

NABCB SECURES INTERNATIONAL EQUIVALENCE FOR MEDICAL DEVICES - QUALITY MANGEMENT SYSTEMS (MDQMS)

The **National Accreditation Board for Certification Bodies (NABCB)**, India's national accreditation body, has secured international equivalence for its accreditation programme for Medical devices - Quality management systems (MDQMS) certification bodies. It signed the **Multilateral Mutual Recognition Arrangement (MRA)** of the **Asia Pacific Accreditation Cooperation (APAC)** for its accreditation programme based on international standards, **ISO 17021-1 and ISO 13485**.

NABCB, a constituent Board of the Quality Council of India, is responsible for **accreditation of Certification, Inspection and Validation and Verification bodies as per applicable international standards** under an international system of equivalence.

APAC is the association of Accreditation Bodies and other bodies interested in the field of management systems, product, services, personnel and other similar certification programme in the Asia Pacific region. APAC is one of the five specialist bodies of the **Asia Pacific Economic Cooperation (APEC)**. **This signifies that the accreditation of Medical devices - Quality Management Systems bodies by NABCB is now accepted as internationally equivalent within Asia Pacific Region.**

NABCB APAC MRA is a step towards signing the **Multilateral Mutual Recognition Arrangement (MLA)** of the **International Accreditation Forum (IAF)** which would confer worldwide equivalence to NABCB's Medical device- Quality Management Systems certification bodies' accreditation programme.

NABCB has already secured international equivalence for its accreditation programme for ISO 9001 certification bodies in 2002 and ISO 14001 certification bodies in 2007, Product certification bodies based on ISO 17065 in 2013, Inspection Bodies based on ISO 17020 also in 2013, ISO 22000 certification bodies in 2014, ISMS certification bodies as per ISO 27001 in 2015, ISO 50001 (EnMS) certification bodies in 2017, ISO 45001 (OHSMS) certification bodies in 2018 and PrCB as per ISO 17024 in 2019.

Accreditation reduces risk for business and its customers by assuring that accredited Conformity Assessment Bodies (CABs) are competent to carry out the work they undertake within their scope of accreditation. Accreditation Bodies (ABs) that are members of APAC and the CABs they accredit are required to comply with appropriate international standards and the applicable APAC application documents for the consistent application of those standards.

ABs that are signatories to the APAC Multilateral Recognition Arrangement (MRA) are evaluated regularly by an appointed team of peers to provide confidence in the operation of their accreditation programs.

Accreditation has become an essential tool for getting acceptance of inspection, testing and certification done in India internationally and it is referenced in many bilateral Free Trade Agreements like the India – Singapore Comprehensive Economic Cooperation Agreement in which NABCB accreditation is a requirement for certification of electrical/electronic and telecom products. Thus, accreditation eliminates technical barriers to trade and facilitates export of Indian products in world market.

NABCB has currently accredited 11 certification bodies for Medical device - quality management systems and has 9 applicants in process.

Now any industry carrying ISO 13485 certificate with NABCB logo will be recognized in Asia Pacific region. The immediate beneficiary of this equivalence is the Indian Industry which is exporting products to various Asia Pacific countries. It can also be used by regulators for establishing confidence in certified units.