

WHITEPAPER

Medical Device Label Designing Important Considerations



Medical Device labeling – an essential aspect of the Medical Device industry that often garners less attention than it deserves. Medical device labeling plays a crucial role in ensuring patient safety, regulatory compliance, and effective communication between stakeholders within the Medical Devices space. From providing vital usage instructions to conveying potential risks and benefits, the label serves as a primary point of reference for patients, healthcare providers, and regulatory agencies.

The importance of clear and accurate labeling, common challenges faced by manufacturers in the medical device industry, and highlight best practices to ensure compliance with regulations such as the FDA's [Unique Device Identification \(UDI\)](#) system and the [EU Medical Device Regulation \(MDR\)](#).

Whether you're a Medical Device manufacturer, seasoned industry professional or a newcomer navigating the complex world of medical devices and labeling, this guide aims to equip you with the knowledge and insights needed to successfully navigate this critical aspect of Medical Devices and regulations. Let's dive in and explore medical device labeling together.

When designing a new medical device, you may work with the mindset of, "It's what's inside that counts." Sure, the inner workings and technology are essential to the product's functionality, but external factors are also important. That includes an often overlooked feature of medical devices – labeling.

Creating [medical device labeling](#) is very different – and more challenging – than printing labels for other non-regulated products. However, it's a critical step in getting your device to market and into the hands of your customers.

Considerations of Medical Device Labeling

If you're not sure where to start with medical device labeling – or want to make sure you're on the right track – here's our list of seven areas to consider.

Patient Safety Information:

A critical aspect of a medical device label is the information for patients. Sure, some of this information is mandated, but the primary purpose is to ensure the safety and well-being of the users. There's specific information that needs to be included, and there are common mistakes to avoid. Also, keep in mind that by FDA and ISO standards, medical device labeling isn't just the label that goes on the device. So, you may need to carefully develop the instructions for all literature, including instructions and packaging, and potentially in multiple languages.

Safety: Patients and medical personnel often need instructions to guide them through using the product or device.

For example, many individuals own epinephrine pens to deliver adrenaline in the case of an allergic reaction. The manufacturers of these devices must attach instructions on how to use the pen in case of an emergency.

Additionally, the manufacturer's label must show how the patient or caregiver should handle the pen during storage and other functions. For instance, a label should indicate if the pen should be kept at a specific temperature to ensure that the medical agent within it still affects patients as intended.

All this avoids potential patient danger ranging from minor allergic reactions to a variety of life-threatening conditions.

Compliance: Regulatory bodies require manufacturers to label medical devices and related products properly. Proper labeling shows these organizations that the company complies with the set guidelines. In the US, medical device labeling requirements are outlined in 21 CFR Part 801, specifying the minimum requirements for all devices. These requirements can include label placement and prominence, what types of information must be included on containers and outside labels, adequate instructions for use, servicing instructions, as well as prescription device requirements.

Additionally, there are a number of other requirements that manufacturers may need to meet depending on the specific category of device.

Manufacturer identification: Both EU and US device labeling guidelines state that manufacturers should add their brand and country of origin. This allows consumers to know where the product hails from;

Regulatory Compliance:

The FDA has specific labeling requirements for medical devices. Adhering to these complex regulations requires collaboration between your designers and compliance team. To ease the burden and reduce the risk of non-compliance, consider working with a manufacturing partner with experience in this field who can navigate you through the complexities. Also, you can look into labeling solutions that are ready-made to meet stringent industry requirements.

Material Consideration:

Selecting the optimal materials for your medical device label is vital for regulatory compliance and ensuring the label is tough enough for its intended environment. For example, if your device could be exposed to liquids, chemicals, or other harsh factors, you will want to consider durable label materials suitable for these conditions.

There are many custom label materials to choose from in designing your medical device: biaxially oriented polypropylene film (BOPP), polyesters, polycarbonates, vinyls, Tyvek, papers, foils, polyimide, steel, and aluminum. For the most durable applications, the obvious choice would be anodized aluminum or metal photo photosensitive aluminum. These asset tags and legend plates last for decades. However, they are unworkable as overlays due to their rigidity. Vinyl makes a relatively durable, easy-to-clean, and cost-effective label. The polycarbonate Lexan is a commonly recommended overlay material, as it is durable, affordable, versatile, easy to emboss, and can be printed in a variety of different ways. It's the All-Star in the overlay game. It does, however, have some limitations, particularly if the device is likely to heat up significantly. For applications involving extreme heat, a polyester, such as Mylar, is a superior choice.

The finish on your substrate matters, as well. I recommend a satin, velvet, or brushed finish. These finishes allow for clarity and strong legibility, while at the same time hiding scratches, nicks, and day-to-day wear and tear. High gloss and semi-gloss finishes can be very eye-catching when applied to the equipment, but readily show wear and tear. Most substrates come in a wide variety of colors, including clear, which can be extremely helpful for certain printing methodologies.

Printing Methods:

The printing process and ink selection also play into regulatory compliance and durability. In addition, the method (and equipment used by your printing partner) can open the door for functional printing techniques, including the next two points.

Let's begin by acknowledging that not every "printing" methodology is technically printing at all. For instance, with anodized aluminum, one would typically laser etch or computer numerical control (CNC) engrave the substrate. Both processes make remarkably durable metal tags for medical devices. Even more durable than those methods, though, is metal photo developing.

The metal photo process actually develops a photographic image beneath an emerald-hard anodic layer of anodized aluminum, making the image virtually impervious. Of the more traditional types of printing, the four most commonly used in printing labels and overlays are screen printing, digital printing, hot stamping, and flexographic printing.

Screen printing is the methodology of choice for most overlays, and creates the most vivid, custom matched colors. Digital printing also is extremely popular for overlays, and is the only way to get full color printing and photo quality images. So, if your overlay is designed with high resolution graphics or full-color pictures, digital printing definitely is the best option. Both hot stamp printing and flexographic printing are great at creating roll labels for tagging your medical equipment. They tend to be very cost-effective and easy to apply. However, there are more significant size and color limitations with these methodologies.

Additionally, there are different ways to protect the print on your label or decal. For instance, all four of these methodologies - hot stamping, flexographic, screen printing, and digital printing can be protected with a layer of over-laminate. In traditional printing, printers apply the ink on top of the substrate, which is called over-printing. With a clear substrate, a good printer can under-print (print on the back of the substrate), so that the substrate itself forms the barrier between the ink and the elements.

A wealth of information, including inventory tagging barcodes, with solid information hierarchy

Traceability: Most medical devices and products require a unique device identification (UDI) for traceability and patient safety. You can enhance the traceability of your device with variable data printing or RFID inlays.

Brand Protection: Techniques can be applied to your medical device label to prevent tampering, counterfeiting, or other actions that hurt your brand's reputation and bottom line.

Sustainability: You can source sustainable materials to minimize the environmental impact of your product.

Sustainability is a frontline priority for all industries across the board. Medical device companies can promote sustainability by adopting environmental friendly disposal practices and packaging materials and still utilize their preferred custom packaging options.

You can also optimize your packaging systems to reduce package weight and size - for instance, by using single sterile-barrier packaging instead of dual sterile-barrier packaging.

Do's of Medical Device Labeling:

- Labeling is a very vivid and vast arena to explore. It can be overwhelming to follow everything stated. Every country in which the device is to be sold has specific labeling & packaging requirements. It's important to check labeling requirements of each country specifically before taking the product into commercialization.
- Sticking to several basic thumb rules can protect you from delays due to labeling issues at the later stage of development.
- Include labeling design at the early stage of the design planning
- Keep the device unique by make, model number, date of manufacture, and batch or serial number
- Include the contact information of the manufacturer/distributor
- Include the box contents with everything inside
- Insert warnings & cautions for the device
- Insert appropriate symbols specific to the device
- Choose the labeling material which remains legible for a long time period
- Include the regulatory teams along with those responsible for Labeling to ensure fast clearance and approval of the new medical device

Don'ts of Medical Device Labeling:

- Do not include anything contradictory to intended use
- Marketing statement with no support data
- Usage of the certifying body (e.g., CSA, ETL, UL) artwork on the product label
- Altering the labeling post receiving device clearance

Conclusion:

Labeling plays an extremely crucial role in communicating correct usage, ensuring correct identification, communicating the safety instructions and much more.
