
seisa
medical

About Us

Seisa is a global market leader in providing contract medical device solutions for mission-critical precision components and finished FDA-Class II and Class III medical devices.

At Seisa, our primary focus in every area of service is that **what we manufacture, what we promise, and what we deliver impacts lives.**

Since its founding in 1983, Seisa has held every employee responsible for adherence to FDA and international regulations.

Product Development

Seisa offers completely customized solutions backed by more than three decades of medical device experience. We leave the choices to you, bringing our team of experts and engineers to any stage of the process to build the right combination of services to meet your needs.

+ Product Design and Development
+ 510K Filing and Submission
+ Prototyping Process and Tooling Design
+ New Product Introduction Support
+ Testing and Sterilization Plans
+ 510K Registered Products and PMA Devices

Manufacturing

Seisa's end-to-end solutions are backed by our company's history of full regulatory compliance with the FDA and international agencies.

Solutions:

Manufacturing and Assembly

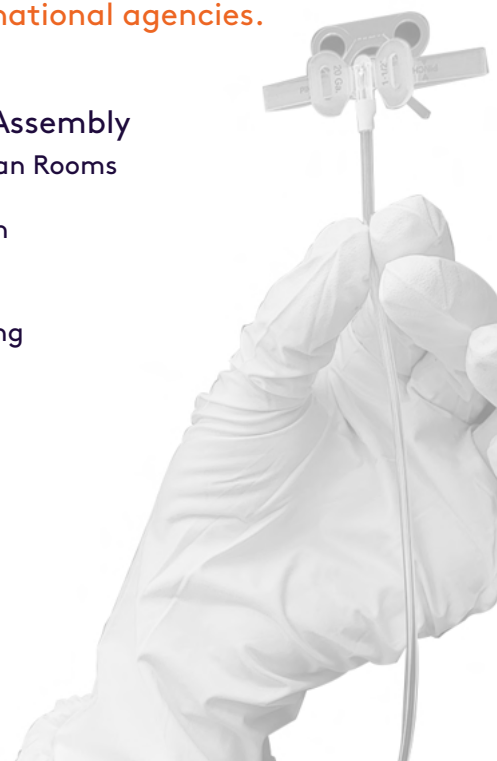
+ Class 7 and Class 8 Clean Rooms
+ Global Footprint
+ Optimized Supply Chain

Metals

+ CNC Precision Machining
+ Laser Processing
+ NiTi and Novel Alloys

Plastics

+ Injection Molding
+ Micro-Molding
+ Extrusion
+ Multi-Lumen Extrusion
+ Thermoforming
+ Rapid Prototyping
+ Tool Building



Products and Components:

Class III Devices

+ Cardiac Stents
+ Structural Heart Implants
+ Endovascular (AAA) Devices
+ Neurovascular Stents

Class II Devices

+ Stent Delivery Systems
+ Cytology Snares and Brushes

Components

+ Guidewires and Introducers
+ NiTi Baskets
+ Balloons

Supply Chain

With specialized manufacturing operations strategically located across North America and Europe, Seisa Medical provides its customers with tailored project management and supply chain solutions.

We capture all elements of the supply chain, including vendor selection, vendor management, inbound and outbound logistics, sterilization management, and ship-to-stock programs. Our expanding offerings and capabilities allow us to optimize the efficiency by which we deliver finished products to our customers.

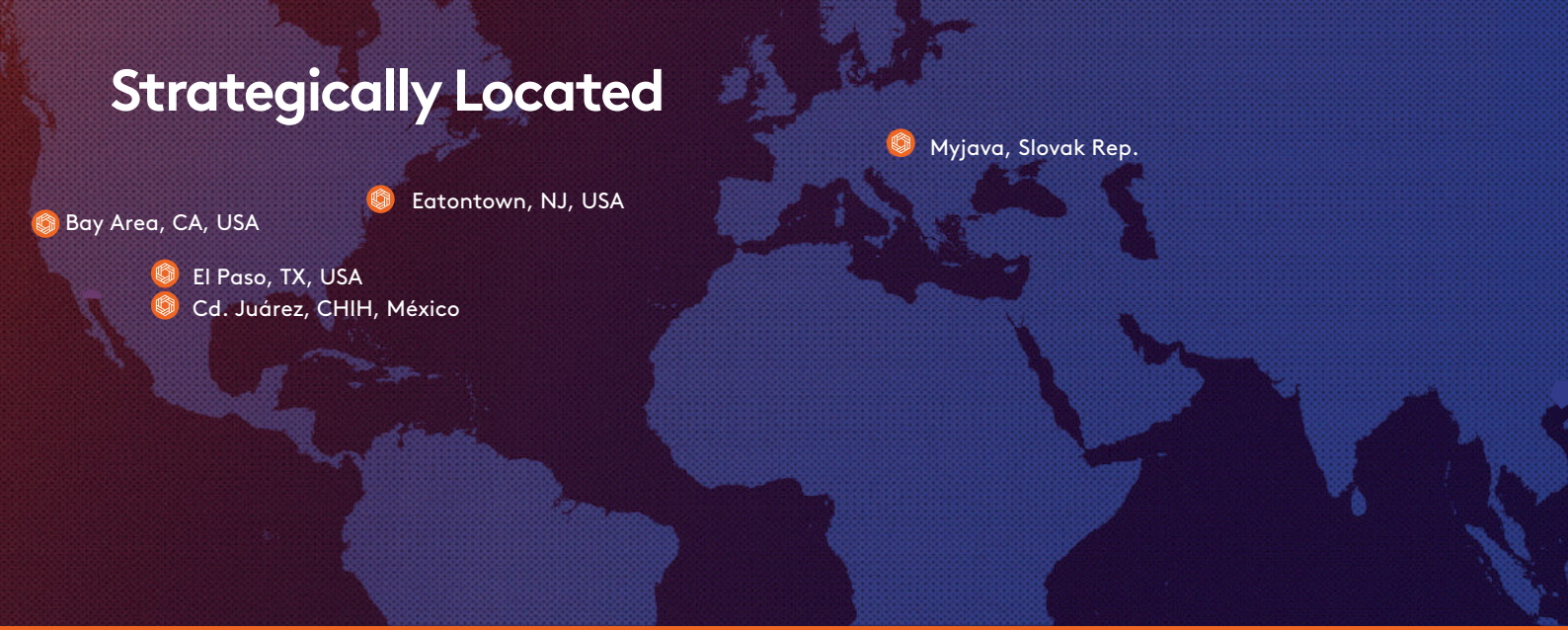
Quality

With over 35 years of experience in compliance with FDA and international regulations and audits, Seisa has developed a thorough understanding of the complex regulatory environment. From concept through validation and commercial release, our team designs and builds with regulatory compliance in focus.

We have been delivering Class II and III devices for over 15 years and our global facilities are all ISO-13485 certified.

+ ISO 13485:2016 Certified
+ In-House Metrology Labs
+ ISO 7 and 8 –Certified Cleanroom-Controlled Environments
+ Class I, II, and III Devices, Including Premarket Approval (PMA)
+ FDA Registered and Compliant with Code of Federal Regulations Part 820
+ Dedicated Quality Planning and Program Management

Strategically Located



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