

# REGULATORY COMPLIANCE

Market									
Agency	EMEA, EU local	US FDA	RUSSIA SID & GP	Health Canada	TGA	IMOH	PMDA	MEDSAFE	ISO 13485
Commercial Supply	✓	✓	✓	✓	✓	✓	MRA	MRA	✓
Clinical Supply	✓								

✓ Approved

MRA Mutual Recognition

✓ Planned