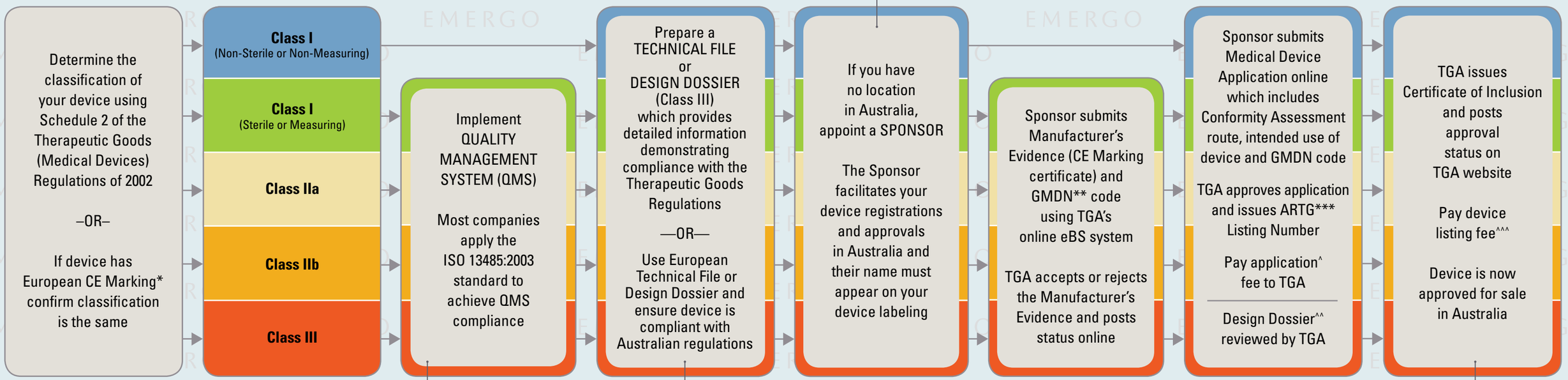
Australia's regulatory process for medical devices

EmergoGroup.com/australia

Emergo Group has been assisting medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the Australian market for the first time or introducing another new device, we can assist with everything from ISO 13485 implementation and audits, to Technical File preparation and Sponsor representation. With offices in Australia and worlswide, Emergo Group can help you obtain regulatory approval, maintain compliance and increase your sales in the world's largest and fastest growing medical device markets.

Professional, independent regulatory representation

Emergo acts as an official "Sponsor" for medical device companies that export their devices to Australia. Although a local distributor can fulfill this role, hiring a professional, independent Sponsor gives you more control of your device registration, approvals and distributor selection. Emergo also offers in-country representation in Europe, China, Japan, Mexico, Brazil and the USA.



An Emergo QMS meet most global requirements

An audited quality system is mandatory for many manufacturers selling in Australia. Most companies apply ISO 13485:2003 to meet this requirement. If you do not already have this implemented, we can do so for you. An Emergo quality system – customized for your needs – also meets the requirements of European CE Marking, US and Canadian regulations.

Technical Files, an Emergo specialty

If your device already has CE Marking, your Technical File is usually accepted in Australia. If not, we have compiled Technical Files for hundreds of devices. We can also assist with ISO 14971, clinical data evaluations, labeling reviews and more.

Let Emergo assess the health of your QMS

We can audit your quality system or review your Technical File/Design Dossier to determine compliance with Australian regulations. If needed, we are also available to conduct audits of key suppliers.

We can help find and manage distributors

Choosing the right distributors is key to your success in Australia. We can help you find, qualify and manage distributors and ensure that they are committed to selling your products and servicing your customers.

* If you have been issued a CE Marking certificate by a Notified Body, this is accepted in Australia.
** GMDN = Global Medical Device Nomenclature
*** ARTG = Australian Register of Therapeutic Goods
^ No application fee for Class I, non-sterile or non-measuring devices.
^^ The TGA reviews Design Dossiers for Class III, Active Implantable, animal derivative and certain other high risk devices.
^^^ The Device Listing Fee is due October 1 each year and is not prorated. If you register your device in July, for example, you will pay the full fee for the current year and pay it again in October for the next year.

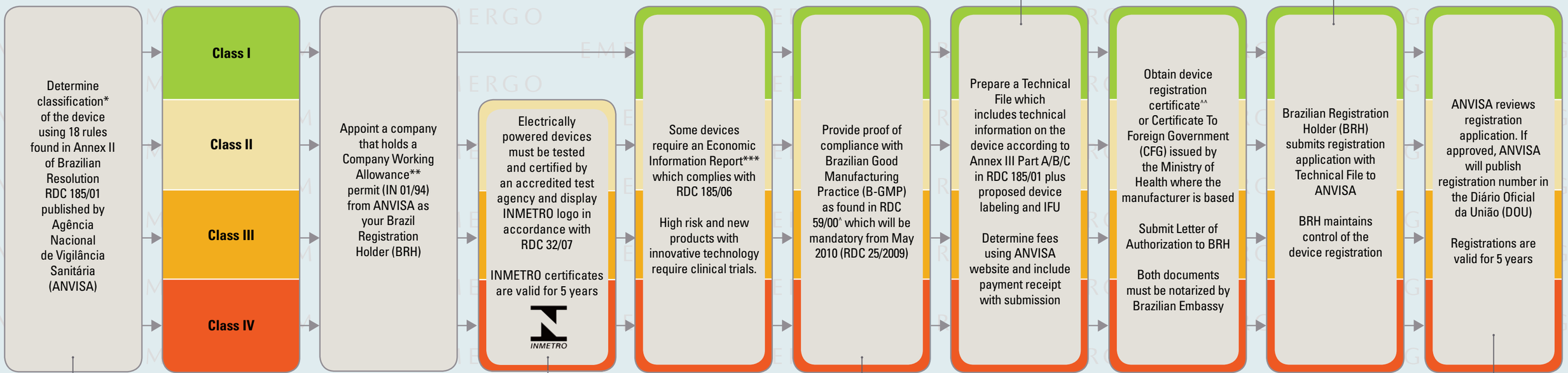
IMPORTANT NOTE: In most cases, Australia has emulated the European regulatory system for medical devices and recognizes European CE Marking. This chart demonstrates the route to compliance for a device that already has CE Marking.

EMERGO GROUP

Brazil's regulatory process for medical devices

EmergoGroup.com/brazil

Emergo Group has been assisting medical device and IVD companies with international regulatory issues and quality management system compliance since 1997. Whether you are entering the Brazilian market for the first time or introducing another new device, we can assist with every step of the process from device classification and ANVISA registration to distributor selection. With offices in Brazil and worldwide, Emergo Group can help you obtain regulatory clearance, maintain compliance and increase sales in the world's largest and fastest growing medical device markets.



Preparation of your Technical File
Our Brazilian consulting team will prepare your Technical File and assist with document and IFU translation into Portuguese. We will also advise you on device labeling requirements in accordance with Brazilian regulations.

Independent Registration Holder representation
Having an independent firm control the registration for your device(s) is critical if you will not have a direct sales office in Brazil. Emergo can assist you with representation through our offices in Brazil.

Proper device classification is critical
Determining the proper classification for your medical device is critical to ensuring a smooth registration process. Our team has many years of experience with medical device classification.

Assistance with INMETRO certification
If you manufacture an electro-medical device, electrical safety testing may be required in Brazil. We can help coordinate this testing on your behalf as the results are critical to the completion of the registration documents.

Compliance with Brazilian quality system requirements
Brazilian QMS requirements are similar to ISO 13485 and US FDA QSR, but not the same. Our consultants will advise you on what modifications must be made to your existing quality system to ensure ongoing compliance with ANVISA requirements.

Finding and qualifying distributors
While your registration is being finalized, our distribution specialists can help you find and evaluate Brazilian distributors in São Paulo, Rio de Janeiro and other markets as needed. Having a local resource to evaluate distribution partners will increase the chances of finding a partner who is qualified and able to sell your products.

* Brazilian Resolution RDC 185/01 is similar to the European Medical Devices Directive (93/42/EEC) and classification is very similar. Class I/II/III/IV in Brazil = Class I/IIa/IIb/III in Europe.
** The Company Working Allowance permit, called an "Autorização de Funcionamento," allows the company to import, distribute, store and sell the product in Brazil. The manufacturer only needs to secure this permit if they will be importing and distributing their own products in Brazil. Otherwise, a distributor or registration holder will already have this permit.
*** The Economic Information Report must include pricing comparisons for other countries, patient/user information, marketing materials, and other data.
^ Brazilian Good Manufacturing Practice (B-GMP) is similar to the US FDA quality system regulations.
^^ The device registration certificate proves that your product is approved for sale in your home market.
IMPORTANT NOTE: Risk management in compliance with ISO 14971:2007 is required for all implants, intrauterine devices and blood bags.

EMERGO GROUP

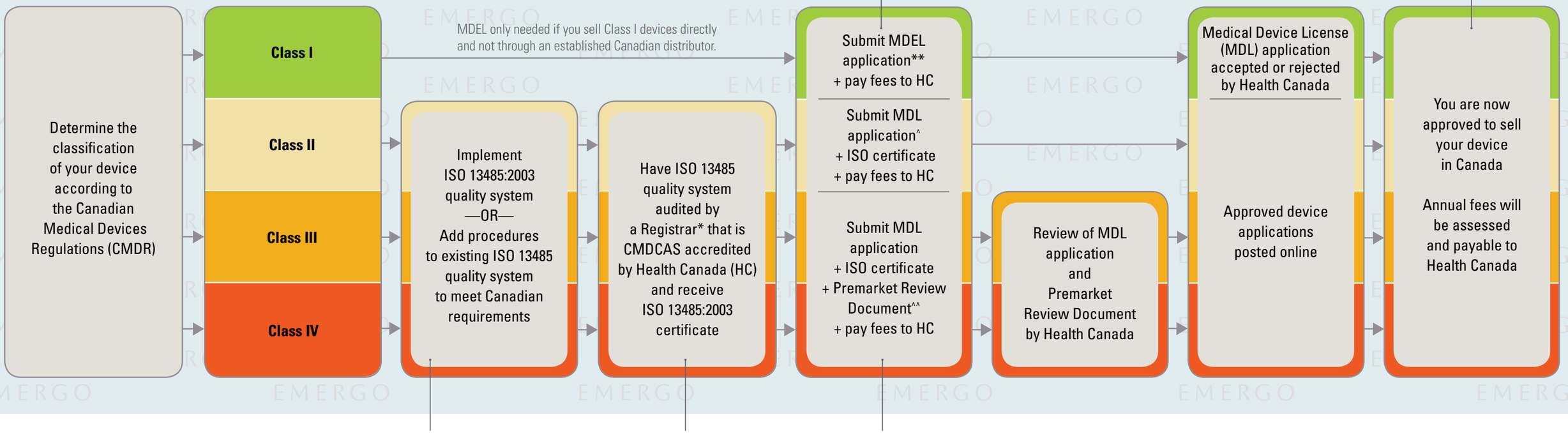
Canada's regulatory process for medical devices

EmergoGroup.com/canada

Emergo Group has been assisting medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the Canadian market for the first time or introducing another new device, we can assist with all aspects of compliance from ISO 13485 implementation and audits, to Health Canada license applications and distributor qualification. With offices in Canada and worldwide, Emergo Group can help you obtain regulatory approval, maintain compliance and increase your sales in the world's largest and fastest growing medical device markets.

Let Emergo prepare your establishment license application
If you sell Class I devices and ship directly to customers in Canada, we can apply for your Medical Device Establishment License (MDEL) and submit the application to Health Canada.

We help find and manage distributors
We can assist you in finding and qualifying distributors in Canada and can also manage distributors to ensure they are fully committed to selling your devices.



An Emergo quality system meets most global requirements
An audited ISO 13485:2003 quality system is mandatory for Class II, III and IV device manufacturers in Canada. We can implement ISO 13485 for you or help modify your existing quality management system to meet the additional requirements of the Canadian Medical Device Regulations (CMDR). An Emergo quality system also meets the quality system requirements of US FDA QSR and European CE Marking.

Independent audits ensure ongoing compliance
We can conduct an audit of your quality system prior to your Registrar audit, or periodically thereafter, to ensure compliance with CMDR and ISO 13485:2003. If we implement your quality system, a pre-assessment audit is included. On-site training can also be conducted.

Let us prepare your medical device license applications
We can help prepare and submit your Medical Device License (MDL) and Premarket Review Document to Health Canada. We have prepared license applications for a wide range of devices and understand how to obtain approval from Health Canada efficiently.

* If you already have ISO 13485:2003 and are audited by a European Notified Body, they may also be "CMDCAS-accredited by Health Canada to perform audits to the Canadian Medical Devices Regulations (CMDR). In this case, you will be issued a new ISO 13485:2003 certificate that also includes CMDR in the scope of registration. Not all Notified Bodies are accredited to be Registrars in Canada.
** MDEL = Medical Device Establishment License. This is for Class I manufacturers selling directly into Canada and not through a distributor. Not required for Class II, III and IV manufacturers as they are required to obtain a Medical Device License (MDL) instead.
^ MDL = Medical Device License. This is for the device itself. Not required for Class I devices.
^^ The Premarket Review Document for Class III and IV devices may require inclusion of clinical trial data. Data from trials conducted in the US or Europe may be acceptable. Clinical data will be reviewed by your Registrar as part of your audit.

EMERGO GROUP

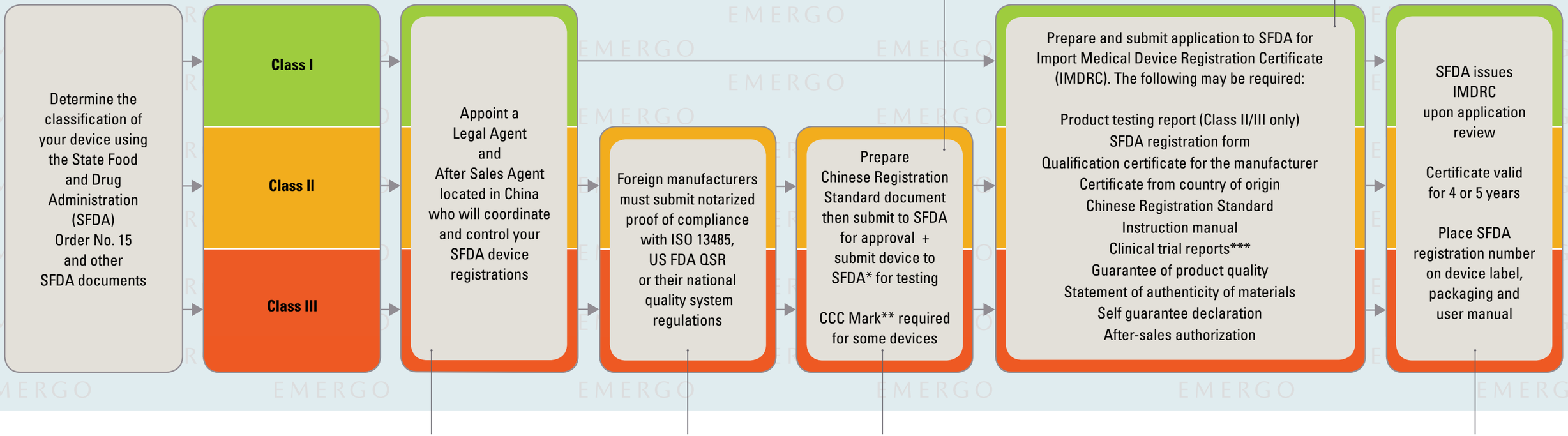
China's regulatory process for medical devices

EmergoGroup.com/china

Emergo Group has been assisting medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the Chinese market for the first time, re-registering an existing device or introducing another new device, we can assist with quality system compliance and audits, clinical trials, Chinese Registration Standard preparation and approvals and much more. With offices in China and worldwide, Emergo Group can help you obtain regulatory approval, maintain compliance and increase your sales in the world's largest and fastest growing medical device markets.

Emergo can prepare your Chinese Registration Standard
If you wish to import a medical device into China, a specific Registration Standard document must be prepared and submitted along with product samples for testing. We can prepare the documentation and work with the designated test site in China to coordinate registration and monitor progress.

License application support
A significant amount of information is needed to obtain a IMDRC (license) from the SFDA and we can prepare your license application. Translation of all documentation into Chinese will also be coordinated.



Professional, independent regulatory representation
Companies selling in China are required to appoint a Legal Agent (LA) and After Sales Agent (ASA). While it is possible to ask a distributor to fulfill this role, doing so severely limits your flexibility to switch distributors since the Agent controls your device approval in China. Hiring an independent Agent ensures that your regulatory responsibilities will be maintained while giving you complete control over distribution.

Meeting Chinese QMS requirements
If you can demonstrate compliance with the quality system requirements of the US FDA, Europe, Canada, Japan or another country, this will be accepted in China. If you do not have a quality management system in place, we can help you implement ISO 13485 and/or FDA GMP.

Application for CCC Mark
Currently, several categories of (mostly) electrical devices require the CCC Mark certification. If your device requires CCC, we will prepare the necessary application and coordinate testing as needed. The SFDA may also require a facility audit of manufacturers of high risk devices.

Ongoing regulatory compliance and auditing
If you appoint us as your Legal Agent (and After Sales Agent), we will keep you updated on the constantly changing Chinese regulatory landscape to ensure you stay in full compliance. We are also available to conduct quality system audits of critical suppliers located in China, if necessary.

* The SFDA Medical Device Quality Supervision and Inspection Center conducts testing on products.
** CCC Mark = China Compulsory Certificate. Required for several categories of devices, most of which have an electrical component. A CCC Mark application must be submitted prior to product registration and a facility inspection is required for CCC Mark approval.
*** Clinical trials may need to be conducted in China for Class II/III devices that do NOT already have regulatory approval elsewhere in the world, long term implantable devices or certain other high risk devices. If clinical trials have been conducted outside China and the device has US, European or other national approval, the data will likely be accepted by the SFDA.

EMERGO GROUP

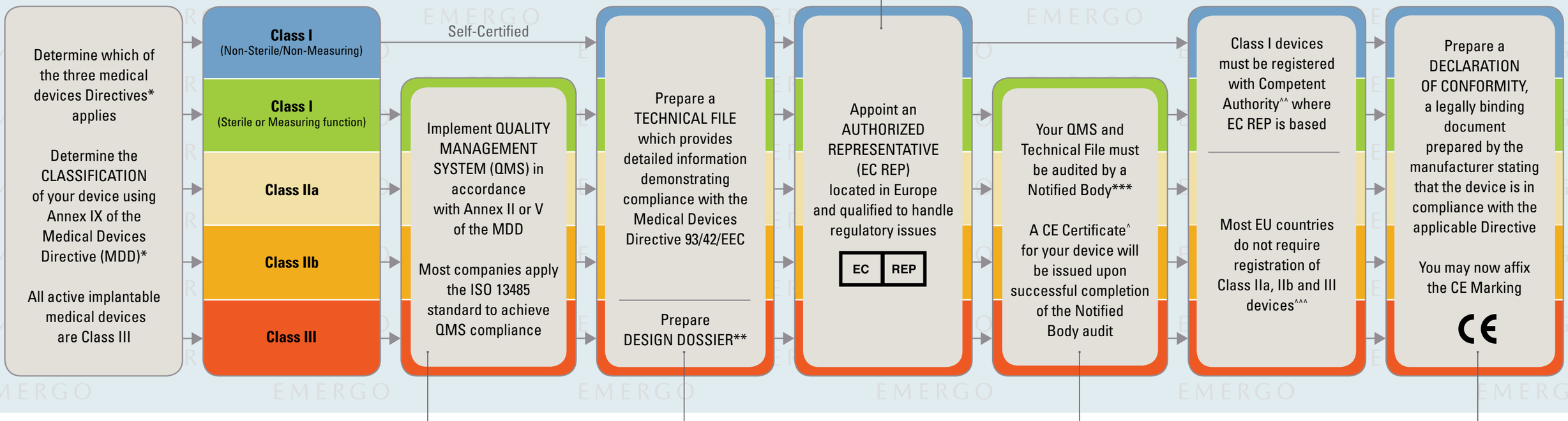
Europe's regulatory process for medical devices

EmergoGroup.com/europe

Emergo Group has been helping medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the European market for the first time or introducing another new device, we can assist with everything from ISO 13485 implementation and audits, to Technical File preparation and distributor qualification. With offices throughout Europe and worldwide, Emergo Group can help you obtain regulatory approval, maintain compliance and increase your sales in the world's largest and fastest growing medical device markets.

Independent, professional regulatory representation

Emergo acts as an Authorized Representative (EC REP) for hundreds of medical device companies worldwide. Although a local distributor can fulfill this role, hiring a professional, independent EC REP gives you the freedom to switch distributors at any time. This is particularly important given that the EC REP name must appear on your labeling throughout Europe. Emergo also provides in-country representation in Australia, Brazil, China, Mexico, Japan and the USA.



An Emergo QMS meets most global requirements

Most manufacturers implement a Quality Management System by applying the ISO 13485:2003 standard and we can assist you with implementation. If you already have a FDA QSR compliant quality system, we can modify your existing system to meet ISO 13485 and ensure that it complies with Canadian requirements as well.

Technical Files, an Emergo specialty

Emergo has compiled Technical Files and Design Dossiers for a wide range of devices from simple surgical instruments to high risk implants. We can also assist with ISO 14971, clinical data evaluations, labeling reviews and more.

Let Emergo assess the compliance of your QMS

Emergo can conduct a pre-assessment audit prior to your final Notified Body audit. If we implement your ISO 13485:2003 quality system, this pre-assessment audit is included. We can also provide on-site training on CE Marking, the Medical Devices Directive and internal auditing for your employees.

We can help find and manage distributors

With 31 countries and over 20 languages, finding distributors in Europe can be a challenge. Our distribution management division can find, analyze, select and manage the right distributors and ensure that they are fully committed to selling your devices.

* European Directives that apply to medical devices include the Medical Devices Directive (93/42/EEC), which was amended by Directive 2007/47/EC, and the Active Implantable Medical Devices Directive (90/385/EEC). This chart does not apply to IVD devices which are subject to the In Vitro Diagnostic Devices Directive (98/79/EC).

** Class III devices require substantial clinical trial data. Clinical trials conducted in Europe must be pre-approved by a Competent Authority. Existing clinical data may be acceptable. All data are reviewed and approved by a Notified Body.

*** Notified Body = EU accredited third party authorized by a national Competent Authority to conduct audits of medical device companies and their devices.

^ A CE Certificate (issued by a Notified Body) is not applicable to Class I, non-sterile, non-measuring devices since you will "self-declare" conformity with the Directive.

^^ Competent Authority = Term used to describe national Ministries of Health which are responsible for ensuring compliance with the Directive in their national market.

^^^ Italy currently requires registration of all devices, regardless of classification. Some countries require registration of high risk devices.

EMERGO GROUP

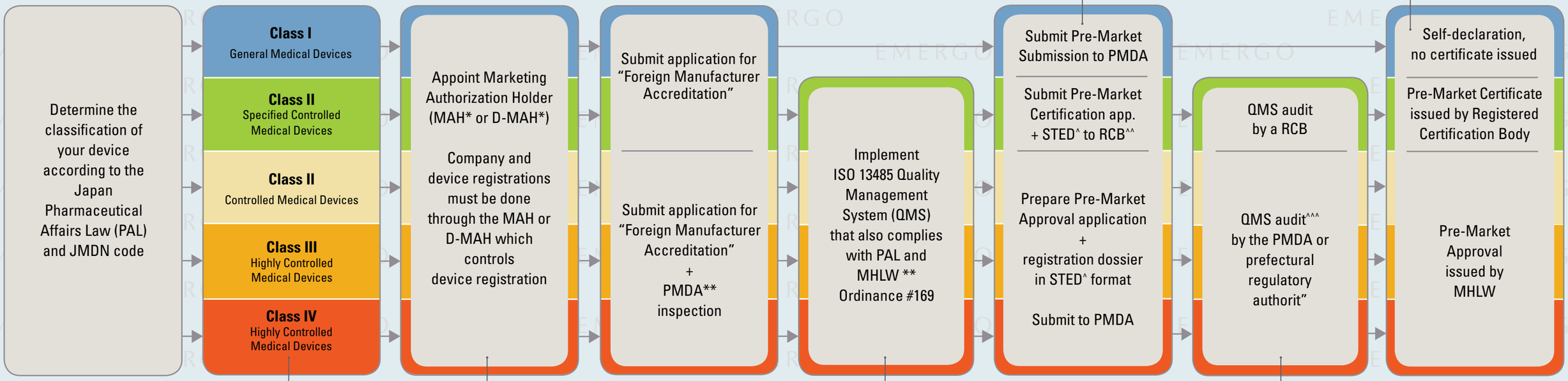
Japan's regulatory process for medical devices

EmergoGroup.com/japan

Emergo Group has been helping medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the Japanese market for the first time or introducing another new device, we can assist with everything from quality system modification and audits, to STED preparation and distributor qualification. With offices in Japan and worldwide, Emergo Group can help you obtain regulatory approval, maintain compliance and increase your sales in the world's largest and fastest growing medical device markets.

Let Emergo prepare your STED submission
A Summary Technical Document (STED) is similar to a US FDA 510(k) or CE Technical File, but in a standardized format. We can assist with preparing your STED documentation to ensure a successful review by the Registered Certification Body or Japanese PMDA.

Full service assistance, from application to approval
Different classes of devices require different certificates and approvals. Determining which approval process applies can be challenging. We can fully assist you with the approval and registration of your devices.



Let us help classify your device in Japan
Japan's classification system differs from the US and Europe so determining classification of your devices can be complex. Through our office in Tokyo, we can help determine the correct Japanese Medical Device Nomenclature (JMDN) code for your device.

Professional, independent MAH representation
Emergo Japan K.K. is a licensed Marketing Authorization Holder (MAH) in Japan. Hiring Emergo as your independent D-MAH (instead of appointing a distributor MAH) will ensure that your regulatory responsibilities are handled properly and give you the flexibility to switch distributors at any time. More importantly, by selecting Emergo Japan as your D-MAH, your device approvals will remain under your control.

Helping you comply with quality system requirements
Japan's Pharmaceutical Affairs Law (PAL) has specific Quality Management System requirements that are similar to ISO 13485 and FDA QSR, but with additional requirements. We can help you modify your existing QMS to comply with PAL and ensure you are ready for your PMDA or Certification Body audit.

Let Emergo make sure you are prepared for your QMS audit
The Japanese approval process is lengthy and the last thing you need is to fail your QMS audit. We will make sure you are fully prepared by conducting a pre-assessment audit and providing the support necessary to modify your QMS system as needed.

* The MAH controls the device approval in Japan. A Designated MAH (D-MAH) acts on behalf of a foreign manufacturer to register medical devices under the Foreign Special Approval System.
** PMDA = Pharmaceutical and Medical Devices Agency. A regulatory agency that works together with the Ministry of Health, Labour and Welfare (MHLW).
^ STED = Summary Technical Document. This is a harmonized submission format that is accepted for certain regulatory submissions in Japan, Australia, Europe and the USA.
^^ RCB = Registered Certification Body. Independent companies authorized by the MHLW to certify Specified Controlled Medical Devices and issue Pre-Market Certifications.
^^^ PMDA may conduct audits for new medical devices, Class IV devices, and devices that require clinical investigations.

EMERGO GROUP

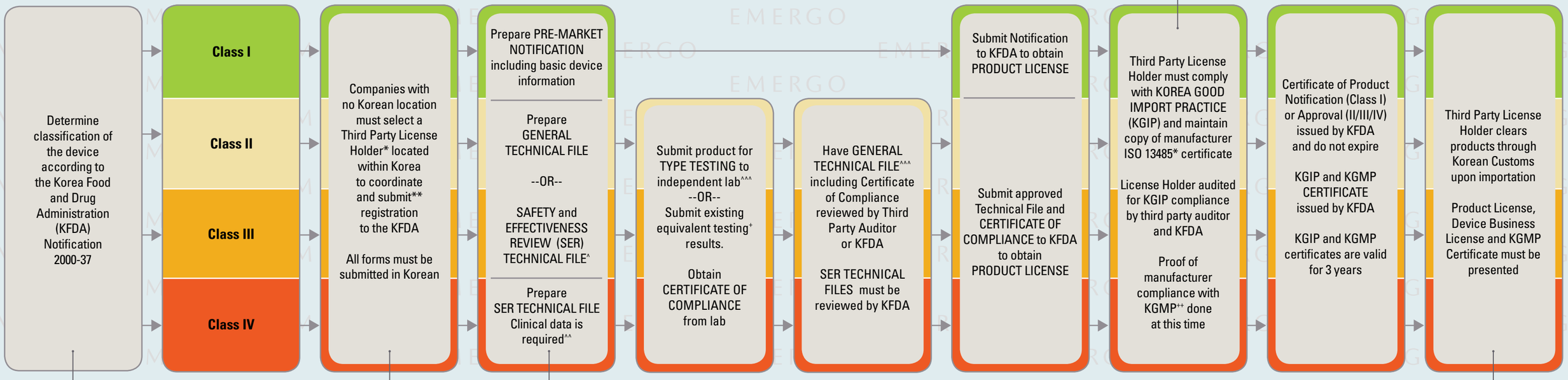
Korea's regulatory process for medical devices

EmergoGroup.com/korea

Emergo Group has been assisting medical device and IVD companies with international regulatory issues and quality management system compliance since 1997. Whether you are entering the South Korean market for the first time or introducing another new device, we can assist with every step of the process from device classification and KFDA registration to distributor selection. With offices in Asia and worldwide, Emergo Group can help you obtain regulatory clearance, maintain compliance and increase sales in the world's largest and fastest growing medical device markets.

Let us help you comply with KGMP quality system requirements

Foreign manufacturers, regardless of device classification, must comply with Korea Good Manufacturing Practice (KGMP). Compliance is most often achieved with help from your Third Party License Holder and we can fully assist you in obtaining your KGMP certificate and maintaining ongoing compliance.



Device classification consulting

Our team in Seoul is extremely well-versed in device classification and will ensure that your device is properly classified, the first step toward ensuring a smooth registration with KFDA.

Third Party License Holder representation

Having an independent firm (not a distributor) control the registration for your device is critical if you will not have a direct sales office in South Korea. Emergo can assist you with Third Party License Holder representation.

Preparation of Technical Files for KFDA Submission

Despite the name, a KFDA Technical File is more like a US FDA 510(k) or PMA than a European Technical File or Design Dossier. We will help prepare the appropriate Technical File for your device, interact with KFDA and assist in having all necessary documents translated into Korean as required by law.

Finding and evaluating new distribution partners

Screening potential distribution partners in Korean can be very challenging for non-Korean based companies. Our Seoul-based consulting team can evaluate potential partners, making sure you maximize your sales in South Korea.

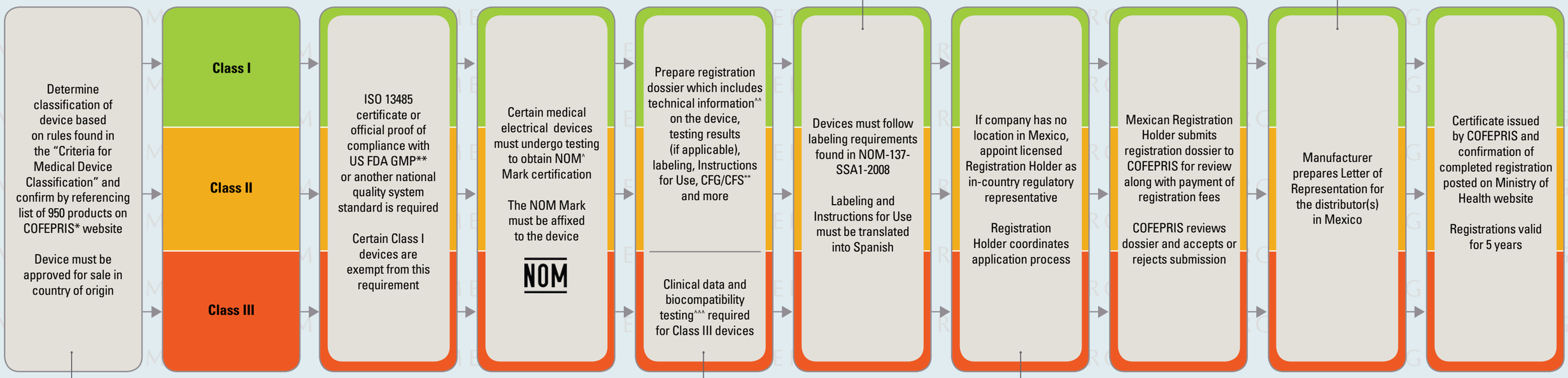
* The Third Party License Holder/distributor must possess a Device Business License (DBL). If the manufacturer will act as itsr own license holder through its local sales office, the manufacturer would obtain the DBL.
** Foreign manufacturers cannot submit applications to the KFDA directly unless they have a local office in South Korea who will also act as the Third Party License Holder.
*** The Safety and Effectiveness Review (SER) Technical File is required for medical devices with innovative features such as new materials, unique modes of action, technology, or effectiveness.
^ The General Technical File is comparable to a US FDA 510(k) submission. The SER Technical File is more like a US FDA PMA submission.
^^ Local clinical trials are not required. Foreign clinical data may be acceptable after being validated. Generally, the KFDA will accept clinical data that has been approved by another foreign government or published in a SCI-listed scientific journal. CE Marking certificates are accepted for products manufactured in Europe, but not, for example, from US companies with a CE certificate.
^^^ The Korea Testing Lab (KTL) is authorized to conduct testing on all categories of medical devices. Several other labs can also conduct testing, but not on all categories of devices.
+ Existing testing must have been completed in accordance with ISO, IEC, ASTM or GLP standards. Performance testing from labs certified to ISO/IEC 17025 are typically accepted.
++ Currently, proof of KGMP compliance for non-Korean manufacturers is usually satisfied with an ISO 13485 certificate, or an ISO 9001 certificate in the case of Class I non-sterile device manufacturers.

EMERGO GROUP

Mexico's regulatory process for medical devices

EmergoGroup.com/mexico

Emergo Group has been assisting medical device and IVD companies with international regulatory issues and quality management system compliance since 1997. Whether you are entering the Mexican market for the first time or introducing another new device, we can assist with every step of the process from device classification and COFEPRIS registration to distributor selection. With offices in Mexico and worldwide, Emergo Group can help you obtain regulatory clearance, maintain compliance and increase sales in the world's largest and fastest growing medical device markets.



Guidance on device labeling and translation

Our office in Mexico City will advise you on device labeling requirements and aid in document translation into Spanish as required by Mexican law.

Finding qualified distributors throughout Mexico

Mexico has several major "markets" for medical devices including Mexico City, Monterrey and Guadalajara. Distributors tend to focus on 1-2 of those areas but rarely have coverage throughout Mexico. We can help find and qualify the best distributors in specific regions of Mexico to maximize your sales in the country. If we act as your Registration Holder, we will assist in authorizing new distributors on your behalf.

Proper COFEPRIS* device classification is critical

The COFEPRIS system of classifying medical devices can be confusing. Selecting the proper classification code is critical to ensuring a smooth registration process. Our team in Mexico City has many years of experience with medical device classification.

Preparing your registration dossier

A completed COFEPRIS registration dossier contains similar information found in US FDA and CE Marking submission documents. We will take information found in one of these documents (if available) to prepare your dossier in the proper format accepted by COFEPRIS.

Mexican Registration Holder representation

In Mexico, the Registration Holder controls the registration of the device. Emergo Mexico s.r.l. is a licensed, independent Registration Holder with offices in Mexico City. We can act as your Registration Holder in Mexico, allowing you the freedom to select or change distributors at any time in the future without impacting your device registration!

* COFEPRIS is the department within the Secretaria de Salud (Ministry of Health) that oversees medical device registration and vigilance.

** The US FDA does not issue GMP quality system certificates so companies most often request an official Certificate to Foreign Government (CFG) from the FDA to demonstrate their compliance with FDA regulations. European Competent Authorities issue a similar document called a Certificate of Free Sale (CFS).

^ NOM is an acronym for "Normas Oficiales Mexicanas." With the exception of NOM testing for electrically powered products, product testing performed to international standards will be accepted.

^^ Although a FDA 510(k) or EU Technical File is not accepted by COFEPRIS, the information contained in these documents will satisfy the requirements needed for the submission with the exception of NOM testing.

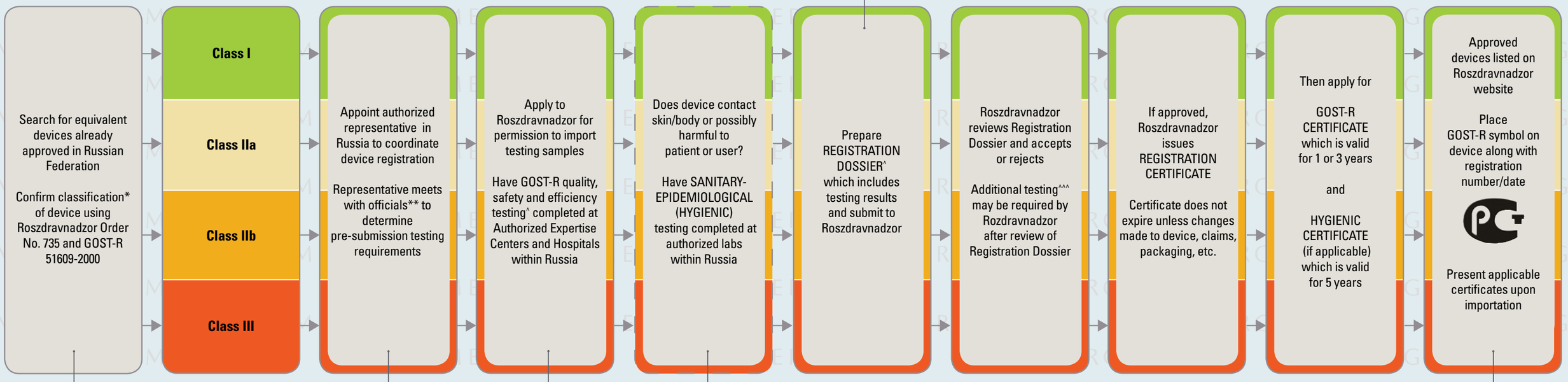
^^^ Foreign clinical data and testing done to international standards will most often be accepted by COFEPRIS.

EMERGO GROUP

Russia's regulatory process for medical devices

EmergoGroup.com/russia

Emergo Group has been assisting medical device and IVD companies with international regulatory issues and quality management system compliance since 1997. Whether you are entering the Russian market for the first time or introducing another new device, we can assist with every step of the process from device classification and registration to distributor selection. With offices in the Russian Federation and worldwide, Emergo Group can help you obtain regulatory clearance, maintain compliance and increase sales in the world's largest and fastest growing medical device markets.



Preparation of the registration dossier

The dossier is the most important part of the registration process and our consultants will ensure that all documents are properly formatted, testing results are included and all documents/certificates are translated into Russian. We will also work with officials from Roszdravnadzor to address issues with the registration as needed.

Device classification consulting

Russia's device classification scheme is similar to Europe's. However, it is more difficult to ascertain the proper classification of a device. Our Moscow-based team has extensive experience with device classification, the first important step toward a smooth registration process.

Independent representation for registering your devices

Many companies have a distributor act as their "authorized representative" and register their device with the Russian authorities. Doing so gives the distributor full control over the device registration. Emergo Group is an independent representative, allowing you to maintain full ownership and control over your device approvals.

Coordination of product testing in Russia

Most products require product testing and we can assist by meeting with Ministry officials to determine which tests will be required and coordinating the testing with authorized test facilities within the Russian Federation.

Finding and managing distributors

Russia can be a challenging market and finding well qualified, reputable distributors can be the difference between success and failure. As the registration process nears completion, we can help you find, evaluate and manage qualified distributors in Russia.

* Classification of devices is very similar to the European system.
** Department of Registration of Foreign Medical Equipment and Devices within Roszdravnadzor. Pre-submission meeting not required if testing requirements are well known.
^ Product testing completed within Russia is required because devices must conform with Russian GOST standards which are not harmonized with international standards, albeit very similar. The Russian GOST-R certificate is similar to a European CE Marking certificate.
^^ All documents and certificates submitted as part of the registration process MUST be translated into Russian.
^^^ For Class I or IIa device which has an approved equivalent in the Russian Federation, additional testing specified by Roszdravnadzor is usually not required.

NOTES: There are three important entities involved in the medical device registration process in Russia:
ROSZDRAVNADZOR – This is the Ministry of Health and the common name of "The Federal Service for Control over Healthcare and Social Development of Russian Federation." This agency oversees all medical devices and controls the registration procedure.
GOSSTANDART – Known as the "Federal Agency for Technical Regulation and Metrology," this agency is responsible for GOST-R certification, ensuring that all medical equipment imported into Russia meets established Russian standards.
ROSPOTREBNADZOR – This is "The Federal Service for Supervision in the Area of Consumer Rights and Welfare Protection." This agency issues Sanitary-Epidemiological (Hygiene) certificates.

EMERGO GROUP

USA regulatory process for medical devices

EmergoGroup.com/usa

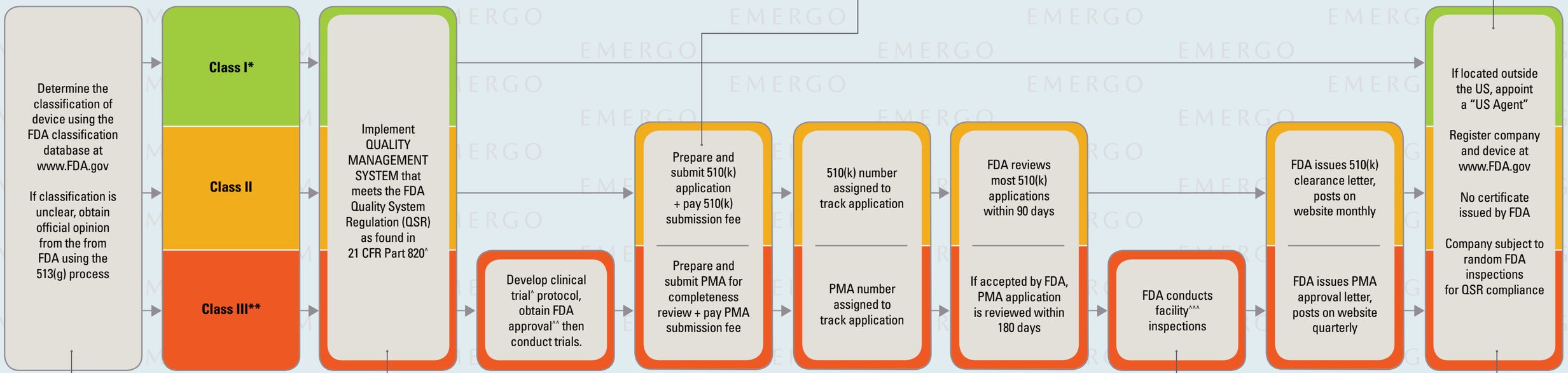
Emergo Group has been helping medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the US market for the first time or introducing another new device, we can assist with everything from US FDA Quality System Regulation (QSR) compliance and audits, to 510(k) preparation and distributor qualification. With offices in the United States and worldwide, Emergo Group can help you obtain regulatory clearance, maintain compliance and increase your sales in the world's largest and fastest growing medical device markets.

FDA 510(k) preparation with fast turnaround

If you are introducing a new device to the US market, let us navigate the FDA process for you. We have prepared hundreds of 510(k) submissions and have experience with a wide range of devices. We can advise you on testing requirements, validation and other issues the FDA requires you to address as part of the 510(k) submission.

US Agent representation for companies worldwide

If you have no US location, you can appoint Emergo Group to act as your professional regulatory representative to the FDA, called a "US Agent." We represent companies from over 35 countries worldwide in this role.



Emergo can help determine FDA classification

Devices can usually be easily classified using the FDA databases online. However, if classification cannot be determined or no "predicate" device matches your device, we can research it for you or prepare a detailed 513(g) submission asking for an official device classification and determination from the FDA.

An Emergo QMS meets most global requirements

Most manufacturers are required to have a Quality Management System that meets the FDA Quality System Regulation (QSR). We have implemented QSR-compliant quality systems for hundreds of device companies and, if desired, we can implement ISO 13485 at the same time.

Let us assess the compliance of your Quality Management System

Unlike ISO 13485, there is no Quality System Regulation (QSR) certification program and no certificate is issued by the FDA. Instead, the FDA conducts random post-marketing inspections to determine compliance. To ascertain their level of QSR compliance, many companies ask us to perform internal audits of their quality system and critical suppliers. This can be done prior to device clearance and thereafter as well.

* Approximately 5% of Class I devices require a 510(k) submission.

** FDA approval of Class III devices is a lengthy and complicated process. This is an extremely simplified version of the steps required for Class III Premarket Approval (PMA). Consult the FDA website at www.fda.gov/medicaldevices for more information.

^ 21 CFR Part 820 (Quality System Regulation) is the section of the US Code of Federal Regulations that specifies current Quality Management System requirements for device manufacturers. The Quality System Regulation is also commonly known as Good Manufacturing Practice (GMP). Some Class I device manufacturers are not required to comply with GMP.

^^ Clinical trials are required for Class III devices (and some Class II devices). Prior to initiating the clinical trial an Investigational Device Exemption (IDE) must be approved by FDA. A few Class II devices require the submission of clinical data with the 510(k) submission. Prior to initiating the clinical trial for a Class II device, an IDE must be approved by an Institutional Review Board (IRB).

^^^ The FDA will conduct an inspection of ALL major suppliers involved in the design, development and manufacturing of a Class III device and these facilities must have a QSR compliant quality system in place before the PMA application is approved by the FDA.

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