Medical Devices Registration in Vietnam

1 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.

2 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

3 REGISTERING MEDICAL DEVICES IN VIETNAM

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	
10	E-signature of the Product-license-holder-company	1 USB	

All the above docs must be translated to Vietnamese by the authorized/ licensed translator in Vietnam or Viet Embassy except for passport

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

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

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4 COMPARISON BETWEEN TWO TRENDS OF CLIENTS

No.	Client is License Holder	Clients don't need to be a License Holder
1	- Right to Import & Distribute - Right to Change Distributor	- Depend on Distributor or Third Party
2	- Have to Establish Company with Two Options: Limited Liability Company or Representative Office	- 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

5 MEDICAL DEVICE PURCHASERS

Government-funded hospitals, health centers, and clinics

Local private hospitals

Foreign-owned or Joint-venture hospitals and clinics

Medical education and research institutions

HOW INCORP VIETNAM CAN HELP?

Regulatory background

Product assessment

Device classification

Distributor selection

Medical device registration requirements

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