



**covue IOR**

**JAPAN MARKET ENTRY SOLUTIONS**

**IOR  
CLASS 1 AND CLASS 2  
MEDICAL DEVICES**

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**PRICING AND INFORMATION FILE**





# Importing Medical Device in Japan

**Class 1 and Class 2 Medical Device Import Applications** are approved by the Japan Ministry of Health Labor and Welfare (MHLW), PMDA division (Pharmaceuticals & Medical Devices Agency).

**PMDA** requires only one manufacturer per import application. There is no limitation to the number of products that can be added to the application. Each application is reviewed and approved by the agency. Once approved, the products may be shipped under the IOR's license as a general approval. No additional applications are required.

PMDA requires only one manufacturer per import application.

## Process

1. **MHLW Pre-Notification** - MHLW will review the Pre-Notification and determine what additional informational requirements will be needed. It will take about 15-25 days.
2. **MHLW Lab Testing** - COVUE requires the testing of all regulated products. Send us the product sample and COVUE will do the testing.
3. **Product Labeling** - Your product requires a Japan Compliant Label. This label must be attached to the consumer packaging before shipping. If the product label cannot be attached before shipping, COVUE is required to attach the label when the product enters Japan. COVUE charges a labeling fee to apply labels. COVUE will create the label as part of your product import application. The label will need to be included with the application.
4. **Shipping Invoice** - Prepare your authorized COVUE shipping invoice from your COVUEIOR account. The destination should be in COVUE's Facility for inspection before the final receiver.
5. **Final MHLW Application** - COVUE will consolidate and prepare the documents and submit them to PMDA. PMDA will review the final application and notify COVUE of approval.

**The process takes about 8 weeks (60 days).**



# IOR Fees for Class 1 Medical Device Products

One-Time Registration Fee:	78.75
Product Liability Insurance (annual fee)	100.00
Subtotal:	178.75
Tax:	17.88
Total:	196.63

Lab Testing fee	Price starts at \$100
Class 1 and Class 2 Medical Device Product Approval Application (up to 150 products from the same manufacturer)	2,500

**Includes:**

- MHLW Manufacturer & Ingredient Pre-Notification
- Product Labeling Compliance
- Product Approval Application

IOR Shipping Fees (charge per shipment )	7%
Up to 99,999,999 ¥ in Value	5%
Over 100,000,000 ¥ in Value	

**NOTE: We only accept Incoterms DDP**

## Ready to proceed?

**REGISTER NOW!**



# Other Services

## AMAZON JAPAN SERVICES

Japan is the 3rd largest economy. It has never been easier to expand to Japan.

With our help, we make it easier for you to be discovered by 127 million Japanese consumers,

Our deep understanding of Japanese culture will free you to reach your goals, grow faster and maximize your return on investment!

### SERVICES

- Account Registration
- Customer Care Support
- Amazon Market Research for Niche
- Amazon Listing Copywriting & Optimization in Japanese
- Advertising and Marketing (PPC)
- Amazon FBA Prep Services
- Gift Handling



## PRODUCT RETURN ADDRESS SERVICES

Some e-commerce platforms such as Amazon Japan require sellers to have an established Return Address for products that have been returned.

COVUE offers Foreign Japan Online Sellers Return Address and After-Sales Services that support any requirement.

- **Product Return Address Services**
- **Export Product Return Address** - Need to return your products to your home country or supplier?
- **Product Disposal** - Japan has strict laws for product disposal. Most products must be broken down for recycling or to contain any hazardous material.
- **Product Repair** - Have a product return that can be repaired? COVUE ONLINE Users with active designated Product Return Address Service have complete control of their product repairs.



# Related Terms

**IOR Registration Fee** - This is a one-time fee with no expiration and covers all types of products under COVUE

**Product Liability Insurance** - Seller will maintain at Seller expense commercial general, umbrella, or liability insurance per occurrence and in aggregate covering liabilities caused by or occurring in conjunction with the operation of Seller business, including products/completed operations and bodily injury, with policy naming CJ and its assignees as additional insureds.

**Product labeling** - All products sold in Japan require Japan Product Labeling compliance.

**Shipping Invoice** - Only COVUE Authorized Shipping Invoice can be used.

**Rules for Foreign Online Sellers** - Japan Customs has simplified the process for Foreign Online Sellers by requiring Foreign Online Sellers to Declare Import Value = Online Selling Price.

**MHLW Lab Testing** - To mitigate (lower) the risk of recall or potential harm to Japanese buyers of COVUE IOR clients. COVUE will require the testing of all regulated products. Product testing will be controlled by COVUE.

## How it works?

- Client will send product samples (minimum of 2 pcs per product) to COVUE Facility for inspection
- COVUE will arrange lab testing to MHLW
- COVUE Compliance team will notify client with the result and proceed with the application process



Got Questions?

Email us at [info@covue.com](mailto:info@covue.com) or visit [www.covue.com](http://www.covue.com)





# WHY choose COVUE?



## We are your #1 gateway to Japan...

With both native Japanese and international teams working side-by-side, we will have you launch faster and your products selling sooner.



## Transparent pricing, no long-term contracts or subscription fees

Services, pricing, and deliverables are clearly communicated, letting you know what your investment is before committing.



## Market-leading customer care

We provide clear and concise information to let you understand Japan market. We let you focus on what matters!



## We value our clients

We subscribe to values that make a difference in our relationships and the operational excellence of our services we deliver.



## Trust is Earned not Given

