

ECOLINE MINI - VERY LOW VOLUME ASSEMBLY CELL FOR MEDICAL DEVICES PRODUCTION

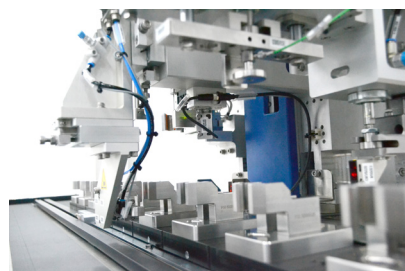
Mikron has been involved in medical devices manufacturing for decades and continues to invest in innovation. Mikron has introduced its new flexible assembly cell EcoLine Mini – for very low volume production of medical devices.



Over the past decade, new players have been entering the sector and taking market share from the traditional drug manufacturers. Every type of medical device is different, forcing manufacturers to adapt their production line depending on the customer. More flexible, scalable solutions are required to produce less volume and more variants, and to reduce time to market.

NEW CHALLENGES

Mikron has been working to meet these challenges. We evolved our strategy five years ago. For more than 40 years, our core business was high-volume automation. We are famous in the market for designing high-performance assembly solutions for high-volume production with complex processes. But the trend is no longer exclusively high volume: We also design small-scale automation assembly solutions.



MIKRON OFFERS A LEVEL OF EXPERTISE UNMATCHED IN THE PHARMACEUTICAL AND MEDICAL DEVICES INDUSTRIES. WE MANAGE PRODUCTION PROCESSES AND **GAMP 5 CERTIFICATION STANDARDS** FOR LOW VOLUME ASSEMBLY

SMALL SCALE TESTING

This versatility is particularly helpful for coping with strict medical regulations. To start with, you need to prove that the way you're choosing to assemble the device will ensure 100% functionality of the device. When you have to produce a few samples to give to the authorities, such as the EMA or FDA, for testing, this is where we can help: with the EcoLine Mini – where processes are under control and components that are very simple to produce are loaded by hand.

This arrangement – allowing customers to test designs on a small scale – ensures that manufacturers never have to change their designs at the last minute, thereby saving them money. This eliminates the nightmare faced by producers in the pharmaceutical industry when they need to revalidate their devices. Once your processes have been fixed, you can no longer change them. And if you need to change them, you have to revalidate the entire production process; this not only requires an enormous effort, it also costs time and money.

SEAMLESS ASSEMBLY

Mikron helps you to make savings in other ways. Once a new medical device has been validated, you can seamlessly switch to a higher-volume line. Our system is very smooth and makes manufacturing more affordable. We start with a lower-volume cell, then when the market picks up, we can scale up to fully automatic line.

It's not an easy transformation. It requires guidance from the beginning. It's not about simply getting two parts and sticking them together. That's why you need to think about where you want to go, right from the beginning. Mikron provides a scalable solution that will support you right through to the fully automatic system. We are able to do this thanks to our vast experience, and we see it as a mark of our quality. The EcoLine Mini assembly solution is a step in the right direction.

ADVANTAGES OF THE ASSEMBLY SOLUTION ECOLINE MINI

PROCESSES DEVELOPPED FOR HIGH VOLUME

The EcoLine Mini use the same technology for the process stations as the standard EcoLine platform. Process stations, for the current setup, are already developed for high speed production and can be 100% reused when you switch to the mass production phase. Thus, the future investments are minimized and lower the cost of ownership.

MEDICAL VALIDATION

Some processes are validated for the current device; when you upgrade to the production phase, validation requirements will be reduced as most of the current processes can be reused.

POSSIBILITY TO INCREASE THE OUTPUT

Higher production volume can be achieved by adding another operator for the handling of the parts.

RISK MITIGATION AND PROVEN PROCESSES

Since over 40 years, Mikron has built more than 3,500 assembly lines (sub assembly and final assembly lines) for customers all around the world and for a wide range of production volume.

Mikron scalable strategy ensure the perfect understanding of the requirements needed to implement the right processes from the beginning of the assembly project.

Cam technology – robust and stable solution, offering high reliability, low maintenance, no air consumption and no sensor .

Similar machine operations (hardware and software), validated processes, shorter learning curve for operators are the advantages when you progress to the mass production phase.