

Class III Medical Device Fabrication Services

Overview

The Hermetic Solutions Group understands that with a Class III Medical Device comes strict regulations and quality standards. With that in mind we offer not only production services, but design and engineering services to complete quality control.

The Hermetic Solutions Group has experience with: pacemakers, sensing implants, ventricular pumps, defibrillators, neural stimulators artificial hearts, cochlear implants, LVADs , stimulation implants and more.

Technical Advantages

Engineering Expertise

The Hermetic Solution Group's engineering staff can assist in the optimal design of your medical device. Our extensive experience in materials, weld-joint design, tool design and laser-based manufacturing will ensure a smooth transition from concept to production.

Full Validation Services

We know that in the medical industry validation is key. At Hermetic Solutions Group, we offer statistically validated processes, so you have all the documents required to support your Class III medical device.

Prototypes to Production Runs

No matter the quantity, we can handle a single prototype run, to several hundreds or thousands of parts. With our commitment to quality you can rest assure that the last part finished will meet the same high standards as the first.



ISO Class 7 Cleanroom Assembly, Final Sealing

The Hermetic Solutions Group is dedicated to providing the highest quality hermetic environment for the welding and sealing your Class III medical devices in an inert environment. To ensure your components are fully protected we've built a ISO Class 7 cleanroom environment equipped with state-of-the-art laser welding and sealing systems and testing centers.

Our ISO Class 7 cleanroom is ESD compliant. We are committed to ensuring that every part that leaves our facility is precise. With that in mind, we welcome audits by your own team of experts to ensure all of our systems and processes are being conducted to the highest standards.



Packaging and Sterilization



Looking for a sterilization solution for your surgical devices and Class III implantable devices? Look no further than Hermetic Solutions Group, where our medical device manufacturing team can not only design, manufacture and assemble your medical devices in an ISO Class 7 clean room but now have the ability to pack and sterilize your product in our Ethylene Oxide (EtO) sterilization system.

Our complete packaging and sterilization solution helps simplify your supply chain management in a number of areas and we partner with organizations that have deep experience in manufacturing tray and pouch tooling that are optimized to meet specific customer requirements. The Hermetic Solutions Group also delivers complete process documentation, custom sterilization cycle development and validation as well as final testing data.

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