

**DECISION FROM MESYUARAT JAWATANKUASA TEKNIKAL PENDAFTARAN UMUM :
REQUIREMENTS ON QMS AND TRACEABILITY FORM**

One of the elements of conformity assessment for the purpose of medical device registration is quality management system.

Table 1 shows decision from Mesyuarat Jawatankuasa Teknikal Pendaftaran Umum Bil3/2023 and Bil7/2023 on QMS requirements and traceability form.

This decision applies to application submission (first) date after 3rd April 2023.

Table 1 : Decision from Mesyuarat Jawatankuasa Teknikal Pendaftaran Umum
Bil3/2023 and Bil7/2023 on 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
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Medical Device Authority
Ministry of Health Malaysia

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