

# Medical Device Services

Our medical device services start from product design & development to batch release; we specialize in product assembly, packaging, sterilization & testing. We use & apply various different techniques, machines & instruments for successful launching of your requirement with considering international harmonized standards. Also helps you to makes your idea workable for customized application.



Mail us:  
[Info@medzushealth.com](mailto:Info@medzushealth.com)  
Web: [www.medzushealth.com](http://www.medzushealth.com)

## 1. Medical devices manufacturing services:

Our medical device manufacturing process services gives you complete solution for your product to be launched in market. We involved in the following segments of sourcing & implementation -

### 1.1 Product Assembly:

- Raw & semi-finished material selection & sourcing
- Product cutting (Mechanical or Laser Techniques)
- Catheter tipping (Open tip type)
- Forming (Close or Open type)
- Hole punching (Mechanical or High Frequency)
- Bonding (Adhesives or Heating)
- Welding (High Frequency & Ultrasonic)
- Sutures swaging & crimping (Absorbable & Non-Absorbable Sutures)

### 1.2 Packaging:

- Packing material selection & sourcing
- Medical grade pouch packaging
- Tyvek & medical grade blister packaging,
- Aluminum blister moisture proof packaging.

### 1.3 Sterilization:

- Ethylene oxide sterilizer installation & commissioning
- Sterilization validation
- Sterilizer calibration
- Protocol & report preparation



Medical Device  
Manufacturing Services

Medical Device Testing  
Services

- Design & Development
- Technical Solution
- Material Sourcing
- QA & Regulatory

## **2. Medical device testing services:**

We give solutions for functional & performance testing of various ranges of surgical medical devices as per FDA, CE, ASTM, and ISO guidelines. Our services help in test method development, method validation, process optimization & process validation. Also provide the best solution for biocompatibility testing, chemical testing, stability testing & clinical evaluation of medical devices.

We specialize in calibration & testing services for all small-bore connectors specified in ISO 80369-1 to 7 & 20. We are able to help with customized testing applications to make your idea workable.

### **2.1 Small Bore Connectors testing as per ISO 80369-20:**

- Gauging test
- Unscrewing torque
- Separation force
- Stress cracking
- Resistance to overriding
- Ease of Assembly

### **2.2 Testing Solution for Needles:**

- Needle sharpness test
- Needle penetration test
- Needle stiffness test
- Needle-hub bond strength test
- Needle bending/resistance to breakage test
- Needle tip inspection test
- Suture needle ductility & elasticity test
- Needle hub connectors (luer) test

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### 2.3 Testing Solution for Syringes:

- Syringe plunger actuation force test
- Leakage test
- Syringe luer test

### 2.4 Testing Solution for Catheters, Tubings, Bags & Bottles:

- Breaking force & connection fastness test
- Leakage & burst test (air & water)
- Flow rate test

### 2.5 Testing Solution for Medical Packaging:

- Medical film & paper tear & pin hole test
- Blister pouch peel off/seal strength test
- Blister burst & leakage test

### 2.6 Chemical Tests Implementation:

- Acidity or Alkalinity
- Metal Ions (barium, chromium, copper, lead, and cadmium)
- Residue on Evaporation
- Resistance to Corrosion
- Ultraviolet Absorption
- Acid Value
- Saponification Value
- Extractable Colour Test
- Ethylene Oxide Residue
- Moisture Content (Karl Fischer -Coulometric)

### 2.7 Biological Tests Implementation:

- Sterility test
- Bacterial endotoxin test
- Biological indicator test

### 2.8 Stability Study Tests Implementation:

- Accelerated or real time ageing of sterile barrier system
- Accelerated or real time ageing of medical devices

### 2.9 Surgical Medical Device Biocompatibility Tests Implementation:

- Cytotoxicity
- Sensitization
- In-Vitro Biological Reactivity
- Intracutaneous Irritation

