MARKET ACCESS TO EU

GLOBAL MEDICAL DEVICE CONSULTING

VEE CARE (ASIA) LTD

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

MD 653109

QUALITY SYSTEM REGISTRATION PROCESS

Quality System Set-up

1-2 months

Stage 1:
Creation & Execution of Tier 1 & 2 Documentation
[Quality Manual / Procedure]

1-2 months

Stage 2:
Creation & Execution of Tier 3 Documentation
[Work Instruction / Form]

1-2 months

Stage 3:
Creation & Execution of Tier 4 Documentation
[Quality Record]

2-3 months

Internal Audit

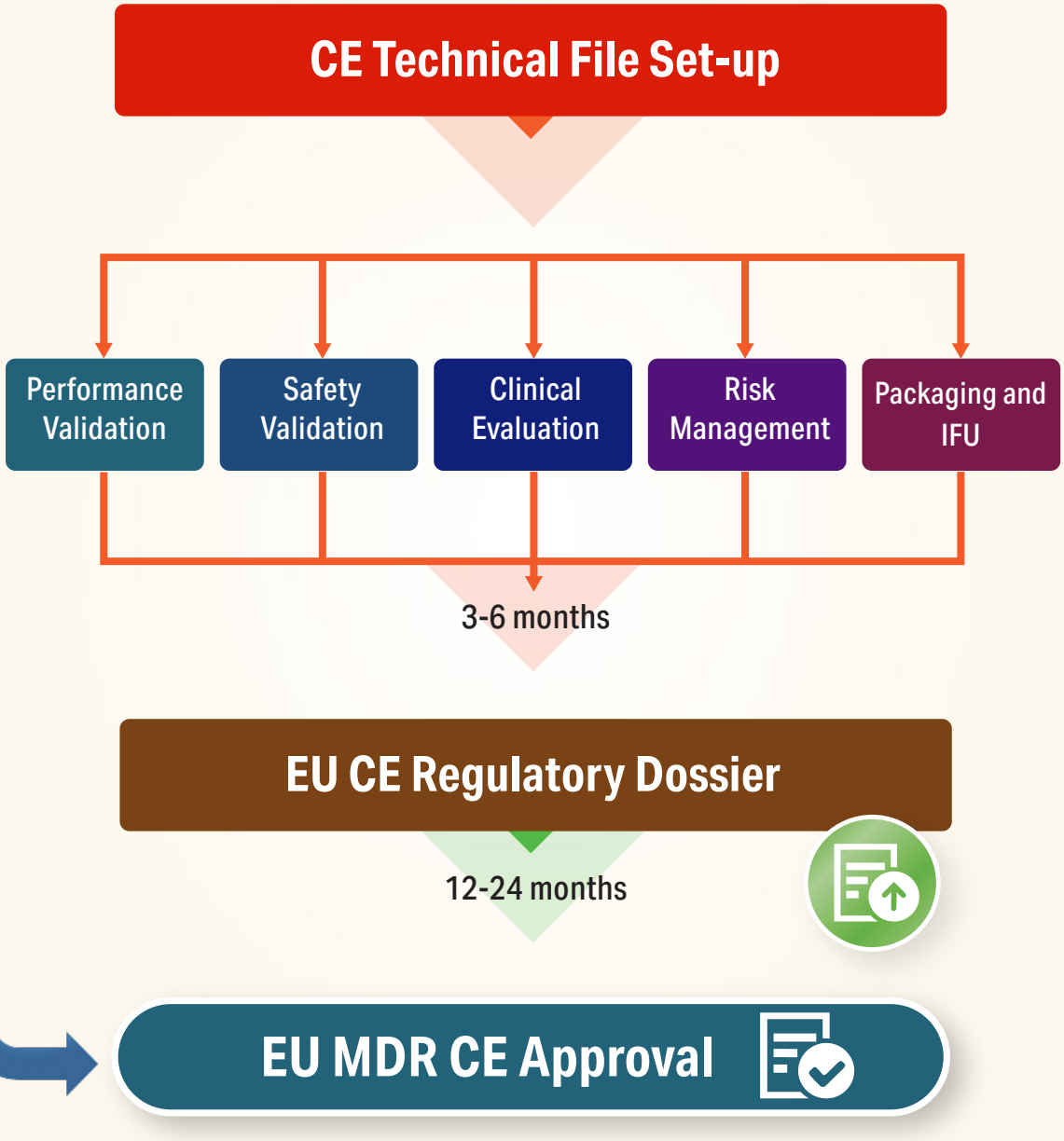
1-2 months

Quality System Audit by NB

1-2 months

ISO 13485 System Part Approved

TECHNICAL FILE REGISTRATION PROCESS



DOCUMENTS REQUIRED

- Device Descriptions and Specification
- General Safety and Performance Requirements (GSPR) Checklist
- Design and Manufacturing Information
- Benefit-Risk Analysis and Risk Management Documentation
- Product Verification & Validation Plan and Results
- Clinical Evaluation
- Information Supplied by Manufacturer
- Post Market Surveillance Plan
- Post Market Clinical Follow-up Plan

Vee Care

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* ISO 13485 Certified Sites