

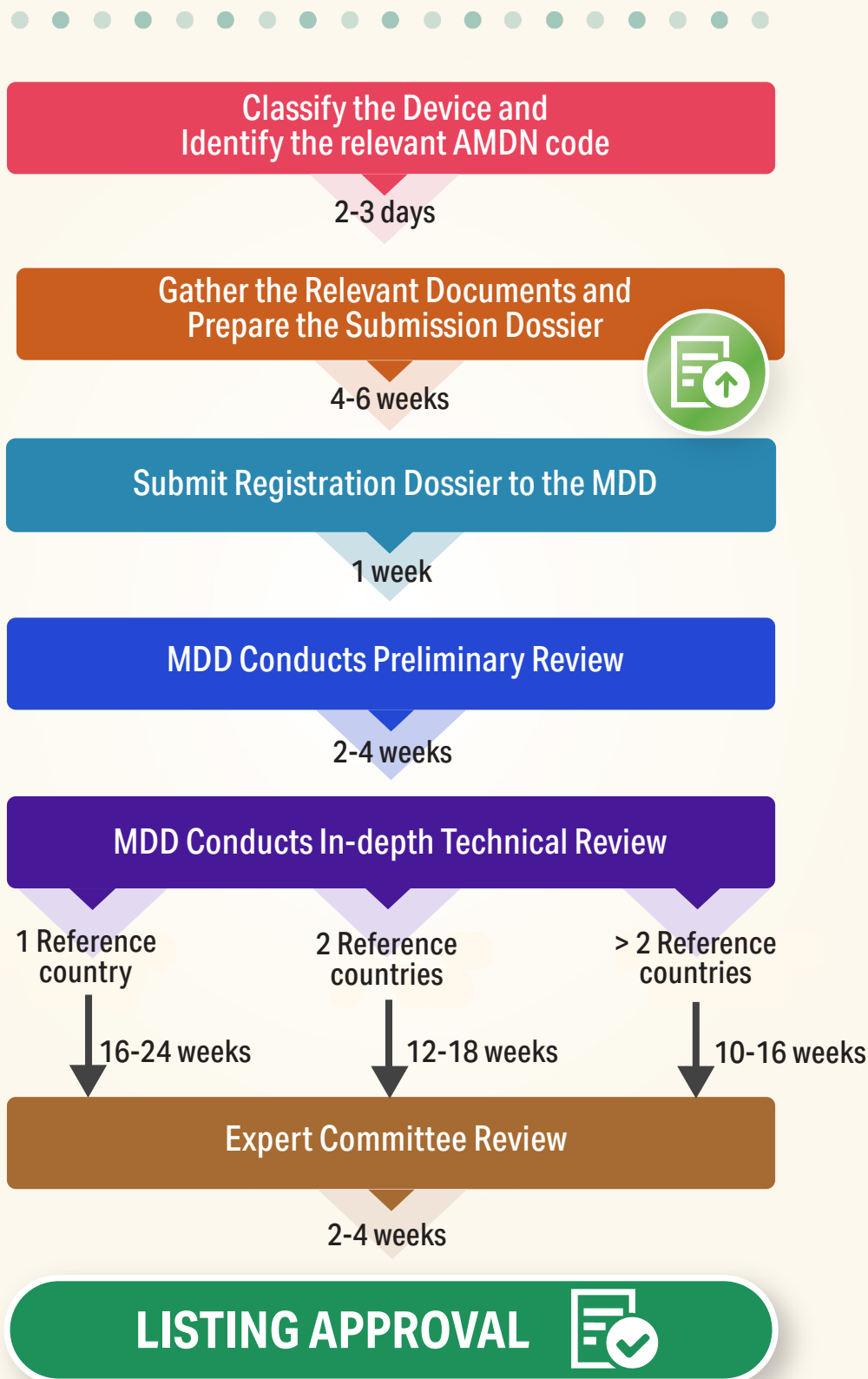
# MARKET ACCESS TO HONG KONG

## GLOBAL MEDICAL DEVICE CONSULTING

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## LISTING PROCESS



Reference Countries are: China, US, EU, Japan, Australia, S. Korea, Singapore and Canada



## DOCUMENTS REQUIRED



Application Requirements	Prepared by LRP	Prepared by MFR
LRP Designation Letter	✓	✓
LRP's BR	✓	
Documentation Procedures	✓	
Application Form	✓	
IFU		✓
Device Labelling	✓	✓
List of Components / Accessories		✓
ISO13485 (Manufacturer and Subcontractors)		✓
Manufacturing Flowcharts		✓
Marketing Approval (e.g., EC Certificate / 510k)		✓
EC Declaration of Conformity		✓
History of Recalls / Adverse Events		✓
Risk Management Report		✓
Bench Test Reports (IEC 60601-1, ISO 10993)		✓
Clinical Investigation / Evaluation Report		✓
Essential Principles Conformity Checklist		✓

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