EU MDR
REQUIREMENTS FOR
INSTRUCTIONS FOR USE

argos multilingual

CONTENTS

EUROPEAN UNION MEDICAL DEVICE REGULATION BACKGROUND

In 2008, efforts began to revise the medical device directive, driven by several high-profile medical device incidents and rising public calls to strengthen the existing CE regulatory system. In 2017, the Medical Device Regulation (MDR) directive (2017/745) was published, aiming to address these concerns and boost confidence in the EU medical device regulatory framework.

Key outcomes of the MDR include:

- Improved oversight of notified bodies
- Enhanced and more rigorous post-market surveillance
- Stronger compliance demands on manufacturers
- Better coordination among member states
- Greater transparency and scrutiny for high-risk devices

All CE-marked products have been affected by the MDR. Changes will impact clinical data requirements, post-market demands, economic operators, quality systems, and labeling, to name a few. All existing CE-marked products must be recertified under MDR to retain the CE mark and continue to sell products in the EU.

This article specifically addresses MDR requirements for Instructions for Use (IFUs).

MDR TIMELINE

The European Medical Device Regulation (MDR) was published in May 2017, initiating a four-year transition period. On May 26, 2021, the MDR fully came into effect. All new medical devices or those renewing their certifications must adhere to the MDR's standards from this date.

MAY 26, 2017
MDR 2017/745 and IVDR 2017/746 regulations came into effect.

NOVEMBER 26, 2017
Notified Bodies were allowed to apply for designation under both MDR and IVDR.

MAY 26, 2021
Deadline for most devices to comply with MDR, except those covered by the extended transition period.*

MAY 26, 2022
IVDR deadline. All IVD products must be compliant with the IVDR to be sold and marketed in Europe.

MAY 26, 2024
Transition period ends for legacy devices that do not meet the conditions for extended transition.

MAY 26, 2024
Deadline to submit an application for MDR conformity assessment and to have an MDR Quality Management System (QMS) in place.

SEPTEMBER 26, 2024
Deadline to sign a written agreement with a notified body and transfer appropriate surveillance to an MDR notified body (where applicable).

MAY 26, 2026
End of derogation for class III custom-made implantable devices.

DECEMBER 31, 2027
Transition period ends for class III and class IIb implantable devices, unless they have specific exemptions (like sutures).

DECEMBER 31, 2028
Transition period ends for other devices, including class IIa, class I sterile/measuring devices, and devices that require the involvement of a notified body for the first time under MDR.

*Initially, the EU MDR deadline was set for May 26, 2020. However, in response to the COVID-19 crisis, the European Commission proposed a one-year postponement of the application date.

WHAT MDR MEANS FOR CE-MARKED IFUS

When companies decide which CE-marked products they want to keep selling in Europe, it's important to review the associated CE-marked IFUs against the MDR's IFU criteria. This comparison can help companies pinpoint missing elements or areas where the current IFU content might need improvement.

Assembling a team from various departments, including regulatory affairs, labeling, risk management, and clinical, is essential. This team will identify gaps, plan how to address them, and then decide on the best wording to ensure IFU compliance.

Reviewing IFUs can be time-consuming, especially if there are many to assess. It's not a small task, so identifying resources early is paramount.

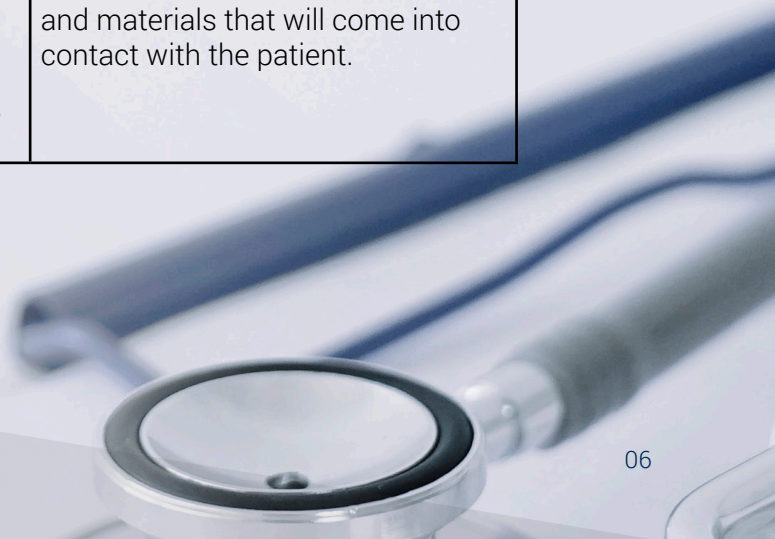
Keep in mind that the MDR also affects patient information, like manuals for implanted devices such as pacemakers and heart valves. These existing patient manuals must also undergo an MDR review.

EU MDR IFU AND PATIENT INFORMATION REQUIREMENTS

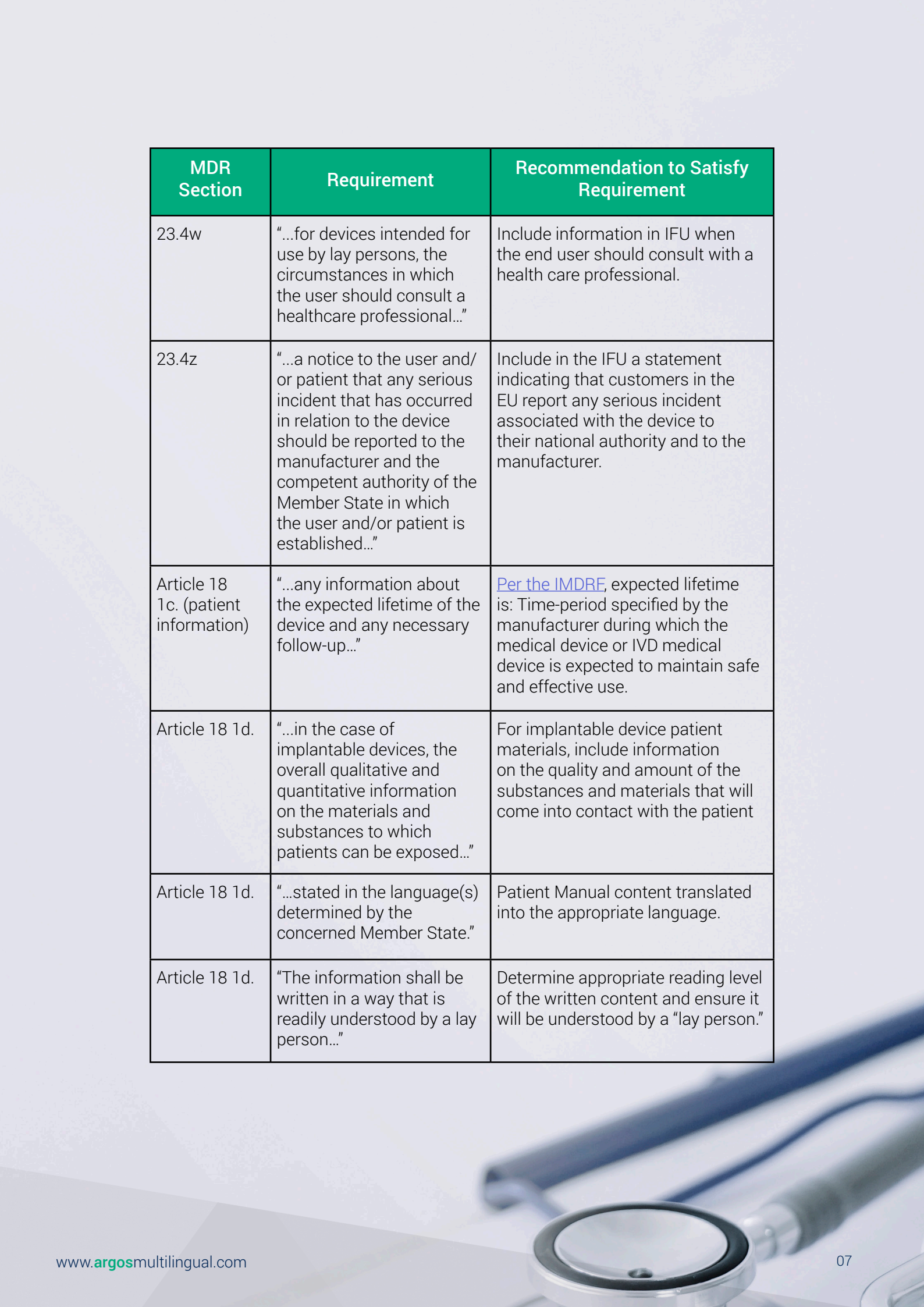
In the MDR, the bulk of the IFU requirements are found in Annex I, Chapter III, section 23.4. Patient information (patient manuals) requirements are mostly addressed in Article 18. Some of the requirements existed in the old MDD and/or AIMDD regulations, but were changed under MDR so an analysis is needed. It is advisable to scour the entire MDR document, as there are some requirements scattered throughout the regulation, in addition to the sections mentioned earlier.

Following are some of the MDR requirements for IFUs and patient manuals that companies need to address.

MDR Section	Requirement	Recommendation to Satisfy Requirement
Annex 1, Chp 3, 23.4b	"… the device's intended purpose…"	"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 and as specified by the manufacturer in the clinical evaluation. This is taken directly from MDR - Chp 1, Article 2 (14).
23.4c	"…where applicable, a specification of the clinical benefits to be expected…"	Identification of expected clinical benefits of the device.
23.4d	"...links to the summary of safety and clinical performance…"	Include in IFU the URL or other location where the SSCP can be found.
23.4u	"...in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed…"	For implantable device IFUs, include information on the quality and amount of the substances and materials that will come into contact with the patient.



MDR Section	Requirement	Recommendation to Satisfy Requirement
23.4w	"...for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional..."	Include information in IFU when the end user should consult with a health care professional.
23.4z	"...a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established..."	Include in the IFU a statement indicating that customers in the EU report any serious incident associated with the device to their national authority and to the manufacturer.
Article 18 1c. (patient information)	"...any information about the expected lifetime of the device and any necessary follow-up..."	Per the IMDRF, expected lifetime is: Time-period specified by the manufacturer during which the medical device or IVD medical device is expected to maintain safe and effective use.
Article 18 1d.	"...in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed..."	For implantable device patient materials, include information on the quality and amount of the substances and materials that will come into contact with the patient
Article 18 1d.	"...stated in the language(s) determined by the concerned Member State."	Patient Manual content translated into the appropriate language.
Article 18 1d.	"The information shall be written in a way that is readily understood by a lay person..."	Determine appropriate reading level of the written content and ensure it will be understood by a "lay person."



EU MDR IFU AND LANGUAGE REQUIREMENTS

Article 10 (section 11) of MDR states:

"Manufacturers shall ensure that the device is accompanied by the information..... in an official Union language(s) determined by the Member State in which the device is made available to the user or patient."

Life Science companies need to conduct a language gap analysis also to determine if any of the EU member state languages are missing. If so, a strategy to add those missing languages is required in order to distribute products in those countries.

COUNTRY	LANGUAGE
Austria	German
Belgium	Dutch, French, German
Bulgaria	Bulgarian
Croatia	Croatian
Cyprus	Greek, Turkish
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish, Swedish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	Irish, English
Italy	Italian
Latvia	Latvian
Liechtenstein**	German
Lithuania	Lithuanian
Luxembourg	Luxembourgish, French, German
Malta	Maltese, English
Netherlands	Dutch
Norway**	Norwegian
Poland	Polish
Portugal	Portuguese
Romania	Romanian
Slovakia	Slovakian
Slovenia	Slovenian
Spain	Spanish
Sweden	Swedish
Switzerland**	French, German, Italian
United Kingdom*	English

*The UK's regulatory framework mirrors many aspects of the EU's regulations but some differences exist.
**These countries are included in the European Free Trade Association (EFTA) and are not technically part of the EU. However, through the EEA agreement, they can participate in trade with the EU with respect to medical devices and medicinal products. Several of these countries are bringing their requirements in line with the MDR so that they can continue to participate in this trade.

View the EU MDR in a variety of languages here.

ABOUT ARGOS

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