

KMC Systems



Ready to Support the Fight Against COVID-19

KMC-COVID-19-ENQUIRY@ELBITSYSTEMS-US.COM

About KMC Systems

KMC Systems, Inc. is a contract manufacturing and engineering firm. We develop, design and manufacture groundbreaking medical instrumentation in close collaboration with our valued OEM customers.

With expertise to bring state-of-the-art invitro diagnostic (IVD) platforms, therapeutic delivery systems, high-volume laboratory automation instruments and point-of-care devices to market KMC has earned the trust of the leading Diagnostic, Medical Device and Life Science companies.

Located in Merrimack, New Hampshire, KMC Systems is part of Elbit Systems Ltd. (NASDAQ: ESLT), a global defense contractor, and a wholly owned subsidiary of Elbit Systems of America.

Capability Overview

FDA registered facility

350,000 square foot ISO 13485 certified facility.

7,000 square foot clean room capacity, available and ready to use.

Conveniently located near Manchester and Boston Airports.

KMC is classified as an essential business during the Covid-19 epidemic, receiving full support from the state.

Supportive local supply base with capacity reserved to support the scale of business.

Fully staffed Quality Department to support FDA requirements for speed of documentation to support regulatory filings.

Large 100+ engineering team to support immediate needs.

3D printing capabilities

Additional available capacity

Roanoke, VA office with 246,000 sq ft manufacturing space.

Fort Worth facility with 43,000 sq ft production area with complex SMT CCS assembly and test capabilities.

Additionally, LRU fabrication, backplane assembly and testing capabilities.

IPC 610 certified/ J-STD certified.

ISO Class 5 clean room approximately 500 sq. feet.

KMC Systems

An Elbit Systems of America Company

Supporting the
fight against

Covid-19

Contract Manufacturing



Leverage our depth of proven expertise in:

- Concept development
- Design engineering
- Contract manufacturing
- Sustaining engineering
- Work flow simulation
- In-house wet lab testing
- FDA compliant quality systems
- Spare parts and refurbishment management
- Global supply chain vendor management

KMC Systems has been manufacturing high-value, complex platforms for use in the clinical environment, from prototypes to full-scale commercial production for over 40 years.

Features:

- ISO13485
- cGMP compliant
- Wet lab testing
- Global supply chain
- Incoming parts inspection (metrology and calibration)
- Biosafety laboratories
- In-house machine shop
- ISO Class 7 and 8 clean rooms
- FDA inspected manufacturing facility

Engineering

KMC Systems has been solving complex medical engineering and design challenges since 1980, conceiving innovative, highly-automated solutions in the development and design of full-system instrumentation.

With skilled engineers in software, systems, mechanical and electrical engineering, plus seasoned program managers, quality control and manufacturing professionals, your medical instrumentation is set up for success.

With Specialties in:

- Optics
- Fluidics
- Robotics
- Hardware design
- Software design
- Chemistry integration
- Motion control
- Thermal control
- Verification and validation
- Sustaining engineering

Engineering Laboratory:

- Breadboard and Prototype build
- Chemistry labs
- 3D Printing
- Optics and Fluidics labs
- Electronic test equipment
- Rapid Prototyping equipment
- Co-Located Teams

KMC Systems

An Elbit Systems of America Company

Supporting the
fight against

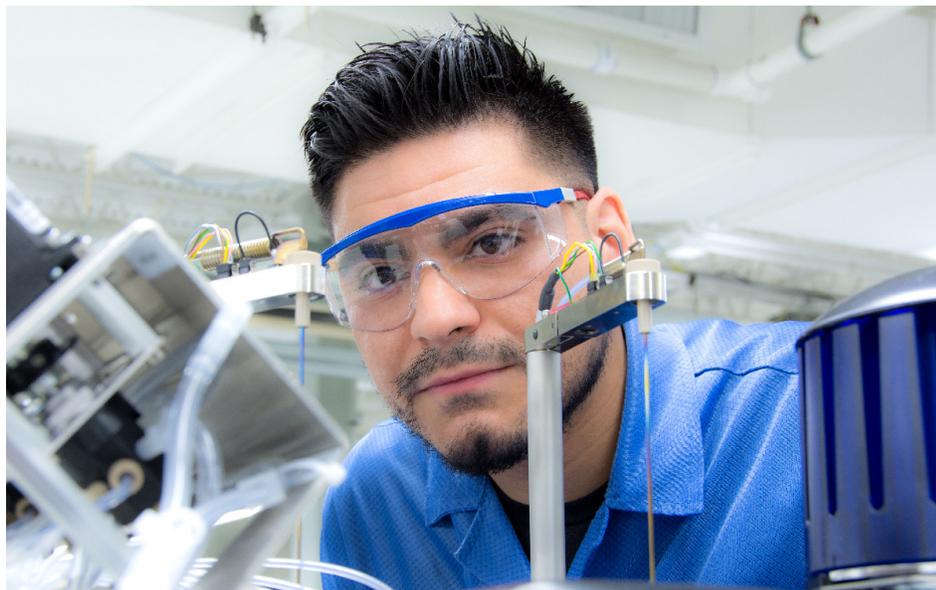
Covid-19

Contact KMC

220 Daniel Webster Hwy
Merrimack, NH 03054
Phone: 866-742-0442
www.kmcsystems.com

*Creating
Innovative
Medical Devices
for a Better
Quality of Life.*

Quality Assurance



Regulatory compliance is not just a requirement—it's our culture. Our quality assurance team adheres to regulatory requirements with confidence and proven success.

Our robust ISO 13485:2016 environment ensures that Design Controls and Manufacturing Operations are compliant. In addition, KMC operates an FDA-inspected site and undergoes numerous industry audits every year.

KMC Systems' robust, FDA-compliant, automated software system has been customized over three decades to adhere to our strict quality assurance processes and

complex applications which ensures greater adherence to regulatory requirements. The resulting KMC Quality Management System (QMS) enables our quality assurance team to adhere to regulatory requirements with confidence and proven success.

ISO 13485:2016
IEC 62304
FDA Current Good Manufacturing Practices (cGMP)
Calibration and Metrology
FDA QSR Parts 820, 803 and 806
Part 11 Compliance