IMPLEMENTATION REQUIREMENTS ON QMS AND TRACEABILITY FORM

The Medical Device Authority has decided for implementation of a transition period for below requirements until 31st December 2023. Starting 1st January 2024, only the recognized QMS standards as stated in the table 1 will be accepted for new and re-registration of medical device.

Table 1 : QMS requirements and traceability form

Quality Management System requirement for local manufacturer

Quality Management System	Type of application
ISO 13485	Class A, B, C, D

Quality Management System requirement for foreign legal manufacturer

Quality Management System	Type of application
ISO 13485	Class A, B, C, D
US Quality System (QS) regulation (21 CFR Part 820)	Class A, B, C, D
Japan MHLW Ordinance 169	Class A, B, C, D
ISO 9001	Empty Gas Cylinder only

Traceability form

Declaration of Traceability of Evidence of Conformity- QMS from manufacturing site/ OEM	Class A

Medical Device Authority
Ministry of Health Malaysia

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