



## ISO 13485 Medical Product Manufacturing

Specialist manufacturing solutions for high-regulatory products

4E specializes in the manufacture and support of high quality, regulatory controlled medical and healthcare products. We are ISO 13485:2016 accredited, ensuring our ability to provide medical devices that consistently meet client's and medical regulatory requirements.

At 4E we have many years' experience of supporting clients' product requirements, from the prototyping stage through to regular production, while continuously managing the product lifecycle. We pride ourselves on the excellent working relationships we forge with our clients, and our record of delivering a successful outcome, whatever the project.

### SERVICES

- ◆ Low to Medium Volume Manufacture
- ◆ Product Lifecycle Management
- ◆ Fast Turnaround Assembly
- ◆ NPI (New Product Introduction)
- ◆ Engineering Support
- ◆ Prototyping | Preproduction
- ◆ Production Set Up

### CAPABILITIES

- ◆ Electronic and PCBA Assembly
- ◆ Hand Assembly, Box Build and Cabling
- ◆ Electro-Mechanical Assembly
- ◆ Test and Verification Services
- ◆ Documentation and Full Traceability
- ◆ ISO 13485 In-House Production Facility



“ Our ISO 13485 accredited system assures high quality medical prototypes. ”



## CASE STUDIES

### Cranial Pressure Monitor

This medical hand-held product, for monitoring of cranial pressure, incorporated an LCD display that was withdrawn by the supplier at short notice. 4E was tasked with upgrading the unit to an alternative display, while minimizing FDA re-qualification, then providing ongoing manufacture of the unit. 4E maintains strict medical documentation and management of the supply chain, including any further obsolescence issues. The unit consists of surface-mount PCBA assemblies, touch screen display, pressure probe transducer, cable assemblies and plastic enclosures.

### Smart Station | Hospital Data Logger

4E provided volume manufacturing to the client for its Hospital Data Logger, a miniaturized electronics unit with push button controls, PCB with radio comms and a display. The system is intended for application to existing storage facilities, and enables the recording of stock taken and stock replaced. The Smart Stations are low cost, cordless devices, manufactured in volumes of 10,000s. After setting up new supply sources for the product from client’s original design drawings, 4E manufactured the units under the ISO 13485 medical quality standard.

### Plasma Surgical | Plasma Jet™

PlasmaJet™ is an innovative device used to coagulate bleeding tissue during surgery. The technology uses a jet of argon plasma to provide fast and precise control of bleeding, leaving a wound sealed. It is used during both conventional and keyhole surgery, greatly reducing the risk and duration of complex procedures and can minimise costs by reducing the patient’s stay in hospital.

As PlasmaJet™ moved into production to meet world-wide demand, 4E worked closely with Plasma Surgical offering supported manufacture. The sheer nature of the unit’s design is so complex, with so many components that it will continue to need support throughout its life, with upgrade requirements, repairs and design changes to overcome component obsolescence.

The result of Plasma Surgical and 4E’s collaborative work is a revolutionary product that is making waves in the medical industry. The PlasmaJet™ was considered one of the most ground-breaking products when it was launched in 2003 in America and 4E are proud to contribute to its continuing success, ensuring an uninterrupted supply of this very exciting product.

“ 4E are brilliant at understanding a brief and are very passionate and sincere about providing a good result. ”

