Market Access To Hong Kong

Global Medical Device Consulting

VEE CARE (ASIA) LTD

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

MD 653109

MARKET ACCESS TO HONG KONG

LISTING PROCESS

Classify the Device and Identify the relevant AMDN code

2-3 days

Gather the Relevant Documents and Prepare the Submission Dossier

4-6 weeks

Submit Registration Dossier to the MDD

1 week

MDD Conducts Preliminary Review

2-4 weeks

MDD Conducts In-depth Technical Review

1 Reference country	2 Reference countries	> 2 Reference countries
16-24 weeks	12-18 weeks	10-16 weeks

Expert Committee Review

2-4 weeks

LISTING APPROVAL

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

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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		✓

Vee Care

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* ISO 13485 Certified Sites