Market Access To Taiwan

Global Medical Device Consulting

VEE CARE (ASIA) LTD

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

MD 653109

MARKET ACCESS TO TAIWAN

REGISTRATION PROCESS

PRODUCTION SITE REGISTRATION (QSD)

Identify the relevant TFDA scope

1 week

Gather the Relevant Documents and Prepare the Submission Dossier

1-2 months

Submit Registration Dossier to TFDA

Simplified Mode - 2 months
Standard Mode - 3 months

TFDA Conduct Initial Review and Request Supplementary Information

2 months

TFDA Review Supplementary Information

1 month

TFDA Conduct Final Review

1-2 months

QSD Approval

PRODUCT REGISTRATION

Identify Possible Predicate and Product Class

1 week

Gather the Relevant Documents and Prepare the Submission Dossier

1-2 months

Submit Registration Dossier to TFDA

1-2 months

TFDA Conduct Adminstrative Review and Request Supplmentary Information

1-2 months

TFDA Conduct Technical Review and Request Supplementary Information

Class I	Class II	Class III	No Predicate
1 month	5-7 months	8-10 months	10-12 months

Product Approval

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DOCUMENTS REQUIRED

Technical Dossier	Vee Care	Manufacturer
Information on previous applications	✓	
Predicate Information (Taiwan registration #, Chinese IFU, indication and specification comparison)	✓	
Application form	✓	
Local MD Dealer License – License Holder	✓	
Legalized Free Sales Certificate from Home Country		✓
Letter of Authorization form Manufacturer to local license holder (original copy)		✓
QSD Certificate of Manufacturing Plant		✓
Subcontractor Agreement (if any)		✓
Packaging artwork & Product Labels (2 sets)		✓
Chinese IFU / Product Manual (2 copies each)	✓	
Product Photo (representative model)		✓
Original IFU / Product Manual		✓
Product Brochure		✓
First introduction country, date, manufacturer name, site & model number		✓
Product drawing, structure, composition, materials, specification, intended use, performance, and safety data		✓
Operation Manual		✓
Maintenance Manual		✓
Radiation Safety Information (if applicable)		✓
Certificate on animal origin materials		✓
The source of animal tissue, raw material extraction process, manufacturing process and raw material quality control (if applicable)		✓
Validation on the clearance or inactivation of viruses or other infectious agents derived from animal tissue sources (if applicable)		✓
Documents in compliance with “Good Tissue Practice, GTP” (if applicable)		✓
DEHP dissolution test and risk assessment report. (if applicable)		✓
Usability evaluation report		✓
Essential requirement checklist (applicable for Class III devices)		✓
STED technical file (applicable for Class III devices)		✓
Risk management file		✓
Preclinical test protocol/report		✓
Finished product specifications, test methods & test reports		✓
Clinical evaluation report		✓
Registration certificates or FSC other than home countries		✓
Quality System Documentation	**Vee Care**	**Manufacturer**
Declaration letter for the plant information (include plant name, address, list of process done by contractors....)	✓	✓
ISO 13485 certificate		✓
Quality Manual & Procedures stated in the Manual		✓
Plant layout & detail layout of the manufacturing area		✓
Product list and Manufacturing process flowchart		✓
Major Equipment list		✓
Medical device file		✓

Vee Care

Your All-in-One Regulatory and Compliance Solution Provider

Please visit our website for more information:

www.vee-med.com

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* ISO 13485 Certified Sites