

Case Study:

# How NiceLabel helped Plastiflex develop a UDI-compliant labeling process



## Background

The Plastiflex Group is a leading manufacturer of flexible hose systems for Original Equipment Manufacturers (OEMs) and distributors worldwide. Founded in 1953 in Orange County, California, Plastiflex operates in three key markets: Health Care, Industrial and Consumer Appliances (pool, floor care and white goods). The company has 7 factories in North America, Europe and China and is headquartered in Belgium.

## Business expansion requires a new approach to labeling

In 2008, Plastiflex decided to expand from its traditional areas of producing flexible hoses for the industrial and appliance markets into the area of healthcare. They began designing, developing and manufacturing health-care hose systems for the respiratory care markets (sleep apnea and ventilation). As a medical device manufacturer, Plastiflex needed a labeling process that complied with medical device regulatory guidelines, such as the FDA UDI and EU MDR requirements. Thus, they began their search for a new labeling solution that would help them comply with these regulations.

**Industry:** Medical device

**Solution:** Software NiceLabel Cloud and Software NiceLabel Label Management System

### Requirements

- Integrated labeling to meet regulations
- Compliance with FDA UDI and EU MDR
- Solution hosted in the Cloud and on-premise

### Solution

- Hybrid labeling solution
- Integration with Infor® ERP
- Out-of-the-box UDI compliance

### Benefits

- Ensured business continuity
- Compliance with industry regulations
- Streamlined validation
- Flexibility to shift production between facilities

# Requirements

## Regulations called for a more integrated labeling process

Plastiflex had a labeling system in place, however it was primarily a local solution. “We operate with a decentralized production plant structure,” explains Patrick Taels, ICT Manager at Plastiflex Group. “We have facilities around the globe that produce different products, and our healthcare production facility is in mainland China. They used a standalone labeling solution at the production plant level. They would produce the label templates and manage data locally, and then verify these with the Group.” However, medical device regulations require that the label design and release process be done in a more controlled manner. “We needed to have a controlled release process that started from our head office in Belgium. So, our goal was to implement an integrated label management process that guaranteed accurate labels and data integrity.”

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Plastiflex began looking for a new labeling solution at the end of 2019. They were on the clock, as they needed to comply with the UDI requirement deadlines. In order to guarantee the traceability of the product from production to patient as required by the UDI regulations, Plastiflex needed a labeling system that connected to the shop floor laser marking machines so that the proper UDI label data was also printed on the product. This had to be a single flow process and Loftware successfully helped during the implementation.

## The quest for a cloud and on-premise solution

One of Plastiflex’s main criteria for a labeling system was that it offered a cloud-based solution that linked to an on-premise solution and could easily be rolled out to multiple locations worldwide. “We were looking for a local version of a label management system, so we could have an on-premise installation on the production shop floor that could then interact and link with a cloud-based labeling solution,” Patrick says. This hybrid solution would enable Plastiflex to guarantee business continuity even in the event of an Internet outage at the local production plant level. “We had to find a solution that was able to operate even with an Internet outage, while making sure that the data integrity and release process and procedures would be 100% correct and synchronized.”

Other requirements included finding a provider with customers in the life sciences sector and one that was able to offer a full-scale solution. Loftware was the only provider that was able to satisfy all of Plastiflex’s requirements.

# Solution

Plastiflex now operates a hybrid installation, using Software NiceLabel Cloud and Software NiceLabel Label Management System (LMS) on premise. The healthcare engineering team in Belgium designs the labels and the quality assurance team approves them. The label templates and master data are stored in the NiceLabel Cloud database and synchronized with the local, on-premise installation of the LMS in the factory in China. The local installation is a read-only setup, and all of the data is validated and approved prior to the one-way sync to the on-premise system.

When it's time to print labels locally, the operator on the shop floor enters the production order number into a customized print application (built using the software's application builder). This number retrieves data from two sources: the Infor® ERP system and an on-premise

database. The customized print application combines the data from both sources – including data for the GS1 data matrix and other UDI information, along with customer-specific details – and ensures all of this information is printed on the label as well as printed using laser marking machines on the product itself.

This hybrid deployment fulfills Plastiflex's requirements and helps them ensure business continuity. "If something happens on the shop floor and they lose connectivity, we can still offer them an offline connection to NiceLabel Cloud," Patrick explains. "Even if the Internet is down for a number of days, production can still continue as they can still connect to an on-premise solution that has been synchronized with the cloud system in Belgium. So, we really have the best of both worlds."



# Benefits

## Loftware offers out-of-the-box UDI compliance

In order to satisfy UDI requirements, Plastiflex had to print a GS1 data matrix code directly on the label. They also had to guarantee that the label release procedures and process management were top-down, and that they had full traceability of who created the label, who managed the changes and who approved it. “All of that was available out of the box with Loftware so we didn’t have to invent anything. We met those compliance goals easily. The only thing we had to do was design the label, provide the master data and set up the role-based access,” comments Patrick.

Plastiflex also benefited from the built-in quality approval process, which includes label versioning and a comprehensive label print history. All of these features helped them implement a compliant labeling solution by the UDI deadline. As Patrick states, “You’re offering a full package service; it’s a product, it’s a management system – you helped us with understanding UDI requirements and how we translate that to a system.”

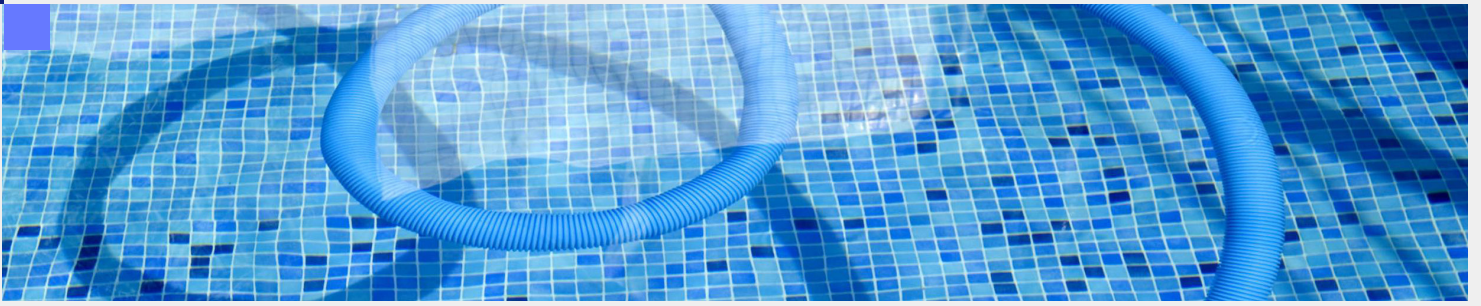
## Loftware’s validation documentation ‘a lifesaver’

Companies operating in the life sciences sector are also required to validate their IT systems before using them. This, according to Patrick, was one of the project’s biggest challenges, as they needed to understand what software validation meant in this context. Here, Loftware’s Validation Acceleration Pack, was a ‘lifesaver’. “I couldn’t have completed the software validation without your documentation. It gave us the main structure that we needed for external audit reasons, in order to document the system correctly. Once we had that, it went really fast. And we succeeded, thanks to this great documentation.”

In addition to assisting with compliance and validation, Patrick’s team also found that user training and adoption were clear-cut with Loftware. “Your product interface is very clean and straightforward, making it very easy for the end user to find their way around the product,” he says.

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## Application builder helps support an integrated label management process

Plastiflex also discovered other benefits of the Loftware NiceLabel platform during the configuration process. “We really appreciated the application builder feature,” Patrick says. “It makes it so much more convenient for creating a streamlined label printing process. From anywhere in the world, we can centrally define and manage what the labels will look like and what data entry fields the operator can fill in on the shop floor. This was a unique feature we didn’t find with any other provider on the market.”

## Creating a scalable, compliant labeling process

Now that Plastiflex has implemented a compliant labeling process in its factory in China, the plan is to replicate this set-up in their production plant in Mexico. “Now that we have an integrated process in place, it makes it easy to roll out similar set-ups in different locations across the world,” Patrick explains. This gives Plastiflex the flexibility to shift production between facilities. “Once we have Loftware NiceLabel in place in Mexico, we’ll be able to move products that were produced in China to our facility in Mexico. This will help us to accommodate our growing healthcare business.”

## Possibility for expansion into other product lines

Other business lines have also seen the advantages of using Loftware’s NiceLabel platform. For example, Plastiflex’ production facilities in Slovakia have decided to switch to the Loftware NiceLabel LMS for their traditional products. Jan Hermans, Project Manager, EU at Plastiflex explains, “The interface was so convincing for them, they decided to switch from their current labeling solution and implement an on-premise version of the Loftware NiceLabel platform.”

While there are no concrete plans as of yet, Patrick and Jan believe that further expansion is likely. “Traceability is not only relevant for the healthcare business; it’s also becoming more important for other business areas,” Jan observes. “Our OEM customers are looking to the automotive industry and its quality systems as an example of how they can improve traceability and manage risk. And we’re already seeing more requirements from these customers regarding their labeling.” As labeling complexity increases in other product lines, implementing Loftware would enable Plastiflex to have one standardized solution across the business. “I think there’s a huge potential for Loftware in the market globally,” Patrick concludes.



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 solutions, Loftware enables supply chain agility, supports evolving regulations, and optimizes business operations for a wide range of industries including automotive, chemicals, consumer products, electronics, food & beverage, manufacturing, medical device, pharmaceuticals, retail and apparel.

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