Conformity Assessment Body Malaysia

Expertise and experience

Malaysian Medical Device Regulations

bsi.

...making excellence a habit.™

As of the 1st of July 2013, the Malaysian Medical Devices Act 2012 (Act 737) will be fully enforced in the country and BSI has been approved as a Conformity Assessment Body (CAB). Working with a CAB is essential for any medical device organization to be certified to a medical device quality management system (QMS) or Good Distribution Practices for Medical Devices (GDPMD), and get their medical devices registered.

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, predictable conformity assessments, evaluations, and certifications.

Malaysian Medical Device Regulations

The regulation of medical devices in Malaysia is carried out by the regulatory authority called Medical Device Authority (MDA), Ministry of Health. Parts of the execution and surveillance of a regulation task of the regulatory authority may be delegated to reliable private bodies called CABs. These CABs are designated and within surveillance of the regulatory authority. BSI has been designated as a CAB, capable of assessing ISO 13485, GDPMD, as well as product conformity assessment.

Medical devices are registered and categorised by class or risk as shown, including some examples of each class:

A Low – Simple, surgical instruments, tongue depressor, liquid in glass thermometer, examination light, simple wound dressing, oxygen mask, stethoscopes and walking aids.

B Moderate – Moderate, hypodermic needles, suction equipment, anaesthetic breathing circuits, aspirator, external bone growth stimulators, hearing aids, hydrogel dressings, patient controlled pain relief, phototherapy unit and X-ray films.

C High – Moderate, lung ventilator, orthopaedic implants, baby incubator, blood oxygenator, blood bags, deep wound dressing, defibrillator, radiological therapy equipment and ventilators.

D High – Pacemakers & their leads, implantable defibrillators, implantable infusion pumps, heart valves, neurological catheters, vascular prostheses & stents.

There are three main stages for medical device registration which are outlined below.

Stage One: Pre-Market

The manufacturer is responsible for:

- Ensuring their products conform to the GHTF recommendations of Essential Principles of Safety & Performance of Medical Devices (EPSP).
- Establish an appropriate/approved quality system for manufacturing their products.
- Collect evidence of conformity.
- The approved CAB will verify the evidence provided.

Stage Two: Placement on Market

- Manufacturers or Local Authorised Representatives (LARs) of manufacturers apply to register medical devices & establishment licenses.
- Importers & distributors are required to apply for an establishment license to import/distribute medical devices. Both must also ensure compliance to Good Distribution Practice and advertising requirements.

Stage Three: Post-Market

- Establishments are required to monitor safety & performance of products and also carry out other post-market obligations like handling complaints, recalls and the GHTF recommendations – Medical Devices Post Market Surveillance: Content of Field Safety Notices.
- Users of medical devices are expected to use, maintain and disposal of medical devices appropriately.
- Users of certain designated medical devices will need to apply for a permit to use & operate these products.

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Malaysian Market

Whilst the medical devices industry in Malaysia enjoys consistent growth over the past few years; many in the industry recognizes that the recently enforced Medical Devices Act 2012 (Act 737) will further improve export quality of medical devices from Malaysia thus driving further growth across the country and region.

This means that all medical device players in Malaysia will have just under two years transition period to comply with the regulation to register their medical devices and under one year to obtain an establishment license to import and distribute medical devices locally in Malaysia.

BSI approval

BSI has been approved for the full scope and registered as a CAB by the Medical Devices Authority (MDA). As such, BSI will be able to assist medical devices manufacturers, distributors, warehousing agents and anyone within the medical devices supply chain to:

- Conduct **medical devices approval reviews** which are necessary prior to registering your devices with the Medical Devices Authority.
- **Assess your medical device Quality Management System** which typically complies with ISO 13485 requirements.
- **Assess your Goods Distribution Practice for Medical Device** in accordance to the regulatory compliance set forth by MDA.

BSI's focus on excellence will provide product certification services up to Class 3 or Class D (with reference to MDA's classification) medical devices since 1901.

What this means for you

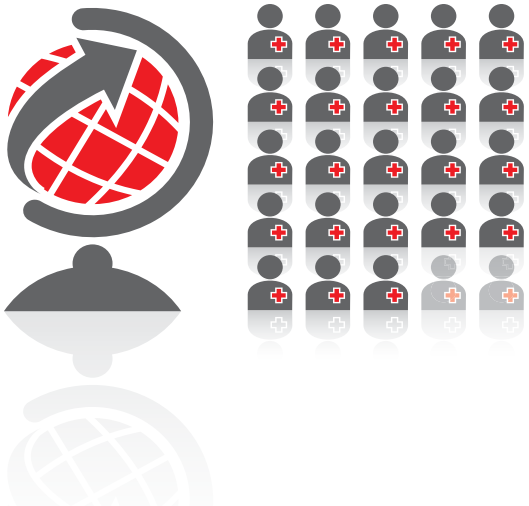
- **You hold a valid relevant ISO 13485 & EC Certification with any Notified Body.**

  BSI shall take consideration of existing certification by carrying out a verification assessment for compliance with the MMDR, this work will include a review of the last audit report from the your current Notified Body to ascertain that the Risk Management, Clinical Evaluation and Essential Requirements are adequate, we will aim to complete this within 45 working days to ensure fast routes to market.

- **You do not have a valid EC certification.**

  BSI shall carry out a full assessment against the MMDR, as a full review would be required the timelines would be the same as a BSI standard service of 90 days.

  Local AR, Distributors and Importers only need a GDPMD certificate from BSI. ISO 13485 is not a requirement.



'Out of the **25** global medical device manufacturers, **23** organizations selected BSI as their trusted partner for CE marking certification against the EU directives.'

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BSI as the industry thought leader

Here to help you:

- We have 2,900 members of staff,
- 65 BSI offices around the world,
- 70,000 clients operating in 150 countries,
- Together our clients account for 54% of the FTSE 100, 40% of the Fortune 500 and 24% of the Nikkei listed companies,
- We are one of the world's largest independent certification bodies for management systems, with over 90,000 registered sites across the globe.

BSI Medical Devices - Interfacing with the Regulatory Authorities and Lobbying

- BSI have representations on the following world leading associations: DG Sanco – EU commission,
- Vice Chair B-Med Notified Body Forum,
- Team-NB (BSI holds Presidency),
- Regulatory Affairs Professionals Society (RAPS) (BSI holds Presidency),
- The Organisation Professional Regulatory Affairs,
- ZLG, German Competent Authority,
- MHRA, UK Competent Authority.

Three Unique reasons to let BSI help you

Experience:
We have a wealth of experience in helping medical device manufacturers achieve their Global access goals, with a specialist local presence you can rely on.

Expertise:
Local experts to deal directly with the MDA, keeping you closer to the market and decisions.

Market Access:
At BSI we understand the importance for companies wishing to sell into new markets. Our Malaysian focus will help you to stay ahead of the competition.

Your partner in worldwide compliance: Call BSI today on +6 03 7960 7801 or visit medicaldevices.bsigroup.com – to start your partnership

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