LIONBRIDGE

EU MDR AND IVDR
LANGUAGE GUIDANCE

An industry language guidance for manufacturers and other Economic Operators wanting to place their medical devices on the European Union market.

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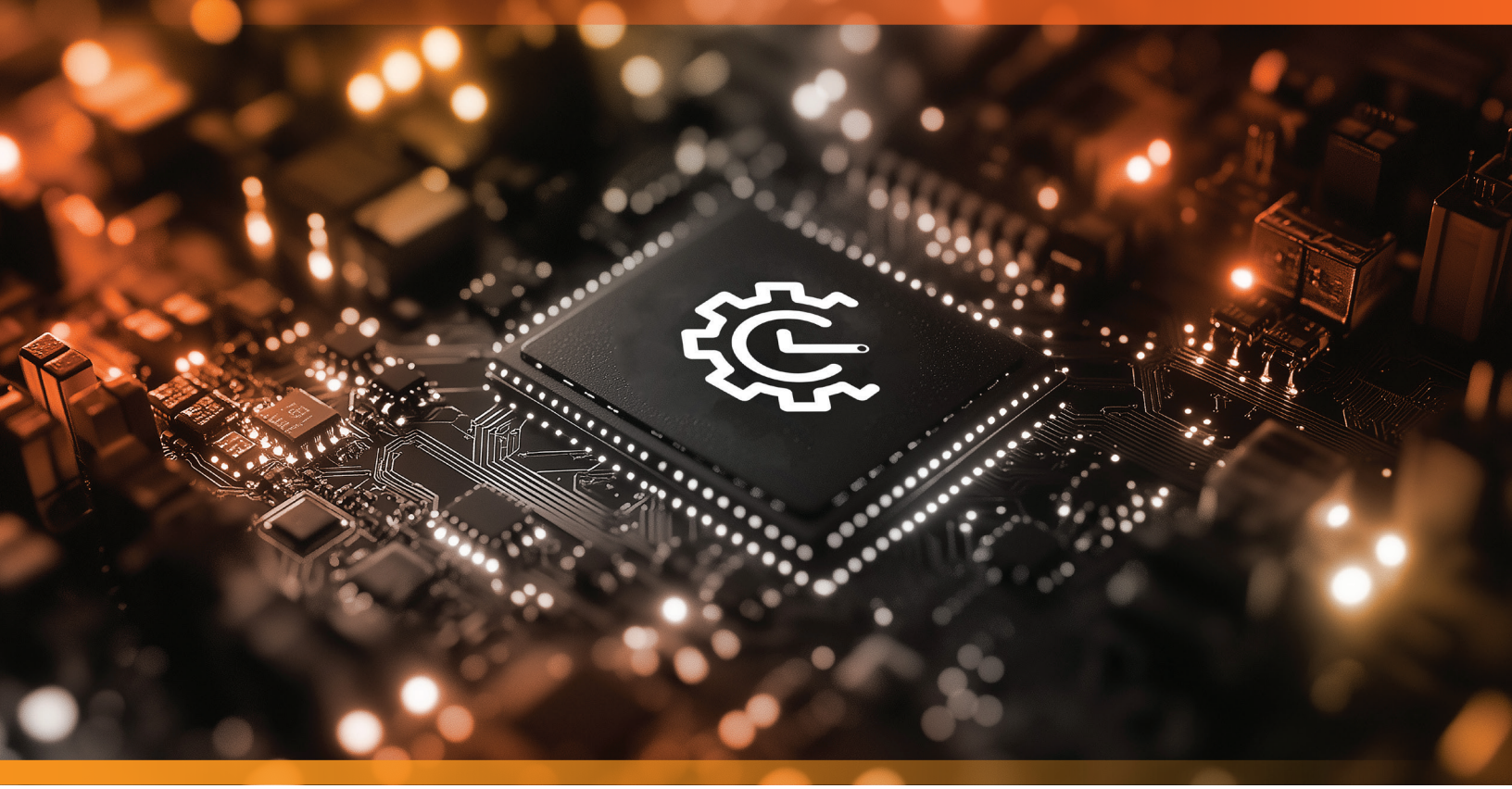


INTRODUCTION

In 2017, the European Union passed a major medical device reform. With the publication in the Official Journal of the European Union of the Medical Device Regulation (MDR, 2017/745) and the In Vitro Diagnostic medical Device Regulation (IVDR, 2017/746), medical devices were set to gradually transition from the European Council Directives of the 1990s into new binding legislative Regulations.

The Regulations are complex legislations intended to strengthen health protection for medical device users and to improve the functioning of the internal EU market for medical device products. The MDR and IVDR mark a regulatory shift from a pre-market focus on the path to CE marking to a more comprehensive life cycle approach, including clinical evaluation, post-market vigilance, and transparency.

The full life cycle approach has significantly increased the documentation and translation burden for manufacturers and other Economic Operators (EOs) wanting to place medical device products in the European Union. In the EU, the free movement of goods is the cornerstone of the European single market, and the union is multilingual with its 24 official languages. Language is, therefore, key to the development, manufacturing, marketing, and surveillance of medical devices under the new Regulations.

This EU MDR and IVDR Language Guidance was developed to aid manufacturers and other economic operators in managing language aspects under these new Regulations. It was developed by Lionbridge, a global leader in life sciences translation, localization, multimedia, and AI-powered solutions.

HOW TO USE THIS GUIDANCE

The guidance is intended for European and foreign medical device manufacturers, as well as other economic operators (EOs) that develop, market, distribute, or import medical devices into the European Union. Foreign manufacturers may particularly benefit from the introduction to the complex multilingual regulatory environment in the EU and the implementation of union and national-level language requirements.

The guidance covers medical devices and implantable medical devices as defined and scoped under the EU Medical Device Regulation MDR, which has replaced the repealed EU Directives on medical devices that went into force in the 1990s (93/42/EEC and 90/385/EEC). In addition, it covers In Vitro Diagnostic medical devices as defined and scoped under the EU In Vitro Diagnostic medical Device Regulation IVDR, which has replaced and repealed the former EU Directive 98/79/EC.

Where relevant, Lionbridge offers guidance and references on authoring and translating information intended for non-professionals or layperson medical device users. Plain language has become increasingly important with transparency and disclosure requirements of the EU reforms.

Finally, with AI and large language models transforming the medical device and language services industries, the guidance also provides recommendations on how an AI-supported life cycle language strategy can facilitate medical device manufacturers in reaching multinational markets and obtaining safe and effective language outcomes.

THIS GUIDANCE IS ORGANIZED INTO THREE PARTS

1. Multilingualism in the EU Regulatory System addressing the unique multilingual environment of the EU single market and how language requirements are generally implemented in the regulatory system and across EU Member States.

2. Language Requirements under MDR and IVDR defining how medical devices and in vitro diagnostic medical devices are regulated on three levels regarding language aspects. This part offers a systematic and comprehensive presentation of language requirements and recommendations for MDR and IVDR.

3. AI Life Cycle Language Strategy for MDR and IVDR focusing on the value of setting up a life cycle language strategy under the new Regulations and how AI and Large Language Models may optimize language outcomes under a risk-based language strategy.

PART 1
MULTILINGUALISM IN THE EU REGULATORY SYSTEM

Selling products on the EU market can be challenging due to the regulatory system's complexity and the union's 24 official languages. To understand how language is regulated and processed under the EU legislative system, economic operators, including manufacturers, importers, and distributors, should be familiar with the multilingual union framework.

EU's Multilingual Policy

The European Union is founded on a **multilingual policy** as part of the union's efforts to promote linguistic diversity, intercultural dialogue, and foreign language competence as essential skills. Under this policy, the European Parliament considers all languages of equal importance, and union-level legal acts are, therefore, published in all 24 official EU languages.

Under the language policy, EU Member States have exclusive rights to determine national language arrangements in their respective jurisdictions. This is established in Articles 6 and 8 of **Regulation No 1** on the determination of languages used by the European Economic Community*:

> **Article 6**: "The institutions of the Community may stipulate in their rules of procedure which of the languages are to be used in specific cases."
>
> **Article 8:** "If a Member State has more than one official language, the language to be used shall, at the request of such State, be governed by the general rules of its law."

Due to the Member States' mandate to determine local language requirements, Union-level legal publications (such as the MDR and the IVDR) do not specify which national languages are required.

As such, language requirements have not been harmonized like the new Regulations' technical requirements. Manufacturers, importers, and distributors will, therefore, need to consult both the EU and national regulations, as well as potentially the Notified Body, to confirm translation needs for the concerned device.

EU's Official Languages

The EU currently has 24 official languages and three alphabets across its 27 Member States. About 60 other languages are spoken in the community, and 175 nationalities live within the EU borders. According to the Special Eurobarometer report "**Europeans and their languages**," 54% of Europeans can converse in at least one additional language, and 25% can speak at least two additional languages. Some Member States, such as Belgium, Finland, and Luxemburg, have more than one official language. In these territories, local languages will often be required in more official languages.

*The European Economic Community (EEC) consists of all EU Member States and, in addition, Norway, Iceland, and Liechtenstein. This means Norwegian and Icelandic may be required for regulatory documentation since these languages are not part of the 24 official EU languages.

THE 24 OFFICIAL EU LANGUAGES ACROSS THE 27 EU MEMBER STATES

BULGARIAN	ESTONIAN	IRISH	PORTUGUESE
CROATIAN	FINNISH	ITALIAN	ROMANIAN
CZECH	FRENCH	LATVIAN	SLOVAK
DANISH	GERMAN	LITHUANIAN	SLOVENIAN
DUTCH	GREEK	MALTESE	SPANISH
ENGLISH	HUNGARIAN	POLISH	SWEDISH

Impact of the Digital Age on Language Diversity in the EU

In 2018, the European Parliament published a **resolution** on language equality in the digital age. According to the resolution, more than 20 European languages are in danger of extinction due to digital communication.

The Parliament states that the EU and its institutions have a duty to preserve and promote linguistic diversity in the union. It calls on Member States to boost the use of multiple languages in digital services, such as mobile applications, and to ensure databases and technologies are available in all EU languages.

Manufacturers and global language services providers are directly impacted by the lack or delay of regulatory multilingual terminologies and databases to support medical devices and harmonized digital communication. An example is the European Medical Device Nomenclature (EMDN), established as part of the European Database for Medical Devices (**EUDAMED**) under MDR and IVDR.

The **EMDN** currently exists only in Italian and English, and the translation into the remaining 23 official EU languages is not yet available. This is even though all official EU languages are recognized as highly important in the **MDCG 2018-2** document published in March 2018 by the Medical Device Coordination Group.

Medical device manufacturers may, therefore, experience a lack of language clarity and consistency in the coming years and when procuring language services through vendors that lack industry-consolidated terminology sources.

When multilingual regulatory terminologies and national requirements are unavailable, manufacturers can benefit from establishing their own language procedures and terminologies specific to their device portfolio.

In Part 2, we will examine the language requirements for medical devices in the EU under the MDR and IVDR.

PART 2
LANGUAGE REQUIREMENTS UNDER MDR AND IVDR

Language recommendations provided in Part 2 cover natural language translations and other aspects of language, such as style, format, readability, and, to some extent, usage of symbols as a replacement for language translations.

The guidance focuses entirely on devices in the European Union (EU). It covers medical and implantable medical devices as defined under the MDR (2017/745) which replaced the EU Directives (93/42/EEC and 90/385/EEC). In addition, it covers In Vitro Diagnostic medical devices as defined under the IVDR (2017/746), which replaced the EU Directive (98/79/EC).

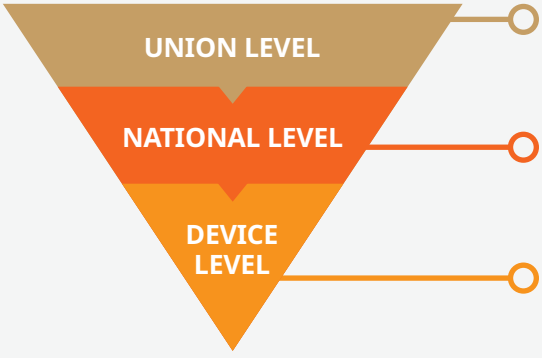
Excluded are General Safety and Performance Requirements (GSPR) and other technical or organizational requirements not related to language, such as Quality Management Systems (QMS), designation, certification, and oversight of Notified Bodies, conformity assessment procedures, EU type-examination procedures, product verification, electronic systems, or responsibilities for stakeholders beyond those of manufacturers and other economic operators.

Three Levels of Language Requirements

When determining language needs under the EU medical device Regulations, a manufacturer should consider the following three levels of language requirements:

- Union-level requirements defined in the MDR/IVDR, the General Product Safety Regulation (GPSR), European Commission (EC) publications, and industry guidance documents published by the Medical Device Coordination Group (MDCG).
- National-level requirements as determined by each Member State's National Competent Authorities and partly enforced by Notified Bodies as part of conformity assessment procedures.
- Device-level requirements as determined by device-specific considerations, such as context of use, device characteristics, or its intended user(s) or purpose(s).

LEVELS OF LANGUAGE REQUIREMENTS FOR MEDICAL DEVICES IN EU



UNION-LEVEL LANGUAGE REQUIREMENTS
Generic language requirements and recommendations as defined by MDR/IVDR, GPSR, EC, or MDCG industry guidance.

NATIONAL-LEVEL LANGUAGE REQUIREMENTS
Specific language requirements and recommendations as determined by National Competent Authorities/Member States.

DEVICE-LEVEL LANGUAGE REQUIREMENTS
Specific language requirements determined by the characteristics of the device and its use.

Union-level Language Requirements

Language requirements falling under the union level are general in nature. Essentially, all consumer products placed in the EU are subject to the **General Product Safety Regulation (GPSR)**. The GPSR requires user instructions, labeling information, and documentation for consumer products to be provided in official languages of Member States where the products are made available.

For products subject to additional safety and performance requirements, such as medical devices and medicinal products, language requirements extend beyond the label and information supplied with the product. They apply, for example, when the manufacturer or other economic operator is responsible for ensuring concise, plain, or local language to support the safety and performance of devices.

Union-level language requirements do not specify which specific national languages are required per individual Member States. In addition, the **Blue Guide on the implementation of EU product rules 2022** states that "Union harmonization legislation does not necessarily specify who has the obligation to translate. Logically, this should be the manufacturer or another economic operator making the product available."

Examples of union-level language requirements include when safety and performance information must be publicly disclosed in local language on the European Database on Medical Devices (EUDAMED). Another example is when special consideration should be given to accommodate vulnerable or non-professional device users, such as trial participants, patients, or the public.

The regulatory risk classification system established in the MDR and the IVDR provide general rules on the types of information or documentation required per device risk class through the device life cycle. High-risk Class III and implantable medical devices, as well as Class C and D In Vitro Diagnostic devices, generally require more regulated information than low-risk devices. This content demand indirectly drives the scope and volume of language needs/activities.

National-level Language Requirements

National Competent Authorities (NCAs) determine which specific national language(s) are required for different types of information for devices in their respective markets. Furthermore, according to the **Blue Guide on the implementation of EU product rules 2022**, NCAs may request information from a manufacturer in a language easily understood by that authority, and this language may be a third language differing from the official languages used.

A rule of thumb is that all content intended for patients must be available in local language(s) in each Member State(s) to ensure patient safety. However, Member State authorities also consider other aspects of communication, such as the reader's literacy levels, technical or medical knowledge, and training. NCAs in the EU differ in terms of whether English is considered a commonly understood language and whether content intended for professional users can be accepted in English. In some Member States, such as France, Italy, and more Eastern European Member States, including Bulgaria, Hungary, and Lithuania, content intended for the market, field safety notifications, and certification are required in local language.

English is accepted as an exemption in a few other countries, such as the Northern European member states Denmark and Sweden. In Denmark, the exemption means the manufacturer or its authorized representative must submit an application for an exception from local Danish language translations. Exceptions may be granted in case the user's qualifications and English language skills are sufficient for safe handling of the device and the device characteristics allow for an exemption.

Device-level Language Requirements

Device-level requirements include unique use cases for certain devices. For example, when an In Vitro Diagnostic device is intended for self-testing or near-patient testing, or when a mobile application is used to capture patient data.

Manufacturers should always consider the specific context of device usage to determine language needs in cases where it's not sufficiently addressed in either union or national-level publications. If in doubt, the Notified Body or the National Competent Authorities should be consulted before placing the device on the market.

Lionbridge generally recommends manufacturers consider language selection and language outcomes not as a regulatory tick box exercise but an important part of making information accessible, readable, and transparent for all users. Additionally, high-quality translations and addressing cultural nuances help manufacturers expand their market presence.

More Content Triggers More Translations

Compared to the repealed EU Directives, the MDR and the IVDR require European manufacturers and other economic operators to generate significantly more content, data, and documentation intended for regulatory authorities, healthcare professionals, patients, and other non-professional users of medical devices. This is partly due to the new requirements on transparency and public access to performance and safety information for medical devices. Also, it's partially due to an increased regulatory focus on clinical evidence, post-market surveillance, and device tracking in the European territory.

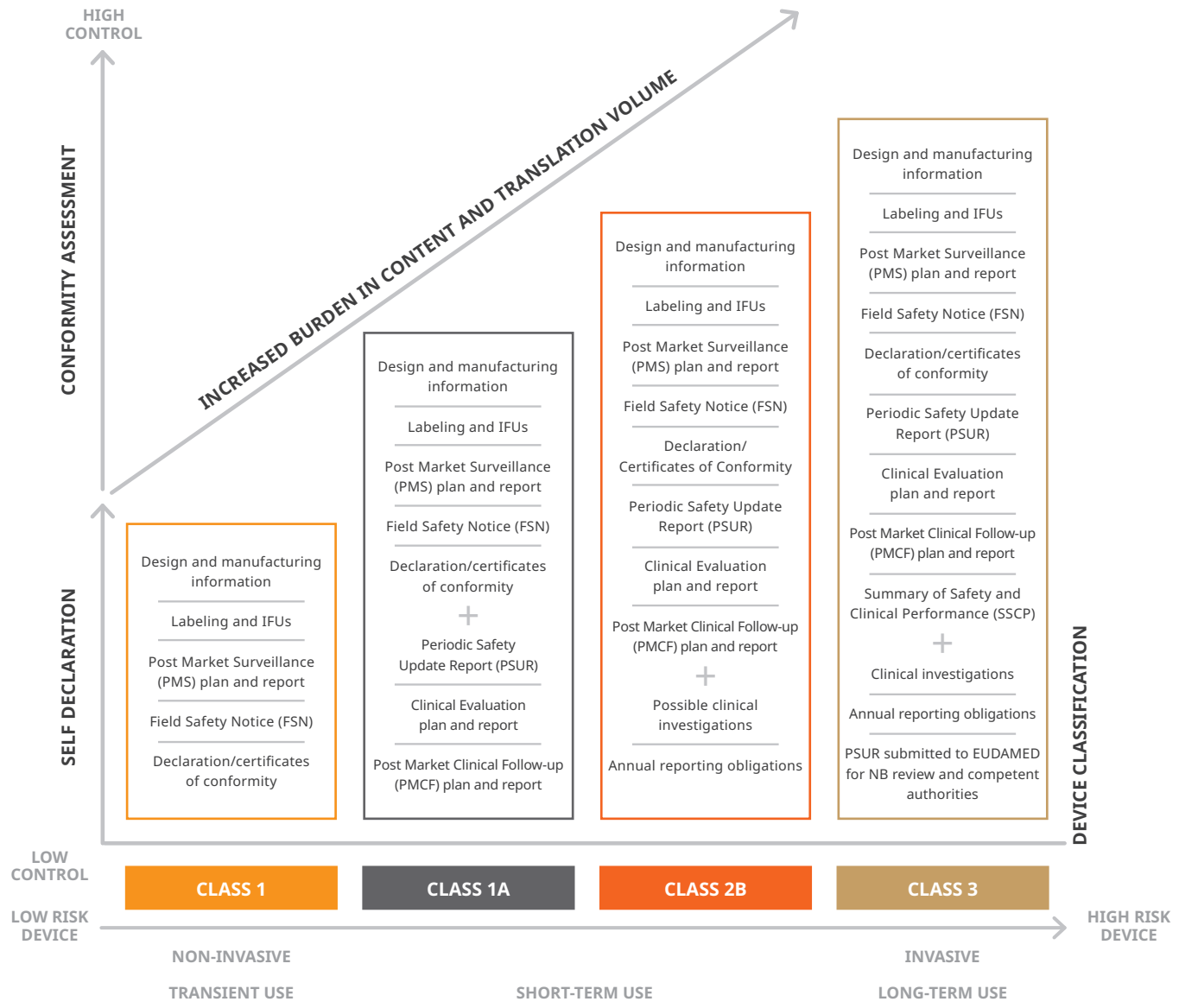
As illustrated below, the regulatory classification of medical devices under the MDR and the IVDR will impact content volumes and language translation needs.

This includes language requirements for:

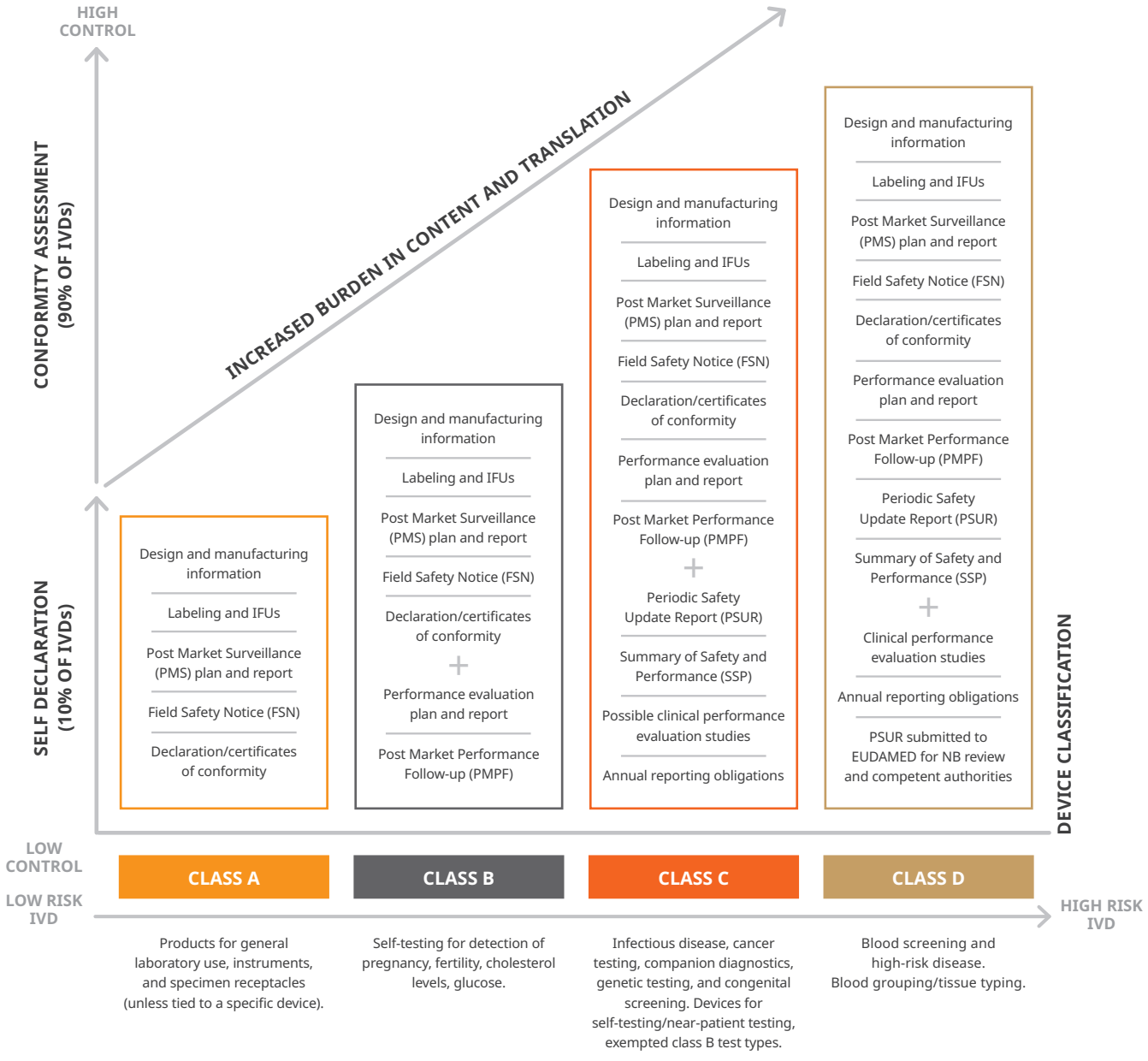
- Labeling/packaging
- Instructions for use
- Clinical investigations
- Post-market surveillance
- Content to be disclosed publicly on the EUDAMED database.

Language requirements under MDR are generally not specified as per sub-classes of class I devices (i.e., class Is: sterile; class Ir: reusable and Class Im: devices with a measuring function) and only to some extent for class II devices (class IIa and IIb). Dental implantable devices are classified as class IIa according to Rule 8 in the MDR. This means some language requirements for labeling may be exempt for dental devices.

CONTENT VOLUMES PER REGULATORY DEVICE CLASS UNDER MDR



CONTENT VOLUMES PER REGULATORY DEVICE CLASS UNDER IVDR



Overview of MDR and IVDR Language Requirements

The table on the following pages is created from a systematic assessment of all Articles and Annexes in the MDR and the IVDR. Its purpose is identifying requirements or recommendations on either language, stylistic or formatting aspects, or symbols related to medical devices, implantable devices and In Vitro Diagnostic devices. For simplicity, only Articles and Annexes containing language perspectives have been included.

References and links are also included to relevant guidance documents primarily published by the Medical Device Coordination Group (MDCG), established under the MDR and IVDR to support implementation and harmonization of the Regulations.

Where relevant, Lionbridge offers recommendations on language aspects obtained from over 20 years as a Language Services Provider to the Life Sciences industry in the EU.

The following abbreviations apply:

- ARs = Authorized Representatives
- EC= European Commission
- EOs= Economic Operators
- NBs=Notified Bodies
- NCAs=National Competent Authorities
- CABs=Conformity Assessment Bodies
- MS=Member State

SECTION	CONTENT/OBJECTIVE	MDR ARTICLE	IVDR ARTICLE	MDCG REFERENCE	PARTY(IES) INVOLVED	DEVICE CLASS
1	Definitions	2	2	NA	All	All
2	Placing on the market and putting into service	5	5		Manufacturer	All
3	Claims	7	7	NA	Manufacturer	All
4	General obligations of manufacturers	10	10	NA	Manufacturer	All
5	Authorized Representative (AR)	11	11	2022-16	ARs	All
6	General obligations of importers	13	13	2021-27	Manufacturer Importers	All
7	General obligations of distributors	14	14	2021-27	Manufacturer Distributors	All
8	Cases in which obligations of manufacturers apply to importers, distributors or other persons.	16	16	2021-26	EOs except Manufacturer	All
9	Implant Card and information to be supplied to the patient with an implanted device	18	NA	2019-8 2021-11	Manufacturer	Implants
10	EU Declaration of Conformity	19	17	NA	Manufacturer	NA
11	CE Marking of Conformity	20	18	NA	Manufacturer EOs	NA
12	Devices for special purposes	21	19	NA	All	Investigational/ Custom-made Devices
13	Medical Devices Nomenclature (EMDN)	26	23	2018-2 2024-2 2021-12	EC Manufacturer All EOs	All
14	Unique Device Identification (UDI) System	27	24	2018-5 2018-7	Manufacturer All EOs	All

SECTION	CONTENT/OBJECTIVE	MDR ARTICLE	IVDR ARTICLE	MDCG REFERENCE	PARTY(IES) INVOLVED	DEVICE CLASS
15	UDI database	28	25	2018-7	All	All
16	Registration of devices in UDI database	29	26	2018-1	Manufacturer	All
17	Summary of Safety and Clinical Performance (SSCP)	32		2019-9	All	Class III Implants
18	Summary of Safety and Performance (SSP)		29	2022-9	All	Class C and D IVDs
19	Language requirements (related to NBs/regulatory authorities)	41	37	NA	NBs NCAs	NA
20	Classification of devices	51	47	2021-24	All	All
21	Conformity assessment procedures	52	48	NA	Manufacturer	NA
22	Certificates of Conformity	56	51	NA	NBs	NA
23	Clinical evaluation, performance evaluation, and clinical evidence	61	56	2020-5 2020-6 2020-13 2020-1	Manufacturer NBs	All
24	Informed consent	63	59		Manufacturer Sponsor Investigator	III Implants Some IVDs
25	Application for clinical investigations and performance studies	70	66	2021-8 2024-3 CG (2023/C 163/06) 2024-5 2022-19	Manufacturer Sponsor Investigator	III Implants Some IVDs
26	Electronic system on clinical investigations and performance studies	73	69	NA	All	III Implants Some IVDs
27	Substantial modifications to clinical investigations and performance studies	75	71	2021-28 2022-20	Manufacturer Sponsor Investigator	III Implants Some IVDs
28	Information from the sponsor at the end of a clinical investigation/performance study or in the event of a temporary halt or early termination	77	73	2023/C 163/6	Manufacturer Sponsor Investigator	III Implants Some IVDs
29	Coordinated assessment procedure for clinical investigations and performance studies	78	74	NA	All	III Implants Some IVDs
30	Recording and reporting of adverse events that occur during clinical investigations and performance studies	80	76	2020-10/1 2020-10/2	Manufacturer Sponsor Investigator	III Implants Some IVDs
31	Post-market surveillance system	83	78	NA	Manufacturer	All
32	Periodic Safety Update Report (PSUR)	86	81	2022-21	Manufacturer	IIa, IIb, III, Implants
33	Reporting and analysis of serious incidents and Field Safety Corrective Actions (FSCAs)	87 | 89 | 92	82 | 84 | 87	2024-1 2023-3	Manufacturer NCAs	All
34	General Safety and Performance Requirements (GSPR)	Annex I and II	Annex I and II	NA	All	All

1. Definitions

Appendices B and C contain a list of definitions from the MDR and the IVDR relevant to the scope of this industry language guidance and the requirements included in content, language, and format.

2. Placing on the market and putting into service

Before making the device available on the EU market, manufacturers should consider national language requirements for labeling and other information accompanying the device. It's essential to plan language activities in due time, given that information supplied with a device requires pre-market conformity assessment by a Notified Body for some device classes.

The content may range from written information in paper or electronic format to Graphical Use Interfaces, which may need validation. Additionally, device users may range from medical professionals to laboratory specialists, nurses, patients, or other non-professional users.

Each EU Member State has the right to determine specific language requirements in their respective territories, depending on the user and device type. Typical cases where local language is waived are for professional use purposes where the device can be safely used based on English (source) language content.

3. Claims

Accurate language plays a critical role for medical device claims and how they're presented in the labeling and instructions for use (IFU), as well as in any of the device's advertising content. Using terminology, images, or language that can lead to potentially misleading, inaccurate, or unsubstantiated claims should be avoided. Promotional language is unacceptable in device labeling and instructions, as is any language that may be ambiguous to the intended user. Omitting important safety information or warnings on device usage may lead to a wrong or biased impression of the performance and device safety. If a product is intended for laypersons or non-professionals, it's vital not to presume they understand technical or medical language. Recommendations on plain language communication are further addressed in section 17.

4. General obligations of manufacturers

As mentioned in Part 1 of this guidance, the device manufacturer must ensure the label, the IFU, and any advertising content are translated into local language of countries where the device is put into service and made available for the intended user(s). The details or particulars on the label must be easily legible, indelible, and clearly comprehensible to the intended user, irrespective of whether the user is a professional or a patient/non-professional. Additionally, the IVDR requires In Vitro Diagnostic devices for self-testing or near-patient testing must be in official local language(s) and written in a way easily understood by the user or patient.

The MDR and the IVDR do not specify the selection of local language requirements per EU Member States due to the multilingual EU policy described in Part 1. Translation requirements for medical device labels and IFUs are generally equivalent to the official languages of the EU Member States where the device is marketed. More languages will be required to ensure safe and correct device usage in some countries.

Refer to Appendix A for more information on official languages in the EU Member States. Local language requirements may be exempt, and the IFU accepted in English only for some devices. This is typically in cases where the device is for professional use only, and the manufacturer determines it can be used safely. Moreover, the IFU may be exempt for class I and IIa devices if they can be used safely without instructions. However, manufacturers should check any exemptions with National Competent Authorities, as exemptions may vary across regulatory territories and depend on a case-by-case assessment based on device type, intended user(s), and device risk profile. Some authorities may require a formal exemption.

In some instances, the National Competent Authorities may ask the manufacturer to submit all information demonstrating device conformity, which may be required in local language. In that case, manufacturers may need to translate large volumes of the technical dossier to avoid legally enforced market restrictions.

5. Authorized Representative (AR)

When a foreign manufacturer has designated an Authorized Representative (AR) within the European Union to perform certain duties, the AR may need access to translated information and documentation from the manufacturer.

Although a contractual delegation is established between a foreign manufacturer and an AR, the manufacturer retains certain obligations, including responsibilities related to the label and the IFUs provided in official Union languages (cf. MDR, Article 11(4).

However, the MDCG 2022-16 specifies that an AR can assist in execution of translations on behalf of the manufacturer. Translation needs will depend on the Member State concerned, and the Member State will determine which local language(s) is required.

An Authorized Representative taking on translation duties for a manufacturer may not have a Quality Management System (QMS) to control the accuracy and quality of translations. It may, therefore, benefit either from the manufacturer's QMS or partnering with a Language Services Provider specializing in regulated translations.

6. General obligations of importers

An importer has several obligations, including checking availability of documentation for market introduction into the EU. Such information includes CE marking, EU Declarations of Conformity, labels, and IFUs. As for labeling, the importer is required to check that any labels added by the importer do not contradict or introduce ambiguous language compared to the label provided by the manufacturer. Although not addressed in Article 13 of MDR and IVDR, Lionbridge presumes that such responsibility also entails the importer should ensure there are no contradictions or inconsistencies between any additional local language labeling content and the original local language label provided by the manufacturer.

According to MDCG 2021-27, national provisions may apply to importers, including language requirements for labeling and other information supplied with the device. In case of relabeling and/or repackaging, the importer may be requested by competent authorities to submit a sample or mock-up of the device, including its translations. The importer should inform the manufacturer if the relabeling/repackaging includes a language not previously notified.

7. General obligations of distributors

In line with the importer's expanded compliance responsibilities under the MDR and IVDR, distributors are obligated to verify compliance with CE marking, EU Declaration of Conformity, labels, and IFUs. Such verification includes confirmation that the information required for the device (Section 23 of MDR and Section 20 of IVDR) is made available by the manufacturer or, if the device is imported, by the importer.

Such responsibility entails the distributor checking that the manufacturer or importer has provided labels in the required Union language(s) for the Member State(s) concerned. Also, the distributor should verify that the labels are indelible, easily legible, and clearly comprehensible to the intended user or patient.

Recommendation on Language Control Across Economic Operators

Under the EU Regulations, local language requirements for devices made available on the EU market are a shared responsibility of the full supply chain. From manufacturers to Authorized Representatives, to importers and distributors. Given the increased compliance responsibilities of the Economic Operators under the EU reforms, Lionbridge recommends that manufacturers implement an operational procedure on language and translation activities during the product life cycle.

Such procedures can clarify how EOs are expected to check local language information supplied with the device, as well as any local language particulars required on the labels. An agreement can be made on how importers or distributors should notify manufacturers of translated relabeling assets. An additional glossary of terms in local languages may help avoid obscuring language across labels and IFUs and ensure an efficient language-compliant supply chain.

Since changes may impact other information on the device linked to labels and IFUs, such as the Summary of Safety and Clinical Performance (SSCP)/the Summary of Safety and Performance (SSP) or the Periodic Safety Update Report (PSUR), the risk of language inconsistencies may be reduced by leveraging central glossaries or language assets via translation technologies.

8. Manufacturer obligations transferred to other EOs

If other economic operators than the manufacturer translated the Instruction for Use (IFU), the original source version of the IFU may be included in the packaging or repackaging of the device. Economic Operators must notify the manufacturer and the relevant national competent authorities of any relabeling or repackaging of devices already on the market, including translations into languages that have not already been notified.

Competent authorities may require a sample or mock-up of the relabeled or repackaged device from an importer or distributor, including its translations. It's generally required that translated IFUs are exact translations of the original manufacturer IFU.

9. Implant Card

Content, layout, and language requirements for the Implant Card are defined in the MDR and the guidance document on the Implant Card published by the Medical Devices Coordination Group (MDCG, 2019-8). Implant Cards are required for all implantable devices, with the exemption of sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.

Accessibility of the Implant Card

The Implant Card not only serves as an identification for patients who have been implanted with a device and require special care. It also enables patients to identify the device and, through the unique device ID (Unique Device Identification, UDI), obtain access to information on the implanted device via EUDAMED and manufacturer's websites. Member States determine the national language requirements for the card. The manufacturer can set up a dedicated website containing updated electronic Implant Cards to facilitate immediate patient access to important or updated safety information. Since Implant Cards are required in local language, it's recommended to partner up with a language services provider that can deliver rapid translations and an efficient workflow to ensure immediate access to any updated card information or supplementary information.

Patients must be provided with a (physical) Implant Card with dimensions similar to a credit card (according to ISO/IEC 7810 ID-1). The content of the card is specified in MDCG 2019-8 guidance.

Use of Harmonized Symbols and Informative Instruction Leaflet

The MDCG guideline (MDCG 2019-8) offers a list of symbols validated by users and submitted and accepted for inclusion in the ISO database on symbols. These symbols are part of the ISO 15223-2 standard.

Together with the Implant Card, the manufacturer must provide an informative instruction leaflet in the language(s) required by concerned Member States to explain the symbols used on the card. They should also provide instructions to the healthcare professional on how to complete the card.

Symbol usage is intended to reduce the need for translations and local language versions. However, the implant card contains a specific field to identify the device type; no symbol exists for this information. A list of "Device Types" is available in English in the MDCG 2021-11 guidance, whereas translation of the terms into other EU languages is currently the manufacturer's responsibility.

Setting up a language glossary containing local language terms for the manufacturer's device types will facilitate translations of the implant card and all other documentation for the device where the device types are referenced.

10. EU Declaration of Conformity

The EU Declaration of Conformity is required in official languages of the EU markets where the device is available. The Member States will determine the official language(s) required. Since the manufacturer is required to continuously update the EU declaration of conformity, updated translations should be anticipated throughout the product's life cycle.

11. CE Marking of Conformity

Annex V of the MDR and the IVDR specifies the form of the CE marking and states that the proportions of the mark must be kept in case the mark is enlarged or reduced in size. Also, the vertical dimensions must remain and not be less than 5 mm, except for small-scale devices where the minimum dimension may be waived. Similar to the labeling, the CE marking must be indelible, legible, and visibly affixed.

12. Devices for special purposes

Devices for special purposes do not need to bear the CE marking except if given for another intended purpose. These include investigational devices for clinical trials, performance studies, or custom-made devices for a particular patient or user. Devices must clearly indicate they're intended for presentation or demonstration purposes only.

For clinical investigations or performance evaluations, the labeling must clearly indicate that the device is for clinical or performance evaluation use only. The specific English phrases defined in the MDR and the IVDR are "exclusively for clinical investigation" and "device for performance study," respectively. Specific wording in local language on investigational labels may be determined by concerned EU Member States.

13. Medical Devices Nomenclature (EMDN)

The European Commission has committed to making available an internationally recognized medical device nomenclature free of charge to manufacturers and other economic operators (EOs). The European Medical Device Nomenclature (EMDN) will be aligned with the International Medical Device Regulators Forum (IMDRF) and the World Health Organization (WHO). The nomenclature consists of updated names and codes. It will be integrated into EUDAMED to help ensure that information is communicated in a standardized manner across healthcare professionals, manufacturers, and EOs.

The Commission decided to adopt the Italian CND ('Classificazione Nazionale Dispositivi medici') as the basis for the EMDN, and the EMDN is currently available in Italian and an English version. Translation into all official EU languages is planned and recognized as highly important. Thus, it's reasonable to expect manufacturers and their EOs will have access to the nomenclature in all official languages once the EUDAMED database is fully functional. As part of the annual updates of the EMDN, it is the intention that translations be validated and made available in all official EU languages.

14. Unique Device Identification (UDI) System

The UDI carriers must appear on the label and all levels of packaging except shipping containers. The UDI will also appear on the EU Declaration of Conformity and be a unique identifier for reporting serious incidents and corrective field safety actions.

Manufacturers and their EOs are required to keep track of UDIs they have assigned to the products to ensure traceability via the UDI system. Given the UDI will appear on various content, including the Summary of Safety and Clinical Performance (SSCP), the Summary of Safety and Performance (SSP), and the Implant Card, it is vital to ensure that any initial or revised translations of these documents carry the correct UDI.

If the language in software user interfaces changes, a new UDI-DI is required, according to MDCG 2018-5. A UDI QC check could be included in the translation procedures recommended in Section 7 of this industry guidance to avoid compliance failures with UDI requirements during translations.

15. UDI Database

The MDCG has released a guidance (MDCG 2018-7) on language issues pertinent to the UDI database. Per the MDCG guidance, the database user interface "shall be available in all official languages of the Union and that the use of free-text fields shall be minimized in order to reduce translations." Furthermore, it states that the information in the database will be publicly available and easily understandable by any European citizen.

The following are defined in the MDCG guidance on the use of free-text, terms/descriptions, codes, and translations for the UDI core data elements:

- **Free-text applies to the following three data elements:** "Additional product description," "Storage and handling conditions," and "Critical warnings or contra-indications." The "Additional product description" data element is optional, whereas the two other elements are required on the label and in the UDI database. All three elements should be available in English language and the official language(s) of the countries where the device is made available. A data element will be set up in the UDI database for each language.

- **Terms/descriptions associated with nomenclature codes should be translated into official Union languages.** However, the guide also states that vendors could consider having the terms only in English language, depending on "budget and legal verifications." Given that an EU tender has been published for translation of the EMDN into all official EU languages, Lionbridge presumes the nomenclature will become available in all 24 languages. Given the currently incomplete guidance on descriptions and translations, Lionbridge encourages manufacturers to consult any future updates of the MDCG guidance to decide translations on a case-by-case basis, depending on the nomenclature code and the concerned device.

16. Registration of devices in UDI database

Manufacturers must assign a basic UDI-DI to each medical device and update the UDI database. For class IIb and class III devices, the UDI-DI must be assigned before the Notified Body is applied for assessment. Before placing the device on the market, the manufacturer must verify and update the information on EUDAMED. Notably, the UDI-DI appears on more document types that may or may not require translations, including the:

- EU Declaration of Conformity (DoC)
- Summary of Safety and Clinical Performance (SSCP)
- Summary of Safety and Performance (SSP)
- Periodic Safety Update Report (PSUR)

Manufacturers and EOs should be attentive to any translations that trigger a new UDI-DI.

17. Summary of Safety and Clinical Performance (SSCP)

Under the MDR, a Summary of Safety and Clinical Performance (SSCP) is required for high-risk devices, including implantable devices, class III devices, and some class IIa/b devices (custom-made and investigational devices are exempt). The MDCG has released a guidance document on the SSCP, intended for manufacturers and Notified Bodies (NBs). The guideline addresses regulatory requirements and recommendations on language, content, as well as regulatory validation requirements (summarized below). The purpose of the SSCP is to publicly grant access to, and transparency on, information on medical device safety and performance.

The purpose is also to do so in an objective and non-promotional way. For a complete description of the content and manufacturer's obligations, refer to the MDCG 2019-9 guidance.

Regulatory Validation Requirements

The Notified Body will validate the SSCP during the technical conformity assessment, and the NB will make it publicly available on EUDAMED upon validation. The validation will focus on whether the required information is included in the summary and its presentation.

Local Language(s) for Validation Purposes

The validation will be based on a single, agreed-upon language between the Notified Body and the manufacturer. Depending on the EU Member States where the device will be sold, the master SSCP (the SSCP for validation) may be accepted in a non-English language.

In such cases, the manufacturer is obligated to provide an English version in addition to the non-English master SSCP. Both will be uploaded to EUDAMED. The English version is required within 90 days after the NB has uploaded the non-English SSCP to EUDAMED.

Local Language(s) for Remaining Markets/Concerned Member States

The MDCG guidance states that the manufacturer should translate the SSCP into all other local language(s) of the EU Member States where the device will be made available. This aligns with the local language requirement for Instructions for Use (IFUs). However, IFUs for devices only used by professionals may be exempt from translations in some Member States.

The NBs do not validate SSCP translations for the local markets. However, according to the MDCG guidance, the manufacturer should ensure the translations are correct via their Quality Management System. The manufacturer must submit all the translations to the NB, which will then upload these to EUDAMED within 15 days of receipt. It's the manufacturer's responsibility to verify that no devices are placed on the market of any EU Member State until the translations have been uploaded.

Notably, all translated versions of the SSCP must clearly indicate the language in which the SSCP was validated by the NB. This requires the manufacturer to keep control of all language versions, including the validated versions and all subsequent local, translated versions.

Intended Audience(s)/User(s)

Depending on the device's intended purpose, the SSCP may need to be developed both for healthcare professionals and patients. Since the SSCP will be publicly disclosed on EUDAMED, the general public is also expected to obtain access to the SSCP.
Serving different audiences in the same document is a communication challenge. Attention should be paid to both language style and layout of the SSCP. One language style will be needed for the summary part intended for professionals. Another part will be required for patients, when applicable. The professional part will contain medical and technical terminology; however, this will not be suitable for patients and other laypersons.

Recommendation on Language Style in the SSCP

The MDR requires the SSCP to be written "in a way that is clear to the intended user". Also, as previously stated, the author of the SSCP may need to consider different audiences with different levels of knowledge.

If the device is intended for healthcare professionals and patients or non-professionals, it should be clear which section is for professional use and which is for patient/non-professional use. Also, there is a significant difference between language conventions in the scientific research community and the patient community. These language conventions are opposites and require very different authoring styles, as illustrated in the figure below.

LINGUISTIC OPPOSITES

SCIENTIFIC AND TECHNICAL LANGUAGE	PLAIN AND NON-TECHNICAL LANGUAGE
Complex syntactical sentence structure	Simple syntactical sentence structure
Technical terminology	Simple and plain terminology
Complex words	Simple words
Professional jargon	Conversational language
Passive language	Active language
Impersonal tone of voice	Engaging and personal tone of voice

With the proper authoring skills across technical and plain language content, the SSCP can be adapted to the intended audience and avoid any misunderstandings or ambiguity. Authoring and summarizing research results for laypersons or public audiences is addressed in the **guideline** on clinical trial results summaries for laypersons from the Clinical Trials Expert Group (CTEG). The guideline is built on health literacy and numeracy principles. It offers advice and practical examples on how to author non-promotional, objective, and plain language research summaries for patients or public audiences.

The high-level principles from the MDCG and CTEG guidance are captured in the table below with focus on the patient part of the SSCP. For the professional part of the SSCP, it should be written in medical/technical terminology and in a clinical context. A more comprehensive guide on plain language content creation and translation is the **Good Lay Summary Practice** guidance, partly authored by Lionbridge and published on **EudraLex Volume 10** in 2021 as part of clinical trial guidelines for the Clinical Trial Regulation (EU CTR, 536/2014).

MDCG	CTEG
Develop one SSCP for each language.	Do not assume any prior knowledge of medical terminology or clinical research in general.
Separate the summary for healthcare professionals and for patients in two parts.	Develop layout and content in terms of style, language and literacy level of the general public.
Do not presume the patient has any prior knowledge of medical/technical terminology.	Keep the document as short as possible. Consider which content to include since plain language may add length to the summary.
Avoid using abbreviation/acronyms or include the full text followed by the abbreviation/ acronym.	Focus on unambiguous, factual information.
If medical terms are used, explain these in plain language followed by the medical term in brackets.	Avoid use of promotional content, e.g. by using neutral language.
Use font type and size that facilitates reading.	Follow health literacy and numeracy principles.
Include both favorable and unfavorable information/data.	Avoid jargon/technical language and be consistent in terms/words throughout the document.
	Use active voice and avoid passive voice.

Language Precautions when Summarizing Results for Patients

Special attention on language should be taken on some content elements in the SSCP. These include the sections on residual risks, side effects, warnings, precautions, and clinical results. The MDCG guidance recommends risks and side effects are "explained and quantified in a way that patients and laypersons can understand." Also, the summary on the clinical evaluation for the device should be objective, balanced, and present all available data, i.e. unfavorable and favorable. Principles of health literacy and plain language writing can help avoid unintentional bias or expectations around side effects.

Lionbridge recommends manufacturers build a glossary of key terminology for devices in all languages, which will help ensure efficiency and consistency in the translation process and at any updates. Specific terms on risks or side effects can be included in such glossary and be 'locked' during translation. Glossaries and language quality assurance can be achieved via translation technology solutions offered by language services providers. Glossaries can also be factored in if large language models are used for AI-powered translations.

Readability Testing

The MDCG recommends the part intended for patients is tested by lay persons to confirm readability. A similar recommendation is also seen in the CTEG guidance for plain language summaries for clinical trials under the new EU Clinical Trial Regulation (EU CTR). While testing the summaries in local language with a lay person audience is ideal from a linguistic perspective, manufacturers may find it too costly or demanding on resources to introduce testing in all languages. An alternative and pragmatic approach is to test the master SSCP version with a lay audience and subsequently ensure a solid translation process with appropriate Quality Control steps and use of glossaries and translation technology. If the master SSCP is of sound quality and the translation process solid (for example, including a back-translation step or a full linguistic review), then the local language versions should be readable and not lead to misrepresentation of the safety and clinical device performance.

Lionbridge recommends the use of advanced readability technologies to aid plain language writing and readability testing which will help obtain a language style appropriate to literacy levels of patients or non-professionals. Additionally, using readability testing on the master SSCP may help identify potential translatability issues before the translation process is kicked off.

Updates of the SSCP

Various changes may trigger an update of the SSCP as well as the translated versions of the SSCP. Such changes may be triggered by CE certificate renewals, regular Periodic Safety Update Reports (PSUR), and at Post Market Clinical Follow-up (PMCF). Re-translation will depend on the changes introduced to the master SSCP. Any updated master SSCP will need to be re-validated by the NB and may impact all translated versions. Controlling the different language versions can be challenging and may call for implementing a translation and language procedure.

18. Summary of Safety and Performance (SSP)

The Summary of Safety and Performance (SSP) is specific for In Vitro Diagnostic devices, but is similar to the SSCP. The MDCG has not provided a specific guidance for the SSP, but only a template. SSPs are required for class C and D IVDs and must be validated by the Notified Body and made publicly available like SSCPs.

An important consideration is IVDs intended for self-testing when a plain language summary must be provided to the patient/lay person user of the device. The SSP template contains a separate section 2 for self-testing devices. Lionbridge recommends IVD manufacturers consult the MDCG 2019-9 guidance on SSCPs and consider the language recommendations addressed in this guide under section 17. The challenges of authoring SSPs are very similar to those of SSCPs.

19. Language requirements

Language requirements under Articles 41 and 37 of the MDR and the IVDR focus on language requirements for the application, assessment, and delegation of Notified Bodies. From that perspective, this Article is not directly relevant for Economic Operators and the conformity assessment of medical device products.

However, in cases where a Notified Body is selected for review by the authority responsible for Notified Bodies, as per Article 45 in MDR and Article 41 in IVDR, the technical documentation may need translation depending on the source language of the dossier.

20. Classification of Devices

Medical devices and In Vitro Diagnostic medical devices are assigned a regulatory risk classification based on their intended purpose and inherent risks. Under MDR, the system ranges from low-risk class I devices, to class IIa, IIb, and high-risk class III. IVDs are similarly classified from low-risk class A to class B, C, and high-risk class D devices.

The classification of devices is both complicated and essential, since it drives:

- Technical safety and performance requirements
- Regulatory reporting requirements
- CE marking requirements
- Clinical requirements
- QMS requirements
- Transparency requirements

A rule of thumb is the higher the risk class, the more content and translations are needed throughout the product's life. For example, for class I and IIa devices, IFUs may be exempt if the low-risk device can be safely used without the instructions, whereas for class IIb and III devices, the IFU is required. Likewise, the SSP is required for class C and D devices, whereas lower-risk class A and B devices are exempt.

21. Conformity Assessment Procedures

During conformity assessment, the Member State of the Notified Body may require translation of parts of the entire technical documentation into an official union language.

22. Certificates of Conformity

Upon successful conformity assessment, the Notified Body will issue a Certificate of Conformity in a language accepted by the Notified Body or in an official union language determined by the concerned Member State. Certificates and any supplements will be made accessible to the public via EUDAMED.

23. Clinical evaluation, performance evaluation, and clinical evidence

If a manufacturer compares clinical device characteristics with another marketed device for purposes of demonstrating equivalence, it's important to consider any differences in the context of use, and hence if the language should be adjusted. A device intended for home use and a device intended for professional use may address the same clinical condition, but have different use environments. For more information related to clinical activities, refer to sections 24-30.

24. Informed consent

Written informed consent is a requirement for medical device studies. It's intended for clinical study participants and/or their legally designated representatives to understand what it entails to participate in a clinical investigation or performance study. Language is a key component of an effective and bioethically sound informed consent process where study volunteers are given adequate information about the study. Informed consent should be seen as a communication process, which is not only about obtaining a signed consent form, but ensuring that the study participant has been given all relevant information about the study and its associated risks. The manufacturer and the investigator should consider the intended study population's ability to process and understand the information. They should avoid any coercion in the informed consent process.

The written informed consent should be developed in clear, concise, unambiguous language with these aspects in mind. It must be understandable to the trial participant or the participant's legally designated representative. Because it cannot be assumed that the participant has any prior or medical knowledge about the study or clinical research in general, the principles of health literacy should be used for authoring informed consent, as well as for any other patient-intended information. Particular care should be taken if a study is conducted in incapacitated participants or minors. In this case, informed consent must be adapted to their age and cognitive development stage.

More information about this is available in the **Good Lay Summary Practice** guidance. As part of the informed consent process, the manufacturer shall also ensure that the participant is informed about the SSCP or SSP, which will be made available after the study. According to Good Clinical Practice, the informed consent and other documentation intended for trial participants must be reviewed and approved by an Ethics Committee as part of the application for a clinical investigation or performance study. Manufacturers may request a Certificate of Translation to confirm ISO compliance of the translations.

25. Application for clinical investigations and performance studies

The application for clinical investigations or, in the case of IVDs, performance studies, contains a number of documents. Some of these documents will be required in local language. These documents include, for example, the:

- Synopsis of the clinical investigation plan/performance study plan
- Written informed consent documentation
- Patient information sheet

Although not explicitly stated in the MDR or the IVDR, any content intended for study participants should be in local language. This is not only for the sake of the participants, but also for Ethics Committee review in the concerned Member State(s), where the study will recruit and enroll participants.

For clinical investigations or performance studies on minors, information provided should be understandable and appropriate for the minor's age and mental maturity.

Medical device studies are expected to follow Good Clinical Practice (GCP), as is the case for clinical interventional studies for medicinal drugs. Lionbridge has found that EU Member States may require more content in local language for the submission, which may include:

- Insurance policies
- Advertising materials
- Newsletters intended for patients
- Investigator agreements or parts thereof
- Parts of the investigator's brochure

The requirements should be confirmed with the national competent authorities/ethics committees, as this is not fully specified in the MDR or IVDR. GCP for clinical investigations for medical devices is described in ISO 14155.

26. Electronic system on clinical investigations and performance studies

Manufacturers and other EOs are advised to follow the development of the electronic system EUDAMED. The European Commission is setting up this system in collaboration with EU Member States for tracking, clinical investigation/performance study applications, and exchange of information pertinent to clinical studies. According to Article 73 of the MDR and Article 69 of the IVDR, the user interface of EUDAMED will be available in all official EU languages.

Some documents will become publicly disclosed. These documents include clinical application documents, clinical investigation/performance study reports and their summaries, and serious adverse events and device deficiencies.

27. Substantial modifications to clinical investigations and performance studies

Although neither the MDR, IVDR, nor the currently available MDCG guidance state any language requirements on substantial modifications to clinical investigations or performance studies, Lionbridge has the following experience in case clinical investigations or performance studies are new to a manufacturer. If new countries are added to a clinical study after it has been initiated, any content intended for patients or users in the added countries will need translation into local language(s) and approval from national competent authorities and Ethics Committees. This is a standard according to Good Clinical Practice.

28. Information at the end of a clinical investigation or performance study

At the end of the clinical investigation or performance study, whether completed on time or terminated prematurely, the Sponsor (manufacturer) must submit a summary with the clinical investigation/performance study report. The summary must be written in terms easily understandable to the intended device user. This means the user's health literacy levels and numeracy should be considered.

In addition, promotional content must be avoided. The report and the summary must be submitted to EUDAMED, presumably in official EU language(s). A European Commission guidance (2023/C 163/06) is available on the content and structure of the summary.

However, the template provided in this guidance is written in medical language style with no advice on language intended for non-medical audiences. For more information on health literacy and plain language appropriate for such summaries, refer to Section 17.

29. Coordinated assessment procedure for clinical investigations and performance studies

Manufacturers should be attentive to the timelines applicable in EUDAMED for clinical applications. The coordinated assessment procedure across the concerned EU Member States is based on a draft assessment report transmitted in EUDAMED within 26 days by the Member State acting as the coordinating Member State. After 12 additional days, the remaining Member States will transmit their comments on the draft assessment report, which will then be finalized by the coordinating Member State by day 45. Member States may require additional information from the manufacturer during the assessment procedure.

The manufacturer has 12 days to provide any missing information. During this time, translations may be required within a very short time frame, which could be one or two days. Failure of the manufacturer to meet the regulatory deadline may result in a rejection of the entire application for all Member States.

As a risk minimization measure, it's recommended that manufacturers plan language services and translations already during preparation of the clinical investigation/performance study plan.

30. Adverse Events During Clinical Investigations and performance studies

Manufacturers should be attentive to reporting obligations on adverse events for any clinical investigation or performance study, such as serious adverse events (SAEs) or device deficiencies.
The timing and reporting requirements for such events may necessitate an initial report, followed by a final report that both must be uploaded to EUDAMED.
As for language, English is the recommended language for SAE reporting, according to MDCG guidance. However, special attention should be given to any national safety reporting requirements since each Member State has the right to define additional local reporting requirements beyond what is mandated in the MDR and IVDR. This is partly because each Member State is allowed (as per MDR Article 82) to define any local requirements to protect study participants. It's partly because separate reporting may be required for local Ethics Committees (MDCG 2020-10/1 Rev. 1, section 7).

31. Post-market surveillance system

Manufacturers will collect data via their post-market surveillance system throughout the device life cycle.
Any translations required to support the documentation and reporting obligations of manufacturers will, therefore, need updates on an ongoing basis.
For example, this includes the Instructions for Use and other labeling content, as well as the SSCP/SSP.
Due to the interdependence and shared content across several technical documents for medical devices, it will be important for manufacturers to version control the source documents as well as the translated documents.
An example is the SSCP/SSP, which is expected to contain a revision history that includes information on which translated version the Notified Body validated.
It's recommended that manufacturers set up a translation plan to ensure control across all such interdependent documents.

32. Periodic Safety Update Report (PSUR)

The PSUR should be consistent in terminology and format, which includes using standardized terms such as those from the **International Medical Device Regulators Forum (IMDRF) Adverse Event Terminology**. The PSUR must be made available in the EUDAMED system for Notified Body and National Competent Authorities for Class III and implantable devices. For class IIa and IIb devices that aren't implants, the PSUR is not submitted to EUDAMED. Instead, it's made available to the Notified Body and the National Competent Authorities.

The preferred language for PSURs is typically English since it's a commonly accepted language in the EU, and the PSUR is not publicly disclosed on the EUDAMED portal. Manufacturers should, however, check for any national regulations. Data in the PSUR must be summarized in a clear, organized, and readily searchable manner. Lionbridge generally advises manufacturers to consider how information from the PSUR is summarized or presented in the SSCP/SSP, which will be publicly disclosed. Aligning language and terminology in regulatory and plain language for aggregated safety data during the device life cycle will help ensure language consistency and clear, updated communication of the device safety.

REQUIREMENTS AND UPDATES OF THE PSUR AND DATA SHARING WITH SSCPs/SSPs

DEVICE CLASS	PSUR UPDATES	EUDAMED SUBMISSION	MADE AVAILABLE	SSCP/SSP
MDs, Class IIa	At least every two years	Only implantable MDs	NBs and NCAs	Only implantable MDs
MDs, Class IIb	At least annually	Only implantable MDs	NBs and NCAs	Only implantable MDs
MDs, Class III	At least annually	Yes		Yes
IVDs, Class C	At least annually	No	NBs and NCAs	Yes
IVDs, Class D	At least annually	Yes		Yes

33. Reporting and analysis of serious incidents and Field Safety Corrective Actions (FSCAs)

In addition to periodic safety update reporting, manufacturers are obligated to report serious incidents and FSCAs related to their devices throughout the device's commercial existence in the EU. Manufacturers must inform device users about FSCAs by submitting Field Safety Notices (FSNs) to EUDAMED.

The language of an FSN must clearly explain the reasons for the corrective action taken without understating the risk level. It must refer to the malfunction and risk for patients and users, as well as the actions they're expected to take. An FSN must be available without delay in the official language(s) determined by the Member States where the corrective action is taken. This requirement ensures transparency and informs users and the public of information relevant to their health and safety regarding the use of the device.

Given that safety information is critical for safe and effective use of devices, Lionbridge recommends manufacturers build a glossary or implement safety terminology language assets in medical and plain language for their devices. This helps ensure language consistency and clear, unbiased communication on safety aspects throughout the device life cycle.

34. General Safety and Performance Requirements (GSPR)

As part of the General Safety and Performance Requirements (GSPR) and the technical documentation for a device, the manufacturer must supply the label(s) on the device and its packaging (including single unit packaging, sales packaging, and transport packaging information) as well as the instructions for use (IFU) in the language(s) accepted by the EU Member States where the device is sold.
The following format, language, and readability requirements are listed in Annex I for the information, which is supplied with the device (note this is an extract, not a full list):

- "The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose, and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams."

- "Labels shall be provided in a human-readable format and may be supplemented by machine/readable information, such as radio/frequency identification ('RFID') or bar codes."

- "Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa [and some IVDs] if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section."

- "Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation **(EU) No 207/2012** or in any subsequent implementing rules adopted pursuant to this Regulation."

- "Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognized symbols. Any symbol or identification color used shall conform to the harmonized standards or CS. In areas for which no harmonized standards or CS exist, the symbols and colors shall be described in the documentation supplied with the device."

For complete information on the content required on the label and in the instructions for use, refer to Annex I in the MDR and IVDR.

Importance of Readability and Language in Device Labeling

Readability is a clear target of the EU reforms on labeling and instructional content, as with the current EU Directives. This requires that labeling and user instructions should be in local language as a general rule and be written in clear, unambiguous language with the user profile in focus. The user's skills and knowledge should be considered for the concerned device. Lionbridge encourages technical skills to be taken into account and also general language and literacy skills in the countries where the device is envisaged to be sold. **English language and literacy skills vary within the European Union** and even within professional use settings.

It may be advised to translate user instructions into local language, even if such instructions are exempt from translations from a regulatory perspective (such as class IIa dental devices). The intent of an IFU is to enable users to act appropriately and ensure the correct, intended performance of the device. Lay users of medical devices and IVDs intended for home settings may not have immediate access to professional help, which should be considered when developing user instructions.

Another general recommendation is that if drawings or diagrams are included as supplements in the IFU, it should be ensured that such visuals serve to aid the understanding of the text and do not contradict or obstruct any written content. Visuals are strong tools that can help understand the instructions if they're used with caution and limitations. Also, the use of visuals should consider whether the user is a professional or a layperson. Too many visuals can confuse or overwhelm a lay user with no prior technical knowledge or routine in processing technical content or procedures. Any captions or labels that go along with graphics should be placed close to the visuals and usage of color should be limited to a few contrasting colors.

Readability testing or 'user consultation' may be useful for some instructions for use, as is often done for package leaflets and labeling for medicinal products. Such testing can be done with users who match the target population/intended user profile. The test persons can provide input on the readability, accessibility, and usefulness of the IFU. Lionbridge encourages manufacturers to consult the **guideline from the European Commission on the readability of the labeling and package leaflet of medicinal products for human use.**

Concluding Remarks

As demonstrated in this guidance, the transition of the medical device Directives from the 1990s into the medical device Regulations from 2017 has expanded the scope of language requirements directly impacting both manufacturers and economic operators. The MDR and IVDR emphasize a life cycle approach to devices developed, manufactured, and made available on the EU market. This new expanded regulatory framework impacts the scope and volume of documentation needed for devices in the EU, including in local language. Manufacturers, therefore, must plan language activities beyond labeling information and throughout the full life cycle and the product's commercial existence on the EU market.

Ideally, language planning should commence during pre-market design control and conformity assessment procedures and continue through to launch and post-market activities. This is especially important for many high-risk and implantable medical devices requiring pre-market conformity assessment and post-market results disclosure on EUDAMED.

In the following Part 3, we recommend, in line with the life cycle approach of MDR and IVDR, manufacturers establish an AI life cycle language strategy which will enable them to leverage Large Language Models for predefined language outcomes.

PART 3
AI LIFE CYCLE LANGUAGE STRATEGY FOR MDR AND IVDR

AI has great potential within medical devices and the medical device industry at large. It can help drive decisions and improvements in diagnostic procedures. Or it can find hidden trends in data for the benefit of patients. Clinical decision support software and diagnostic image enhancement analytics are often highlighted in promising AI narratives on medical technologies.

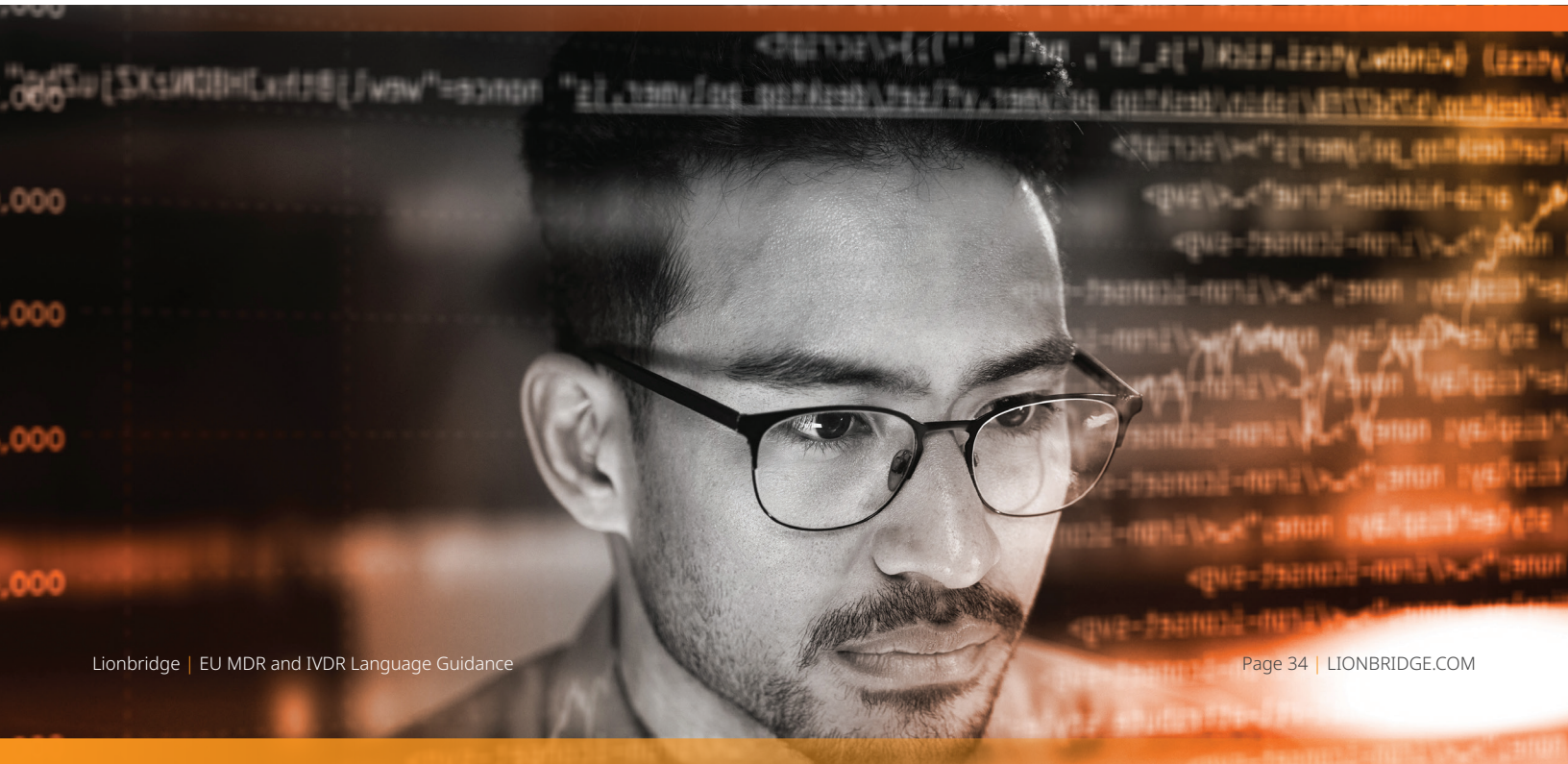
Just like in drug development, AI has the potential to alleviate the burdens of manual processes, clinical trial execution, submission procedures, or regulatory reporting, to name a few. It can help medical device manufacturers work faster and smarter across the full product life cycle, from R&D, to operations, to regulatory submissions, to marketing, sales, and customer support.

Additionally, AI and large language models can significantly benefit translations and other language services if manufacturers develop an AI language strategy for full device life cycles.

MDR and IVDR as AI Use Cases

The MDR and the IVDR are strong potential use cases for leveraging LLMs at scale for translations and language processing required throughout a device's life. The strict performance, safety, and transparency requirements under these Regulations and aggressive regulatory review windows may challenge medical device manufacturers. Increasing volumes of content must be created, translated, summarized, and updated —sometimes for both professional and non-professional audiences. Some of this content must be validated by Notified Bodies and/or publicly disclosed on EUDAMED, as described in Part 2.

Lionbridge recommends manufacturers establish a language strategy for the entire device life cycle to meet the MDR and IVDR language requirements and harness the full value of LLMs. Such a strategy can be designed based on the device risk profile, intended uses, content types involved, and intended audiences. Mapping the content will help determine the appropriate level of LLMs and the extent of a human-in-the-loop required during translations and/or other language outcomes.



Key Definitions

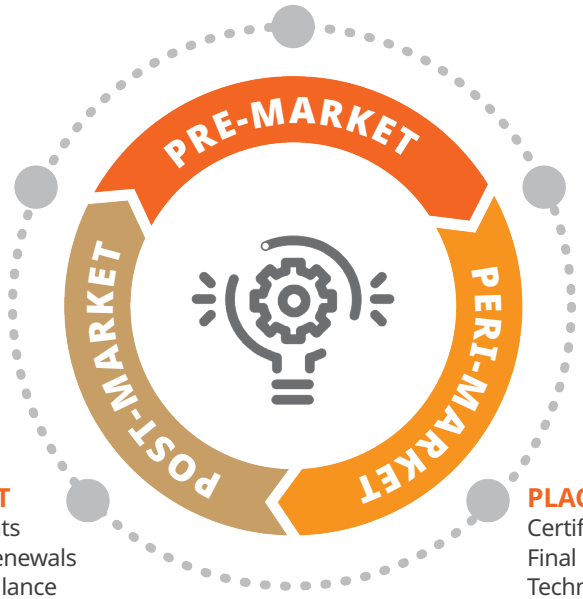
Artificial Intelligence (AI)
A branch of computer science focusing on systems that can perform tasks that typically require human intelligence. These can include natural language understanding, pattern recognition, decision-making, etc.

Generative AI (GenAI)
AI systems that generate new content, such as text or images, based on prompts and extensive training. They create outputs that appear human-generated.

Large Language Models (LLMs)
These are generative AI models trained on massive datasets of text and software code. They're capable of summarizing, translating, and generating text. LLMs have applications in various industries, including life sciences.

Human-in-the-loop
A human-in-the-loop approach is crucial for consistency and reliability in language outcomes, especially for regulated device documentation. This approach involves human intervention, fine-tuning of LLMs, prompt engineering, and reviewing automated outputs to ensure compliance and high-quality services.

LIFE CYCLE LANGUAGE STRATEGY



RESEARCH AND DEVELOPMENT
Design, verification, and validation
Clinical investigations + performance evaluation

PORTFOLIO EXPANSION
Modified device
Substantial equivalence

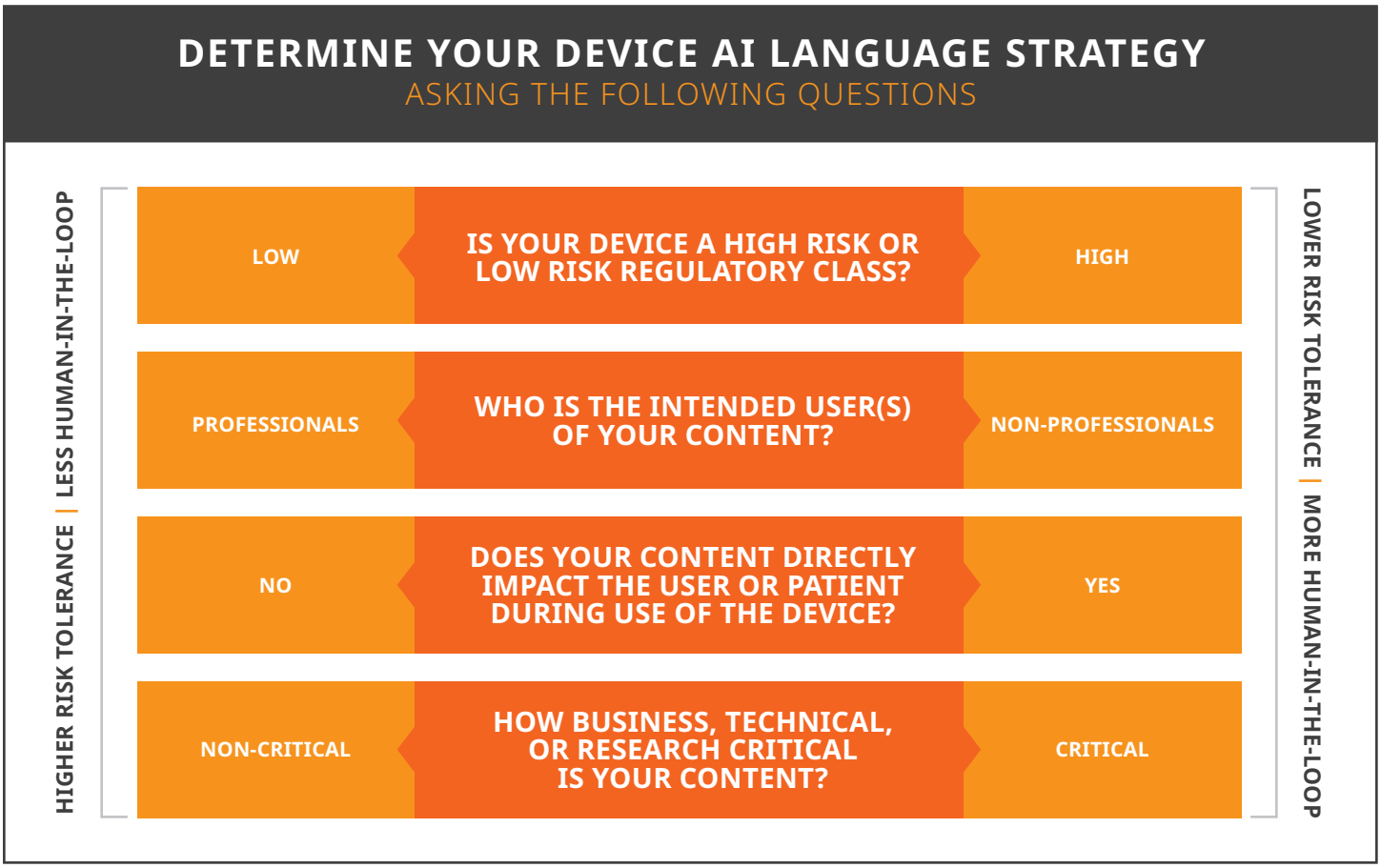
CONFORMITY ASSESSMENT + PRE-MARKET APPROVAL
Technical dossier
Initial labelling
Initial SSCP/SSP for validation

KEEPING ON THE MARKET
Product changes + supplements
Certificate re-assessments + renewals
Post-market surveillance + vigilance
Post-market clinical follow-up + studies

PLACING ON THE MARKET
Certificates + Declarations of conformity
Final labeling
Technical manuals
Final SSCPs/SSPs for EUDAMED

A Risk-Based Framework for Safe and Effective Use of LLMs

Large language models are not without risks when applied to translations of regulated content. Therefore, an AI-supported language strategy should be based on a risk assessment that considers several aspects. Generally, all AI-powered translations of regulated content are recommended to have some level of human-in-the-loop or supervision. Today, it's possible to set up different bespoke and AI-supported translation workflows for different types of content. Manufacturers can do the assessment based on a series of questions, as exemplified below. Each type of content can then be categorized and assigned an appropriate translation workflow from these questions. Content types in this context refer to different document types with specific purposes and intended users, e.g., the SSCP, the IFU, FSNs, clinical documentation, etc.



Implementation and Scalability of Life Cycle Language Strategies

It may be challenging for manufacturers to assign internal resources to own and implement a full life cycle language strategy since this requires insights into all language needs for a device throughout its life. In such cases, a manufacturer may be able to delegate the early setup and management to a language services provider with expertise in AI, medical devices, and language. Once a medical device's initial life cycle language strategy has been set up, the model can be adapted to other devices in a manufacturer's device portfolio. Some devices will have similar risk profiles and similar characteristics.

These devices can potentially fall under the same language strategy, as long as the language levels addressed in Part 2 are considered.

GENERAL BENEFITS OF LLMS

The current Neural Machine Translation (NMT) paradigm is ending.
A new paradigm will replace it, likely based on LLMs.

As this development materializes, you can expect the following outcomes:

- **Reduced translation costs.**
- **Greater productivity and the ability to generate content at greater scale.**
- **Improved translation quality — text that appears to have been written by a human.**
- **Enhanced customer experience.**
- **New opportunities to enter more markets.**

Concluding Remarks

LLMs hold great promise for translations of regulated content for medical devices. However, to obtain their scalable benefits and control their risks manufacturers should plan and strategize language outcomes. As we've shown in this language guidance, there are multiple content types to manage under the EU medical device reforms. Additionally, language requirements are not harmonized to the same extent as technical requirements because language remains a national matter under the multilingual Union policy.

As a global leader within regulatory translations and the EU market, Lionbridge can help manufacturers and other economic operators navigate their product language needs in the EU.

APPENDIX A
MEMBER STATE AND LANGUAGE OVERVIEW

EU MEMBER STATE	OFFICIAL LANGUAGE(S)	LANGUAGE CODE(S)	NCA	NON-PROFESSIONALS/ LAY PERSON CONTENT	PROFESSIONAL CONTENT
Austria	German	de	Austrian Agency for Health and Food Safety (AGES)	German	German (preferred) or English
Belgium	German, French, and Dutch	de, fr, nl	Federal Agency for Medicines and Health Products (FAMHP)	German, French, and Dutch	English or French, Dutch or German (CONDITIONS)
Bulgaria	Bulgarian	bg	Bulgarian Drug Agency (BDA)	Bulgarian	Bulgarian
Croatia	Croatian	hr	Agency for medicinal products and medical devices of Croatia (HALMED)	Croatian	Croatian and/or English (CONDITIONS)
Cyprus	Greek	el	Ministry of Health (MoH)	Greek	Greek or English
Czech Republic	Czech	cs	State Institute for Drug Control (SUKL)	Czech	Czech or English (CONDITIONS)
Denmark	Danish	da	Danish Medicines Agency (DKMA)	Danish	Danish or English (EXCEPTION/ UPON REQUEST)
Estonia	Estonian	et	State Agency of Medicines (RAVIMIAMET)	Estonian	Estonian or English (CONDITIONS)
Finland	Finnish and Swedish	fi	Finnish Medicines Agency (FIMEA)	Finnish and Swedish	Finnish, Swedish, or English (CONDITIONS)
France	French	fr	National Agency for the Safety of Medicine and Health Products (ANSM)	French	French or English (EXCEPTION)
Germany	German	de	Federal Institute for Drugs and Medical Devices (BFARM)	German	German or English (WHEN JUSTIFIED)
Greece	Greek	el	National Organization for Medicines (EOF)	Greek	Greek
Hungary	Hungarian	hu	National Centre for Public Health and Pharmacy (NNK)	Hungarian	Hungarian
Ireland	English and Irish	ie	Health Products Regulatory Authority (HPRA)	English, English and Irish	English, English and Irish
Italy	Italian	it	Italian Medicines Agency (AIFA)	Italian	Italian
Latvia	Latvian	lv	State Agency of Medicines (ZVA)	Latvian	Latvian or English (CONDITIONS)
Lithuania	Lithuanian	lt	State Medicines Control Agency (VVKT)	Lithuanian	Lithuanian
Luxembourg	Luxembourgish, German, and French	lu	Ministry of Health	French, German or Luxembourgish	French, German or Luxembourgish or English (DEVICE-SPECIFIC)
Malta	English and Maltese	mt	Malta Medicines Authority (MMA)	Maltese and/or English	Maltese and/or English

EU MEMBER STATE	OFFICIAL LANGUAGE(S)	LANGUAGE CODE(S)	NCA	NON-PROFESSIONALS/ LAY PERSON CONTENT	PROFESSIONAL CONTENT
Netherlands	Dutch	nl	Medicines Evaluation Board	Dutch	Dutch or English
Poland	Polish	pl	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL)	Polish	Polish or English (CONDITIONS)
Portugal	Portuguese	pt	National Authority for Medicines and Health Products (INFARMED)	Portuguese	Portuguese (ENGLISH UNCERTAIN)
Romania	Romanian	ro	National Authority of Medicines and Medical Devices of Romania (ANM)	Romanian	Romanian or English (EXCEPTION/UPON REQUEST)
Slovakia	Slovak	sk	State Institute for Drug Control (SUKL)	Slovak	Slovak or English (CONDITIONS)
Slovenia	Slovenian	sl	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP)	Slovene	Slovene or English
Spain	Spanish	es	Spanish Agency of Medicines and Medical Devices (AEMPS)	Spanish	Spanish
Sweden	Swedish	se	Swedish Medical Products Agency	Swedish	Swedish or English (CONDITIONS)

EEA COUNTRIES	OFFICIAL LANGUAGE(S)	LANGUAGE CODE	NCA	NON-PROFESSIONALS/ LAY PERSON CONTENT	PROFESSIONAL CONTENT
Iceland	Icelandic	is	Icelandic Medicines Agency (IMA)	Icelandic or English/ Nordic language except Finnish for Class I and IIa	Icelandic or English
Liechtenstein	German	de	Office of Health/Department of Pharmaceuticals (LLV)	German	German or English (CONDITIONS)
Norway	Norwegian	no	Norwegian Medical Products Agency (DMP)	Norwegian	Norwegian or English (for DoC/Conformity Assessment)

APPENDIX B
EU MDR DEFINITIONS

(1): 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: 1) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease; 2) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability: 3) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state: 4) providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

(3): 'custom-made device' means any device specifically made in accordance with a written prescription of any person authorized by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

(5): 'implantable device' means any device, including those that are partially or whole absorbed, which is intended: 1) to be totally introduced into the human body, or 2) to replace an epithelial surface or the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure.

(12): 'intended purpose' (or intended use) means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.

(13): 'label' means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.

(14): 'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.

(15): 'unique device identifier (UDI)' means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

(22): 'performance' means the ability of a device to achieve its intended purpose as stated by the manufacturer.

(28): 'placing on the market' means the first making available of a device, other than an investigational device, on the Union market.

(30): 'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

(32): 'authorized representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specific tasks with regard to the latter's obligations under EU MDR.

(33): 'importer' means any natural or legal person established within the Union that places a device from a third country on the Union market.

(34): 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.

(35): 'economic operator' means a manufacturer, an authorized representative, an importer, a distributor or the person referred to in Article 22(1) and 22(30 of the EU MDR.

(37): 'user' means any healthcare professional or lay person who uses a device.

(38): 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline.

(40): 'conformity assessment' means the process demonstrating whether the requirements of the EU MDR relating to a device have been fulfilled.

(42): 'notified body' means a conformity assessment body designated in accordance with EU MDR.

(43): 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the EU MDR and other applicable Union harmonization legislation providing for its affixing.

(44): 'clinical evaluation' means a systematic and planned process to continuously generate, collect, analyze and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits of the device when used as intended by the manufacturer.

(45): 'clinical investigation' means any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device.

(49): 'sponsor' means any individual, company, institution or organization which takes responsibility for the initiation, for the management and setting up of the financing of the clinical investigation.

(52): 'clinical performance' means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer.

(54): 'investigator' means an individual responsible for the conduct of a clinical investigation at a clinical investigation site.

(55): 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorization or agreement from their legally designated representative to include them in the clinical investigation.

(56): 'ethics committee' means and independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organizations'

(57): 'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device'

(60): 'post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

(64): 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

(69): 'field safety notice' means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action.

APPENDIX C
EU IVDR DEFINITIONS

The following are definitions specific for In Vitro Diagnostic devices and in addition to the terms in Appendix B.

(2) 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used in alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following: (a) concerning a physiological or pathological process or state; (b) concerning congenital physical or mental impairments; (c) concerning the predisposition to a medical condition or a disease; (d) to determine the safety and compatibility with potential recipients; (e) to predict treatment response or reactions; (f) to define or monitoring therapeutic measures. Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices

(5) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services'

(6) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional

(12) 'intended purpose' means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements or as specified by the manufacturer in the performance evaluation

(13) 'label' means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices

(14) 'instructions for use' means the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken

(21) 'placing on the market' means the first making available of a device, other than a device for performance study, on the Union market

(36) 'clinical evidence' means clinical data and performance evaluation results, pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer

(39) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting that intended purpose

(41) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user

(42) 'performance study' means a study undertaken to establish or confirm the analytical or clinical performance of a device

(44) 'performance evaluation' means an assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device

(46) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;

(57) 'sponsor' means any individual, company, institution or organization which takes responsibility for the initiation, for the management and setting up of the financing of the performance study

(58) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular performance study, after having been informed of all aspects of the performance study that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorization or agreement from their legally designated representative to include them in the performance study

(60) 'adverse event' means any untoward medical occurrence, inappropriate patient management decision, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a performance study, whether or not related to the device for performance study

APPENDIX D
REFERENCES

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385)

European Parliament resolution of 11 September 2018 on language equality in the digital age (2018/2028(INI))

Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (Text with EEA relevance)

European Commission Notice
The 'Blue Guide' on the implementation of EU product rules 2022 (Text with EEA relevance) (2022/C 247/01)

ISO 15223: Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied

Summaries of Clinical Trial Results for Laypersons, Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, Version 2.

Good Lay Summary Practice, Version 1, 4 October 2021, EudraLex – Volume 1- - Clinical trials guidelines.

ISO 17100, Translation services — Requirements for translation services

ISO 14155: Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)

Commission Guidance on the content and structure of the summary of the clinical investigation report, 2023/C 163/06

COMMISSION REGULATION (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices

Guideline on the readability of the labeling and package leaflet of medicinal products for human use revision 1, 12 January 2009

MDR – Language requirements for manufacturers – Rev. 2, European Commission

IVDR – Language requirements for manufacturers – Rev. 2, European Commission

ABOUT LIONBRIDGE

Lionbridge partners with brands to break barriers and build bridges all over the world. For over 25 years, we have helped companies connect with their global customers and employees by delivering translation and localization solutions in 350+ languages. Through our world-class platform, we orchestrate a network of passionate experts across the globe who partner with brands to create culturally rich experiences. Relentless in our love of linguistics, we use the best of human and machine intelligence to forge understanding that resonates with our customers' clients. Based in Waltham, Massachusetts, Lionbridge maintains solution centers in 24 countries.

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