Circulated to:
ACB Certification Bodies
ACB Assessors
ACB Officers

MINISTRY OF INVESTMENT, TRADE AND INDUSTRY
DEPARTMENT OF STANDARDS MALAYSIA

ACB CIRCULAR 3/2024

MEDICAL DEVICE QUALITY MANAGEMENT SYSTEMS (MDQMS) - RISK CLASSIFICATION OF TECHNICAL AREAS BASED ON IAF MANDATORY DOCUMENT 8 – APPLICATION OF ISO/IEC 17011:2017 IN THE FIELD OF MEDICAL DEVICE QUALITY MANAGEEMENT SYSTEMS (ISO 13485)

1 INTRODUCTION

International Accreditation Forum - Mandatory Document (IAF MD) 8:2023 – Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485) was published on 20 November 2023 with an application date on the same date.

2 OBJECTIVE

This circular aims to inform Certification Bodies (CBs) applying and accredited to MDQMS on JSM requirements for the risk classification of technical areas based on IAF MD 8 and actions required by JSM accredited CBs.

3 REQUIREMENTS

3.1 Applicant CBs:

3.1.1 The applicant CB shall state the following in FM 202 – Technical Areas of Accreditation and Sector Competence of Auditors:

a) Risk classification scheme. The risk classification scheme is the regulatory scheme that the medical device needs to comply to. Examples of risk classification schemes are (EU) 2017/745/746 – European Medical Device Regulations (MDR)/ In Vitro Diagnostic Medical Devices (IVDR), ASEAN

Medical Device Directive (AMDD), Malaysia Medical Device Act 2012 [Act 737];
b) Identification whether the risk classification scheme is an international or national risk classification scheme; and
c) The risk class of the medical device based on the risk classification scheme.

3.1.2 JSM reserves the right to request witnessing based on the risk classification scheme in order to accredit the CB for the scopes applied.

3.2 Accredited CBs

3.2.1 On a periodic basis, as determined by JSM, the accredited CBs shall declare the number of certificates issued based on the following:

a) Risk classification scheme. The risk classification scheme is the regulatory scheme that the medical device needs to comply to. Examples of risk classification schemes are (EU) 2017/745/746 – European Medical Device Regulations (MDR)/ In Vitro Diagnostic Medical Devices (IVDR), ASEAN Medical Device Directive (AMDD), Malaysia Medical Device Act 2012 [Act 737];
b) Identification whether the risk classification scheme is an international or national risk classification scheme; and
c) The risk class of the medical device based on the risk classification scheme.

3.2.2 JSM reserves the right to request witnessing or conduct verification assessment based on the risk classification scheme in order to determine and/or maintain the competence of the CB for the scopes accredited.

4 IMPLEMENTATION

4.1 The implementation of this circular takes effect immediately.

Approved by:

Director of Accreditation