

# IMPLEMENTATION REQUIREMENTS ON QUALITY MANAGEMENT SYSTEM (QMS)



This implementation on **REQUIREMENTS ON QUALITY MANAGEMENT SYSTEM (QMS) AND TRACEABILITY FORM** applies to new medical device applications and re-registration medical device applications submitted from 1 January 2024.

## LOCAL MANUFACTURER

- ✓ ISO 13485 accept for Class A, B, C, D.
- ✓ MDSAP accept for Class A, B, C, D

## FOREIGN MANUFACTURER

- ✓ MDSAP accept for Class A, B, C, D
- ✓ ISO 13485 accept for Class A, B, C, D.
- ✓ US Quality System (QS) regulation accept for Class A, B, C, D.
- ✓ Japan MHLW Ordinance 169 accept for Class A, B, C, D.
- ✓ ISO 9001 accept for Empty Gas Cylinder only.