

Medical Device Import/Export Compliance Checklist – FDA, EU, Global Trade

FDA Importer Requirements

- Establishment registration completed
- Device listed with FDA
- Labeling includes UDI and IFU
- Importer of Record identified
- Customs clearance SOP in place
- Quality Agreement in place between foreign manufacturer and U.S. Importer (if applicable)

U.S. Exporter Requirements

- CFG or Certificate of Exportability requested
- FDA compliance letter (if applicable)
- Destination country approval verified
- Commercial invoice and HS code verified
- CE marking or local authorization (for non-U.S. markets)

EU/Global Trade Considerations

- Notified Body engagement for CE (if required)
- EU Authorized Representative appointed
- MDR-compliant Technical File prepared
- Product registered in EUDAMED (if applicable)/ UDI registration in EUDAMED (required for Class III and II devices as of May 2025)
- Export country labeling/local language compliance
- PRRC (Person Responsible for Regulatory Compliance) designated by manufacturer and AR or UKRP (in case of UK), whichever is applicable
- Country specific trade documentation