How to Set Up an Orthopedic Implant Export Business

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The global orthopedic implant market is projected to reach $66 billion by 2030, with fastest growth in Southeast Asia, Sub-Saharan Africa, the Middle East and Latin America. For importers and distributors, the opportunity is real — but regulatory and quality requirements are exacting.

Step 1: Regulatory Mapping

Map the registration requirements for each target market before selecting a manufacturer. Most developing-market regulators accept CE Mark and/or FDA clearance as primary evidence, with additional local documentation (translated labels, local AR, product samples). Key bodies: CDSCO (India), Saudi SFDA, UAE MOHAP, Singapore HSA.

Step 2: Manufacturer Qualification

Require ISO 13485:2016 certification, current CE Mark certificate from an accredited NB, FDA Establishment Registration, sterilisation validation reports and willingness to provide Certificates of Free Sale and Origin.

Step 3: Distribution Agreement

Negotiate: exclusive/non-exclusive territory; minimum order quantities; product liability indemnification; regulatory support obligations; instrument loan set provision; and surgical training commitments. Engage a commercial lawyer familiar with medical device distribution law.

Step 4: Logistics and Customs

Most orthopedic implants classify under HS Code 9021.10 or 9021.90. Import duty ranges from 5–15% plus VAT in most markets. Free Trade Agreements can reduce duty significantly — work with a medical

device customs specialist.

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