LIONBRIDGE

LANGUAGE REQUIREMENTS UNDER THE NEW EU MDR

Lionbridge offers our perspectives on the language challenges and obligations that medical device manufacturers should consider under the new European Medical Device Regulation (MDR).

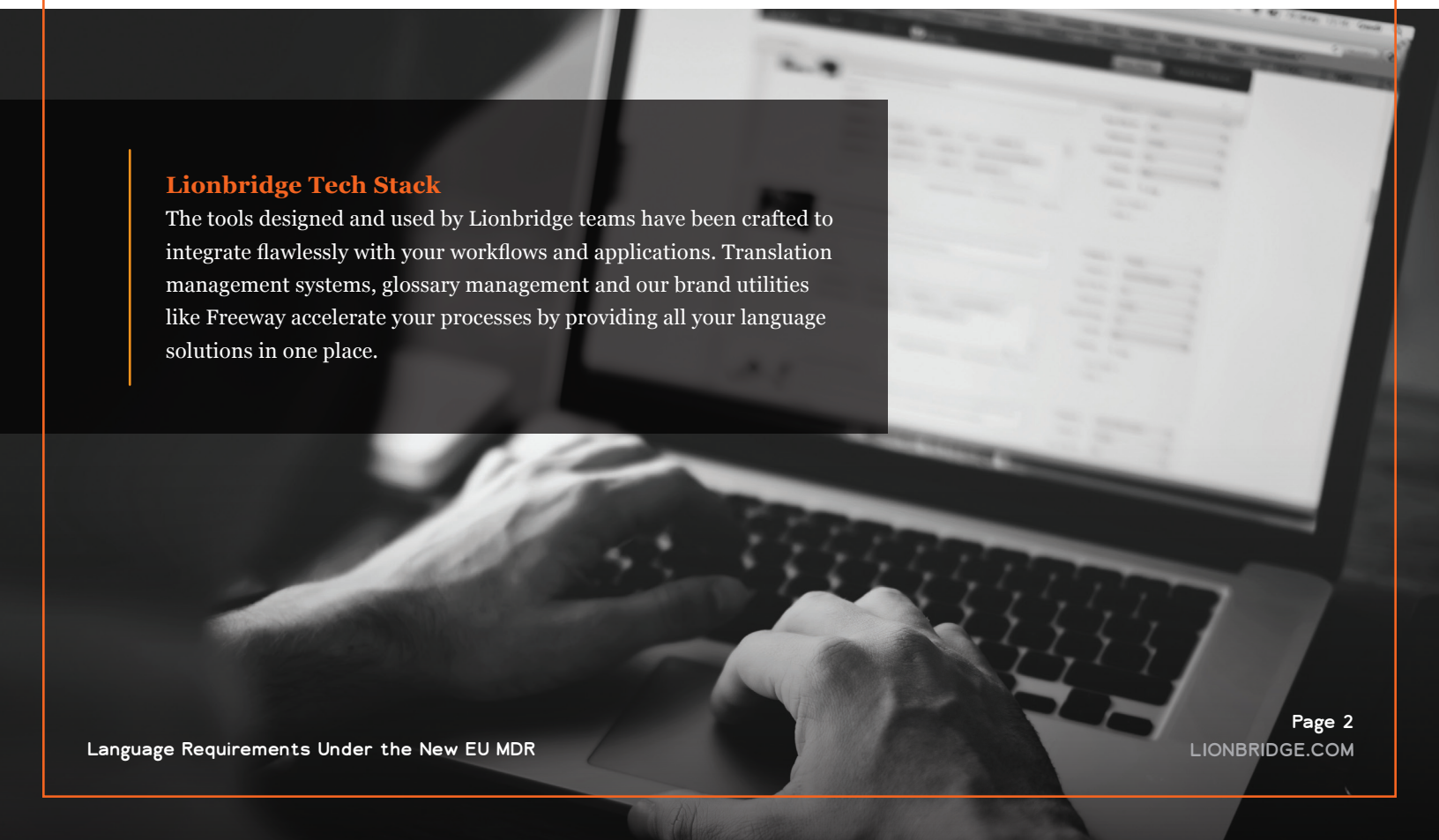
THE UNSOLVABLE PUZZLE OF LANGUAGE HARMONIZATION UNDER THE EU MDR

As a Language Services Provider (LSP), Lionbridge has carefully observed the MedTech industry from within for over 20 years. Under the new MDR, language has become more essential, more complex and more challenging for medical device manufacturers that wish to place their devices on the European Union (EU) market. Despite harmonization being a major incentive for legally elevating the current Medical Device Directives (MDD/AIMDD) into a regulation, harmonization has limited justification when it comes to language standards across the EU because the Union is founded on a multilingual policy. As a manufacturer, you will need a strong LSP with medical device expertise to help manage both the complexity of language requirements under the new regulatory landscape in the EU and the language diversity of the EU market.

Depending on the extent and diversity of your device portfolio, you may also benefit significantly from partnering with a LSP to centralize translation workflows and build and leverage language assets across your device portfolio.

What is harmonization?

Standards harmonization is the movement to unify regulations across political and geographic boundaries. It simplifies compliance and smooths international trade. Regulatory convergence is one benefit of multi-state associations like the EU.



Lionbridge Tech Stack

The tools designed and used by Lionbridge teams have been crafted to integrate flawlessly with your workflows and applications. Translation management systems, glossary management and our brand utilities like Freeway accelerate your processes by providing all your language solutions in one place.

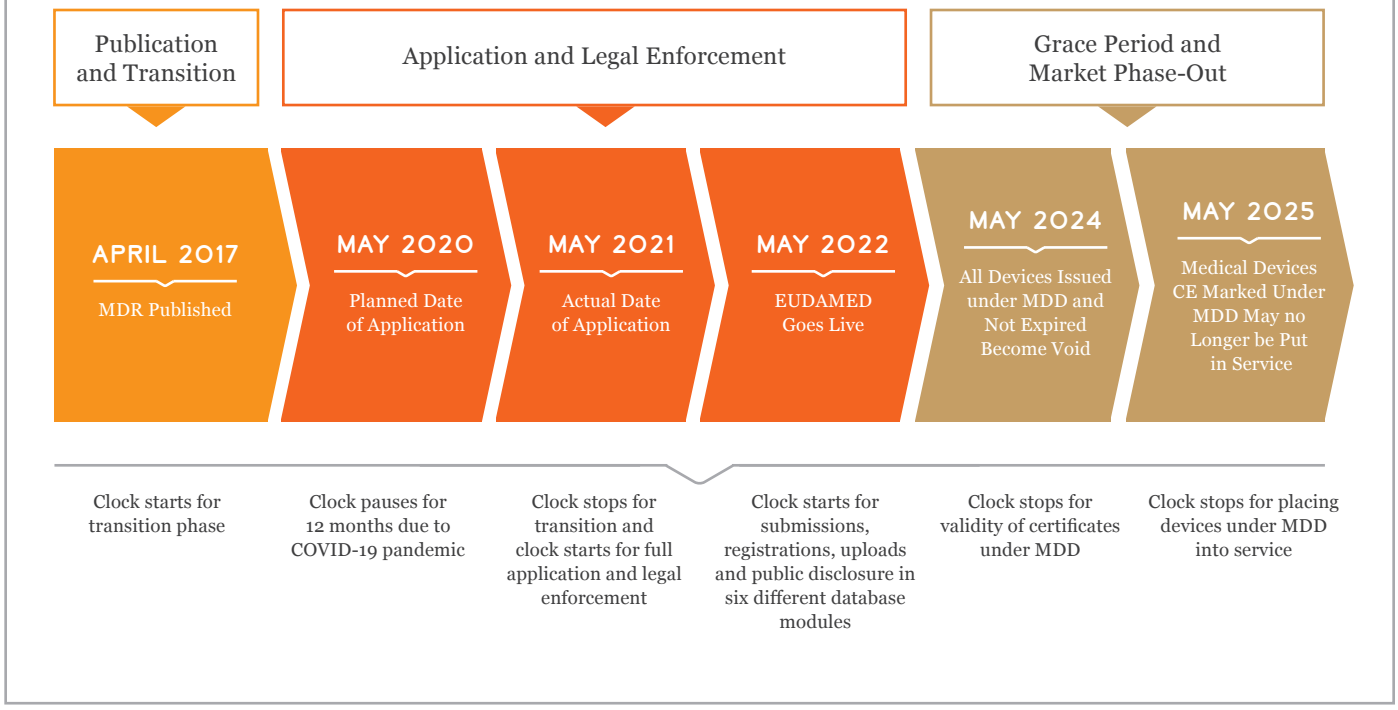
A SHORT RECAP OF MDR TIMELINES

The MDR applies from May 26, 2021. This Date of Application completes a multi-year transition phase since the Regulation was officially published on April 5, 2017 in the Official Journal of the EU. Including a necessary 12-month delay caused by the COVID-19 pandemic, the full application of the MDR has now been in progress for four years.

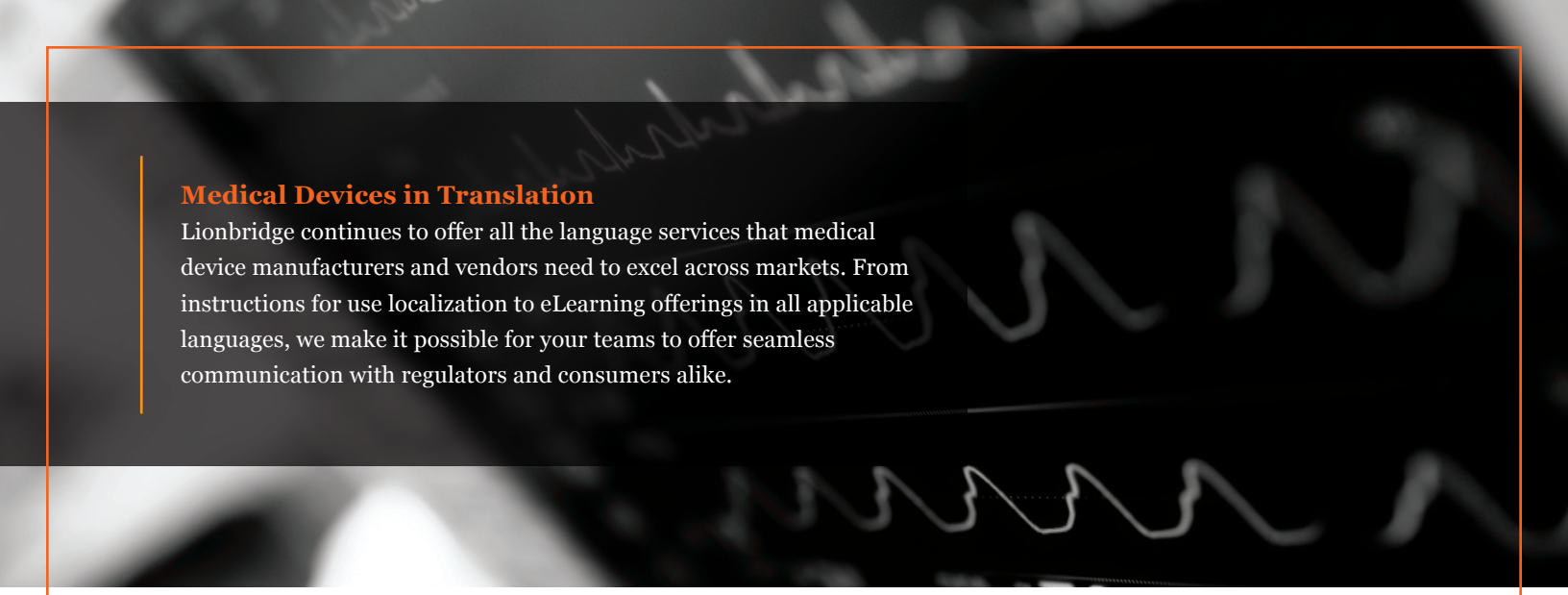
This transition sounds long for good reason. The increased burden of conformity with the new regulation called for a long preparation process for the entire medical device ecosystem. Manufacturers and economic operators have been preparing for MDR readiness under significant pressure and concerns over lack of regulatory progress and guidance. Some requirements have gradually been implemented dependent on the type and risk classification of devices. In addition, some devices certified under the MDD may still remain valid during a grace period until May 27, 2024, when all certificates granted under the MDD become invalid.

The MDR allows such devices to be put into service for one additional year, until May 27, 2025, to allow the sale of previously manufactured stock and ensure continuity of care.

MDR TIMELINES: A PHASED APPROACH



With the transition phase now complete, many manufacturers have assessed their product portfolio and identified a strategy for compliance with the general safety and performance requirements of the MDR. However, fewer manufacturers have performed a similar thorough assessment of language activities necessary under the new regulatory demands.



Medical Devices in Translation

Lionbridge continues to offer all the language services that medical device manufacturers and vendors need to excel across markets. From instructions for use localization to eLearning offerings in all applicable languages, we make it possible for your teams to offer seamless communication with regulators and consumers alike.

HOW LANGUAGE MATTERS (EVEN MORE) UNDER THE MDR

Because of the multilingual policy of the EU, language has always been an essential part of placing medical devices on the EU market. At the very minimum, translations into local language have been required for labeling as part of ensuring the correct and safe use of a device. National competent authorities in each EU Member State interpreted language requirements from medical device directives in force since the 1990s and imposed them via local law. Despite the new harmonized regulatory framework around the CE mark, language compliance has now become more difficult under MDR. Several aspects of the MDR drive the increased role of language:

- A significant increase in content types and volumes to create and maintain throughout the life cycle of devices
- New requirements on transparency and public access to information on medical devices including identity, performance, safety, adverse events and field safety incidents
- Regulatory emphasis on the quality, clarity, relevance and readability of language, especially for content intended for plain language audiences
- Increasing use of symbols on labeling and implant cards and associated standard translations, where relevant
- Increased responsibilities for economic operators that become obligated to check compliance of manufacturers on labeling and other local language information supplied with the device
- Increase in shared content and interdependence across the technical dossier and post-market reporting which will require updated translations and control of local language documentation throughout the device life cycle

Manufacturers need to develop, disseminate and maintain information across multiple target audiences with different levels of technical knowledge, language and literacy levels. Furthermore, they need to understand when each type of information requires translation into local language(s). Examples of content types that require these insights include the Summary of Safety and Clinical Performance (SSCP), clinical investigation applications, the implant card, instructions for use and post-market reporting.

Concise and Precise: Lionbridge for Readability Assessments

Crafting language appropriate for multiple audiences is complicated in one language, let alone several. Our readability solution for plain language communication includes sophisticated readability and language profiling technologies that build on principles of health literacy, numeracy, industry guidance on plain language results communication and existing readability measurement tools. Lionbridge's automated readability technologies, in combination with subject matter expertise, provide feedback and language improvement recommendations to ensure consistent communication that is adapted to the readability and literacy levels of the target audience.

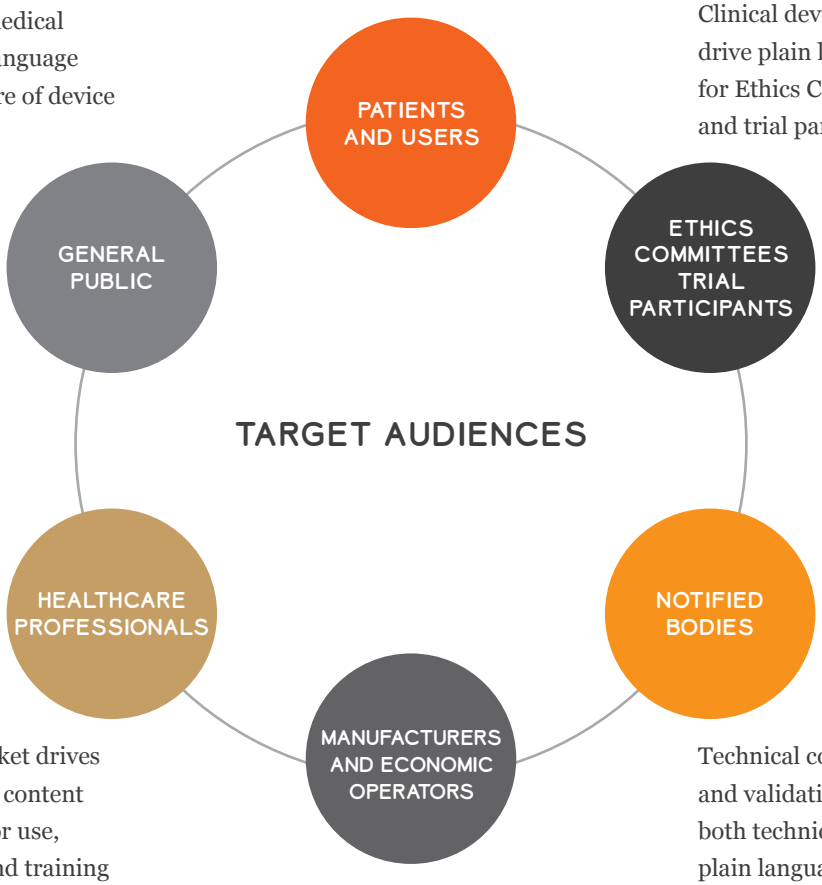
DIVERSITY OF TARGET AUDIENCES FOR MDR CONTENT AND LANGUAGE IMPACT

PLAIN LANGUAGE AND LOCAL LANGUAGE

Placing devices on the market drives plain local language labeling and instructions for patients and users

EUDAMED database for medical devices drives plain local language content for public disclosure of device performance and safety

Clinical device investigations drive plain local language content for Ethics Committee approval and trial participation



Placing devices on the market drives technical English language content for labeling, instructions for use, manuals, user interfaces and training with some translations

Technical conformity assessment and validation of SSCPs drive both technical language and plain language content with some translations

Compliance with MDR and national Member State requirements drives technical English language content with some translations

TECHNICAL LANGUAGE (ENGLISH AND LOCAL LANGUAGE)

Social Listening and Post-Market Surveillance Services

Reporting requirements for medical devices, drugs and interventions extend across a seemingly infinite expanse of online forums and social media platforms in addition to more traditional venues. The Lionbridge solutions for reporting at scale include machine translation and a dedicated portal. Industry-leading medical and pharmaceutical organizations rely on Lionbridge to track the impact of their work after distribution.

MULTILINGUALISM IN THE EU

Under the joint multilingual policy of the EU, the Member States have exclusive rights to determine national language requirements when products are released to the local market. For this reason, union level laws such as the MDR do not specify or enforce local language or translation requirements for medical devices. These are instead determined by the national competent authorities of each Member State and within the official language(s) of the Member States concerned.

The EU currently has 24 official languages and three alphabets. About 60 other languages are spoken in the community and 175 different nationalities live within the EU borders. Although the United Kingdom (U.K.) has left the union, English remains an official language since it is an official language of both Ireland and Malta.

Some Member States have more than one official language. In this case translations often will be required in each official language. Member States may, as an exception, accept certain content in English-only depending on the intended use, the risk profile of the concerned device and the English literacy levels in the relevant Member State.

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

THREE LANGUAGE LEVELS YOU MUST KNOW AS MANUFACTURER

To comply with language obligations within the new EU regulatory framework for medical devices, manufacturers need to implement and navigate across three regulatory language levels:

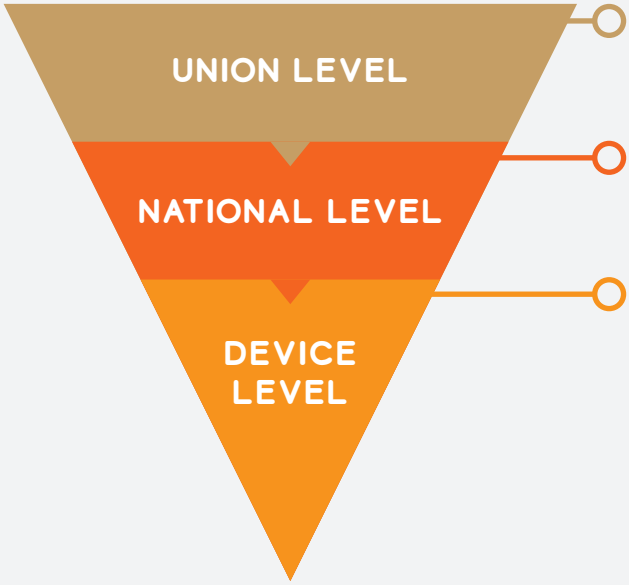
- **A union level** which defines some general requirements or recommendations. These include a general requirement to translate instructions for use, clinical investigation synopses and SSCP into official EU languages.

  It also includes general quality and stylistic aspects of language such as the obligation of manufacturers to ensure that labels are indelible, easily legible and clearly comprehensible to the intended user or patient. Furthermore, it includes general recommendations on the presentation of and readability testing for the part of the SSCP which is intended for patients.

- **A national level** which specifies local language requirements for different types of content or purposes within each EU Member State. National level requirements include for example which official language(s) are required, particular phrases to accompany clinical investigational devices or clinical investigation applications, local language notifications for custom-made devices and translation requirements for conformity assessment procedures.

- **A device level** where language requirements or recommendations may depend on the risk profile of the device, the intended user and/or the type of content. The classification of a medical device will impact language to some extent and as a principle, the higher the risk class, the more content and translations will be needed.

  For example, the classification of a device will impact the translation burden of labeling and packaging, instructions for use, clinical investigations, post-market surveillance and content to be disclosed publicly on EUDAMED.



UNION LEVEL LANGUAGE REQUIREMENTS

Generic language requirements and recommendations as defined in EU MDR and MDCG guidance.

NATIONAL LEVEL LANGUAGE REQUIREMENTS

Specific language requirements and recommendations as determined by EU Member States.

DEVICE LEVEL LANGUAGE REQUIREMENTS

Specific language requirements determined by the classification of the device, the intended users and content type.

HOW LIONBRIDGE CAN HELP MANAGE YOUR LANGUAGE CHALLENGES

In a partnership model, Lionbridge will help you understand, implement and manage language challenges in the EU and obtain efficiencies throughout the individual device life cycle or across your device portfolio. Our medical device language services include translations of technical as well as plain language content, user interface testing, readability testing and linguistic validation for COAs/eCOA used in medical device investigations.

Lionbridge subject matter experts have developed a unique MDR language manual to help manufacturers and economic operators understand their language obligations and the multilayered complexity of language requirements and standards in the EU market. In this manual, we systematically assess all MDR articles and Annexes as well as guidance documents from the MDCG. Our team continuously updates this piece with new information and will continue to do so until the MDCG has released all guidelines.

To learn more about how Lionbridge can help with translation requirements for the new EU MDR, reach out to our team today.

About Lionbridge

Lionbridge partners with brands to break barriers and build bridges all over the world. For 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' customers. Based in Waltham, Massachusetts, Lionbridge maintains solution centers in 23 countries.

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