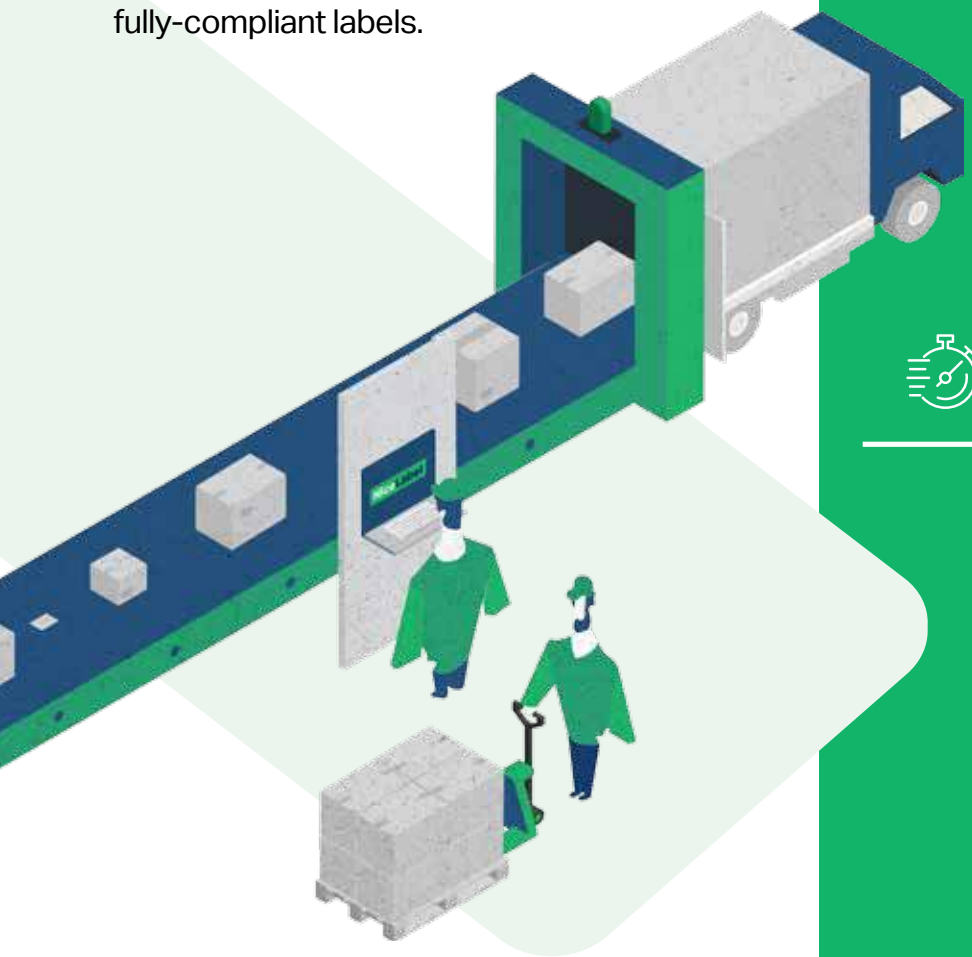
NiceLabel®

Digitally transform for compliant labeling

There seems to be no end to the number of regulations hitting the medical device industry. And while many of the regulations have a shared set of requirements, there are just enough differences to make complying across markets challenging.

At NiceLabel, we help medical device manufacturers of all sizes digitize their labeling process in order to comply with regulatory requirements. We offer a validated solution that is the quickest path to fully-compliant labels.



Digitally transform **label design** and reduce direct costs

Our Label Management System (LMS), moves label design and maintenance out of the IT department and into the hands of the business users. It incorporates universal templates that enable you to significantly reduce the number of label variations. Using our easy-to-use label designer, you can save time, reduce the cost of label design and free up costly IT resources to perform more value-adding tasks.

Digitally transform **quality assurance** and reduce indirect costs

In the highly-regulated world of medical device manufacturing, quality assurance is paramount. Our LMS streamlines quality assurance through digitization. The digital label catalog, built-in approval workflows and comprehensive audit trail ensure that every label you create is accurate, approved and traceable. This digital transformation of quality streamlines regulatory compliance and results in lower risk and higher quality, at a lower cost.

Digitally transform **label management** for a faster time-to-market

For those working in the medical device industry, it may feel like new regulations are popping up every day. In addition to international requirements like the EU Medical Device Regulation (MDR), individual countries are also implementing their own regulations, aimed at tracking medical devices.

To meet the ever-increasing number of regulations, you need an agile labeling process capable of adapting quickly to new requirements. Our LMS helps you manage labeling across all of your sites and countries. The built-in document management system enables you to rapidly fulfill the specific labeling requirements in each country where you do business and get your products to market faster.

www.nicelabel.com/medical-devices

Built for life sciences

1 Streamline compliance with regulatory requirements.

- Control and streamline your label lifecycle management with the built-in digital label catalog.
- Get everything you need to comply with FDA and EU regulations, including role-based access, document versioning, configurable approval workflows and electronic records and electronic signatures (ERES).
- Use universal templates and the graphical "label comparison" tool to consolidate label designs and reduce the number of label variations.

2 Fast-track validation.

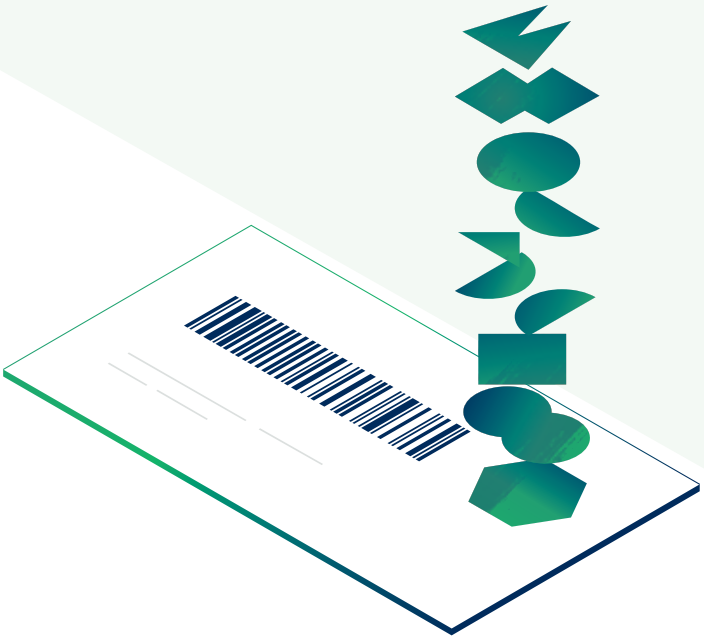
- Get a standardized approach to streamline validation with the Validation Acceleration Pack (VAP).
- VAP simplifies alignment with industry standards and can easily be adapted to your specific requirements.
- Work with our professional services group to get the IQ, OQ and PQ validation packages and services that meet regulatory requirements.

3 Successfully handle SKU proliferation.

- Manage hundreds or even thousands of SKUs with ease.
- Using label variant technology, our software integrates with your master label data for each SKU and merges it with templates in real time, creating a snapshot of "print compliant labels" that are ready for approval.
- You can approve every label variant for every SKU without having to manually create numerous label variations.

4 Improve traceability.

- Get full traceability and visualization of every label ever printed.
- Document every change request and system event, including user, location and timestamp information.
- Generate electronic PDF documents reflecting physically printed labels for submission to 3rd party content management or PLM solutions.



Medical Device manufacturers who have transformed their labeling.

sonova · Aerin Medical · Baxter · B Braun Sharing Expertise · Essilor · Fisher&Paykel Healthcare · LiNA · Medi-Globe The Spirit of Care · Medivation · Mölnlycke Health Care · Sorin Group · NuVasive · Zimmer MedizinSysteme · Quotient · Ultradent Products, Inc.

Digitally transforming labeling leads to **TANGIBLE RESULTS**

82%
of our customers have experienced cost savings from error reduction.

24%
of our customers have achieved indirect cost savings of more than $10,000 per location.

$30,000
A customer from the medical devices industry has streamlined label quality control processes, resulting in annual savings of $30,000.

WHY NICELABEL

Established in 1993, NiceLabel is a leading global developer of label management systems built to meet the labeling needs of life science companies. **71%** of the medical device manufacturers companies on the Fortune 2000 list use our technology.

With the help of our label management systems, medical device manufacturers are able to digitally transform their entire label printing and production process. The result is a leaner, more agile operation that enables them to respond more quickly to changing regulatory requirements, ensure accurate, consistent labels and get products to market faster.

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