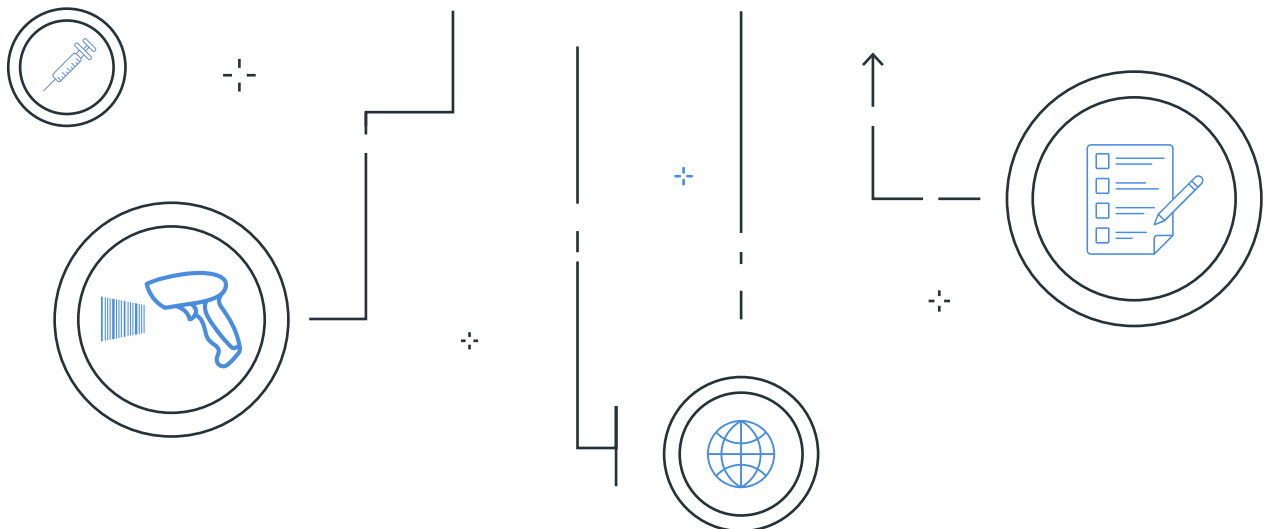


WHAT YOU NEED TO KNOW

eIFU's, Implant Cards & The EU MDR





eIFUS

eIFU BASICS

Providing and maintaining product information online is now mandatory for manufacturers who have a website.

The EU MDR states:

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website:

- It shall be protected against hardware and software intrusion
- It shall fulfill the requirements of Directive 95/46/EC (since replaced by General Data Protection Regulation (GDPR))
- All previous versions of the instructions for use issued in electronic form and their date of publication shall be available on the website

Industry leaders have discussed how to fulfill these new requirements. So far, the sticking point has been the manufacturer's website – if you have one, you're required to comply. Manufacturers have no choice but to post information needed to identify their devices to a website that has objective evidence that it meets the EU MDR requirements.

What are eIFUs, and why does your company need them?

Electronic Instructions for Use (eIFU) are Instructions for Use (IFUs) that have been made available via the internet, electronically. Previously, not all manufacturers had an incentive to expend the resources needed to provide IFUs electronically, however the new EU MDR means all manufacturers who have a website must address this issue.

THE OPTIONS FOR eIFU'S

Basic EU MDR eIFU Requirements

To meet these new requirements, there are three paths that can be followed:

1 Take your existing IFU and post it to an acceptable website.

To meet the letter of the law, companies can post a .pdf of their most current IFU to a website. This meets the “resistant to software or hardware intrusion” and the GDPR requirements. This website must also be controlled to show the current as well as previous versions of the IFU that have been posted in electronic format. This could be the least expensive method of meeting the requirement, however builds ongoing management into a process that doesn't provide any tangible benefit aside from compliance.

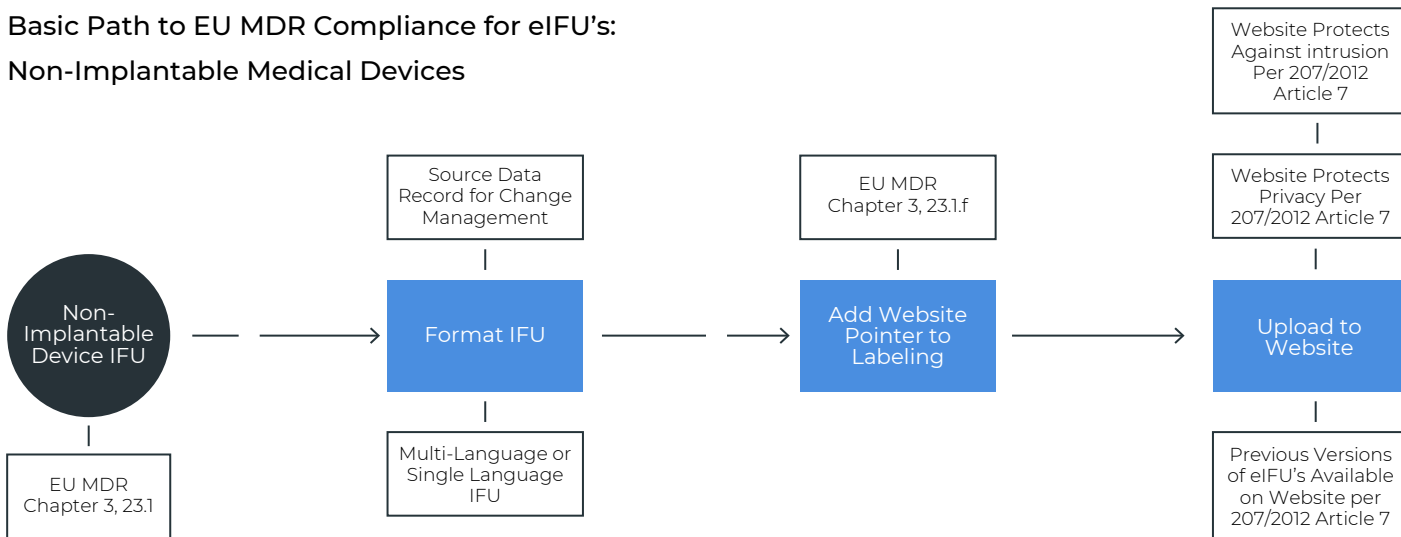
2 Separate your existing IFU into single-language IFUs and post these to an acceptable website.

Similar to the process mentioned before, this option takes existing IFUs and separates them into single-language IFUs before uploading them to an appropriate website. This approach potentially makes access to eIFUs easier for consumers as they are pointed directly to an eIFU in their language of choice instead of a multi-language version. Additionally, this approach can be used as the first step toward the eLabeling mentioned below and to on-demand printing.

3 Create a new document to post to an acceptable website.

In some cases, instead of posting an IFU, it may be advantageous to create a new document that is more general in nature and covers a wide range of products. While this would create a new document that has to be controlled, it may reduce the effort to manage the website by having fewer documents that require less updating.

Basic Path to EU MDR Compliance for eIFU's: Non-Implantable Medical Devices



THE APPROACH FOR IMPLANT CARDS

If a device qualifies as an implant, per Article 18 of the MDR, you will need to provide an Implant Card.

This card must contain the device description, serial number, lot number, the UDI, device model, device name, address and the website of the manufacturer. It must also provide warnings, precautions, expected lifetime of the device and any other information to ensure safe use.

The implant card has turned into an implant book that likely will not fit into anyone's pocketbook or wallet. Manufacturers will have to supply all the required information in all the languages of the markets where the product is registered.

One approach is to supply a "lay person IFU" with the product. This would allow an "at-a-glance card" with an information leaflet that the patient could store in their files. The Healthcare Professional (HCP) have to be instructed to pass this "lay person IFU" on to the patient. Each manufacturer would have to make a business decision to determine the number of languages to be provided per leaflet.

Many in the industry has found a much more practical approach through the wording of this requirement. In this method, the information provided on the card itself is limited to the basic identifying information, while the "warnings, precautions, and any other information to ensure safe use..." would be offered on an easy-to-access website.

Information included on implant card:

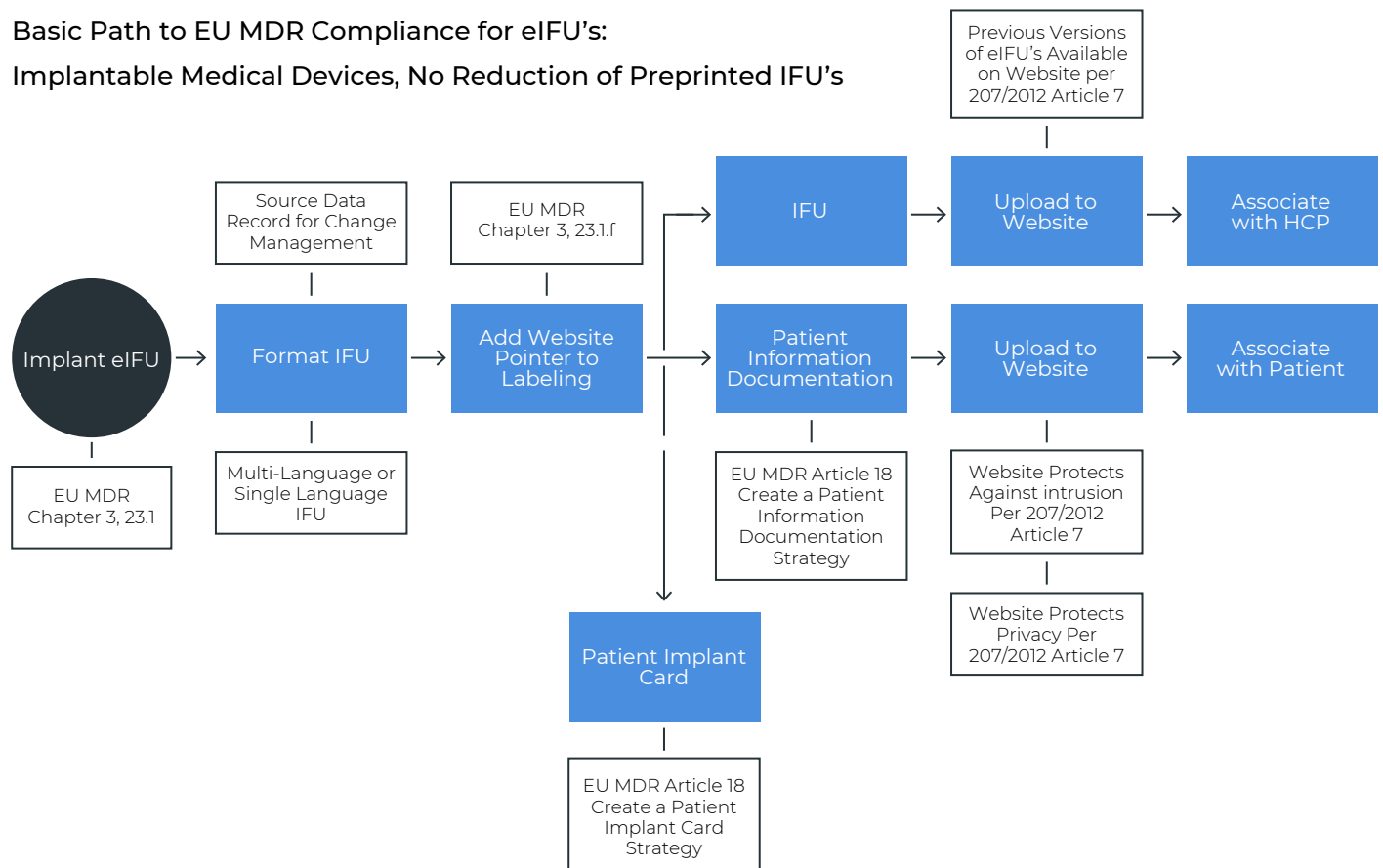
- Device name
- Serial number
- Lot number
- UDI (device identifier)
- Device model
- Name of manufacturer
- Address of manufacturer
- Website of manufacture

THE APPROACH FOR IMPLANT CARDS

Using an Implant card, the manufacturer can provide a practical article for the patient to carry while still ensuring that the warnings, precautions, etc., are available online for reference.

Although not specifically allowed per the letter of the regulation, manufacturers are building the rationale into their risk management documents that this method of delivering the long-form information is significantly easier for the patient, or the patient's health care provider, to access, rather than a multi-language booklet. Since this approach lends itself to better access of information for patients, most believe this approach will be approved by the Notified Bodies.

Basic Path to EU MDR Compliance for eIFU's: Implantable Medical Devices, No Reduction of Preprinted IFU's



POTENTIAL COST SAVINGS USING eLABELING

EU MDR

This approach has the trappings of the 207/2012 eLabeling rule that allows certain implant providers the ability to provide their IFUs electronically and to forgo the printed IFUs. While it may be impracticable to eliminate all preprinted IFUs, since many markets still require printed IFUs, manufacturers can save money by reducing the number of languages that are supplied in preprinted IFUs and still meet all EU MDR IFU requirements.

Eligible manufacturers that haven't taken advantage of eLabeling are using this eIFU requirement to initiate projects to put their IFUs on the web and take most of the languages out of their packaging. While these projects are multi-step, touch every bill of material and take a long time to complete, companies are seeing multi-million-dollar cost savings while taking thousands of tons of paper out of the waste stream.

MedTech Europe, Europe's medical device industry advocate, is lobbying the EU to broaden the scope of medical devices that are eligible for eLabeling. This effort proposes eLabeling for devices "to be used by professionals, in particular, consumable devices". While this is in draft stage at the time of this writing, it may be in place for 2020 as 207/2012 has to be rewritten due to the EU MDR becoming effective in 2020.



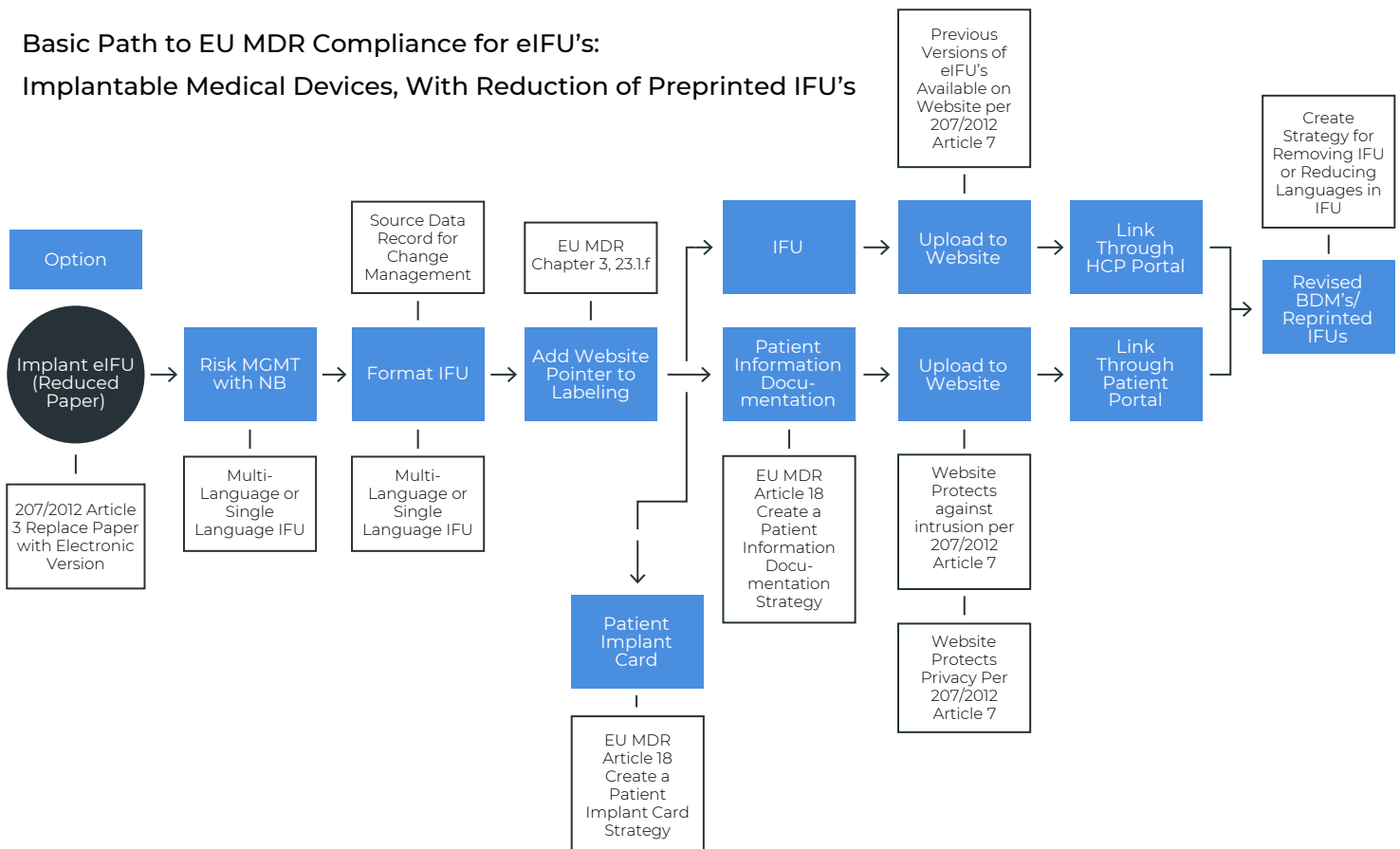


EU MDR

WHERE TO UPLOAD IFU'S

The EU MDR states that if a manufacturer has a website, then specific information to identify a device and its manufacturer, along with relevant safety and performance information, must be made available on the website. To comply with this requirement, manufacturers have two choices regarding where to upload the information and make it accessible to others.

Basic Path to EU MDR Compliance for eIFU's: Implantable Medical Devices, With Reduction of Preprinted IFU's



WHERE TO UPLOAD IFU'S

There are two options for IFU Upload

1 Use an existing website.

Since the regulation applies to manufacturers that already have a website, the simplest solution is to use a section of the existing website to host this information, most likely in .pdf format. While this approach comes with the benefit of using an existing website, manufacturers must be sure that the website complies with all requirements. The EU MDR references EU regulation 207/2012 to require that the website a manufacturer chooses to use meets three requirements.

The website must:

- Be protected against hardware and software intrusion
- Fulfill the requirements of Directive 95/46/EC (since replaced by GDPR)
- Make available all previous version of the instructions for use issued in electronic form and their date of publication

2 Use a contract web hosting service.

The second option to consider, is using a contract web hosting service. These services are built for eLabeling hosting and are validated to meet not only the EU MDR eIFU website requirements listed above, but all the requirements for 207/2012. A contract web hosting service offers an appealing option for manufacturers unsure if their websites meet the necessary requirements or for those who don't want to bear the monetary and time costs associated with bringing an existing website into compliance.

The new eIFU requirements in the EU MDR create unique challenges for the industry. Each manufacturer must develop, implement and maintain a plan to make new information available online and to maintain that information once it is there. While the EU MDR's new requirements pose challenges for all manufacturers, they also create the possibility for increased access to information and increased safety for patients and healthcare providers. Compliance with the new EU MDR requirements also offers the possibility for future cost savings through the removal or reduction of paper IFUs.



ABOUT

NETWORK PARTNERS

Network Partners is a professional services firm that helps clients complete the work necessary to provide their products to patients. We serve the medical device, pharmaceutical and biopharmaceutical industries with core competencies in Regulatory Affairs, CER, Packaging Engineering, Labeling, Quality and Project Management.

Our business model allows team leaders to turn under-resourced teams into productive groups that are better for the company and morale. This approach delivers right-sized pricing as well as quantifiable ROI on stalled projects, cost-savings initiatives and much more. We consistently deliver on time and on budget, helping clients get work done and avoid project delays.

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