AbroadLink translations

ISO 13485 certified
translation services

Translation and Medical Devices

A Complete Guide to Ensuring Compliance in the EU

Abbreviations

AIMDD	Active Implantable Medical Device Directive
CE	European Conformity
MD	Medical device
EMA	European Medicines Agency
EMDN	European Medical Devices Nomenclature
EUDAMED	European Database on Medical Devices
FDA	Food and Drug Administration
LSP	Language service provider
IFU	Instructions for use
ISO	International Organization for Standardization
IVDR	In Vitro Diagnostic Medical Device Regulation
IVDD	In Vitro Diagnostic Medical Device Directive
MDD	Medical Device Directive
MDR	Medical Device Regulation
MedDRA	Medical Dictionary for Regulatory Activities
TM	Translation memory
NB	Notified body
PRRC	Person Responsible for Regulatory Compliance
PMS	Post-market surveillance
QMS	Quality management system
SNOMED	Systematized Nomenclature of Medicine
CAT	Computer-assisted translation

Introduction

[...] The new Regulations and their requirements affect the entire process of placing medical devices on the European market, the various economic operators in the medical device supply chain, as well as the competent authorities and notified bodies.

According to various sources, the medical device sector in Europe has around 37,000 companies, of which approximately 700 are in Spain. For several years now, these companies have been facing major regulatory changes, especially when Regulations (EU) 2017/745 and (EU) 2017/746 entered into force in 2021 and 2022 respectively. These Regulations have replaced the European Directives 93/42/EEC (MDD), 90/385/EEC (AIMDD) and 98/79/EC (IVDD) in force at the time, introducing a number of changes and improvements. The new Regulations and their requirements affect the entire process of placing medical devices on the European market, the various economic operators in the medical device supply chain, as well as the competent authorities and notified bodies.

Among all these requirements, translation plays a significant role and cannot be overlooked. But what exactly is its role? What requirements do the Medical Device and In Vitro Diagnostic Medical Device Regulations introduce regarding translations? How can we ensure compliance with these requirements?

With so many questions, it is not always easy to know where to start.

> "This guide has been specifically designed to help you navigate the process."

01. The Regulations

01. The Regulations

1.1. The MDR and IVDR

The Regulations (EU) 2017/745 and (EU) 2017/746 on medical devices and *in vitro* diagnostic medical devices, which can be abbreviated to 'MDR' and 'IVDR' respectively, are regulatory texts that contain a set of requirements that medical devices and in vitro diagnostic medical devices must meet in order to be placed on the European market.

These new texts have several objectives, the main ones being:

- √ To harmonise regulations at the European level
- √ To increase user safety (healthcare professionals and patients) and the performance of medical devices
- √ To increase transparency of devices and their traceability

For manufacturers, these new provisions have a major impact as they introduce stricter requirements in terms of safety, performance and post-market surveillance.

For manufacturers, these new provisions have a major impact as they introduce stricter requirements in terms of safety, performance and post-market surveillance. In order to comply with the new Regulations and to cope with these regulatory changes, manufacturers must adapt and work thoroughly on the following:

- Collecting all the technical documentation related to the device.
- Establishing a quality management system (QMS) and all its related documentation, including risks, traceability, post-market surveillance (PMS), etc.
- Implementing a collaborative certification process with a notified body for medical devices with a risk class higher than Class I.

Given the difficulty for manufacturers to comply with the requirements and obtain CE conformity certificates, the authorities have decided to extend the deadlines, which vary according to the device risk class. On the one hand, this postponement reflects the complexity of implementing the requirements for manufacturers and, on the other hand, a recognition of the presumptuous nature of the requirements and deadlines initially foreseen.

For the time being, this decision will prevent supply shortages that could have severely impacted the healthcare sector if the deadlines had been strictly enforced. While this has granted temporary relief, manufacturers continue to condemn:

- The high cost of the certification process to companies
- Excessive time to obtain certification, possibly due to a lack of resources in notified bodies
- Requirements that are sometimes too strict

Translation plays an essential role in this whole process, particularly due to its importance in placing medical devices on the markets of the EU Member States. What do the Regulations really say about translations?

1.2. Regulatory requirements regarding translations

The translation of regulatory documents is one of the obligations that manufacturers must fulfil to ensure that the information is readable and accessible to all.

The translation of regulatory documents is one of the obligations that manufacturers must fulfil to ensure that the information is readable and accessible to all, with the ultimate goal of protecting users. So far, this is nothing new compared to the European Directives 93/42/EEC (MDD), 90/385/EEC (AIMDD) and 98/79/EC (IVDD) previously in force.

The list of documents that may require translation is substantial, both those intended for users and patients and those intended for authorities. Among the most relevant documents are:

- Instructions for use
- Labelling and CE marking
- Declaration of CE conformity
- Technical documentation
- Risk management plan
- Post-market surveillance (PMS)

Some must be translated into one of the official languages of each Member State where the device is made available on the market and, for others, it will depend on the national legislation of each country.

1.2.1. Critical task

Providing the above-mentioned documents is mandatory. Furthermore, it is a 'critical task' of the certification process. A critical task can be defined as any essential activity related to the safety or performance of a medical device, or to regulatory compliance in relation to it. Due to their importance, these tasks are often the cause of delays or refusals of certification. Thus, translation, which is inherent to documentation, becomes a critical task.

1.2.1. What do the MDR and IVDR say about the quality of translations?

Not much. The text is rather vague as it only sets out three 'qualitative' requirements. Thus, translations must:

- be clear, accurate and understandable;
- not create ambiguities that could affect the safety or correct use of the device;
- faithfully reflect the original documents to avoid misinterpretation.

Since these requirements relate to the quality of translations, they do not clearly set a benchmark or threshold from which manufacturers can consider their translations to be compliant with the Regulations.

Failure to comply with the intended purpose or the misuse of a device as a result of an inaccurate translation could lead to adverse effects or incidents and have tragic consequences for its users (healthcare professionals and patients).

Although they are imprecise and leave room for interpretation by manufacturers, these requirements appeal to the common sense of manufacturers regarding the safety and correct use of devices in patients. Failure to comply with the intended purpose or the misuse of a device as a result of an inaccurate translation could lead to adverse effects or incidents and have tragic consequences for its users (healthcare professionals and patients).

Furthermore, manufacturers also face penalties depending on the degree of non-compliance, which may include:

- refusal of the CE conformity certificate;
- withdrawal of medical devices from the market;
- fines and legal action under national law.

This moral and, above all, legal responsibility makes the manufacturer fully aware of the importance of translations and their quality. It is therefore evident that it will be necessary to turn to translations carried out by professionals with expertise in the medical field.

1.3. What documents need to be translated and into which language(s)?

There are many questions surrounding the translation of documents related to medical devices. What documents need to be translated? Into which language(s)? Is it mandatory? Does the risk class have an influence?

From the provisions of the MDR and IVDR, the following can be deduced:

- All documentation may be subject to translation, but not all must necessarily be translated.
- The languages required vary according to the document and local requirements of the target audience.
- The risk class has an indirect influence on the need for translation.

[...] whether the recipient is a lay person or a healthcare professional has an impact on several regulatory aspects, including requirements related to translation, labelling and instructions for use.

It is also worth mentioning that the complexity and accessibility of the information provided has created the need to distinguish between two different target audiences. Thus, whether the recipient is a lay person or a healthcare professional has an impact on several regulatory aspects, including requirements related to translation, labelling and instructions for use.

According to Article 2 of the MDR and IVDR, a lay person is an individual who does not have formal education in a relevant field of healthcare or medical discipline.

On the other hand, a healthcare professional is qualified and trained to use medical and *in vitro* devices.

In summary, there are some general principles and many specific cases.

How can we know exactly which documents to translate and into which language?

In August 2024, the European Commission published the updated version of a document listing all the requirements of each European country, the documents to be translated and the language of translation.

1.4. Risk class and translation

The higher the risk, the greater the number of mandatory documents, and, consequently, the greater the number of translations that must be carried out.

The risk class of a medical device is a key element that is determined according to its intended purpose, invasiveness and duration of use.

There are four risk classes in both the MDR (Class I, Class IIa, Class IIb and Class III) and the IVDR (Class A, B, C and D).

This classification may have an indirect effect on translation needs, as some documents are mandatory depending on the risk class of the medical device.

It is important to note that the quality requirement applicable to the translation of the same document does not vary according to the risk class.

1.5. Responsibility for the compliance of translations

Making medical devices available on the market is the result of a long process that includes many stages and involves many interested parties. The classification of these devices indicates the degree of risk they may present to users. Poor documentation of the device can lead to incidents that result in penalties, withdrawals and recalls by the manufacturer, and even legal action.

These intermediaries are the authorised representatives, importers and distributors. They play a key role in placing and making devices available on the European market, and are guarantors of their local conformity.

Medical devices are exported to many countries around the world and must comply with local requirements. In most cases, manufacturers partner with local economic operators to facilitate making them available on the market. These intermediaries are the authorised representatives, importers and distributors. They play a key role in placing and making devices available on the European market, and are guarantors of their local conformity. To this end, they must comply with a number of obligations and are therefore also responsible or co-responsible for the conformity of the device.

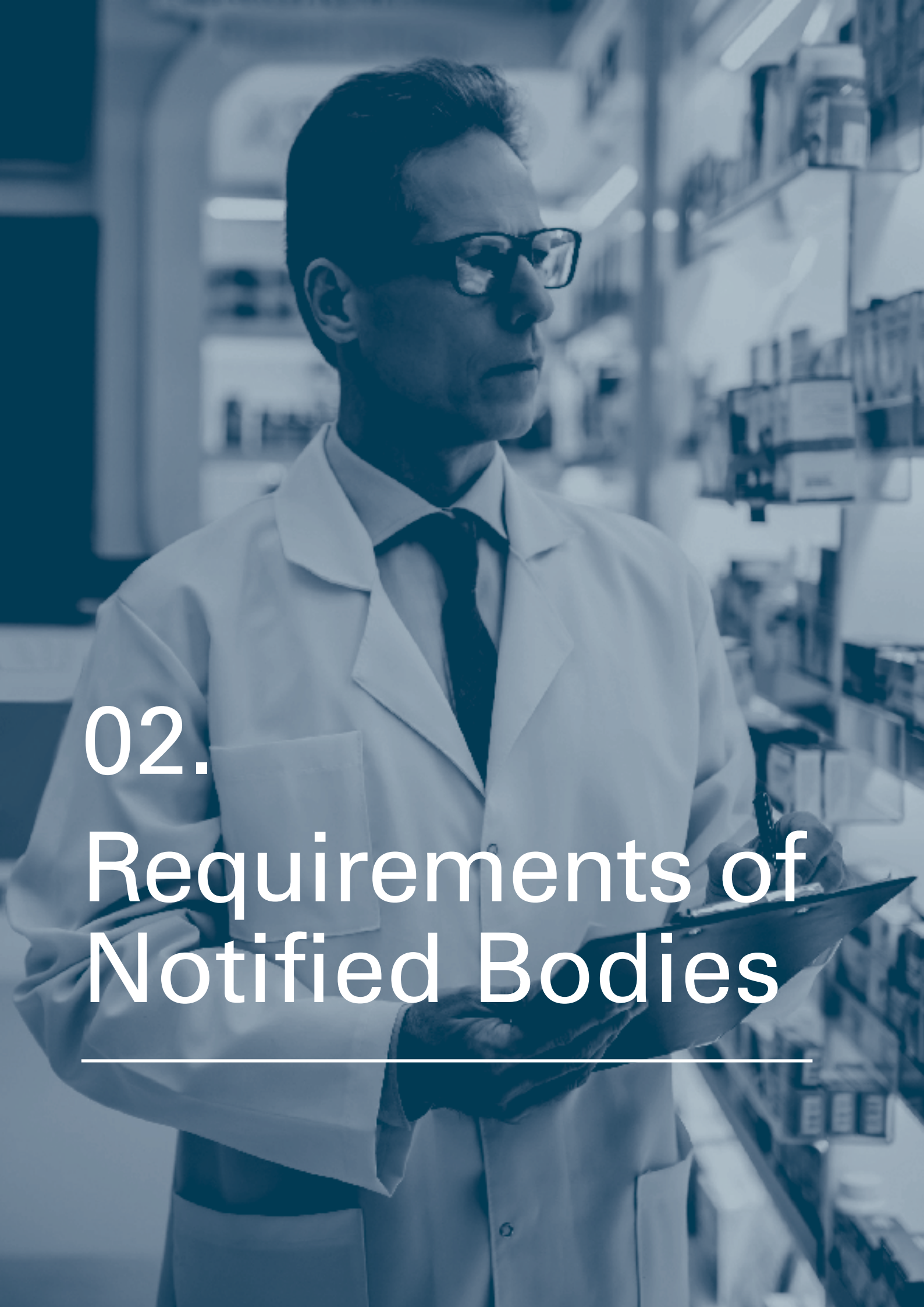
In Article 16 of the MDR, which addresses cases in which obligations of manufacturers apply to importers, distributors or other persons, paragraph 3 states the following: **"Distributors and importers shall ensure that they have in place a quality management system that**

includes procedures which ensure that the translation of information is accurate and up-to-date [...]".

1.5.1. So who is responsible for the translations: the manufacturer, the authorised representative, the importer or the distributor?

Although the manufacturer remains the main responsible party and the guarantor of the translations, the other parties have obligations in terms of verifying the compliance of certain documents and must report any non-compliance with the Regulation or local requirements.

There is no single answer to this question, but several. Although the manufacturer remains the main responsible party and the guarantor of the translations, the other parties have obligations in terms of verifying the compliance of certain documents and must report any non-compliance with the Regulation or local requirements. As outlined in the cases set out in Article 16 of the MDR and IVDR, obligations and responsibilities may fall directly on the importer, distributor or any other natural or legal person; for example, if they make a device available on the market under their own name. There is therefore a wide variety of possible cases, depending on the document, the economic operator and the country.



02. Requirements of Notified Bodies

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2.1. Can the distributor do the translations themselves?

This is a relatively common practice in the industry, although there are no official reports on this subject to estimate its frequency. Distributors are agents who are often fluent in the local language and may be specialists in the medical field.

Is this enough to be able to produce compliant translations?This is not an easy question to answer...

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Indeed, a person with extensive experience in the medical field and who is fully fluent in the source and target languages seems, in theory, to be the ideal person to translate documents such as instructions for use. In fact, their translation may be completely accurate, use the appropriate terminology, and meet conformity requirements.

But how likely is that to be the case? Do all distributors have this person on their staff?

The use of freely accessible machine translation tools also seems to be quite widespread, as it considerably reduces the translation budget. However, is sufficient quality achieved? Above all, one question remains: do notified bodies and competent authorities accept this practice?

As mentioned above, there is no official stance among notified bodies, and neither the MDR nor the IVDR provide clear guidelines in this respect. However, Article 16(3) of the Regulations states the following:

> **"Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date [...]".**

[...] manufacturers, distributors and importers (if they carry out translations) are obliged to document the processes that ensure the quality of the translations of their medical devices.

Given the requirements set out in the Regulations, manufacturers, distributors and importers (if they carry out translations) are obliged to document the processes that ensure the quality of the translations of their medical devices. For example, they can develop and implement a procedure, documented in the quality management system (QMS), which is accompanied by documents allowing the identification and traceability of translators and translations. Therefore, it is more difficult to demonstrate the quality of a non-professional translation, as seen in the examples mentioned above of translations done by the distributor itself or by machine translation platforms. The obligation for all manufacturers to feed and document a QMS can be complex if the translator cannot provide evidence to ensure that they are qualified to carry out these translations.

It is also worth remembering that in the case of high-risk medical devices, health and safety issues are important and even vital. They leave no room for error or approximation.

In order to be able to incorporate the relevant documentation into the QMS and comply with MDR and IVDR requirements, as well as to provide the documents that the auditor or notified body may request, it is recommended to use professional services, unless there are professional linguists on staff.

In order to be able to incorporate the relevant documentation into the QMS and comply with MDR and IVDR requirements, as well as to provide the documents that the auditor or notified body may request, it is recommended to use professional services, unless there are professional linguists on staff. These professional services have all the resources necessary to ensure quality and compliant translations, and to provide all the information and evidence needed to validate it.

2.2. Translation or review? Certified or sworn translation?

Language service providers (LSPs) offer different services, the scope of which is not always clear to a lay person. Is it necessary to request a translation, a review or both? In the case of translation, is it better to have it certified or sworn? What do the Regulations require? Let's take it step by step...

2.2.1. Translation, review or both?

In the translation field, we talk about 'workflows' to designate different services. Translation and review are two different workflows that can be combined.

In addition to the meaning, the translator also seeks to maintain the style and tone of the text to obtain a translation that is as accurate as possible and to ensure that the message has the same effect on the reader.

Translation is the process by which the translator transposes a text from a source language into a target language, respecting the linguistic conventions of the latter. In addition to the meaning, the translator also seeks to maintain the style and tone of the text to obtain a translation that is as accurate as possible and to ensure that the message has the same effect on the reader. These aspects vary greatly if the text is, for example, an advertising text.

A review is an optional process that follows the translation and consists of reading the original text and its translation in order to detect possible errors and make improvements.

A review is an optional process that follows the translation and consists of reading the original text and its translation in order to detect possible errors and make improvements. This work is carried out by a second translator, usually an expert in the field, and offers the most thorough quality control possible. It allows a translation to be validated and thus guarantees optimal quality.

Although all translations are intended to be faithful, accurate and of high quality, a review is always recommended to ensure that there are no misinterpretations, incorrect use of terminology or omissions.

The nature and scope of certain texts can be crucial and even vital; for example, official, legal or medical documents, for which a review is highly recommended.

In the field of medical devices, the MDR and IVDR do not explicitly mention the need to include this process. The decision to include it lies with the manufacturers and is generally influenced by the device's risk class. As far as notified bodies are concerned, the more manufacturers can demonstrate the quality of their translations, the stronger their presumption of conformity and the greater the chances of obtaining certification.

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2.2.2. Certified or sworn translation?

A certified translation is a translation that is delivered with a statement signed by the translator certifying that it is an accurate and complete translation of the original text.

A sworn translation is a translation carried out by a sworn translator appointed by higher governmental bodies, such as the Ministry of Foreign Affairs, European Union and Cooperation in Spain. It is delivered with a declaration of conformity signed and stamped by the translator. This gives the sworn translation an official character, recognised in the administrative and judicial fields.

Sworn translation is only required for certain documents, such as Civil Registry certificates, legal documents, court decisions or notarial documents.

Thus, the difference between certified and sworn translation lies mainly in the status of the translator who performs it and in the official nature of the translation.

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In the case of documentation related to a medical device, there is no need for a sworn translation as a certified translation is sufficient. In fact, sworn translation is not advisable, as sworn translators are usually specialised in the legal field and not in the technical-medical field.

2.3. Should the manufacturer audit its translation provider?

Language service providers (LSPs) are part of the long list of subcontractors whose products and services have a direct influence on the medical device lifecycle.

The number of external agents that have a direct influence on the medical device lifecycle may vary and, more importantly, their contribution can have a greater or lesser impact on its quality, compliance and safety for users.

The number of external agents that have a direct influence on the medical device lifecycle may vary and, more importantly, their contribution can have a greater or lesser impact on its quality, compliance and safety for users. In some cases, this leads to external audits being carried out in order to document the QMS and to ensure the identification, traceability and control of subcontractors, among others.

Is this the case for translations?

While it is true that no medical device standard (MDR and IVDR in Europe, 21 CFR in the United States, etc.) explicitly mentions the obligation for manufacturers to audit the LSPs used, they are nevertheless obliged to exercise control over all subcontracted work and services.

Article 10 of the MDR and IVDR on general obligations of manufacturers states in paragraph 9 that "The quality management system shall address at least the following aspects: [...] (d) resource management, including selection and control of suppliers and sub-contractors".

Article 10 is complemented by Annex VII, which sets out the requirements to be met by notified bodies, in which paragraph 4.5.2 on quality management system auditing states that:

> **"(a) As part of the assessment of the quality management system, a notified body shall prior to an audit and in accordance with its documented procedures:**
>
> **[...] identify links between, and allocation of responsibilities among, the various manufacturing sites, and identify relevant suppliers and/or subcontractors of the manufacturer, and consider the need to specifically audit any of those suppliers or subcontractors or both,**
>
> **[...]**
>
> **(b) [...] based on relevant technical documentation and in order to determine whether the manufacturer meets the requirements referred to in the relevant conformity assessment Annex, review and audit the manufacturer's processes and subsystems, in particular for:**
>
> **[...] product documentation;**
>
> **[...] if not already covered by the audit programme, audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers; [...]".**

Finally, in Chapter I, paragraph 2.3 of Annex IX on conformity assessment based on a quality management system and on assessment of technical documentation, it is stated that "**The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes**".

These excerpts from the Regulation indicate that during the conformity assessment carried out by the notified body, the latter may request information from a subcontractor in order to verify its level of compliance. For services related to 'critical procedures' or if there is any doubt about the compliance of a third party, the notified body may even decide to have an external audit carried out.

Documentation relating to the device is one of the key elements of the device and is considered a 'critical procedure'. However, translation is an inherent part of documentation and is therefore also considered a 'critical procedure'.

In summary, with the reinforced oversight requirements introduced by the new Regulations, it is strongly recommended that manufacturers implement control measures, including external audits, in relation to their LSPs and incorporate the relevant documentation into their QMS [...].

In summary, with the reinforced oversight requirements introduced by the new Regulations, it is strongly recommended that manufacturers implement control measures, including external audits, in relation to their LSPs and incorporate the relevant documentation into their QMS. This ensures having complete documentation to demonstrate their compliance, thus facilitating the assessment carried out by the notified body.

2.4. How to demonstrate the compliance of translations

The MDR and IVDR do not clearly, precisely and definitively indicate what manufacturers should make available to the authorities to demonstrate the compliance of their translations. However, after a careful reading of the Regulations, the pieces of the puzzle fall into place, revealing the tools needed to demonstrate the quality of these translations.

2.4.1. It's all in the QMS.

[...] the QMS is the linchpin on the road to compliance. It is important to remember that its application is mandatory. The QMS ensures control of the entire process that affects the quality and safety of the medical device.

Indeed, the QMS is the linchpin on the road to compliance. It is important to remember that its application is mandatory. The QMS ensures control of the entire process that affects the quality and safety of the medical device, and it is largely based on the description of procedures and associated documentation.

For translations, the manufacturer can:

- Formalise translation requirements (requirements for the LSP, translators, review, validation at local subsidiary level, by experts, external audits, etc.).
- Establish and document the different steps and associated validation decisions.
- Have all these elements available to present them to the notified bodies and other competent authorities.
- If the LSP is ISO 13485 certified, the certificate serves as evidence of both the quality of the translations provided and the provider's commitment to regulatory compliance.

03. ISO 13485 certified translations

03. ISO 13485 Certified Translations

3.1. The ISO 13485 standard

The full name of the standard is 'ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes'.

It is a standard relating and specific to medical devices, and is intended primarily for manufacturers of this type of product. However, the standard also affects all interested parties involved in the devices' lifecycle, from design and manufacture to distribution and maintenance. It therefore concerns:

- Manufacturers
- Subcontractors and suppliers
- Distributors and importers
- Service companies
- Assessment and certification bodies

It ensures compliance with a set of requirements relating to the Quality Management System (QMS) that are mandatory for medical device manufacturers.

It ensures compliance with a set of requirements relating to the Quality Management System (QMS) that are mandatory for medical device manufacturers, as set out in Article 10, paragraph 9 of the MDR. Its approach is based on risk management and focuses on ensuring a high level of safety throughout the design, manufacture, installation and maintenance of medical devices by implementing a documented process.

These requirements imply a presumption of conformity with the MDR and IVDR Regulations and therefore make ISO 13485 a key asset in obtaining the CE certificate of conformity.

Being ISO 13485 certified is a guarantee of quality and compliance with regulatory requirements that is particularly recognised and appreciated by various economic operators and stakeholders, such as competent authorities and notified bodies.

3.2. The top five benefits of ISO 13485 certified translation services

On the one hand, we have the regulatory requirements, that is, the legislation, which sets out a number of criteria that must be met in order to make a medical device available on the market. Then we have the NBs, the oversight body, which examines compliance with these requirements in order to be able to issue a certificate of conformity. For the manufacturer, this means that it must:

- Have quality translations
- Have proof of this quality

Using an ISO 13485 certified language service provider (LSP) is a safe way to achieve both.

To understand this better, here are five benefits of using an ISO 13485 certified LSP:

- **Expertise**

  Being ISO 13485 certified is a sign of knowledge, mastery and compliance with the MDR/IVDR requirements.

- **Quality**

  ISO 13485 requires that specific criteria be established for the selection of suppliers (in this case, translators) to ensure that the services provided comply with regulatory requirements.

- **Terminological compliance**

  Translators use the appropriate terminology on account of their qualification, experience and familiarity with the nomenclatures relating to the medical field (MedDRA, SNOMED CT, EMDN).

- **Traceability**

  The LSP can provide a translation certificate that constitutes 'objective evidence', which can be integrated into the QMS and can be requested at any time by the notified body.

- **Time savings**

  The translation of certain documents is considered a 'critical task' under the Regulations (e.g. instructions for use or labelling). To ensure that the subcontractor complies with the requirements, the manufacturer must establish a procedure to evaluate its providers and this may sometimes result in a second-party audit. However, if the subcontractor is ISO 13485 certified, it is obliged to have a

[...] To ensure that the subcontractor complies with the requirements, the manufacturer must establish a procedure to evaluate its providers and this may sometimes result in a second-party audit.

QMS, which allows it to provide all the documents and information required by the manufacturer to add to its own QMS. You just have to ask for them! This significantly streamlines the control work for the manufacturer and makes second-party audits unnecessary.

3.3. What language resources should be used to ensure compliance?

Terminological consistency is essential to ensure the compliance of translations in different countries. To achieve this, LSPs can use several tools and resources. What are they?

[...] The LSP integrates these terms and definitions into its translation memory (TM) and interactive glossaries. Therefore, the terms are automatically suggested by the computer-assisted translation (CAT) tools used by translators.

- Article 2 of the MDR and IVDR is a first important resource as it contains more than seventy definitions of the terms used in the text and which are necessarily found in the documentation relating to medical devices. The LSP integrates these terms and definitions into its translation memory (TM) and interactive glossaries. Therefore, the terms are automatically suggested by the computer-assisted translation (CAT) tools used by translators.

[...] This function used by CAT tools makes it possible to find occurrences of a word, phrase or segment in the TM, thus ensuring linguistic consistency and increasing the relevance of translations.

- The TM is also continuously fed with all the translation work carried out by the LSP, so that it is enriched with more and more material, consolidating the resource and optimising the 'concordance search'. This function used by CAT tools makes it possible to find occurrences of a word, phrase or segment in the TM, thus ensuring linguistic consistency and increasing the relevance of translations.

- Harmonised ISO standards act as a shield of immunity, guaranteeing maximum compliance with legislation. Indeed, they are said to be harmonised because they are specifically designed to meet regulatory requirements. For example, ISO 13485 is said to be harmonised with the MDR and IVDR Regulations. In the case of translation, this is reflected in the use of translations of official texts as a terminological resource.

Appendix I

Five good practices to reduce translation costs

The complexity of the process, along with the investment in material and human resources and the time required to obtain certification, all represent a considerable cost for the manufacturer. Translation can represent a significant portion of this expenditure, as the number of documents and the amount of text can result in a large translation volume.

Here are some suggestions and practical advice to help you optimise texts and thus reduce your translation budget.

1. Use existing translations

Many manufacturers, and therefore medical devices, existed before the new MDR and IVDR Regulations entered into force. Under the MDD, which previously governed them, a good part of the documentation relating to medical devices was already mandatory.

We can mention, for example, the IFUs, labels, etc. If these documents have already been translated in the past, their translations, although not compliant today, can serve as a reference for an LSP to produce a new translation. At the same time, a translation memory can be created to support future translations.

2. Use English as the source language

English is one of the most widely spoken languages in the world, especially in business, science and technology. In Europe, it is one of the official languages of the European Union and approximately one third of the population speaks English either as a native or foreign language. It is one of the most widely taught languages in schools and is almost always used for business communication.

Its universal status can also be observed in the translation sector, where a large number of translators translate from English into their mother tongue. As a result, it is easier to find an *English → Croatian* translator than a *Finnish→ Croatian* translator. It is statistically unlikely to find a *Finnish→ Croatian* translator specialising in medical translations and, more specifically, medical device translations, with a minimum of five years' experience, etc.

Furthermore, the LSP will most likely first translate from *Finnish → English* and then from *English → Croatian*, resulting in a project with two translators, two translations and therefore twice the cost.

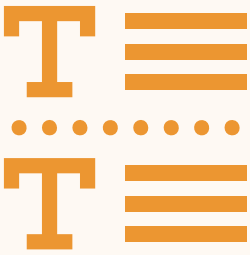
In conclusion, using English as a source language can, in many cases, help avoid this situation and have a significant impact on translation costs.

3. Review the IFUs

Among the documentation relating to medical devices, IFUs are one of the most important documents in terms of translation, as they can be quite extensive depending on the type of medical device. In many cases, they are not written by professional writers, but by company employees.

By carrying out a review to make corrections to the text, it can be modified in order to optimise and reduce its length. Of course, it is not possible or desirable to remove the necessary information. However, if we manage to reduce the number of words by 10-15%, we can make a big difference.

4. Use repetitive text patterns



In documents such as IFUs, which contain a large volume of words, a simple trick can save a lot of money. IFU texts are not intended to be literary, but rather serve a functional purpose. In other words: style is of very little importance. What counts is the message and whether it is easily understood. By repeatedly using the same text patterns throughout the text, it is possible to significantly reduce the number of words that appear only once and, in turn, the number of words to be translated.

Not only that, the text will be easier for the reader to understand. It's a win-win situation!

5. Do not use non-editable text

Documentation relating to medical devices may contain images and diagrams with text. However, these formats make it difficult to extract the text and complicate the translation process, potentially impacting the cost.

To avoid such issues, it is recommended not to use images containing text and to always provide the documents in their original format with all the editable parts.

Appendix II

Useful resources

MDR and IVDR Glossary - Download

Terms defined in Article 2 of Regulations 2017/745 and 2017/746 in all EU languages.

ISO 13485 Terms Glossary - Download

Glossary of key ISO 13485 terms in German, English, French and Spanish (official translations)

ISO 15223 Terms Glossary - Download

Glossary of key ISO 15223 terms in German, English, French and Spanish (official translations)

MDR Language Requirements Summary Table - Download

Revision 2, August 2024; prepared by the Directorate-General for Health and Food Safety

IVDR Language Requirements Summary Table - Download

Revision 2, August 2024; prepared by the Directorate-General for Health and Food Safety

List of MDR and IVDR Notified Bodies - Download

Working languages, specifications, quote request, general information...

Legal notice and disclaimer

The information provided on the AbroadLinkTranslations S.L. website is for information purposes only and is intended to help medical device manufacturers to better understand the applicable regulatory requirements, in particular within the framework of Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR), and other applicable standards.

[...] In no event shall it be a substitute for consulting official texts, guidance from competent authorities or the advice of experts on legal and regulatory matters.

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We therefore encourage manufacturers and stakeholders to refer directly to official sources, such as:

- The Official Journal of the European Union for legislative and regulatory texts
- The European Commission and national competent authorities
- The European Medicines Agency (EMA)
- Notified bodies and specialised professional associations

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We strongly recommend that each medical device manufacturer check the applicable regulatory requirements and consult an expert in the field if necessary.

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