

Import-Export Compliance Checklist for Medical Devices

U.S. Market Entry & Trade Readiness

- Confirm device classification under FDA rules
 - Determine if 510(k), De Novo, PMA, or exemption applies
 - Verify FDA establishment registration requirements
 - Confirm U.S. Agent requirements for foreign manufacturers
 - Review intended use and claims consistency
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Product & Quality Compliance

- Maintain compliant Quality Management System
 - Ensure design and manufacturing records are current
 - Verify labeling meets FDA requirements
 - Confirm UDI compliance, where applicable
 - Ensure complaint handling and CAPA systems are active
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Documentation

- Commercial invoice
 - Packing list
 - Bill of lading / airway bill
 - FDA product codes, where applicable
 - Certificates / declarations if required
 - Importer of record information
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U.S. Customs & Entry

- Correct HTS classification
- Duties/tariffs reviewed
- Customs broker aligned
- Country of origin declarations accurate
- Shipment value documentation complete
- Post-Market Readiness
- MDR reporting procedures ready
- Recall procedures established
- Distributor controls in place
- Record retention system active