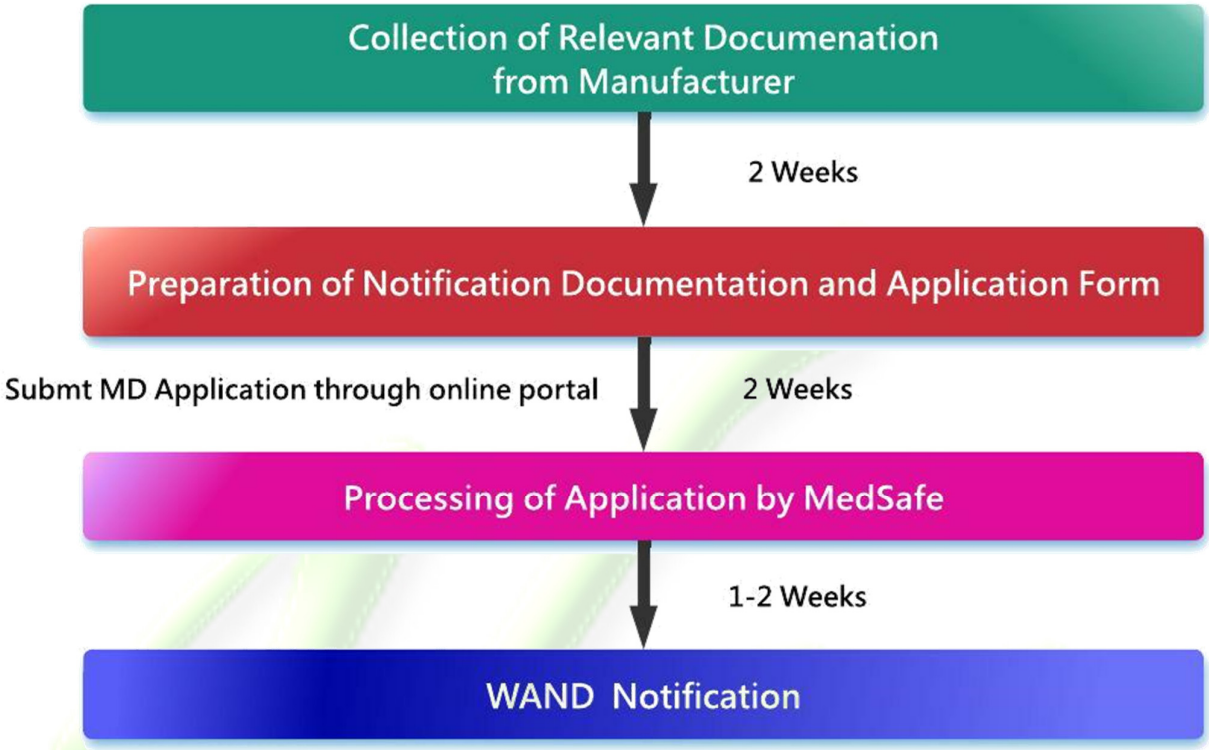
REGISTRATION PROCESS



MARKET ACCESS TO NEW ZEALAND

DOCUMENTS REQUIRED

Application Requirements	Prepared by Sponsor/Representative	Prepared by MFR
SOW/Sponsorship agreement	✓	✓
Device and Manufacturer's details		✓
Manufacturer details registered on WAND database	✓	
Classification, GMDN & IP of Medical Device		✓
Labelling & IFUs	✓	✓
Notify information about becoming the medical device sponsor	✓	
Sufficient information is available to substantiate compliance with the Essential Principles	✓	✓
Appropriate evidence to support New Zealand Medsafe WAND entry.		✓
PMS Plan & Report	✓	✓
Adverse or Reportable Events		✓