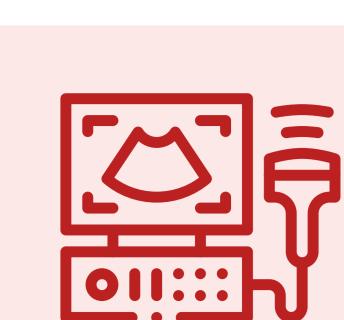


Medical Devices Registration in Vietnam

WHAT ARE MEDICAL DEVICES?



Medical devices encompass a range of tools, materials, in-vitro diagnostic chemicals, and software, used individually or together as specified by the owner, to fulfill various purposes.

MEDICAL DEVICE CLASSIFICATION

Based on the Global Harmonization Task Force (GHTF) & the ASEAN Medical Device Directive (AMBDD)

Class A	Class B	Class C	Class D
Low Risk	Low Moderate Risk	Moderate-High Risk	High Risk

Based on the Food and Drug Administration (FDA)

Class I	Class II	Class III
Common Low Risk Low Complexity	More Complex Greater Risk to Patient Partially Implanted	Fully Implanted Greater Risk Regulate Body Functions

REGISTERING MEDICAL DEVICES IN VIETNAM 3

Required Documents for Medical Device Class A Registration			
No.	Required Documents For Class A	Items required	Note
1	Classification	01 Original copy	Issued by qualified Lab/ Company in Vietnam.
2	Documents evidencing the priority right	01 Legalized at Viet Embassy	
3	Letter of Authorisation	02 Original	InCorp will support client to draft this form If Required
4	The certificate of warranty qualification issued by the product owner (except for disposable medical devices defined by the product owner or there are documents proving that the device is not under warranty)	01	InCorp will support client to draft this form If Required
5	Brief description of the medical device in Vietnam language (The document contains the description of functions and specifications of the medical device)	01	InCorp will support client to draft this form If Required
6	Declaration of Conformity (of the manufactory)	01 Scan copy of Original	
7	The instruction manual of the device	01 Scan copy of Original	
8	A sample of the label for the devices sold in Vietnam	01 Original in PDF	Good quality file
9	CFS	01 Legalized at Viet Embassy	

Viet Embassy except for passport

All the above docs must be translated to Vietnamese by the authorized/licensed translator in Vietnam or

1 USB

Required Documents For Class

Required Documents for Medical Device Class B, C, D Registration

E-signature of the Product-license-holder-company

10

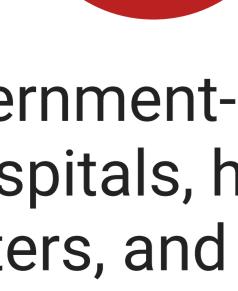
No.	Required Documents For Class B, C, D	Items required	Note
1	Classification	01 Original copy	Issued by a qualified Lab in Vietnam
2	ISO certificate (ISO 13485)	01 Legalized at Viet Embassy	Has to be in English (if not, has to be translated into Vietnamese)
3	(POA) The Owner of Product authorises Company in Vietnam to be license holder	02 Legalized at Viet Embassy	InCorp will support client to draft this form If Required
4	CFS	01 Legalized at Viet Embassy	Has to be in English (if not, has to be translated into Vietnamese)
5	Brief description in Vietnam language	01 Original copy	Has to be in English (if not, has to be translated into Vietnamese InCorp will support client to draft this form If Required
6	Catalogue	01	Translated into Vietnamese
7	The instruction manual of the device	01	Translated into Vietnamese
8	Label	01 Original	Good quality PDF file
All the above docs must be translated to Vietnamese by the authorized/ licensed translator in Vietnam or Viet Embassy except for passport			

COMPARISON BETWEEN TWO TRENDS OF CLIENTS

1	Right to Import & DistributeRight to Change Distributor	- Depend on Distributor or Third Party
2	- Have to <u>Establish Company</u> with Two Options: <u>Limited Liability Company</u> or <u>Representative Office</u>	- Reach out with Two Options: Distributor or Third Party (removes dependence on Distributor)
3	- Find Distributor	- Find Distributor (if Clients use Third Party)
4	- Start Importing & Distributing	- Start Importing & Distributing
5	- Same for Local & Foreign Companies - Same if Remote/ Online Procedures	- Same for Local & Foreign Companies - Same if Remote/ Online Procedures
Product License Holder is a holder of Product Registration Paperwork		

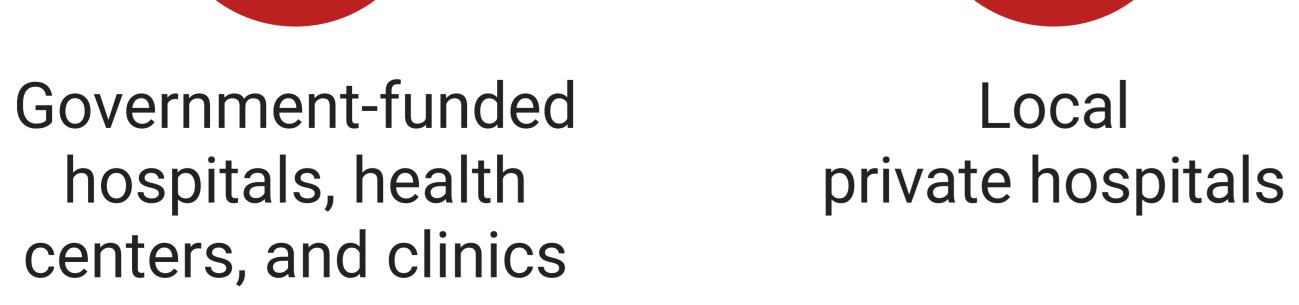
MEDICAL DEVICE PURCHASERS

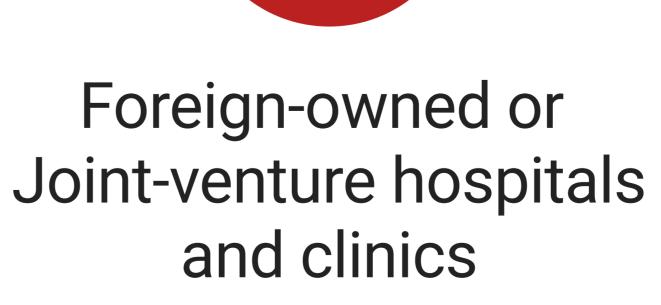
Client is License Holder

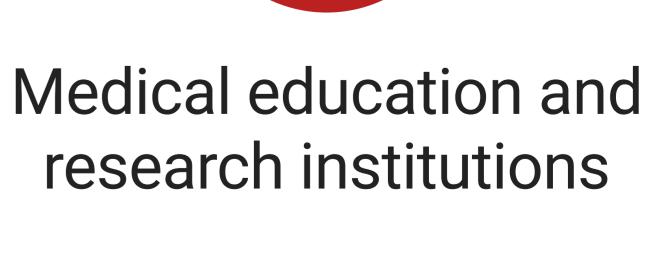


5

No.







Device classification





Regulatory background







Distributor selection

CONTACT US

vietnam@incorp.asia



Product assessment

registration requirements

Clients don't need to be a License Holder



9 +84 28 3535 0019

Medical device

