

### **MicroMed Solutions guarantees superior quality finished components, ready for use in clinical or life science markets.**

Because your reputation is invested in your product, we are committed to exceeding your quality standards using our extensive Quality Management System which is comprised of an ISO 13485:2003 certification, our clean room operations, and the collection of analytical data throughout the production process. MicroMed Solutions welcomes customer quality audits for you to confirm our compliance and discuss any unique requirements associated with your product. At MicroMed Solutions, we're as concerned about the quality of the parts we produce as you are.

#### **Clean Room Operations**

MicroMed Solutions understands the critical importance of achieving accurate results from IVD and assay tests. The outcome of these tests can become compromised and complications arise due to debris and contaminants. As a result, LasX performs precision digital converting in a Certified Class 10,000 (ISO Class 7) clean room. This environment promotes a high level of cleanliness during component processing which, in combination with a superior attention to detail, yields a more accurate finished product. A highly controlled process environment ensures that each customer receives world-class quality components for use in IVD and microfluidic devices.

#### **ISO 13485:2003 Certification**

MicroMed Solutions is dedicated to superior operational performance. To reflect this commitment, we have obtained an ISO 13485:2003 certification and adhere to the associated international standards of quality. The format of this program fosters better communication between MicroMed Solutions and each customer in regards to quality-related issues and requirements. Additionally, our Quality Management System allows customers to more easily achieve and maintain FDA approvals and related documentation.

#### **Statistical Process Control**

Meeting the design requirements to obtain repeatable, high tolerance accuracy is crucial in the manufacturing of high-performance medical devices. This is imperative in the alignment of layers for laminate structured fluidic devices as well as single layer components. MicroMed Solutions uses vision metrology equipment to monitor and document each stage of the converting procedure. The data is entered into SPC software, which provides histogram, Cp, and Cpk data for analysis throughout the manufacturing process.