when a product is 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 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, which requires planning, as label space may be in short supply.

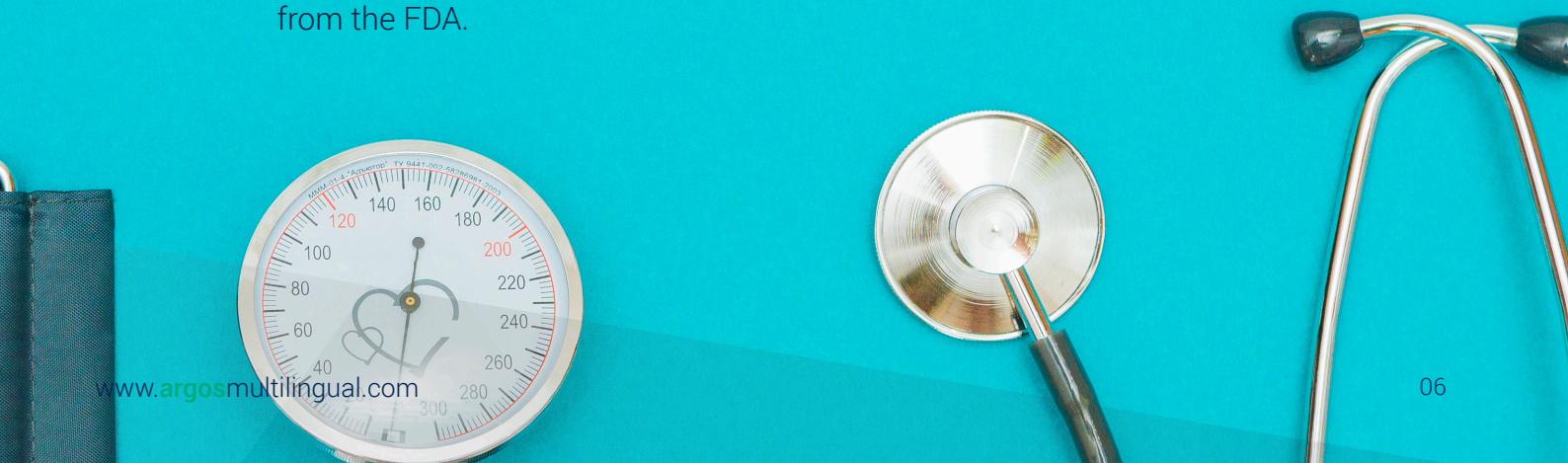
One of the benefits is that once a manufacturer's products have been assigned a UDI and the relevant information has been supplied to EUDAMED, device registration is done at the EU single market level, making multiple national level registrations a thing of the past.

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 marketed legally in the United States may 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.

The MDR and IVDR include responsibilities for stakeholders such as notified bodies, importers, distributors, and authorized representatives. Manufacturers may also be 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). This agreement recognized the regulatory standards of different economic bodies, such as the FDA's quality system standards 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 even though ISO 13485:2016 is generally recognized as the industry standard for medical devices in the EU. 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 13485 certified, manufacturers can reduce their exposure to risk. Argos Multilingual is proud to be among the few language service providers certified to the ISO 13485:2016 standard.

REGULATORY LANGUAGE REQUIREMENTS AND THE EU

Working closely with a translation and localization vendor, particularly one that specializes in medical language services, 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 with 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 mentioned earlier, manufacturers can reduce their exposure to supply-chain risk by selecting a LSP certified to ISO 13485:2016.

It is important to recognize the difference between vendors who are actually certified and those who present themselves as ISO "compliant." The difference is as significant as a medical device manufacturer "promising" compliance with the respective directives but not physically displaying a CE mark. To regulatory bodies, an ISO-certified LSP is equivalent to having an in-house translation team with vetted processes that can be audited at any time.

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

Our certifications include:

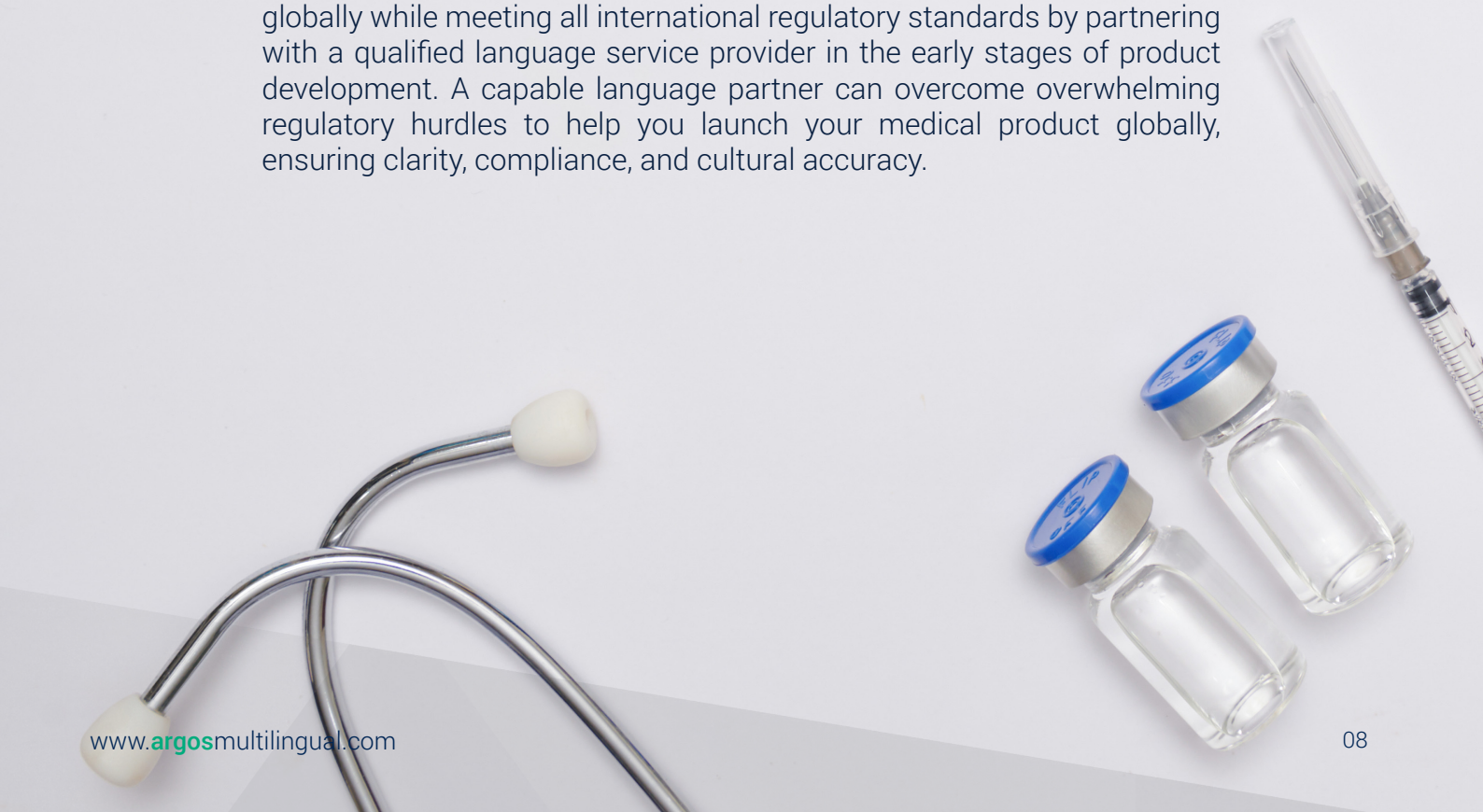
- ISO 9001:2015
- ISO 17100:2015
- ISO 13485:2016
- ISO 27001:2013
- ISO 18587:2017

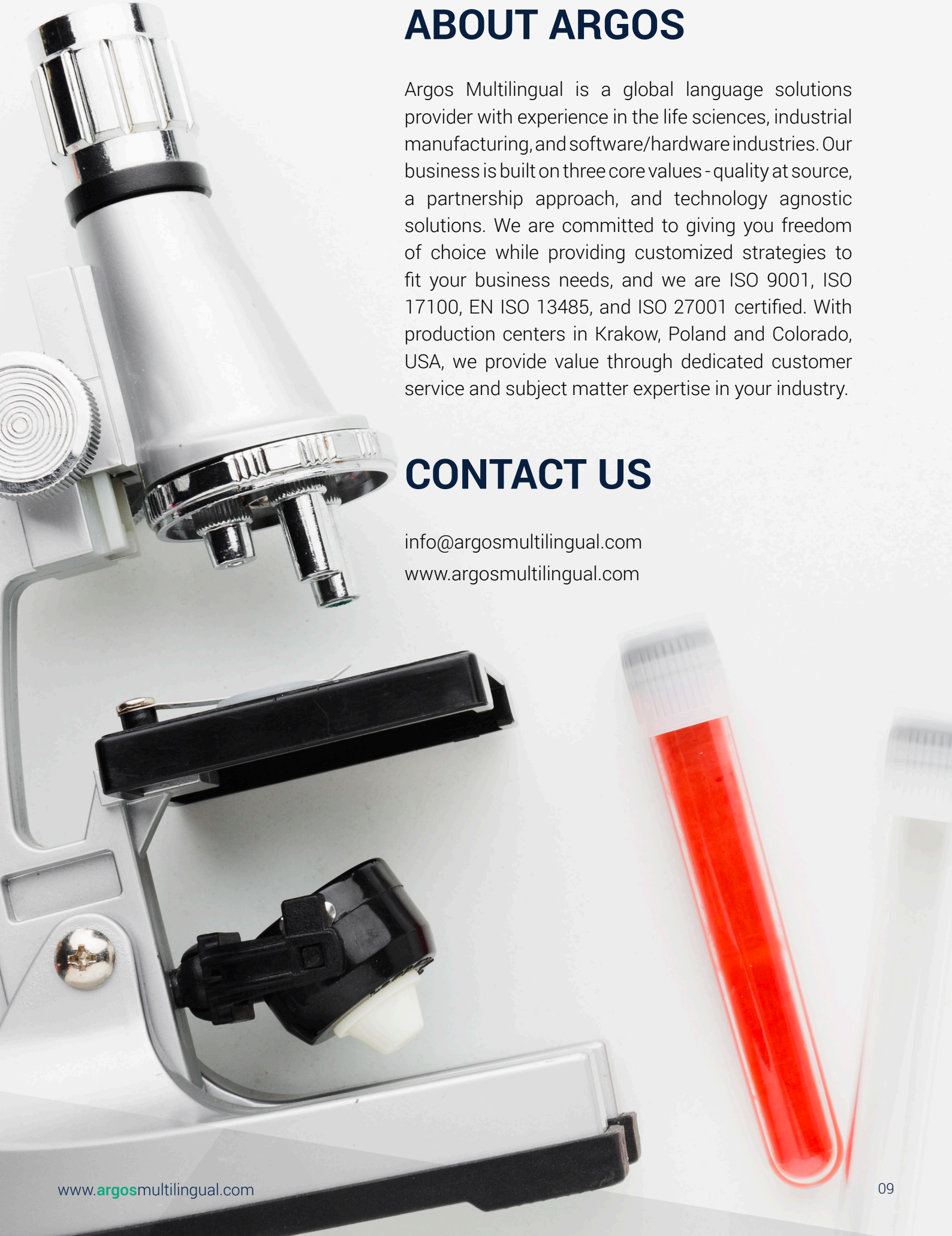
For more information on our certifications, visit our ISO page.

CONCLUSION

Complex and ever-changing international regulations governing the marketing and use of medical devices mean device manufacturers must prioritize language translation and localization in their global development strategies. As the EU mandates all product information be in local official languages — a list that's expanding with the growth of the EU — language requirements have become an essential part of the process.

Medical device manufacturers can cost-effectively market their products globally while meeting all international regulatory standards by partnering with a qualified language service provider in the early stages of product development. A capable language partner can overcome overwhelming regulatory hurdles to help you launch your medical product globally, ensuring clarity, compliance, and cultural accuracy.





ABOUT ARGOS

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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