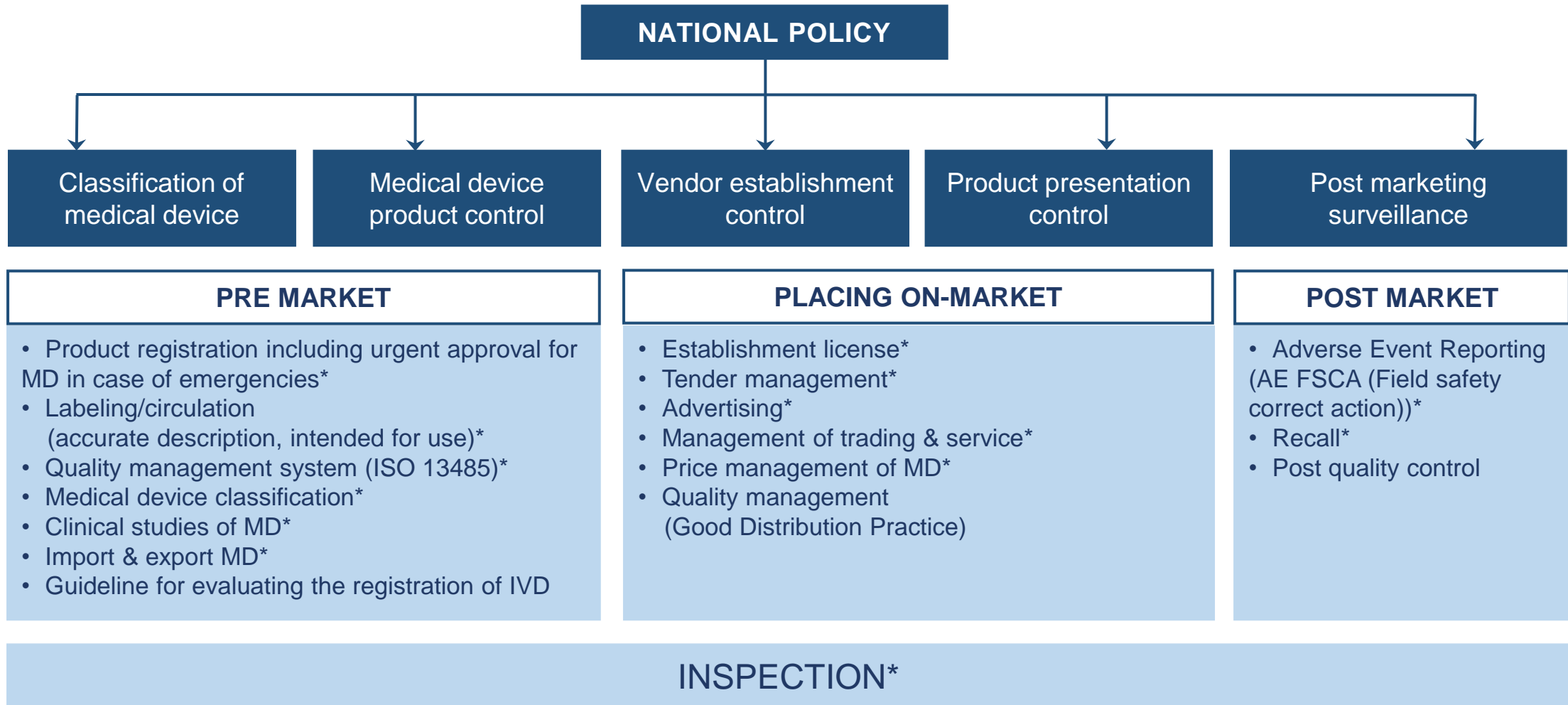




# VIETNAM MEDICAL DEVICE REGULATIONS

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# MANAGEMENT ON PRODUCT LIFE-CYCLE



\* already established policy

# REGULATIONS MAPPING



## PRE MARKET

## PLACING ON-MARKET

## POST MARKET

Manage of medical devices (MD) including the classification of MD; manufacturing of MD; clinical study; the manufacturer, free sale certificate of MD and provision of services related to MD; information and label of MD and the management and use of MD at medical facility.  
Decree 98/2021/ND-CP dated 08 Nov 2021, amended by Decree 07/2023/ND-CP dated 03 Mar 2023 on MD Management  
Circular 05/2022/TT/BYT dated 01 Aug 2022 on elaborating Decree 98/2021/ND-CP  
Circular 06/2022/TT/BYT dated 01 Aug 2022 of list and registration number of medical equipment serving Covid-19 control in case of emergencies

### *Import Medical device*

Decree 98/2021/ND-CP dated 08 Nov 2021, amended by Decree 07/2023/ND-CP dated 03 Mar 2023 on MD Management

### *Medical device risk classification*

- Circular 05/2022/TT-BYT dated 01 Aug 2022

### *Tender management*

Tender Law 43/2013/QH13 dated 26 Nov 2013

### *Advertising*

- Law 16/2012/QH13 dated 12 Jun 2012
- Decree 98/2021/ND-CP dated 08 Nov 2021

### *Inspection management*

- Decision 7115/QD-BYT dated 01 Dec 2016.
- Decree 98/2021/ND-CP dated 08 Nov 2021

Penalties for administrative violations in Medical field : Decree 117/2020/NĐ-CP dated 28 Sep 2020, amended by Decree 124/2021/NĐ-CP dated 28 Dec 2021

### *Provide for fees in medical sector*

Circular 59/2023/TT-BTC dated 30 Aug 2023

### *Goods label including Medical Device and Accessory*

Decree 43/2017/ND-CP dated 14 Apr 2017, amended by Decree 111/2021/ND-CP dated 09 Dec 2021 on goods labels

# REGULATIONS

## REGISTRATION

Registration	Type of registration	License validity	Registration fee
Class A & B	Self-declaration by License Holder	Permanent	1 Mio VND (~45 USD)
Class C & D	Pre-approval by IMDA - VN MoH	Permanent	Class B: 3 Mio VND (~135 USD) Class C, D: 6 Mio VND (~250 USD)

### Medical Device Classification

The classification in Vietnam is responsible by the license holder.

# REGULATIONS

## ▶▶ *Key Notes*

**Vietnam's evolving legal frame work for medical devices and harmonizing portions with those of the ASEAN and AMMD.**

### **Regulatory System in Vietnam**

- Internationally Harmonized
- Risk based approach
- Quality systems approach
- Post-market surveillance
- Commitment for International Cooperation



**THANK YOU  
FOR YOUR  
LISTENING**