

【 Flow Chart: Steps to Importing Medical Device-Class I 】

1. Finalize product to be imported

2. Prepare information of product

By Manufacturer, including specification with the international classification, efficacy, the way of use, and manual of the product.

3. Check classification of product

By Medilex, check if the product is complied to Standard of General Medical Device (Class I) in Japan (JPY10,000 /product)

NG/Revise

4. Overall Review & Consultation

By Medilex, check if product meets the definition (efficacy and indication) of General Medical Device (Class I) in Japan

Unclear

Safety Study by either Medilex or Manufacturer

NG

Cleared

5. Registration of Foreign manufacturer

By Medilex, apply registration of foreign manufacturer to PMDA (Fee to PMDA:JPY90,000/manufacturer)

6. Product Registration

By Medilex, submit notification of manufacture and marketing to PMDA

7. Labeling/ Attached reference

By Medilex, create Japanese label data and attached reference

8. Start Import!

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Import Given Up...



...After the conclusion of the contract

