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# EMERHUB

## **Knowledge Empowers Business – Forum 2025**

A Workshop on Compliance and Global Market Access

Jingjiang, Jangsu, 10/11 July 2025











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# EMERHUB

### Expand anywhere in Southeast Asia with Emerhub

# Regional Presence in Southeast Asia Seamless Multi-Market Expansion

### Centralized Management via Entity Management System







### **Medical Device Outlook in Indonesia**

- Market Overview
  - Medical Device Market in Indonesia
    - 2025: ~\$5.5–6 billion (estimation)
    - 2033 (Projected): \$10.47B
    - CAGR (2024–2033): 9.1%; (Source: Statista)
- Positioning
  - Why Indonesia? Opportunities for Foreign Medical Device Manufacturers
  - Provide:
    - Key drivers: large population and government health initiatives EMERHUB





# Medical **Devices** Regulatory Structure

#### **Business Activity**

#### 46691

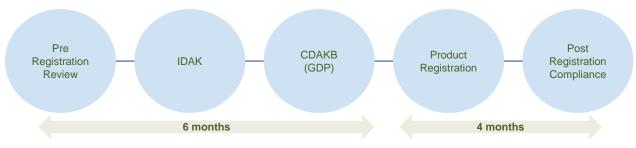
Wholesale of Laboratory Equipment, Pharmaceutical Equipment and Medical Equipment for Humans

#### 47725

Retail Trade of Laboratory Equipment, Pharmaceutical Equipment and Medical Equipment for Humans

- IDAK : *Izin Distribusi Alat Kesehatan* (Medical Device Distribution Permit)
- CDAKB : Cara Distribusi Alat Kesehatan yang Baik (Good Distribution Practices for Medical Devices)

**Registration Procedure (for wholesale - import product)** 



#### **Risk Class of Medical Devices in Indonesia**

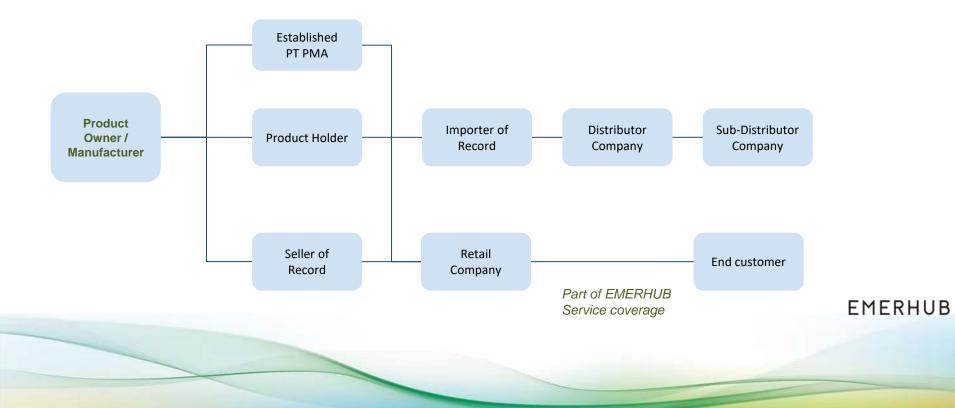
CLASS A (Low Risk) Bandages, Surgical Gloves, Tongue Depressors, Manual	CLASS B (Low-Moderate Risk) Suction pump, Nebulizer, Digital Thermometer, Infusion Set
Toothbrush	Iniusion Set
CLASS C	CLASS D
(Moderate-High Risk)	(High Risk)
Blood glucose meter,	Dialysis machine,
Ultrasound machine, Contact lenses	Implantable pacemaker, Heart valve



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# How to Enter the Market

For the Medical Devices (Injectable)





#### Seller/Merchant of Record

### Market Entry Via Local License Holder



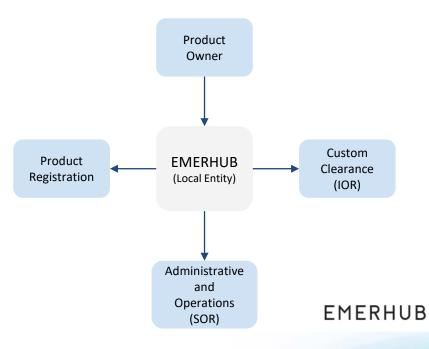
**Skip** half the process

No need for you to apply the facility (warehouse) registration, which will speed up the process (up to 3 month) No need to take care the complication of the Company Administrative Operation, the only focus is the product and the sales

Focus on

your sales

operation



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## Summary

Foreign Manufacturer  $\rightarrow$  Local SOR + IOR (Emerhub)  $\rightarrow$  Regulatory Submission  $\rightarrow$  Distribution

Key points:

- Required for product registration
- Owns product license in Indonesia
- Enables regulatory compliance without entity setup (best choice for market testing)



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