MEDICAL DEVICE REGULATIONS IN THE MAIN GLOBAL MARKETS

A SUMMARY OF THE MARKET ENTRY REGULATIONS FOR MEDICAL DEVICES IN THE THIRTEEN MAIN MARKETS
EXECUTIVE SUMMARY

This paper summarises the main aspects of the medical device regulations that currently apply to the thirteen main global markets. It gives an indication of the main requirements, approvals and registrations needed by the manufacturer before devices can be legally sold in that market. The regulations are listed alphabetically by country and each section contains links to related external websites for easy access to all additional information.

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This white paper will undergo regular review, but there may be market entry regulation changes that occur in between the published updates. It is recommended that this is used as a guide and expert advice is also sought.
I. AUSTRALIA

The regulatory authority is the Therapeutic Goods Administration (TGA), part of the Australian Government Department of Health and Ageing. The TGA is also the conformity assessment body for Australian manufacturers and some foreign sites.

REGULATIONS
The current regulations are the Australian Therapeutic Goods (Medical Devices) Regulations 2002. They are supported by several legislative standards and orders covering animal tissue, sterilisation and risk management. Originally based on EU directive 93/42/EEC, the Australian regulations can be considered technically equivalent to this directive, with a few exceptions.

SCOPE AND CLASSIFICATION OF DEVICES
The regulations cover medical devices but not in vitro diagnostic (IVDs) devices. Classification is based on the European system of Class I, IIa, IIb, III and Active Implantable Medical Devices (which are considered Class III). Classification rules are not always identical to 93/42/EEC.

TECHNICAL DOCUMENTATION
Technical documentation is required showing compliance to the Essential Principles of the regulations. Clinical evidence and risk management play a very important role in this documentation. The regulations make certain standards such as ISO 11135 and ISO 11137 effectively mandatory. When assessment of technical documentation is required as part of the pre-market assessment, it is undertaken by the TGA or by an EU Notified Body approved by the TGA.

QUALITY SYSTEMS
The standard for quality management systems (QMS) is ISO 13485:2003 and a QMS audit is required for manufacturers of all classes except Class I (not sterile or without a measuring function). The QMS audit is carried out by a Notified Body as part of the CE mark certification, or by the TGA. Australian manufacturers must use the TGA for Australian registration.

LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION
Foreign manufacturers must have an Australian sponsor. The sponsor assumes certain regulatory responsibilities and applies for registration on the Australian Register of Therapeutic Goods (ARTG). Following registration, devices can be placed on the market. It should be noted that Global Medical Device Nomenclature (GMDN) terms are required for Australian registration.

CURRENT AND FUTURE DEVELOPMENTS
The past few years have seen several draft changes in the regulations, including the possibility of a combined Australia/New Zealand regulatory authority; however, a combined authority is unlikely now. Other significant changes that are expected include the appointment of conformity assessment bodies.

FURTHER INFORMATION
For further information please consult the TGA website.
II. BRAZIL

ANVISA (Agência Nacional de Vigilância Sanitária), established in 1999 under Brazil’s Ministry of Health, is responsible for the regulation and oversight of medical devices in Brazil. The regulation of medical devices is through a series of resolutions or RDCs.

REGULATIONS
Resolution RDC No. 185 of October 22, 2001 is the primary regulation applicable to the registration of all medical devices, except for IVD devices, which are covered by Resolution RDC No. 206 of November 2006. RDC No. 185 describes the applicable device registration protocol and lists the documents required to legally register a medical device in Brazil.

SCOPE AND CLASSIFICATION OF DEVICES
All medical devices are covered by Brazilian regulations but a distinction is made according to Annex II of RDC No. 185. It describes the classification structure applicable to medical devices, assigning medical devices to one of four risk classes (I, II, III, and IV) according to 18 different rules. The classification structure for medical devices in Brazil corresponds to the system used in the European Union (EU) under Council Directive 93/42/EEC. The classification rules for IVD devices follow the Global Harmonisation Task Force (GHTF) classification rules.

TECHNICAL DOCUMENTATION
All devices must have technical documentation for the safety and performance of the device showing compliance with the Brazilian regulations. In addition, electro-medical devices must obtain INMETRO (ie the National Institute of Metrology, Standardisation and Industrial Quality) certification from the third-party certification body. The classification rules for IVD devices are different from those under the scope of these standards must be INMETRO certified. Importantly, under RDC No. 27 and IN-3, the third edition of IEC 60601-1 is now acceptable in Brazil for INMETRO certification. This is a significant change from RDC No. 32, which omitted the third edition of IEC 60601-1 from the Brazilian certification scheme.

QUALITY SYSTEMS
Good manufacturing practice (GMP) certification, based on an inspection conducted by ANVISA, is required for registration (RDC No. 25, May 21, 2009). The GMP certificate must be submitted with the registration application for all Class III and IV devices, as well as for Class I and II devices noted on the Exemption List (Instruction IN-2, June 6, 2011). GMP inspections are also required to revalidate or update existing registrations. The GMP certificate is valid for two years, and ANVISA determines whether subsequent evaluations can be completed remotely through a paperwork audit or another site inspection.

In addition to an ANVISA inspection, where applicable, all manufacturers who require INMETRO certification must receive an annual factory inspection from a third-party certification body. The scope of the pre-licence inspection includes verification of compliance with some clauses of ISO 13485:2003. An auditor conducting a pre-licence inspection will also look for evidence that the following production tests are being performed by a manufacturer on 100% of medical devices bearing the INMETRO mark:

- Leakage current (earth, enclosure, patient) (Clause 19 of IEC 60601-1)
- Earthing (protective/functional and potential equalisation) (Clause 18 of IEC 60601-1)
- Dielectric strength (Clause 20 of IEC 60601-1)
- Functional test

LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION
All foreign manufacturers must have a local distributor or representative. All devices, with a few exceptions, must be registered with ANVISA. Local manufacturers register directly.

CURRENT AND FUTURE DEVELOPMENTS
ANVISA plans to extend the number of foreign manufacturers subject to audits.

FURTHER INFORMATION
The ANVISA website contains all other relevant information.
Health Canada, the Federal department responsible for the Canadian Medical Devices Regulations (MDR) and the Canadian Medical Devices Conformity Assessment System (CMDCAS), regulates all medical devices manufactured or sold in Canada.

REGULATIONS
Introduced in 2003, the Canadian MDR have not undergone any significant changes and are now well established. Medium and higher risk devices require third-party certification and Health Canada, in collaboration with the Standards Council of Canada (SCC), developed the CMDCAS to support the MDR by providing a framework to accredit CMDCAS Recognised Registrars. CMDCAS Recognised Registrars perform Canadian medical device certification audits and issue CMDCAS Certificates against ISO 13485:2003.

SCOPE AND CLASSIFICATION OF DEVICES
The Canadian MDR cover general medical devices, active implantable medical devices and IVDs. All medical devices receive classification into Class I, II, III or IV. There is one set of rules for medical devices and one set of rules for IVDs. The rules for medical devices are similar, but not identical, to the rules in Annex IX of EC Directive 93/42/EEC. In addition, some products considered medical devices in Canada fall outside the scope of the European medical device directives.

TECHNICAL DOCUMENTATION
All manufacturers must have technical documentation or a technical file showing the devices meet the Safety and Effectiveness Requirements of the MDR. Although there are differences between the Canadian Safety and Effectiveness Requirements and the European Essential Requirements, the technical documentation required is in general similar to the requirements for CE marking. While testing to ISO and CAN product standards is not usually mandatory, it is advisable for manufacturers to adopt and test to recognised international standards.

QUALITY SYSTEMS
Manufacturers of Class II, Class III and Class IV devices must operate a QMS certified by a CMDCAS Recognised Registrar to be in accordance with ISO 13485:2003 and the requirements of the MDR. Own Brand Manufacturers are not exempt from the QMS requirements. Manufacturers of Class II devices have the option to exclude design from their QMS. CMDCAS certification is required before making an application for a Health Canada Licence.

LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION
Manufacturers exporting to Canada are not required to use local authorised representatives (ARs). If used, distributors or importers need to hold a medical device establishment licence (MDEL) from Health Canada. The appointment and use of a Regulatory Correspondent is an option for manufacturers outside of Canada in order to facilitate licence applications and other regulatory functions.

Manufacturers of Class II, III and IV devices must apply to Health Canada and obtain a Medical Device Licence before placing any products on the market. Applications need to be supported by the CMDCAS certificate and varying levels of technical documentation dependent on the class. Class I manufacturers only require the MDEL. All current licences are shown on the Medical Devices Active Licence Listing (MDALL).

CURRENT AND FUTURE DEVELOPMENTS
The MDR is unlikely to be fundamentally changed in the near future. However, Guidance Document GD 211, effective from January 1, 2012, imposes specific requirements on the audit reports produced by CMDCAS Recognised Registrars. Certified manufacturers will notice a changed and, in many cases, a more detailed report format. This is part of a long-term harmonisation process between Health Canada and the US FDA. So far, the result is a pilot joint audit programme (pMAP) and the acceptance of GD 211 compliant CMDCAS audit reports under the FDA Voluntary Audit Report Submission Pilot Program.

FURTHER INFORMATION
The Health Canada website contains information on licence application, fees and technical guidance, plus all the necessary links to supporting websites such as the Supreme Court of Canada (SCC).
IV. CHINA

The State Food and Drug Administration (SFDA) is directly under the State Council, and has the responsibility for the supervision of the safety management of food, health food and cosmetics and is the competent authority for drugs and medical devices.

REGULATIONS
Since April 1, 2000, medical devices have been subject to the Regulations for the Supervision and Administration of Medical Devices. Under SFDA, the main role of the Department of Medical Devices Supervision is to: organise the formulation of national medical device standards and supervise their implementation; draw up the classification list of medical devices; take charge of registration and regulation of medical devices; take charge of registration and regulation of medical devices; take charge of registration and regulation of medical devices; take charge of registration and regulation of medical devices; and organise the adverse events monitoring, and medical device re-evaluation and elimination.

SCOPE AND CLASSIFICATION OF DEVICES
The regulations cover general medical devices, active implantable medical devices and some IVD devices. All medical devices are classified into Class I, II or III; with one set of rules for medical devices and one set of rules for IVDs. The rules for medical devices are similar but not identical to the rules in Annex IX of EC Directive 93/42/EEC.

TECHNICAL DOCUMENTATION
All manufacturers must have technical documentation in Chinese showing the devices meet the Safety and Effectiveness Requirements in the regulations. Usually all medical devices must meet appropriate Chinese state or industrial product standards, many of which are technically identical to equivalent international product standards. If no such product standards exist, the manufacturer must establish a company standard for each device, which must be registered with the competent authority. The technical documentation for Class II and III devices shall include a recent (within one year) Type Test Report produced by a medical devices quality test agency recognised by the SFDA. A clinical trial report is required for some medical devices as specified in appendix 12 of the Provision of Medical Device Registration (SFDA Order No. 2004(16)).

QUALITY SYSTEMS
When applying for a Medical Device Manufacturing Enterprise Licence, domestic manufacturers of Class II/III devices require an assessment of their QMS from SFDA in accordance to the Provision of Medical Device Quality System Assessment. The QMS must incorporate all the requirements of the Regulations. Own Brand Manufacturers are not allowed in these requirements. SFDA will exempt from such assessments parts from manufacturers who produce Class II products without sterilisation if the applicant holds a valid YY/T0287-2003 (identical to ISO 13485:2003) certificate issued by an SFDA recognised certification body.

To meet GMP requirements for medical device registration, sterile medical devices and implantable medical devices must be audited by SFDA or provincial FDA based on the GMP interim requirements (SFDA Order No. [2009] 833 issued in Dec. 2009). Foreign manufacturers will require an accredited ISO 13485:2003 certificate but will not be subject to a separate audit under Chinese regulations.

LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION
All domestic Class II/III manufacturing sites must hold a Medical Device Manufacturing Enterprise Licence. All domestic distributors of Class II / III devices must hold a Medical Device Distributing Enterprise Licence. All medical devices sold in China need to have a registration certificate, and the registration certification for all imported medical devices must be approved by the SFDA via the foreign manufacturer’s Legal Representative in China. It is a mandatory requirement to have a registered distributor or importer in China with a Medical Device Distributing Enterprise Licence approved by the provincial FDA.

FUTURE DEVELOPMENTS
There are some significant changes planned for the immediate future (including, device registration, recall procedures, etc) as outlined in a recent SFDA draft regulation for comment.

FURTHER INFORMATION
All other relevant information can be found on the SFDA website.
The Egyptian Ministry of Health (MOH) is responsible for the standardisation and co-ordination of the registration and approval, and importation and manufacturing of medical devices.

**REGULATIONS**

Official regulations are currently being formulated and have not yet been published. In practice, regulations based on the EC directives are being implemented and all local or foreign manufacturers must hold CE certificates or FDA registration.

**SCOPE AND CLASSIFICATION OF DEVICES**

The scope and classification of devices is identical to the current EC medical devices directives (ie Class I, Ila, IIB and III under directive 93/42/EEC).

**TECHNICAL DOCUMENTATION**

Technical documentation required to achieve CE marking is needed.

**QUALITY SYSTEMS**

Local manufacturers of Class I devices require ISO 13485:2003 certification and local manufacturers of higher classes require ISO 13485:2003 and Annex II, V or VI to achieve CE marking. Foreign manufacturers will require certification to achieve CE marking but no direct Egyptian certification.

**LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION**

All foreign and local manufacturers must register devices with the MOH based on existing CE marking. Foreign manufacturers can do this directly or by Local Agent or Private Registrations Offices.

**CURRENT AND FUTURE DEVELOPMENTS**

Local regulations are expected to be finalised in June 2013. At present, all local manufacturers must hold a CE marking and ISO 13485 certificate. Failure to achieve or hold the required certification prevents products from being sold in Egypt.

**FURTHER INFORMATION**

For all further relevant information please consult the MOH website.
VI. EUROPE

The Medical Devices Directives is the set of EU legislative texts, agreed by the European Commission, which aim to harmonise the laws on safety and performance of medical devices sold within the EU.

There are three separate Medical Devices Directives covering medical devices:

- Directive 90/385/EEC for active implantable medical devices (AIMD)
- Directive 93/42/EEC for medical devices (MDD)
- Directive 98/79/EC for in vitro diagnostic medical devices (IVDD)

These EC Directives are the legal requirement for all manufacturers placing their products on the market in the EU, EFTA, Switzerland, Turkey, and some countries wishing to join the EU such as Croatia. Only one directive applies to each type of medical device, so it is important to understand the definitions and function of an individual device at an early stage in order to decide which directive applies.

For the majority of medical devices, certification from an EC Notified Body (a conformity assessment body designated by the EC) will be required. Unlike other regulatory systems, there is often a choice of conformity assessment route (type of certification) for manufacturers. The approval process for each Directive is as follows:

**DIRECTIVE 90/385/EEC ACTIVE IMPLANTABLE MEDICAL DEVICES**

The active implantable medical device (AIMD) Directive 90/385/EEC was the first medical device directive, implemented in 1993, and applies only to active devices that are intended to be permanently implanted into humans. Notified Body certification is required for all products covered by this directive. It has since been significantly amended by Directive 2007/47/EC and the requirements described include these amendments.

**Scope and Classification of Devices**

The scope of Directive 90/385/EEC applies only to active implantable medical devices and classifies them as either general, non-custom made AIMD or custom-made AIMD. Special provisions are made for devices that are only intended for clinical evaluation. AIMDs are usually electrically-powered or radioactive. AIMDs include heart pacemakers, cochlear implants and radioactive seeds for cancer treatment.

**Technical Documentation**

Manufacturers must prepare technical documentation in a European language to support compliance of the device with the Essential Requirements of the Directive. European harmonised standards exist for many types of devices and generic features, and compliance by manufacturers is an important, but not a legal, requirement. EC guidance on technical documentation is available and manufacturers that wish to CE mark should follow this. Clinical evaluation and risk management documentation is a mandatory part of this technical documentation. Technical documentation will be assessed by a Notified Body as either Design Examination (Annex 2) or as an EC Type Examination (Annex 3).

**Quality Systems**

While EN ISO 13485:2012 is the harmonised standard for quality systems compliance under Directive 90/385/EEC, the extra requirements of this directive must be included. Under conformity assessment procedures for AIMD, a Notified Body assesses both design and manufacture for all devices. For general AIMD, the Notified Body certification is either Full Quality Assurance (Annex 2) or a combination of EC Type Examination (Annex 3), coupled with EC Verification (Annex 4) or EC Conformity to Type (Annex 5). Custom made devices require the manufacturer to follow Annex 6.

**Local Distributors, Licences and Registration**

Manufacturers must register their AIMD with the Competent Authority of the member state in which they are legally registered for business. If the manufacturer is based outside of the EU, then they require an AR within an EU member state to register on their behalf. This requirement also applies to Own Brand Labellers. The European Databank allows other Competent Authorities to share the registration information. There is no requirement for other distributors to register.

**Current and Future Developments**

A proposal for a regulation on medical devices was published in September 2012 for probable implementation in 2015-2016 when the AIMD will be combined with the MDD. However, this will not change the required conformity assessment routes for active implantable medical devices. The recently harmonised EN ISO 13485:2012 imposes no extra or changed requirements over the previous ISO 13485:2003 the difference being only in the table linking the standard to the AIMD.

**Further Information**

This website links to the text of the directive, MEDDEV guidance documents and a list of standards harmonised under AIMD.

**DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES**

Implemented in full in June 1998, the medical devices directive (MDD) 93/42/EEC was the second MDD to be introduced. It covers all medical devices used on humans that are not covered by the other two directives. This directive covers the majority of medical devices sold. Notified Body certification is required for all Class 1 (sterile or measuring function), Class IIa, Class IIIb,
and Class III devices. Directive 2007/47/EC has since significantly amended the requirements and all amendments are included here.

It should be noted that a few medical devices are also covered by other EC directives (ie. Personal Protective Equipment Directive) and in such cases manufacturers must comply with both directives.

Scope and Classification of Devices

The scope of this directive is wide and covers medical devices as diverse as electrical equipment, wound dressings, implants, sterile single use products and disinfectants. The directive has the potential to overlap with many other EC regulated products (ie cosmetics, pharmaceuticals, biocides and consumer products) some of which require a CE mark and others that must not be CE marked. This is an important distinction to understand as it is illegal to CE mark a product that is not eligible, illegal to CE mark under an incorrect directive, and also illegal to not CE mark when required. As both the scope and classification of medical devices is complicated, it is essential that manufacturers new to CE marking under this directive seek advice at an early stage.

Most products that are covered by this directive are classified into four classes of increasing risk, Class I, IIa, IIb, and III. Directive 93/42/EEC contains 19 rules in Annex IX that allow correct classification but accurate interpretation of these rules requires experience and knowledge of the many associated guidance documents. Classification is important to allow the choice of the correct Notified Body certification. Certain small groups of devices are covered by this directive but do not need CE marking, these include devices for clinical investigation, custom made devices and systems/procedure packs.

Certification Options

The choice of Notified Body certification depends on the device classification and is often determined by the highest class of device that a manufacturer makes. The most popular certification is Annex II followed then by Annex V and these options are the most cost-effective for most manufacturers.

<table>
<thead>
<tr>
<th>MDD CLASS</th>
<th>CONFORMITY ASSESSMENT OPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I sterile</td>
<td>Annex II or V</td>
</tr>
<tr>
<td>Class I (measuring)</td>
<td>Annex II, IV, V, or VI</td>
</tr>
<tr>
<td>Class IIa</td>
<td>Annex II, IV, V or VI</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Annex II or Annex III + IV, + III + V or + III + VI</td>
</tr>
<tr>
<td>Class III</td>
<td>Annex II or Annex III + IV or + III + V</td>
</tr>
</tbody>
</table>

| Annex II   | Full Quality Assurance, audits of the full QMS                  |
| Annex III  | EC Type Examination, type testing by the Notified Body           |
| Annex IV   | EC Verification, batch or 100% testing by the Notified Body      |
| Annex V    | Production Quality Assurance, audits of the QMS excluding design|
| Annex VI   | Product Quality Assurance, audits of the QMS excluding design and manufacture |

Own Brand Labellers also require certification to the appropriate annex

Technical Documentation

Manufacturers must prepare technical documentation in a European language to support compliance of the device with the Essential Requirements of the Directive. European harmonised standards exist for many types of devices and generic features, and compliance by manufacturers is an important, but not a legal, requirement. EC guidance on technical documentation is available and should be followed by manufacturers wishing to CE mark.

Clinical evaluation and risk management documentation is a mandatory part of this technical documentation. The technical documentation is assessed by a Notified Body for all classes of device except Class I (non-stereile, non-measuring function) as part of Full Quality Assurance (Annex II), EC Type Examination (Annex III), EC Verification (Annex IV), Production Quality Assurance (Annex V), or Product Quality Assurance (Annex VI) certification.

Quality Systems

EN ISO 13485:2012 is the harmonised standard for quality systems compliance under Directive 93/42/EEC, but the extra requirements of this directive must be included. In all cases, with the exception of Annex IV, the Notified Body requires an audit of the QMS before certification and CE marking. Own brand labellers may obtain CE mark certification with a limited QMS.

Local Distributors, Licences and Registration

Under Directive 93/42/EEC manufacturers within EU only have to register Class I, custom made devices and system/procedure packs; but many individual European countries require registration of a wider range of devices. However, there are no medical device licences required in the EU. Manufacturers outside the EU have to appoint an AR within the EU and the AR
name and address must appear with the manufacturer’s name and address on the labelling. However, the legal responsibilities of the AR are flexible and may be limited.

Current and Future Developments

The recently harmonised EN ISO 13485:2012 imposes no extra or changed requirements over the previous ISO 13485:2003 the difference being only in the table linking the standard to the MDD. In the wake of the PIP breast implant scandal it is likely that the EC will require a more stringent application of the current legislation from 2013. This will involve closer scrutiny of technical documentation and clinical evidence, improved documentation by manufacturers and the addition of unannounced inspections. The scope and competence of Notified Bodies is also being reviewed and it is expected that many Notified Bodies will disappear or have their scope reduced over the next few years.

A proposal for a regulation on medical devices replacing the MDD was published in September 2012, which is anticipated for implementation in 2015-2016. This will bring a number of significant changes, including:

- A wider scope to include cosmetic implants and devices with non viable human tissue
- Stronger supervision of Notified Bodies
- Wider powers and obligations for Notified Bodies to undertake unannounced inspections and sample testing
- Clarification of rights and responsibilities for manufacturers, authorised representatives importers and distributors
- An extended European database
- A Unique Device Identification (UDI) system for better traceability

- Stricter requirements for clinical evidence
- Improved co-ordination between Competent Authorities (including Vigilance)
- Increased involvement of the authorities in the pre-market approval of high risk devices

Further Information

This [website](#) links to the text of the directive, MEDDEV guidance documents and a list of standards harmonised under MDD. This [website](#) links to the proposal for the regulation and background documents.

**IVD MEDICAL DEVICE DIRECTIVE 98/79/EC**

Regulations

IVD devices are regulated by the third of the family of medical device EC directives, the IVD medical device Directive 98/79/EC. This has been mandatory in Europe since December 2003. The Common Technical Specifications (CTS) provide the conformity requirements for List A devices. Notified Body certification is required for all List A, List B and Self Test devices.

Scope and Classification of Devices

The scope of the IVD Directive (98/79/EC) includes all types of IVD devices, which are a specific category of medical devices. The legal definition of an IVD device is defined in the directive. IVD devices are classified by a definitive listing of devices, rather than classification rules in the MDD. Annex II of Directive 98/79/EC identifies certain devices as List A ‘high risk’ (eg, HIV test kits) or List B ‘medium risk’ (eg blood glucose meters), both of which require Notified Body certification. Further special requirements apply to Self Test devices (for use by lay persons such as, a pregnancy test kit), and they too require Notified Body certification. All other ‘low risk’ general IVD devices are usually referred to as ‘non-Annex II’ or ‘general IVD’s’ and do not need Notified Body certification.

Manufacturers new to CE marking should seek advice on classification at an early stage. The conformity assessment route that the manufacturer can choose depends on the device classification and is often determined by the highest class of device that a manufacturer makes. The most common conformity route for IVD manufacturers who require Notified Body certification is Annex IV.

<table>
<thead>
<tr>
<th>IVD Type</th>
<th>Conformity Assessment Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>List A</td>
<td>Annex IV or Annex V + Annex VII</td>
</tr>
<tr>
<td>List B</td>
<td>Annex IV or Annex V + Annex VI or Annex V + Annex VII</td>
</tr>
<tr>
<td>Self-test devices</td>
<td>Annex III section 6 (or the options for List B)</td>
</tr>
<tr>
<td>Non-annex II</td>
<td>Annex III</td>
</tr>
<tr>
<td>Annex III</td>
<td>EC declaration, with specific requirements for self-test under point 6</td>
</tr>
<tr>
<td>Annex IV</td>
<td>Full Quality Assurance, audits of the full QMS</td>
</tr>
<tr>
<td>Annex V</td>
<td>EC Type Examination, type testing by the Notified Body</td>
</tr>
<tr>
<td>Annex VI</td>
<td>EC Verification, batch or 100% testing by the Notified Body</td>
</tr>
<tr>
<td>Annex VII</td>
<td>Production Quality Assurance, audits of the QMS excluding design</td>
</tr>
</tbody>
</table>

*For List A devices there is an additional requirement for post-approval 'batch verification' which is performed by the Notified Body for each batch manufactured*
Technical Documentation

All IVD device manufacturers must prepare technical documentation in a European language to support the compliance of their device(s) with the Essential Requirements of the IVD Directive, regardless of the classification of the device. Performance evaluation and risk management documentation is a mandatory part of this technical documentation. Where a Notified Body is involved, the technical documentation is assessed, but for List A IVD’s a specific in-depth ‘Design Dossier’ examination is performed on the device design (under Annex IV).

Harmonised EU standards provide technical support for compliance, but are not mandatory. The CTS effectively count as a harmonised standard for List A devices. EC guidance on technical documentation is available and should be followed by manufacturers wishing to CE mark.

Quality Systems

For all IVD devices EN ISO 13485:2012 is the harmonised standard for quality systems compliance under Directive (98/79/EC) but the extra requirements of this directive must also be included. Legal manufacturers of List A and List B devices must choose a conformity assessment procedure where the Notified Body audits both design and manufacture. This is either Annex IV for full quality assurance system or a combination of EC type-examination of design (Annex V) with Annex VII for production quality system. List B devices have the further option of Annex VI, production verification. Self-test devices require a design examination under Annex III, or can follow the same routes as the higher risk products. Under Annex IV, the Notified Body requires an audit of the QMS, including a review of the product Technical Documentation or an EC Design Examination (for List A products) before certification and CE marking.

Local Distributors, Licences and Registration

All IVD devices, regardless of classification, must be registered by the manufacturer with the Competent Authority of the member state in which they are legally registered for business. If the manufacturer is based outside of the EU, then they require an AR within an EU member state to register on their behalf, and the AR name and address must appear on the labelling along with the manufacturer’s. These requirements also apply to Own Brand Labeller manufacturers. The European Databank allows other Competent Authorities to share the registration information. There is no requirement for other distributors to register.

Current and Future Developments

The recently harmonised EN ISO 13485:2012 imposes no extra or changed requirements over the previous ISO 13485:2003 the difference being only in the table linking the standard to the IVDD. An amendment to the CTS was issued in December 2011 to specifically include vCJD in the List A classification. A proposal for a regulation on in vitro diagnostic medical devices replacing the IVDD was published in September 2012, which is anticipated for implementation in 2015-2016. This will bring a number of significant changes, including:

- Reinforced rules for performance evaluation and pre- and post-market clinical data
- Other changes similar to those described for the MDD above

Further Information

This website links to the text of the directive, MEDDEV guidance documents and a list of standards harmonised under IVDD. This website links to the proposal for Regulation and background documents.
The Hong Kong Department of Health (DOH) has set up the Medical Device Control Office (MDCO) as the executive agency for an administrative framework to control medical devices on the Hong Kong market, which was put in place from 2004 onwards until the legislative framework becomes mandatory. This initial administrative scheme and future mandatory regulations are to be based on the Global Harmonisation Taskforce (GHTF) guidance on medical device regulations.

REGULATIONS
Currently, there are no specific legislative requirements for the importation and sales of medical devices in Hong Kong. However, in preparation for future legislation the MDCO and the Medical Device Administrative Control System (MDACS) have been set up by the DOH.

MDACS is a voluntary scheme that has three main elements:
1. An adverse incident reporting system
2. Obligations for a Local Responsible Person (LRP)
3. Listing system for medical devices and IVD’s by both local manufacturers and importers

MDCO has established a recognition scheme for Conformity Assessment Bodies (CAB) to allow the assessment and voluntary listing of higher risk medical devices (Class II, III and IV) and high risk IVD medical devices (initially Class D); however, listing is not required for Class I medical devices. Tenders for government contracts may require listing.

SCOPE AND CLASSIFICATION OF DEVICES
The MDACS covers general medical devices, active implantable medical devices and IVD devices. Medical devices are classified according to the risk level associated with their intended use. All medical devices are classified into Class I, II, III or IV with one set of rules for medical devices and one set of rules for IVD’s. The rules for medical devices are similar but not identical to the rules in Annex IX of EC Directive 93/42/EEC, and the rules for IVD devices are based upon the GHTF classification guidelines for IVD’s.

TECHNICAL DOCUMENTATION
All manufacturers/LRP are responsible for technical documentation demonstrating that the device conforms to the Essential Principles of Safety and Performance of Medical Devices in the MDACS. Both the statutory control and administrative control system are largely based on the recommendations of GHTF.

ISO or international product standards are not usually mandatory but manufacturers are advised to adopt where possible recognised international standards. A European technical file with the addition of local labelling will cover most technical documentation requirements.

QUALITY SYSTEMS
ISO 13485:2003 is used as the basis for the quality system of local manufacturers and overseas manufacturers. Where an overseas manufacturer already has ISO 13485 certification, and possibly European medical device/IVD Directive Notified Body certification, it may often be more efficient and quicker to gain certification under MDACS through an MDCO recognised CAB. A MDCO recognised CAB can provide certification against the international ISO 13485:2003 standard, EU Directives and provide certification for compliance to MDACS requirements.

LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION
If a manufacturer does not have a registered place of business in Hong Kong, then they are required to have a Local Responsible Person (LRP) under MDACS, to act on their behalf as devices can only be listed on MDACS through an LRP. Manufacturers in Hong Kong can either nominate an LRP, or act as their own LRP; but the LRP must be a legal person incorporated in Hong Kong, or a natural or legal person with business registration in Hong Kong. It is not a legal requirement to have a registered distributor or importer in Hong Kong but MDCO recommends that local manufacturers, LRP/overseas manufacturers, importers, and products undergo voluntary MDACS listing.

CURRENT AND FUTURE DEVELOPMENTS
Voluntary listing of Class D IVD Medical Devices came into effect from December 2009 (with voluntary listing for Class II, III, IV of medical devices already in place), with the voluntary listing of Class B and C IVD’s expected in 2012-2013. The application forms for listing devices were updated in August 2011, and these new versions must be used for all applications and re-applications.

Legislation to make the assessment and listing of devices mandatory rather than voluntary is expected in 2013-14, and it is expected to focus initially on higher risk devices.

FURTHER INFORMATION
The MDCO’s website has information, guidance documents and application forms on the voluntary regulations for IVD’s and Medical Devices within Hong Kong. It also gives access to an online database of listed devices, local manufacturers, importers and LRP’s.
VIII. JAPAN

The Ministry of Health Labour and Welfare (MHLW) is responsible for the Japanese Pharmaceutical Affairs Law (JPAL) and regulates all medical devices manufactured or sold in Japan.

REGULATIONS
Since 2005, a revision of the Japanese Pharmaceutical Affairs Law (JPAL), under the jurisdiction of the MHLW, came into effect in order to bring regulations in-line with global practices and ISO 13485:2003. The legislation established the Pharmaceutical and Medical Devices Agency (PMDA) to undertake certain technical tasks, and approved certain third parties as Registered Certification Bodies (RCB). With the exception of low risk Class I devices, all medical devices products need regulatory approval.

SCOPE AND CLASSIFICATION OF DEVICES
All medical devices and IVDs are covered and are classified into three classes: Class I; Class II; and Class III/IV. Some class II devices, which have clearly established standards and essential principles, have been defined as Designated Controlled Medical Devices.

TECHNICAL DOCUMENTATION
Technical documentation must be submitted for approval. It is mandatory for this documentation to include evidence of compliance with approved standards and essential principles via test reports; and/or proof of equivalence to existing medical devices in the Japanese market. An RCB is responsible for the review of technical documentation of Designated Controlled Medical Devices; however, the review for higher risk classes is undertaken by the PMDA.

QUALITY SYSTEMS
The MHLW Ordinance #169 regulations define a Japanese QMS, which except for some additional requirements is in many respects similar to ISO 13485:2003. With the exception of certain low risk Class I device manufacturers, all manufacturers require QMS audits. For Designated Controlled Medical Devices, these audits are undertaken by an RCB, and for higher risk devices by the PMDA.

LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION
All foreign manufacturers must appoint a licensed Market Authorisation Holder (MAH) before they can consider approval and selling in Japan. The MAH for foreign manufacturers can either be a Japanese distributor, an independent Japanese company or the Japanese subsidiary of the manufacturer. The MAH must apply for and obtain a device licence for all products before they are placed on the market. Foreign manufacturing sites also need a business licence (Accreditation) from the PMDA and this can be granted by either document review or onsite inspection.

CURRENT AND FUTURE DEVELOPMENTS
In 2005, there was 382 standards established for the medical devices; however, the number has now increased to 823 standards covering most of the Class II medical devices based on Japanese Medical Devices Nomenclature (JMDN). It is proposed to increase the range of medical devices that can be certified by RCBs in the future.

FURTHER INFORMATION
For further information regarding medical devices approval visit the PMDA website.
IX. KOREA

The regulatory authority in Korea is the Korean Food and Drug Administration (KFDA), which is an independent agency under the supervision of the Ministry of Health and Welfare (MOHW).

REGULATIONS
Since 2004, the Medical Devices Regulations (MDR) have applied to medical devices.

SCOPE AND CLASSIFICATION OF DEVICES
The MDR covers general medical devices, active implantable medical devices and in vitro diagnostic (IVD) medical devices. All medical devices are classified into Class I, II, III or IV; with one set of rules covering both medical devices and IVDs. Classification has been determined by KFDA and the rules for medical device classification are different to the rules in Annex IX of EC Directive 93/42/EEC.

TECHNICAL DOCUMENTATION
All manufacturers must have technical documentation showing the devices meet the Safety and Effectiveness Requirements in the MDR. ISO and Korea Standard (KS) product standards are not usually mandatory but manufacturers are advised to adopt where possible recognised international standards. Medical devices can be categorised in three ways: i) an equivalent product, ii) an improved product, or iii) a new product according to whether or not the device for approval is substantially equivalent to another legally marketed device product. If a medical device categorised as an equivalent product is approved three times by a full technical file review then the product type and specification will be listed as an ‘equivalence designated device’. Devices listed as such, will not be subject to full review but only to a limited review and limited testing at a KFDA approved laboratory.

QUALITY SYSTEMS
Domestic manufacturers of all classes of devices must operate a QMS conforming to Korea Good Manufacturing Practice (KGMP which is similar to ISO 13485:2003) An onsite GMP certificate will be required for all foreign manufacturers of Class II, III and IV devices. Currently audits from a KFDA Recognised Registrar are required for distributors and importers. This is to be replaced by audits on foreign manufacturers. A KFDA Recognised Registrar (one of four Korean institutes) accompanied by a KFDA officer carry out all audits. KGMP/Onsite GMP certification must be renewed every three years, while device licences and establishment licences are valid permanently (although changes may require re-registration).

LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION
For all devices (Classes I-IV), it is a requirement to have a registered distributor or importer in Korea and those that do operate need an Establishment Licence from KFDA. Before going on sale in Korea, Class II, III and IV devices need a Device Licence from KFDA, and the application must be accompanied by a KGMP/Onsite GMP certificate. The Device Licence application is made by the Korean distributor or importer and is based on documents supplied by the manufacturer.

According to recently revised rules, as soon as the notification form of Class I devices is registered in the KFDA system it is equivalent to a product licence. For Class II devices, the third party (technical document review agency) may review the technical files of certain Class II medical devices, which are designated by KFDA. The third party must be registered with KFDA in accordance with the guideline. KFDA deals with all procedures of approval for Class III and IV devices, and all classes of IVDs.

CURRENT AND FUTURE DEVELOPMENTS
GMP audits will be undertaken on foreign manufacturers of Class IV devices from 2012, on foreign manufacturers of Class III devices from 2013 and on foreign manufacturers of Class II devices from 2014. The list of manufacturers due for a three year renewal will be posted on the KFDA website.

FURTHER INFORMATION
All further relevant information can be found on the KFDA website.
The Saudi Food and Drugs Authority (SFDA) is the national organisation that is responsible for the Saudi Arabian Regulations (IR) and the Saudi Arabian Medical Devices Marketing Authorisation System (MDMA). The SFDA regulates all medical devices manufactured or sold in the Kingdom of Saudi Arabia.

**REGULATIONS**

The SFDA was established as an independent Authority reporting to the Council of Ministers. The SFDA launched a comprehensive marketing authorisation programme intended to safeguard public health as it relates to medical devices. They currently apply the Medical Devices Interim Regulation, complemented by Implementing Rules, with the requirement that only medical devices that have been authorised by one of the Founding Members of the GHTF have access to the KSA market. The interim regulatory scheme issued by the SFDA Board of Directors comprises the Medical Devices Interim Regulation and eight Implementing Rules adopted by the SFDA. The SFDA has appointed third party conformity assessment bodies but manufacturers and Authorised Representatives (AR) do not communicate with them directly but with the SFDA.

**SCOPE AND CLASSIFICATION OF DEVICES**

The SFDA system does not define a specific classification scheme for medical devices. The system requires that all devices meet the requirements of one of the GHTF member states registration (ie Europe, USA, Canada, Australia or Japan) and the respective classification required for the selected member state. There are additional requirements stated in the Interim Regulations and Implementing Rules that cover issues specific to local conditions (eg Power Supply Requirements and Local Environmental Conditions, etc).

**TECHNICAL DOCUMENTATION**

All manufacturers must have technical documentation or a technical file showing the devices meet the Safety and Effectiveness Requirements in accordance with the requirements of the GHTF member state the manufacturer has selected to apply for product licensing. The SFDA requires the location of the technical documentation/file to be stated in case of a need to conduct a review based on issues seen within the market.

**QUALITY SYSTEMS**

Manufacturers must operate a QMS that conforms to the requirements of the GHTF member state selected (ie for CE marked product (Non Class 1) ISO13485).

**LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION**

Manufacturers exporting to the Kingdom of Saudi Arabia are required to use local ARs. The AR should be licensed in accordance with MDS – IR5 implementing rule on licensing of ARs. The manufacturers AR must apply for product licensing through the Medical Devices National Registry (MDNR).

**CURRENT AND FUTURE DEVELOPMENTS**

The Interim Regulations and associated regulations will be amended and updated to SFDA Regulations as part of a medium term implementation plan; however, there are no stated timeframes for this.

Starting in October 2012 the SFDA will be enforcing a staged port closure to devices without a MDMA licence. This will be a multi-stage implementation based on device type/class over one to two years and is aimed at ensuring that all medical devices exported are appropriately authorised.

**FURTHER INFORMATION**

The SFDA website contains information on licence application, fees, technical guidance, and links to the Medical Device Electronic Services, plus all the necessary links to supporting websites.
The Medical Device Branch of the Health Science Authority (HSA) is responsible for a range of assessment and monitoring activities that ensure medical devices available in Singapore meet standards in accordance to the Health Products Act and Health Products (Medical Devices) Regulations.

REGULATORY CONTROL
In 2002, the implementation of the Voluntary Product Registration Scheme lead HSA to undertake an active post market monitoring and surveillance programme for medical devices. With the Health Products Act of 2007, HSA has now implemented the Health Products (Medical Devices) Regulations to better regulate medical devices in Singapore.

REGISTER OF MEDICAL DEVICE MANUFACTURERS LICENCE HOLDERS
Since August 10, 2010, any company that manufactures finished medical devices in Singapore is required to obtain a manufacturer’s licence from HSA. Certification to ISO 13485 is one of the pre-requisites for the manufacturer’s licence.

From 2010, there have been a series of HSA regulations expanding and changing the registration requirements mainly for imported devices:

Import and Supply Control (with effect from August 10, 2010)
Only licensed dealers are allowed to manufacture, import or wholesale medical devices (regardless of the risk classification of the medical devices).

Import and Supply Control (with effect from January 1, 2012)
All medical devices regardless of risk classification (unless exempted from product registration), including medical devices that are licensable under the Radiation Protection Act (Cap. 262) by the Centre for Radiation Protection and Nuclear Science (CRPNS) of the National Environment Agency (NEA), imported and supplied must meet one of the criteria below:
- Listed on the Singapore Medical Device Register (SMDR)
- Listed on the Transition List
- Authorised via one of the Authorisation Routes

Enhancements to the regulatory system for Class A medical devices
Since May 1, 2012, all Class A medical devices, except sterile Class A medical devices, are exempt from product registration. Dealers manufacturing and importing products that are exempted from product registration will, however, be required to declare the list of such products in the importer’s and manufacturer’s licences and update the list every half-yearly.

Enhancements to the regulatory system for Class B medical devices
Since September 1, 2012, HSA has a new Immediate Registration route for Class B medical devices to allow immediate access to medical devices that have already been approved by at least two of HSA’s independent reference regulatory agencies (ie US FDA, EU/TGA, Health Canada, Japan MHLW) and marketed for at least three years without safety concerns.

HSA is also creating an Expedited Registration route, with a turnaround time of 60 working days excluding stop-clock. Product registration applications will qualify for this new route if the medical device meets one of the following criteria:
1. Approval by at least two of HSA’s independent reference regulatory agencies
OR
2. Approval by one of HSA’s independent reference regulatory agencies and marketed in Singapore or that reference agency’s jurisdiction for at least three years without safety concerns

Special Authorisation Routes
All special authorisation licences (GN-27, GN-28, GN-29, GN-30(CUR), GN-30(CR)) that have been submitted from March 1, 2012, onwards will have a validity period of 12 months for importation. Guidance is currently in the process of revision to reflect this new requirement.

For the importation of unregistered medical devices for exhibition purposes, the importing party shall seek authorisation from HSA prior to importing the specific consignment.

SCOPE AND CLASSIFICATION OF DEVICES
Currently, there are four classes (ie A, B, C, and D) for medical devices in Singapore. The classification rules for medical devices are available in GN-13: ‘Guidance on the risk classification of general medical device’ which is based on the GHTF classification rules.

TECHNICAL DOCUMENTATION
Only product registration is required for Singapore, therefore, submission of full technical documentation is not required. Product registration applications for medical devices submitted to HSA must be prepared in the format set out in the Association of Southeast Asian Nations (ASEAN) Common Submission Dossier.
Template (CSDT) documents (ie GN17: ‘Guidance on Preparation of Product Registration Submission for General Medical Devices using the ASEAN CSDT’ and GN18: ‘Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostic (IVD) Medical Devices using the ASEAN CSDT’).

QUALITY SYSTEMS
In order to apply for the establishment licence-manufacturer, all local manufacturers of all classes of devices must operate a QMS conforming to ISO 13485 or its equivalent.

LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION
For all Classes (A, B, C and D) of devices, in order to apply for the establishment licence (ie importer and wholesaler) the companies have to be audited and certified against the Good Distribution Practices of Medical Devices Scheme (GDPMDs), TS-01. Foreign manufacturers must register devices via a local importer.

FUTURE DEVELOPMENTS
As part of efforts to enhance economic integration among ASEAN member states, ASEAN has been working on developing a standardised framework for regulating medical devices. This draft set of broad principles, targeted for implementation by December 2014, is called the ASEAN Medical Devices Directive (AMDD) and it is now ready for industry consultation. In Singapore, several aspects of the AMDD have been incorporated into legislation as part of the Singapore Health Products Act, including risk classification and post-market surveillance systems.

FURTHER INFORMATION
Further information regarding medical device approval in Singapore can be found on the HSA website.
XII. TAIWAN

The Taiwan Food and Drug Administration (TFDA) under the Department of Health (DOH) is the controlling authority in Taiwan for medical devices.

REGULATIONS
Medical devices are controlled under Pharmaceutical Affair Law (updated in 2012) and related regulations including the Regulations for Governing the Management of Medical Device, Regulations for Registration of Medical Device, and others.

SCOPE AND CLASSIFICATION OF DEVICES
All medical devices and IVDs are categorised into 17 medical specialties, these are referred to as panels and listed in the Regulations for Governing the Management of Medical Devices. There are three classes of device, each representing an increase in risk: Class I, Class II and Class III. These follow, in most cases, the US FDA classification; however, some devices considered by the FDA as devices are excluded but spare parts are included, unlike in EC directives.

TECHNICAL DOCUMENTATION
Technical documentation in traditional Chinese or English needs to be submitted for registration of medical devices. From July 1, 2013, an ISO 17025 and/or GLP accredited laboratories should perform all testing in support of the safety and essential performance of devices. Manufacturers who have approval for both Europe (MDD or IVDD certification) and the USA (notification letter for FDA 510 (k)) require only an Abbreviated Submission, with a less stringent review by the TFDA. To support any submission often documented confirmation is required from the EC Notified Body on the exact list of devices covered by their certification.

QUALITY SYSTEMS
Manufacturers of all devices, except non-sterilised Class I devices listed in annex II of Regulations for Governing the Management of Medical Devices, must hold a GMP licence for their quality system. This must include design control activities and a post market vigilance system in order to comply with the Taiwan adverse reaction reporting and products recall regulations. Taiwanese institutions (known as Designated Auditing Organisations or DAOs) perform GMP audits for domestic manufacturers every three years. For manufacturers located in the EU and Switzerland, audits can be undertaken by certain certification bodies designated under an EU/Taiwan Technical Cooperation Program. In these cases, the CAB issues documentation confirming compliance to Taiwanese regulations, in addition to an ISO 13485:2003 certificate. The manufacturer must submit detailed documentation in English via the Quality System Documentation (QSD) route if: the certification body is not designated; the manufacturer chooses not to take advantage of the scheme; or where the manufacturer is located outside of Europe.

A mutual recognition agreement exists between the TFDA and the US FDA which aids manufacturers located in the USA with a recent FDA QSR establishment inspection report (EIR) and an ISO 13485:2003 certificate.

LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION
All foreign manufacturers must have a Taiwan Authorised Distributor, as it is only the latter who can apply for device licences and GMP recognition. All devices must receive a licence before any product is placed on the market.

CURRENT AND FUTURE DEVELOPMENTS
TFDA announced that effective from January 1, 2013, there is to be harmonisation of medical devices GMP with ISO 13485:2003. All the class I devices manufacturers must comply with the requirements of GMP. The trial of STED submissions for class I, II or III device licence, which was announced May 1, 2012, has now been postponed pending further discussion.

FURTHER INFORMATION
Further information can be found on the English language section of the TFDA website.
XIII. USA

The regulatory authority for medical devices is the US Food and Drug Administration (FDA).

REGULATIONS FOR MEDICAL DEVICES

The relevant legislation is the Medical Device Amendments of May 28, 1976, to the Federal Food Drug and Cosmetic Act. These are implemented by regulations Title 21 Code of Federal Regulations (21 CFR) Parts 800-1299, and cover general medical devices and IVDs. These regulations define a medical device, set out the classifications and describe the conformity assessment and registration requirements for medical devices.

SCOPE AND CLASSIFICATION OF DEVICES

There are 1700 generic types of devices and 16 medical specialities. The classification regulations are defined in 21 CFR 862-892. Each of these generic types of devices is given a Class based on the level of control necessary to assure the safety and effectiveness of the device. There are three classes, Class I, II, and III, and the class and exemptions define the regulatory requirements which apply to them:

- Class I with exemptions
- Class I without exemptions
- Class II with exemptions
- Class II without exemptions
- Class III

*There is also a de novo process for truly innovative devices that are not high risk.

REGULATORY APPROVAL ROUTES

The FDA, not third parties, issues all approvals and the regulatory approvals required depend on the class of device. General controls apply to all devices and specify requirements including labelling and adverse event reporting. Special controls such as conformance to specified standards or tracking may be required for certain Class II and III devices. Class I exempt devices need no premarket notification or FDA clearance prior to sale in the USA.

Class I non-exempt, most Class II devices and some Class III devices require Premarket Notification 510(k) (21 CFR Part 807). This is a marketing clearance process whereby an application is submitted to the FDA at least 90 days before marketing. The applicant must demonstrate Substantial Equivalence (SE) to a legally marketed device in the United States.

Class III devices, other devices that cannot demonstrate SE, and ‘New’ devices with no basis for SE require a Premarket Approval (PMA) (21 CFR Part 814) from the FDA prior to sale in the USA.

TECHNICAL DOCUMENTATION

Premarket Notification 510(k)

Manufacturers who want to market a Class I, II, and III device intended for human use in the US, for which a PMA is not required, must submit a 510(k) to the FDA; unless the device is exempt from the 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions. 21 CFR 807 Subpart E describes the requirements for a 510(k) submission which should be in English.

Before marketing a device, each submitter must receive an order letter from the FDA which finds the device to be SE and states that the device can be marketed. The SE determination is usually made within 90 days and is made based on the information submitted.

Premarket Approval (PMA)

PMA is the FDA’s process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices and can often be quite lengthy. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. PMA is the most stringent type of device marketing application required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by the FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). This submission must be in English.

FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer. Before approving or denying a PMA, the appropriate FDA advisory committee may review the PMA at a public meeting and provide FDA with the committee’s recommendation on whether FDA should approve the submission. After FDA notifies the applicant that the PMA has been approved or denied, a notice is published on the Internet announcing the data on which the decision is based, and providing interested persons an opportunity to petition the FDA within 30 days for reconsideration of the decision.

QUALITY SYSTEMS

The QMS requirements are defined in 21 CFR Part 820 and are described as GMP because they are not yet fully in line with ISO 13485:2003. An ISO 13485:2003 QMS addresses much of the GMP requirements and certification is considered advantageous and can be used as part of the Voluntary Audit Report Submission Pilot Program.

The current regulations require that all domestic or foreign manufacturers have a QMS for the design, manufacture, packaging, labelling, storage, installation, and servicing of finished medical devices intended for commercial
distribution in the United States. 21 CFR Part 820 defines the requirements for quality management and organisation, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labelling control, device evaluation, distribution, installation, complaint handling, servicing, and records. It should be noted that there are several significant requirements that exceed the requirements of ISO 13485:2003 and that several additional regulations must be incorporated into the QMS.

Unlike other regulatory systems, there is not always a requirement to have the QMS audited prior to sale in the US. Devices that need a premarket notification do not need an FDA audit prior to sale but will have an audit scheduled at a later date. Devices that need a premarket approval will require an FDA audit (site inspection) prior to sale. If certain conditions are met, a limited number of third parties approved under the Accredited Persons Program can undertake an audit on behalf of the FDA, but usually the first audit will be undertaken by the FDA themselves.

**LOCAL DISTRIBUTORS, LICENCES AND REGISTRATION**

All manufacturers are required to register their establishment and list the devices prior to commercialisation. This now includes contract manufacturers and contract sterilisers. Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the US are required to register annually with the FDA. This process is known as establishment registration for which there is a fee. Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the US, then the owner/operator should also submit the FDA premarket submission number (510(k), PMA, PDP, HDE).

Foreign manufacturers must meet applicable US medical device regulations in order to import devices into the US even if the product is authorised for marketing in another country. In addition, the foreign manufacturers, including contract manufacturers and contract sterilisers, must designate a US agent. The agent is not listed on the label but only identified during the establishment registration process. However, when a distributor or importer is not required, the foreign establishment can market the device and correspond with the FDA on their own behalf.

**CURRENT AND FUTURE DEVELOPMENTS**

In recent years the FDA has been working with other GHTF regulatory authorities (Canada, Australia, Japan, and Europe) to reduce duplicate site audits. A pMAP program is in place that allows certain certification bodies to combine CMDCAS and FDA inspections. Launched in 2012, the Voluntary Audit Report Submission Pilot Program allows manufacturers to submit ISO 13485 reports, with certain conditions, to the FDA. QMS in good standing may have the requirement of a FDA inspection waived or delayed.

**FURTHER INFORMATION**

The FDA has an extensive website and makes more guidance information available than many other regulatory authority.
ABOUT SGS

SGS is the world’s leading inspection, verification, testing and certification company. Recognised as the global benchmark for quality and integrity, we employ over 70,000 people and operate a network of more than 1,350 offices and laboratories around the world. As one of the leading medical device certification bodies and testing organisations, SGS is committed to obtaining all global medical device approvals and accreditations.

With most major markets for medical devices requiring manufacturers or their authorised representatives to register devices or obtain approvals for their products, SGS can help ensure your medical devices are safe, legal and approved for market in the minimum amount of time. In most cases where the regulations require third party certification or testing, SGS possesses the required approval and can act as your partner in medical device certification, supporting you in getting your products to market faster.

SGS has a global network of qualified medical device and pharmaceutical auditors able to provide worldwide auditing and training services from more than 40 countries. SGS also operates a network of electro-medical and other testing laboratories. This allows us to support customers in meeting their regulatory obligations and in obtaining recognised certification across a range of regulatory schemes essential for marketing products around the world: including North America, the EU and Asia Pacific.

Our reputation for independence, excellence and innovation has established us as the market leader in providing services that improve efficiency, reduce risk and deliver competitive advantage for you.

FOR MORE INFORMATION, VISIT WWW.SGS.COM/MEDICALDEVICES OR EMAIL MEDICALDEVICES@SGS.COM

DISCLAIMER

PLEASE NOTE:

In all cases the manufacturer and their authorised representatives take the legal responsibility for meeting the appropriate legal requirements. Failure to comply with the relevant regulations may result in goods being stopped at customs, goods being impounded, fines and/or imprisonment. Therefore, a full and detailed understanding of the medical device regulations that apply in each of the markets where the device is sold or exported is of high importance.

As a certification body, SGS is committed to impartiality and freedom from conflict of interests and so we cannot offer consultancy or legally represent manufacturers of medical devices. However, we are allowed to answer specific questions and provide advice to our customers and prospective customers on medical device regulations. As medical device regulations and standards are constantly changing, SGS will regularly update this document but we recommend in all cases for manufacturers to also consult the further information links to check the accuracy and currency of the information within this document.