Transform Compliant Medical Device
Labeling with the Cloud

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

Move label design **to the Cloud** and reduce direct costs

Cloud labeling moves label design and maintenance out of the IT department and into the hands of business users. It incorporates universal templates that enable you to significantly reduce the number of label variations. With an 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.

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

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

In the highly-regulated world of medical device manufacturing, quality assurance is paramount. Cloud labeling 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. You can quickly comply with regulatory requirements resulting in lower risk and higher quality, at a lower cost.

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

Streamline labeling 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. The Cloud 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.

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

Loftware™

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Built for life sciences

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.

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 to meet regulatory requirements.

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.

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.

Loftware is the world's largest cloud-based Enterprise Labeling and Artwork Management provider, offering an end-to-end labeling solution platform for companies of all sizes. Maintaining a global presence with offices in US, UK, Germany, Slovenia, China, and Singapore, Loftware boasts over 35 years of expertise in solving labeling challenges. We help companies improve accuracy, traceability and compliance while improving the quality, speed, and efficiency of their labeling. As the leading global provider of Enterprise Labeling and Artwork Management, along with Clinical Trials Labeling and Regulated Content Management, Loftware enables supply chain agility, supports evolving regulations, and optimizes business operations for a wide range of industries. Those include automotive, chemicals, consumer products, electronics, food & beverage, manufacturing, medical device, pharmaceuticals, retail and apparel.

Kreski Spółka Jawna
ul. Mory 12, 01-303 Warszawa

telefon: +48 22 666 22 40
fax: +48 22 398 70 71
e-mail: kreski@kreski.pl

CONTACT US

Americas
+1 262 784 2456
sales@loftware.com

EMEA
+386 4280 5000
sales@loftware.com

Germany
+49 6104 68 99 80
sales@loftware.com

China
+86 21 6249 0371
sales@loftware.com