EU MDR
FROM PREPARATION TO **TRANSLATION**

argos multilingual

CONTENTS

INTRODUCTION

The European Medical Device Regulation (MDR) represents a pivotal shift in European medical device regulations since the 1990s. In effect since May 26, 2021—postponed by a year from its initial date due to the COVID-19 pandemic—this regulation mandates medical device manufacturers targeting the EU market to adhere to new standards. While the MDR is intricate and requires careful interpretation for compliance, its significance is underscored by its universal binding legal force within the EU. Non-compliance is not just about navigating complex requirements; it could also lead to substantial legal consequences.

OUT OF ONE MANY

Under the previous EU medical device regulations, 28 sets of regulations were consolidated into a single framework. This allowed proactive medical device manufacturers to obtain the "CE" product label and sell their products throughout the EU without the need for additional testing or approvals. In the past, individual member states decided the languages for translation and localization, but now under the MDR all regulated medical device content must be accessible in all 24 official languages of the member states where the devices are distributed.

THE SOLUTION

To fulfill this requirement, partnering with the right language service provider (LSP) is critical. Under the requirements of the EU MDR, translations must be accurate, consistent, and technically correct. LSPs need to be able to provide documented processes that involve native-speaking linguists with expertise in both translation and medical devices. To deliver consistency and quality as well as reduced costs, the LSP should integrate terminology management and computer-assisted translation solutions.

Manufacturers will need to have internal systems for risk and quality management. They'll need to conduct clinical evaluations and apply a conformity assessment procedure, and they are entirely responsible for having the right legal cover in place once their devices hit the market. A reputable LSP can support this by improving quality control in the translation process.

THE ARGOS PROCESS

Our experience has taught us that "one size fits all" solutions typically don't fit anyone. That's why we adapt our process to make sure it aligns with the quality requirements of our clients. Our translation workflow is established during the onboarding stage and is specific to each industry and content type. It includes client-requested automated workflows that involve translation, final verification, third-party review, subject matter expert (SME) review, and back translation.

READY FOR ANYTHING

At Argos Multilingual, we only work with carefully selected and qualified professional linguists who are experts in their field or industry. These linguists are part of dedicated linguistic teams who receive tailored training to build product expertise. After completing multiple successful projects, a linguist can achieve a "qualified" status, which is maintained through consistent and exemplary performance reviews.

Particularly in the medical field, we prioritize retaining top-tier linguistic talent. Our experts are always on standby, ensuring immediate availability when our clients require their expertise. Additionally, we're fully equipped to manage the in-country review process with the assistance of our seasoned professionals.

A FOCUS ON QUALITY

The EU Medical Device Regulation (MDR 2017/745) has significantly transformed the regulatory landscape for medical devices within the European Union. An important aspect of the EU MDR is its stress on a comprehensive Quality Management System (QMS).

While the latest regulations don't mandate a specific ISO standard, ISO 13485:2016 is widely acknowledged as the international standard for quality management systems for the medical device sector. It contains provisions related to regulatory requirements and is designed to be used by organizations throughout the life cycle of medical devices, from conception to post-market.

ISO 13485:2016 requires stringent selection and oversight of tasks performed by third parties. By ensuring their supply chain is appropriately certified, manufacturers can minimize risk. In the eyes of government regulatory agencies, partnering with an ISO-certified language service provider is the same as having an in-house translation and localization department with approved processes that can be audited at any time.

One note: There's a big difference between providers who are truly certified and those merely claiming ISO "compliance." We take pride in being among the small number of LSPs certified to ISO 13485:2016.

Manufacturers should always consult with regulatory experts and review the specific requirements of the EU MDR to ensure full compliance. It's also essential to keep up to date with the latest guidance and interpretations of the regulations, as these change over time.

PACKAGING AND LABELING

The EU MDR language requirement applies to packaging, labeling, instructions for use, and anything else associated with medical devices. It also contains a requirement that labeling must be not only in the national language but "clearly comprehensible to the intended user or patient." That applies to virtually everything written on a device, as well as to the inside and outside of the packaging.

This may present a challenge for some manufacturers, as any company selling in smaller markets will have to either provide compliant labeling in every official language or leave the market. To address these issues, we've assembled a specialized DTP team with custom tools that make labeling and packaging simple. No matter what file format you throw at them, they've seen it and they know how to work with it.

GOING GLOBAL

A significant portion of the European medical device market consists of devices patented and manufactured in the United States. Given the prominence of the EU MDR, it's understandable that US medical device manufacturers need to understand its implications for exports.

Medical devices legally marketed in the US can be exported globally without prior Food and Drug Administration (FDA) notification. However, they must still adhere to the provisions of the Food, Drug, and Cosmetic Act (FD&C). This often means manufacturers might need to obtain an export permit letter or certificate.

The MDR and IVDR have introduced new roles for notified bodies, importers, distributors, and authorized representatives. This might necessitate manufacturers to provide evidence of a product's regulatory status as defined by the FDA. To assist with this, manufacturers can request an export certificate from the FDA, detailing the regulatory status of their products.

EU MDR IFU AND LANGUAGE REQUIREMENTS

According to the EU MDR's Article 10 (section 11), manufacturers must provide device information in the official language(s) chosen by the Member State where the device reaches the user or patient. For distribution in the EU, Life Science companies should assess their current language coverage. If any EU member state languages are missing, they'll need a plan to include them.

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.

View the EU MDR in a variety of languages here.

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.

CONTACT US

info@argosmultilingual.com
www.argosmultilingual.com