



How Digital Quality and Production Solutions Help a Manufacturer of Cardiacsense Products Rest Easy.

Client case study by Orcanos



Company Overview.

Founded in 2012, Cardiacsense currently manufactures four products. Backed by a strong IP portfolio that includes developments in optics, mechanics, and signal processing, CardiacSense has developed a unique, state-of-the-art watch for long-term, continuous monitoring of heart arrhythmias (such as atrial fibrillation or cardiac arrest) and blood pressure. The highly accurate CardiacSense watch is currently in the advanced stages of FDA and CE certification.

The company has grown, and relevant regulations have evolved. Cardiacsense recognized the growing need to modernize how they manage quality documents and production records with digital solutions.



Medial Device



Caesarea, Israel



74 Employees

Cabinets Filled With Paper. Uncontrolled Documents. Poor Collaboration.

Before Orcanos, everything was paper-based at Cardiacsense. Folders of procedures, forms, and production records filled cabinets, taking up space and making document management unwieldy and collaboration time-consuming.

“All our procedures and production records were printed and written out by hand. Procedures were typed, but they had to be printed as hard copies. And when we needed a form, we would have to go find it, make copies of it, handwrite it or scan it, and try and type over it,” according to Asaf Omer, Cardiacsense’s Regulatory Compliance Manager. Not only does paper require a lot of effort to maintain and physical space to store manually, it also creates unnecessary opportunities to lose vital documents as they move through various stages of the manufacturing process.

“From the production area, they’d get moved to the boxing area and then stacked up,” according to Yaniv Inbar, VP of Operation at Cardiacsense. “The documents traveled from place to place before they were finally closed and filed.”

Relying on paper also makes manufacturers vulnerable to other common but devastating problems – including damaged or destroyed records. In the production area, where the company makes assembly of, the finished good, files and paperwork were left exposed to the physical environment. And when paper-based production records are completed and stored in cabinets, they risk being destroyed in the event of a disaster. For Cardiacsense, the risk of losing physical paper records during engineering, production, and after was a significant driving force for digitizing with Orcanos.

Collaboration was also a challenge, with personnel emailing files back and forth. And because many of the company's paper-based procedures made collaboration difficult, some procedures hadn't been looked at in years and risked becoming outdated.

As the company has grown and created more procedures and required more collaboration, managing paper documents was no longer practical.

The complexity of the product manufacturing process also required strong change management on the parts catalog and the BOM so 3rd party manufacturers could have the most accurate information in near real-time.

"With paper, it just takes time to keep everything together, which carries extra regulatory risk by having procedures with very long revision dates," Asaf says.

"Orcanos will improve our accessibility of information and visibility of our finished product and how it's handled and what it's made of. I see record retrieval, the ease of access to information, as a big value for us.

– **Yani Inbar VP Operation, Cardiacsense**

Quality, and Production Solutions – Implemented in Parallel.

When Cardiacsense engaged with Orcanos, they wanted documents, training, and manufacturing solutions. As a company with 75 employees, four products, and four master production record templates, it made sense to implement an electronic quality

management system (eQMS/QMSR) and an electronic engineering BOM/DMR/ECO record solution at the same time.

Yaniv, who started in production before moving into his role overseeing quality at Cardiacsense, didn't want to spread the process of digitizing quality and production records longer than necessary. He was impressed by how easy and seamless the whole process of digitizing these records was.



"It's scary and a little bit daunting to think we're moving our entire QMS to the electronic world. But the way it was implemented, methodically, worked for us – it was pretty simple," according to Yaniv. "I was really happy with how quickly we were able to implement Orcanos's quality and manufacturing solutions simultaneously."

Engineers workers picked up the electronic design records after only a couple of training sessions.

"I think Orcanos designed the solution very well in that it doesn't require a lot of direction," Asaf says. "So, user adoption is very good."

Accessible, Visible Information.

Improved Data Integrity.

ERP Integration.

Cardiacsense bought a cloud solution to increase collaboration. The data is accessible from any device, computer for the engineers, where much of the work takes place, and future iPad for everybody on the manufacturing floor or Mobile for management monitoring.

In the design area, workers are no longer filling out paper and signing documents. They're electronically reporting all the inputs that Cardiacsense wants to document, going through the record, and validating systems. Paper in the engineering booth is gone, improving access to real-time data and visibility of the entire product life cycle.

"Orcanos will improve our accessibility of information and visibility of our finished product and how it's handled and what it's made of," according to Cardiacsense.

"I see record retrieval, the ease of access to information, as a big value for us. I'm confident that Orcanos will add a lot of value, including in ways we don't know about yet."

The company is in the process of integrating Orcanos with its enterprise resource planning (ERP) software, NetSuite, so that materials information can be pulled directly into the electronic production record. This will eliminate data integrity issues, such as mistyping lot numbers for raw materials and improve the ability to analyze more data.

Ultimate Result: Rapid Review and BOM Release

For Cardiacsense, the BOM release process before using Orcanos took too

long. The process was made more complicated if the product needed to be released, but nobody was there to do it. As the product still evolves, changes need to be made, creating additional problems during the release of an ECO.

"It would go through quality assurance (QA) testing, so we would have to walk the entire paperwork packet over to the operation. And then they'd do their release, fill out the forms. And then it would come back to me, and then I would review it, and it would go to somebody else who would review it, do another accurate count of BOM finished goods before releasing it in the ERP," Yaniv says.

"With paper, it just takes time to keep everything together, which carries extra regulatory risk by having procedures with very long revision dates.

– Asaf Omer, Regulatory Compliance Manager, Cardiacsense

Using Orcanos's electronic production BOM records, Cardiacsense can quickly release products every day without having to carry paperwork to different departments. The time to release ECO has roughly been halved because no time is spent waiting for somebody to add their information.

"With the advance ERP in the cloud and Orcanos also in the cloud, I can potentially integrate them both and release products from anywhere in the world," says Asaf. "Orcanos is probably the greatest investment we've made for streamlining our processes and getting rid of paper."