

Milestone Localization Releases A Guide On The EU MDR Translation Requirements

A comprehensive guide to assist manufacturers with medical device translations

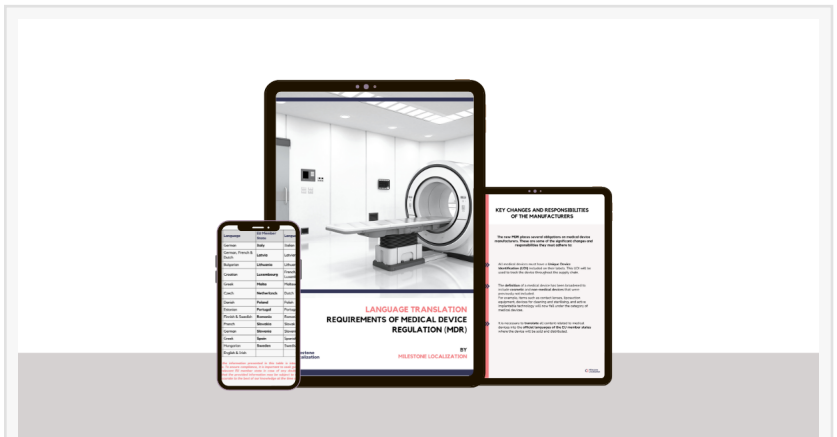
SOLIHULL, UNITED KINGDOM, August 21, 2023 /EINPresswire.com/ -- [Milestone Localization](https://www.milestonelocalization.com/), a leading provider of translation and localization services, has released a comprehensive guide that highlights the intricacies of the language translation requirements as outlined by the European Medical Device Regulation (EU MDR).

Milestone has published this guide to assist medical device manufacturers and industry stakeholders in navigating the language landscape of EU MDR compliance seamlessly and ensure regulatory alignment.

The guide offers a comprehensive overview of the EU MDR's stipulated requirements, addressing the challenges manufacturers might encounter during the translation process and presenting solutions offered by translation service providers.

About the European Medical Device Regulation

The European Union Medical Device Regulation (EU MDR) has been established to ensure a high degree of safety and quality for medical devices manufactured in or supplied to EU member



Guide to EU MDR language translation



Milestone Localization

states.

Officially published on 5th, May 2017, the regulation places significant emphasis on patient safety and effective communication through accurate translations across languages. MDR has introduced stricter guidelines regarding the language and translation requirements for various documents related to medical devices.

Manufacturers are held accountable for providing precise translations of all necessary documents in one or more official languages of the European Union (as specified).

Milestone's Guide on Language Translation Requirements of Medical Device Regulation

Nikita Agarwal, Director and Head of Growth at Milestone Localization says: "As a Language Service Provider, we recognise the challenges manufacturers may face in complying with the EU MDR language requirements. Our guide has been thoughtfully developed after a thorough analysis of the EU MDR regulations, aiming to serve as a comprehensive tool that will effectively guide manufacturers through the complex and dynamic environment of EU MDR language translation."

Here is an overview of what the guide entails:

1. Essential information about Medical Device Regulation: This section provides clarity on what constitutes a medical device under the EU MDR, establishing a foundational understanding of the scope of the regulation.
2. Updated Timelines: Stay informed about the constantly evolving timelines associated with the EU MDR to ensure adherence to deadlines.
3. Key Changes in the European Medical Device Regulation: Gain insights into the significant changes introduced by the EU MDR and their implications for medical device manufacturers.
4. Responsibilities of the manufacturer: This section highlights the responsibilities assigned to medical device manufacturers under the EU MDR to meet regulatory standards.
5. Language Requirements: Comprehend the precise language requirements outlined within the European Medical Device Regulation and the role of accurate translations in ensuring product safety and effective communication.
6. Accepted Languages in EU Member States: This section provides a complete overview of the languages accepted by EU member states for medical device documentation.

The guide on Language Translation Requirements as per EU MDR is available for free on Milestone Localization's website at [A Comprehensive Guide To EU MDR Language Requirements](#)

Role of a Language Service Provider in Medical Device Translation

Quality of [medical device translations](#) cannot be compromised. Even minor errors can cause an impact on patient safety and regulatory compliance. Medical device translations must be clear, precise and maintain the highest quality standards.

Partnering with a specialised Language Service Provider (LSP) can streamline the process. They are well equipped with extensive experience, knowledge of regulatory requirements, and a network of global translators with subject matter expertise.

LSPs utilise advanced tools and technologies in their translation processes that boost efficiency and ensure accuracy. Collaborating with a trusted translation provider enables manufacturers to ensure accuracy and precision in their translations, meeting the highest standards.

An LSP specialised in medical device translations will also have the licenses required to deliver a certified translation that can be required for certain regulatory filings.

About Milestone Localization:

Milestone Localization is an ISO 17100: 2015 language service provider helping organisations across the globe fulfil their language requirements. Having extensive experience working with companies in the medical & healthcare sector, Milestone is well-equipped to handle complex and large-scale medical device translations.

They work with a network of highly skilled medical translators with subject matter expertise and follow a robust quality management process to deliver high-quality translations in 70+ global languages.

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