

## The behind-the-scenes role of an equipment label manufacturer



A prominent medical device manufacturer has partnered with us to manufacture their equipment labels for upwards of 20 years. Recently, they approached us with a specification drawing of an [identification nameplate](#) for a cardiac mapping device for us to review and, ultimately, bring to life.

The purpose of the label was simple:

- Display the device name and OEM.

- Contain a QR code, which a device operator could scan to access the product manual.
- Show the safety compliance organizations (TUV, CE) which have certified the product and its bill of materials.
- Leave a clear window, through which a separate label (printed on-demand during their device assembly process) would display device-specific identification information including the serial number and barcode.
- Simplify manual label application during the device assembly process.

The label would be comprised of a velvet-textured polyester film, a high-performance acrylic adhesive from 3M and a polycoated kraft liner.

The peel tab would make removing the label from the liner easy. And dotted guides printed on the adhesive side of the label would show assemblers where to line up the edges of the barcode label before affixing the two-label assembly to the device.



A quick glance at the artwork file showed that we'd have to print on both sides of the film. The front of the label would display all identifying information, and the back would contain those dotted guidelines.

There was just one problem — as it was written, the spec wouldn't result in a label that matched the client's vision.

Here we'll narrow in on what, exactly, the problem with this label was. And we'll walk you through the exhaustive spec review process we went through to identify it.

## **Walking through the spec review process**

Equipment and nameplate label clients typically fall into one of two camps: They either have a finished spec and simply need it to be taken through to the finish line, or they require our help engineering the spec from the ground up.

This client fell into the first camp.

But even when a client has a finished spec, we consider it our duty to conduct a thorough review. They expect us to serve as a final quality check, identifying any potential problems before the print run — minimizing waste, cost and lead times for them.

## **Checking for compliance requirements**

Equipment labels and nameplates are functional components of the devices to which they're adhered. Because of this, OEMs will sometimes have to submit the label to regulatory bodies (e.g., UL or CSA) for approval as part of the bill of materials.

We always check the spec for any compliance requirements. In this case, UL and CSA compliance is not listed in the spec — meaning it wasn't a requirement for this particular label.

## **Evaluating the label construction**

Looking at the spec, the construction, dimensional tolerances and tooling die requirements were clearly laid out.

The window was to be left clear, and adhesive was to fully cover the back of it. While we'll often selectively apply adhesive, leaving the back of windows clear to enhance transparency, the note about full-coverage adhesive didn't set off any alarms for two reasons. First, the window isn't being used as a lens and second, adhesive is required to adhere the barcode label behind it.

The label was to be die cut (cut through the material *and* liner) around the perimeter of the label except between the peel tab and the label, where the material would be kiss cut (cut through the material, but *not* the liner). This would allow an assembler to quickly remove the nameplate from the liner by bending the peel tab back.

All of this was well within our capabilities. But a potential problem surfaced when we cross-referenced the tooling die requirements with the specified label materials.

## **Ensuring the compatibility of the label materials**

The label materials were all compatible with the substrate (lightly textured, high-surface energy

molded plastic) and the performance challenges of permanent medical device labels.

But the chosen adhesive product was incompatible with the tooling requirements of the label. They specified 5 mils of adhesive on a 4.2-mil polycoated kraft liner.

The actual adhesive is well-suited for this application — it's an acrylic product boasting performance attributes like slippage resistance, short-term repositionability and excellent heat resistance.

And the 5-mil thickness of the adhesive is compatible with the texture of the substrate. If the surface were smooth, they could get away with 2 mils, but greater thickness is required for the label to fully adhere to the peaks and valleys of the textured surface.

The liner was the problem.

4.2 mils was too thin. Doing a kiss cut between the peel tab and the label as specified would be impossible — the die would cut through the liner completely.

We recommended a simple redline: Switch from the previous product to another one that was exactly the same but with a thicker, 6.2-mil liner.

They did an engineering change notice, initialing our redline as an approved document, and a potentially costly problem was averted. The change notice allowed us to begin production while they went through the lengthy process of approving the change internally.

The rest of our spec review was relatively smooth. We took note of their packaging requirements, double checked to make sure the revision number matched our purchase order and we were off to the races.

## Driving quality by design

On its surface, the job of an [equipment label converter](#) is to manufacture and deliver labels exactly to spec. But the reality is that we must first ensure that the spec perfectly matches the client's vision for the label. And that means reviewing every spec with careful eyes, calling out any potential problems and making course-correcting recommendations.

It's just part of the job.

Resource Label Group is a UL-recognized, CSA-accepted label converter with deep expertise in manufacturing equipment labels, nameplates and overlays. If you need a label produced to-spec — or require assistance developing a new spec — [reach out to us today](#). Our team of labeling experts is here to take your labeling project through to the finish line.