SMC Global Presence

**United States**
Santa Rosa, California  
Somerset, Wisconsin  
Amery, Wisconsin  
Twinsburg, Ohio  
Devens, Massachusetts

**Central America**
San Jose, Costa Rica

**Europe**
Cambridge, UK

**Asia**
Bangalore, India

Production Facilities are FDA Registered and ISO 13485 Certified
Markets Served

- Pharma
- Diagnostic
- Device
Medical Device Manufacturing High Level Requirements

• Manufacturing:
  • Scientific manufacturing
  • GMP

• Quality:
  • Quality management system
  • Verification and validation
  • Document management

• Regulatory:
  • Certification/registration with relevant regulatory authorities
  • Risk assessment and management
Material Requirements for Plastics in Medical Devices

Medical Grades of Plastics

- Stringent performance requirements
- Biocompatibility
- Toxicity
- Resistance to sterilization, drugs, chemicals, solvents, etc.
- Country specific regulatory requirements based on efficacy and safety
Types of Plastics used in Medical Devices

Commodity: PVC, Polylefins, Styrenics, COCs

Engineering: Acrylics, Polycarbonates, Polyurethanes, Polyesters, Polyamides, Polyacetals

High Temperature Engineering: Polysulphones, Polymides, Polysulfides, Polyketones, LCPs, Fluoropolymers

Thermoplastic Elastomers: SEBS, TPUs, TPVs

Silicones: LSR/LIM
Typical Classification and Applications of Medical Devices

Low Risk
Stethoscopes, enema kits, bed pans, in vitro diagnostic devices, reusable surgical tools (knives, scalpels), tongue depressors, thermometers, urine collection bottles and bags, dental instruments, inhalers

Moderate Risk
Syringes, MRI, video endoscope, digestive tract catheter, contact lenses, pregnancy kits, tracheostomy tubes, glucose monitors, dental and bone implants, haemodialysis systems, diagnostic ultrasound systems, respirators, blood bags, infusion pumps, nebulizers, inhalers

High Risk
Ventilators, implantable pacemakers, cardiovascular catheters, valves and stents
Overview of Emerging Opportunities

• PPE
  • Disposable face masks, gloves, coveralls

• Diagnostic kits

• Respiratory devices:
  • Asthma inhalers, oxygen delivery devices, nebulizers, CPAP/BIPAP machines, ventilators
  • Nasal cannula
  • Intubation devices: laryngoscope blades, endotracheal tubes, tracheostomy tubes
Thank You