ARGENTINA

The medical device regulatory approval process

Determine classification of your device using 18 rules listed in Annex II of Disposition 2318-2002 published by ANMAT.
ANMAT classification rules are very similar to those in the European Medical Devices Directive MDD 93/42/EEC, including Amendment 2007-47-EC.

Class I	Class II	Class III	Class IV

Appoint a local company to act as your Argentina Authorized Representative (AAR). Your AAR must have ANMAT Good Manufacturing Practice (GMP) certification in accordance with ANMAT Disposition 3266-2013. Your representative's certificate must also cover your type of device and they should have an authorization permit according to ANMAT Disposition 2319-2002.

Obtain a Certificate of Free Sale (CFS) or Certificate to Foreign Government (CFG) from the US, Canada, Switzerland, Australia, Japan, any European Union country or any other country with recognized agreements with ANMAT.

Prepare a Dossier that includes device classification, manufacturer information, labeling, Instructions For Use (IFU) and a technical file in accordance with Annex III, Part A, B and C in Disposition 2318-2002 and Disposition 727-2013. Documents must be translated into Spanish.

Your AAR will submit the following documents to ANMAT: CFS or CFG, Dossier, Letter of Authorization, History of Commercialization, and Affidavit agreeing to report any recall and Field Safety Corrective Actions in any markets where your device is sold.

Your AAR pays the applicable fee, submits application to ANMAT and manages your device registration on your behalf.
Your AAR will control your device registration in Argentina.

ANMAT reviews submission. If your registration is approved, ANMAT issues an approval certificate according to Disposition 2318-2002.
Registrations are valid for 5 years. If any changes are made to your device, you must submit a Modification Dossier for ANMAT approval.

5207-0913

Learn more about Argentina:
EmergoGroup.com/argentina

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ARGENTINA

Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by ANMAT.	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months	13 months	14 months	15 months	16 months	17 months	18 months	19-24 months	25-30 months	31-36 months	36+ months
CLASS I - Imported						*	*	*	*													
CLASS I - Local									**	**	**	**	**	**	**							
CLASS II - Imported									*	*	*	*										
CLASS II - Local									**	**	**	**	**	**	**	**	**	**				
CLASS III - Imported												*	*	*	*							
CLASS III - Local												**	**	**	**	**	**	**				
CLASS IV - Imported												*	*	*	*	*	*	*				
CLASS IV - Local																		**	**			

= Period during which approval may occur.

NOTE: The time frames shown above are typical for the majority of medical device submissions prepared by Emergo Group but assume that your device does not contain animal tissue or medicinal substances. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, additional requirements/questions from ANMAT after submission, and how much time you take to address additional information requests. Also, while many Ministries of Health publish internal goals for registration review time frames, those should generally be viewed as "best case" scenarios and often reflect working days, not calendar days. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

* Imported medical devices qualify for an abbreviated review time frame if the registration documentation submitted to ANMAT includes a Certificate of Free Sale (CFS) from a recognized authority or Certificate to Foreign Government (CFG).

** Devices manufactured in Argentina, or which do not have approval from a recognized authority, are subject to ANMAT standard review times.

Learn more about Argentina:

EmergoGroup.com/argentina

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AUSTRALIA

The medical device regulatory approval process

Determine classification using Schedule 2 of the Australian Therapeutic Goods (Medical Devices) Regulations. If a device has European CE Marking, the classification will likely be the same. A CE Marking certificate from a Notified Body would be accepted as part of your registration in most cases.

Non-Sterile **Class I** Non-Measuring	Sterile **Class I** Measuring	**Class IIa**	**Class IIb**	**Class III**
If you have no local presence in Australia, appoint a TGA Sponsor. The Sponsor facilitates your device registration and approval, and the Sponsor's name must appear on your device and labeling.				
Have current Technical File or Design Dossier (Class III) and Declaration of Conformity ready for submission.				
	Sponsor submits Manufacturer's Evidence (CE Marking) plus the Global Medical Device Nomenclature (GMDN) codes for your device(s) using TGA online eBS system. TGA accepts or rejects Manufacturer's Evidence.			
Sponsor submits Medical Device Application online. The Application should include Intended Purpose statement, classification and GMDN code. Pay application fee.				Level 2 audit. Design dossier reviewed by TGA. Pay application fee.
The TGA will approve or reject your application and issue a listing number for the Australian Register of Therapeutic Goods (ARTG).				
TGA issues Certificate of Inclusion and makes a public summary of your listing available in the ARTG database on its website. Registrations do not expire as long as you do not make changes to your product or its intended use, and pay the annual ARTG listing fee.				

IMPORTANT: This chart demonstrates the route to compliance in Australia for devices that already have CE Marking and which do not include medicinal components or animal tissue.

5004-0713

Learn more about Australia:

EmergoGroup.com/australia

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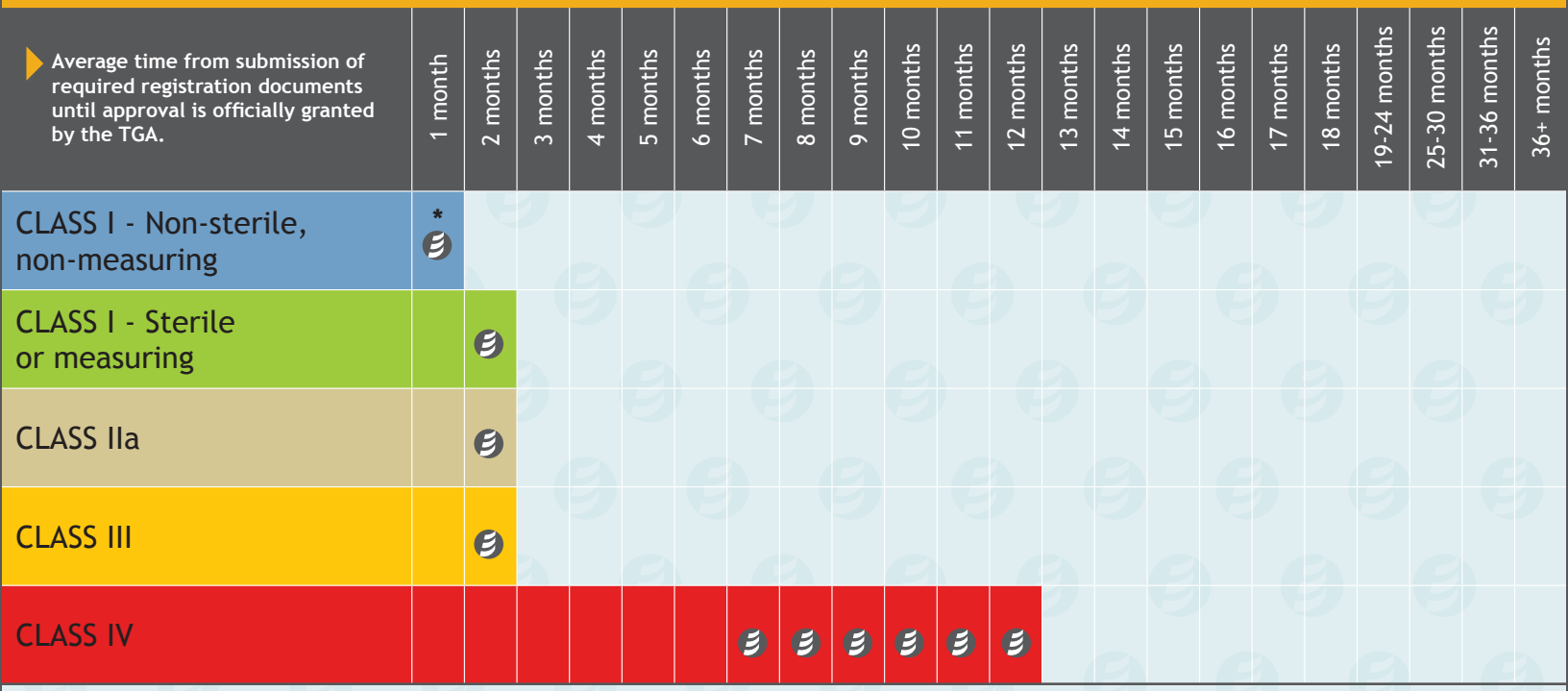
AUSTRALIA

Typical approval time frames for medical devices



= Period during which approval may occur.

NOTE: The TGA recognizes European CE Marking, and most non-Australian companies have CE Marking Certification before entering the Australian market. These time frames assume that your device has CE Marking but does not contain animal tissue, human blood/plasma derivatives or medicinal substances. The review times shown above are typical for the majority of TGA submissions prepared by Emergo group. However, the TGA reserves the right to perform an application audit even if the device already has European CE Marking. A TGA audit can lengthen review times by 6 months or more. Class III device applications are automatically audited by the TGA. Also, while many Ministries of Health publish goals for registration review times, those should generally be viewed as "best case" scenarios and often reflect working days, not calendar days. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

* Class I devices that are NOT provided sterile and which do NOT have a measuring function can be self-registered (self-declared). As such you will be able to sell your product in Australia within one week of submitting the necessary paperwork to the Therapeutic Goods Administration (TGA).

Learn more about Australia:

EmergoGroup.com/australia

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BRAZIL

The medical device regulatory approval process

Determine classification of your device using rules found in Annex II of Brazilian Resolution RDC 185/2001 published by Agência Nacional de Vigilância Sanitária (ANVISA).

Class I	Class II	Class III	Class IV

Appoint a company that holds a Company Working Allowance permit from ANVISA as your Brazil Registration Holder (BRH).
Foreign manufacturers do not need to obtain this permit unless they plan on importing and distributing their own products in Brazil.

Submit BRH Letter of Authorization to ANVISA. Your BRH will submit your registration application and Technical File to ANVISA.
Your BRH maintains control of your device registration and BGMP certification.

Certain devices (mostly electro-medical) require INMETRO Certification. Testing for electro-medical products performed outside Brazil is usually accepted if performed by an ILAC-certified lab. IEC 60601 series test reports must be less than two years old. INMETRO certification is valid for 5 years.

Class I and II devices listed in IN 2/2011, or any Class III or IV devices, must provide proof of compliance with Brazil Good Manufacturing Practice (BGMP) as found in RDC 16/2013. BGMP is similar to ISO 13485. Fees must be paid every two years.

Prepare Technical File that includes information on your device in accordance with Annex III, Part A/B/C in RDC 185/2001, as well as proposed labeling and instructions for use.

Some devices require an Economic Information Report (EIR) compliant with RDC 185/2006.
This report includes pricing comparisons for other markets, patient/user information, and marketing materials.

Obtain Certificate of Free Sale (CFS) or device registration certificate proving home-country approval from your Ministry of Health
– OR –
Show proof of registration in two other markets and provide reason your device does not have home-country approval.

ANVISA reviews registration application. If approved, ANVISA will publish registration number in the Diário Oficial da União (DOU).
Registrations are valid for 5 years. Cadastro (low-risk Class I and II) application reviews typically take less time than Registro (higher-risk Class III and IV) reviews.

5041-0713

Learn more about Brazil:

EmergoGroup.com/brazil

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BRAZIL

Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by ANVISA.	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months	13 months	14 months	15 months	16 months	17 months	18 months	19-24 months	25-30 months	31-36 months	36+ months
CLASS I					*	*	*	*	*	*								**	**	**		***
CLASS II					*	*	*	*	*	*								**	**	**		***
CLASS III																		**	**	**		***
CLASS IV																		**	**	**		***

= Period during which approval may occur.

NOTE: The time frames shown above are typical for the majority of medical device submissions prepared by Emergo Group. These review times also assume that your device has US FDA or European CE Marking approval but does not contain animal tissue or medicinal substances. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, additional requirements/questions from ANVISA after submission, and how much time you take to address additional information requests. Also, while many Ministries of Health publish internal goals for registration review time frames, those should generally be viewed as "best case" scenarios and often reflect working days, not calendar days. YOUR SUBMISSION(S) MAY TAKE MORE THAN WHAT IS SHOWN ABOVE.

* These abbreviated review times apply to Class I and II devices NOT listed in IN 2/2011.

** These review times apply to specific devices listed in IN 2/2011 and all Class III and IV devices. However, in order to qualify for these abbreviated review times, you must: 1) file a lawsuit against ANVISA to force a Brazil GMP inspection within 6-8 months, or 2) appoint a Brazil Registration Holder that is a member of ABIMED (Emergo Group is a member) and 3) your company must already have ISO 13485 certification or other internationally accepted GMP certificate. Existing ISO 13485 certificates may suffice as temporary proof of compliance with Brazil GMP. Companies must still schedule and pass a Brazil GMP audit by ANVISA while the registration may proceed in parallel, and ANVISA reserves the right to revoke certification at any time in case of noncompliance. Ask us for more details.

*** These review times apply to the specific list of Class I and II devices shown in IN 2/2011 and all Class III and IV devices assuming: 1) your Brazil Registration Holder is NOT a member of ABIMED and 2) you are NOT suing ANVISA to expedite a Brazil GMP inspection by ANVISA. The primary reason review times are so much longer is that ANVISA requires all companies selling products listed in IN 2/2011, and Class III and IV devices, to comply with, and be audited for, Brazil Good Manufacturing Practice (BGMP). Only after the audit has been completed and a BGMP certificate has been received can you submit your registration documents to ANVISA for review. In total, this process can take 4 years or longer. Ask us for more details.

Learn more about Brazil:

EmergoGroup.com/brazil

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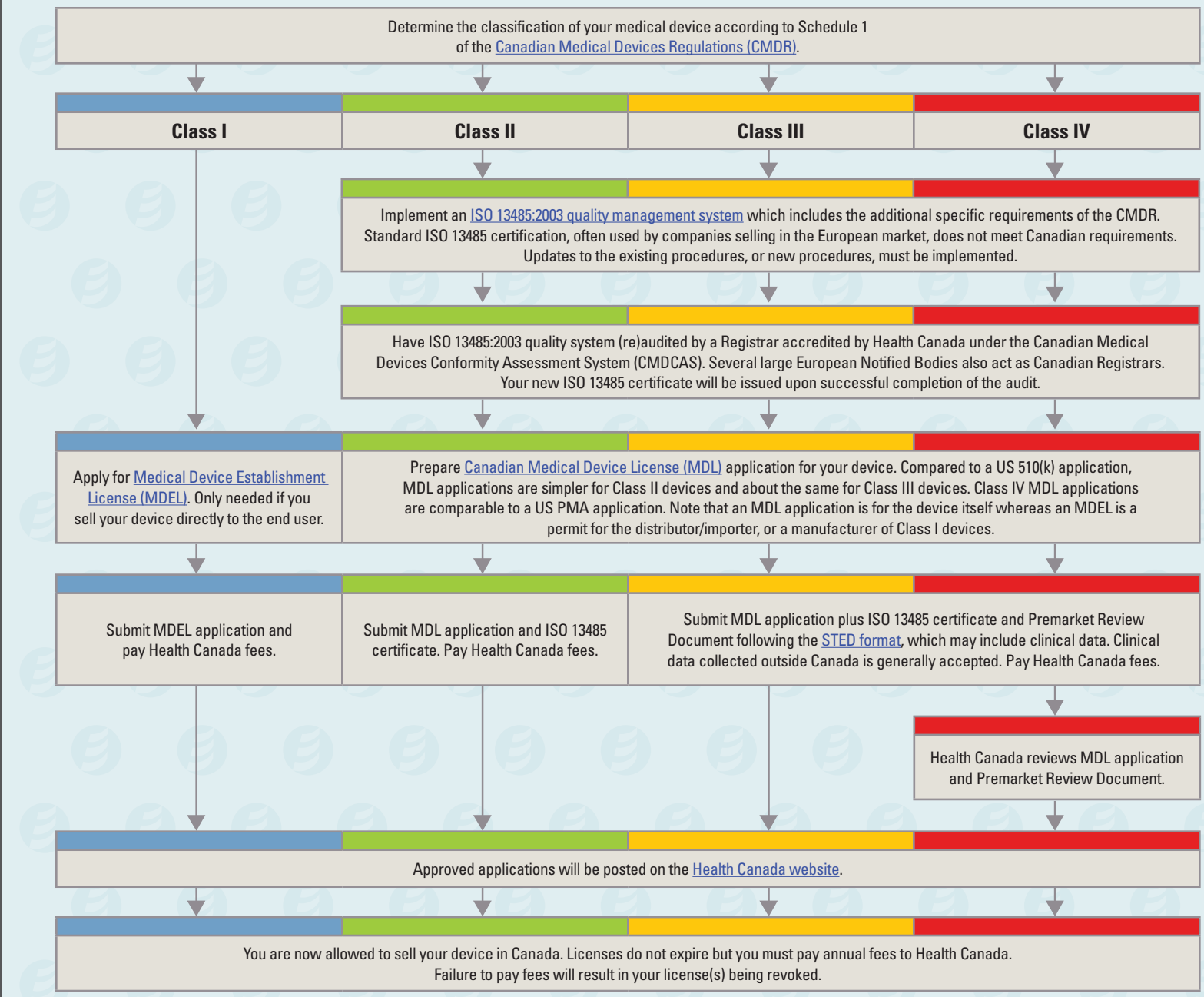
The medical device regulatory approval process



5003-0713

Learn more about Canada:

EmergoGroup.com/canada

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Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by Health Canada.

	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months	13 months	14 months	15 months	16 months	17 months	18 months	19-24 months	25-30 months	31-36 months	36+ months
CLASS I		*	*	*																		
CLASS II		**																				
CLASS III				**	**																	
CLASS IV						**	**	**														

= Period during which approval may occur.

NOTE: The time frames shown above are typical for the majority of medical device submissions prepared by Emergo Group but assume that your device does not contain animal tissue or medicinal substances. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, additional requirements/questions from your Canadian Registrar (Class II, III and IV only) after submission, and how much time you take to address additional information requests. Also, while many Ministries of Health publish goals for registration review time frames, those should generally be viewed as "best case" scenarios and often reflect working days, not calendar days. YOUR SUBMISSION(S) MAY TAKE MORE THAN WHAT IS SHOWN ABOVE.

* Class I devices do not require a Medical Device License (MDL). However, if you plan to ship your Class I device directly to an end customer (and not through an established Canadian distributor) you will require a medical Device Establishment License (MDEL). MDEL applications are reviewed by Health Canada.

** Class II, III and IV devices require a Medical Device License (MDL) and these registration dossiers are reviewed by Registrars authorized by Health Canada. Many of these Registrars are also European Notified Bodies.

Learn more about Canada:

EmergoGroup.com/canada

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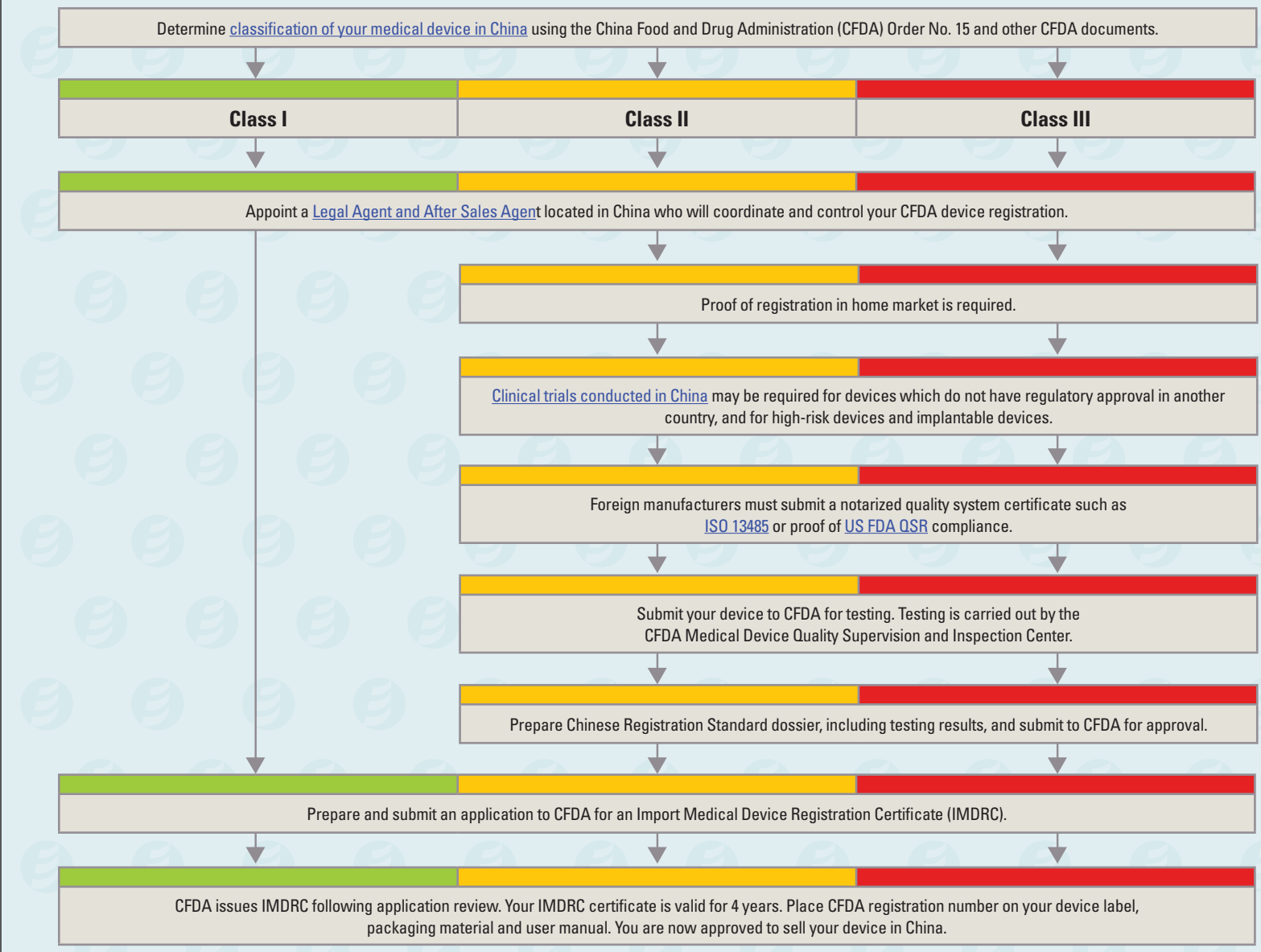
The medical device regulatory approval process



5001-0713

Learn more about China:

EmergoGroup.com/china

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CHINA

Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by the CFDA.	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months	13 months	14 months	15 months	16 months	17 months	18 months	19-24 months	25-30 months	31-36 months	36+ months
CLASS I											●	●										
CLASS II																	●	●	●	●		
CLASS III																	●	●	●	●	●	

● = Period during which approval may occur.

NOTE: The time frames shown above are typical for the majority of medical device submissions prepared by Emergo Group but assume that your device does not contain animal tissue or medicinal substances. However, review times DO assume that your device already has home country approval outside China. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, time needed for product testing, additional requirements/questions from China's State Food and Drug Administration (CFDA) after submission, and how much time you take to address additional information requests. Also, while many Ministries of Health publish goals for registration review time frames, those should generally be viewed as "best case" scenarios and often reflect working days, not calendar days. YOUR SUBMISSION(S) MAY TAKE MORE THAN WHAT IS SHOWN ABOVE.

Learn more about China:

EmergoGroup.com/china

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The IVD regulatory approval process

EUROPE

Determine the CLASSIFICATION of your IVD in accordance with the In Vitro Diagnostic Medical Devices Directive (98/79/EC). IVD

General IVD	Self Test IVD*	List B IVD	List A IVD
	Implement Quality Management System (QMS) in accordance with Annex IV, V, VI or VII of 98/79/EC. Most companies apply the ISO 13485 standard to achieve QMS compliance.		
Prepare a Technical File which provides detailed information demonstrating compliance with the In Vitro Diagnostic Devices Directive 98/79/EC.			
Appoint an Authorized Representative (EC REP) located in Europe and qualified to handle regulatory issues. Place EC REP name and address on Instructions for Use and packaging wherever sold in Europe. EC REP			
	Your QMS and Technical File must be audited by a European Notified Body. CE Marking certificate for your device will be issued upon successful completion of the Notified Body audit.		
Your IVD(s) must be registered with the European Competent Authority (Ministry of Health) where your Authorized Representative is based. Additional notifications to other countries may be required.			
Prepare a Declaration of Conformity, a legally binding document prepared by the manufacturer stating that your IVD is in compliance with the applicable Directive. You may now affix CE Marking to your IVD. CE			
CE certification does not expire as long as you remain in compliance with the applicable Annex of 98/79/EC.	You will be audited by a Notified Body every 6-12 months to ensure ongoing compliance with the applicable Annex of 98/79/EC. Failure to pass the audit will invalidate your CE Marking certification.		
			Conduct ongoing batch testing and forward results to your Notified Body. LOT

* Self-test IVDs exclude devices that are included in **Annex II**, List A and List B.

5177-0713

Learn more about Europe:

EmergoGroup.com/europe

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The medical device regulatory approval process

EUROPE

Determine which Medical Device Directive applies to your device:
93/42/EEC – Medical Devices Directive (MDD)
90/385/EEC - Active Implantable Medical Devices Directive (AIMDD)

Determine classification of your device using Annex IX of the Medical Devices Directive (MDD).
Active implantable medical devices are subject to the same regulatory requirements as Class III devices.

Non-Sterile **Class I** Non-Measuring	Sterile **Class I** Measuring	**Class IIa**	**Class IIb**	**Class III**
	Implement Quality Management System (QMS) in accordance with Annex II or V of the MDD. Most companies apply the ISO 13485 standard to achieve QMS compliance.			
Prepare a Technical File which provides detailed information on your medical device demonstrating compliance with MDD 93/42/EEC.				Prepare a Design Dossier*
Appoint an Authorized Representative (EC REP) located in Europe. They should be qualified to handle regulatory issues. Place EC REP name and address on Instructions for Use and packaging. EC REP				
	Your QMS and Technical File or Design Dossier must be audited by a Notified Body, a third party accredited by European authorities to audit medical device companies and products.			
	You will be issued a CE Marking Certificate for your device and an ISO 13485 certificate for your facility following successful completion of your Notified Body audit. CE Marking certificates are typically valid for 3 years. ISO 13485 certification must be renewed every year.			
All Class I devices must be registered with the Competent Authority where your EC REP is based.	Most EU member states do not require registration of Class IIa, IIb or III devices.			
Prepare a Declaration of Conformity, a legally binding document prepared by the manufacturer stating that the device is in compliance with the applicable Directive. You may now affix the CE Marking. CE				
CE certification does not expire as long as you remain in compliance with 93/42/EEC.	You will be audited by a Notified Body each year to ensure ongoing compliance with 93/42/EEC or 90/385/EEC. Failure to pass the audit will invalidate your CE Marking certification.			

* Class III / AIMD devices will likely require clinical study data. Existing clinical data may be acceptable. Clinical trials in Europe must be pre-approved by a European Competent Authority.

Learn more about Europe:
EmergoGroup.com/europe

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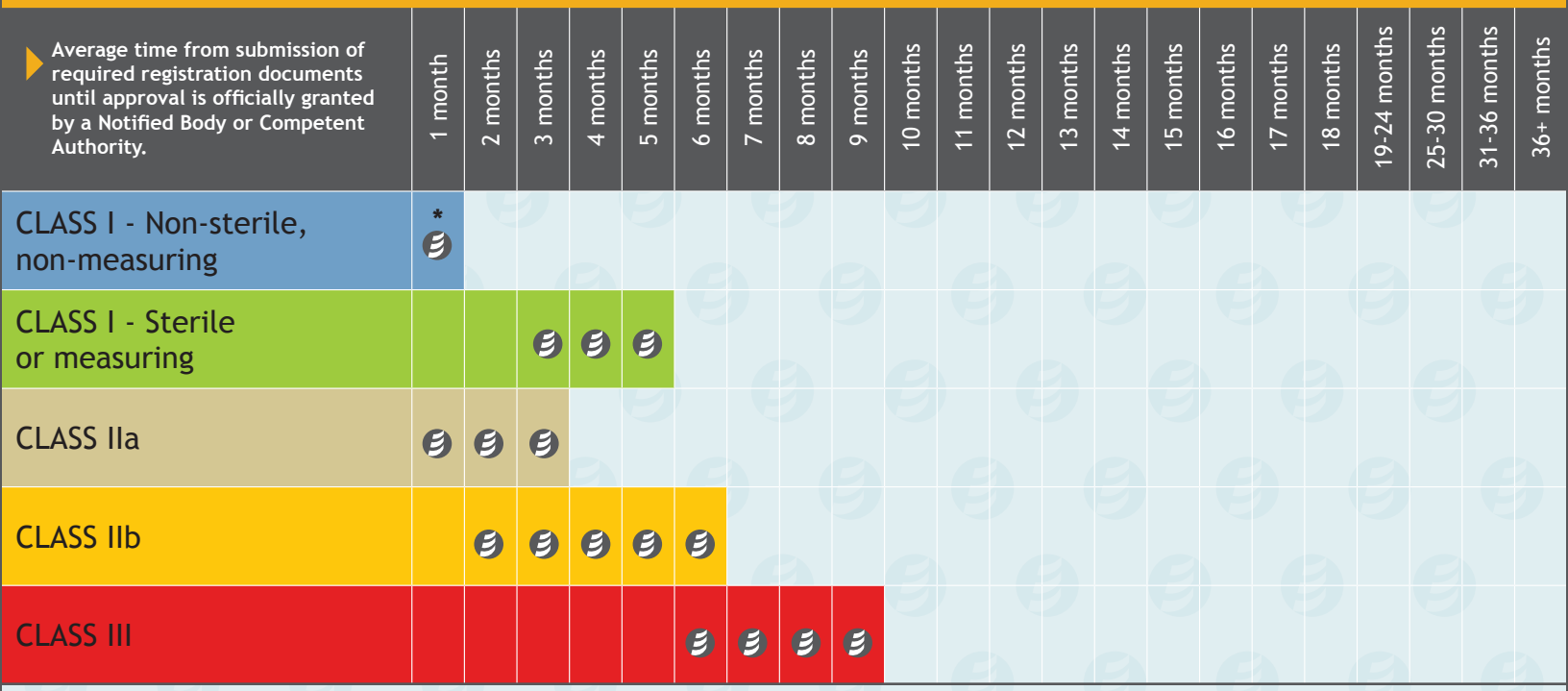
EUROPE

Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by a Notified Body or Competent Authority.



= Period during which approval may occur.

NOTE: The time frames shown above are typical for the majority of medical device submissions prepared by Emergo Group but assume that your device does not contain animal tissue or medicinal substances. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, additional requirements/questions from your Notified Body after submission, and how much time you take to address additional information requests. YOUR SUBMISSION(S) MAY TAKE MORE THAN WHAT IS SHOWN ABOVE.

* Class I devices which are not provided sterile and which do not have a measuring function can be self-certified (self-declared). As such you will be able to sell your product in Europe within one week of submitting the necessary paperwork to the Competent Authority in which your European Authorized Representative is based.

Learn more about Europe:

EmergoGroup.com/europe

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INDIA

The medical device regulatory approval process

Is your product on the list below of "Notified Medical Devices" and IVDs which require device registration in India?
Blood Component Bags, Blood Grouping Sera, Bone Cements, Cardiac Stents, Catheters, Condoms, Disposable Hypodermic Needles, Disposable Hypodermic Syringes, Disposable Perfusion Sets, Drug Eluting Stents, Heart Valves, IV Cannulae, Internal Prosthetic Replacements, Intra Ocular Lenses, Intra Uterine Devices, IVD Devices for HIV, HBsAG and HCV, Orthopedic Implants, Scalp Vein Sets, Skin Ligatures, Surgical Dressings, Sutures and Staplers, Tubal Rings, Umbilical Tapes

IVD but not on list above

Medical Device or IVD on list above

Appoint an India Authorized Agent to interact with the Central Drugs Standard Control Organization (CDSCO) on your behalf. Your Agent must have a valid wholesale license (Forms 20B and 21B).

Grant Power of Attorney to your India Authorized Agent to manage your registration in India.

File application for Device Registration Certificate to CDSCO using Form 40. Schedules D-1 and D-2 must be included, as well as verification of compliance with US, Canadian, European, Japanese or Australian regulations.

Device manufacturers new to India require a Form 45 (New Drug License) in support of the Form 40 application.

Obtain Registration Certificate Form 41 from CDSCO. Certificate is valid for up to 3 years.

Identify your distributor in India (holding forms 20B and 21B).

Apply for Import License using Forms 8 and 9 available from CDSCO. You must identify your chosen distributors on these forms as well.

Obtain Import License (Form 10) from CDSCO. License valid for 3 years.

You are now authorized to market your device or IVD in India.

5119-0713

Learn more about India:
EmergoGroup.com/india

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INDIA

Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by CDSCO.	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months	13 months	14 months	15 months	16 months	17 months	18 months	19-24 months	25-30 months	31-36 months	36+ months
Non-notified IVD devices			●	●																		
List of notified medical devices or IVD						●	●	●	●													

● = Period during which approval may occur.

NOTE: There are only a small number of “notified medical devices” and IVDs which require registration in India. The time frames shown above are typical for the majority of notified medical device submissions prepared by Emergo Group. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, additional requirements/questions from the Central Drugs Standard Control Organization (CDSCO) after submission, and how much time you take to address additional information requests. Also, while many Ministries of Health publish internal goals for registration review time frames, those should generally be viewed as “best case” scenarios and often reflect working days, not calendar days. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

Learn more about India:

EmergoGroup.com/india

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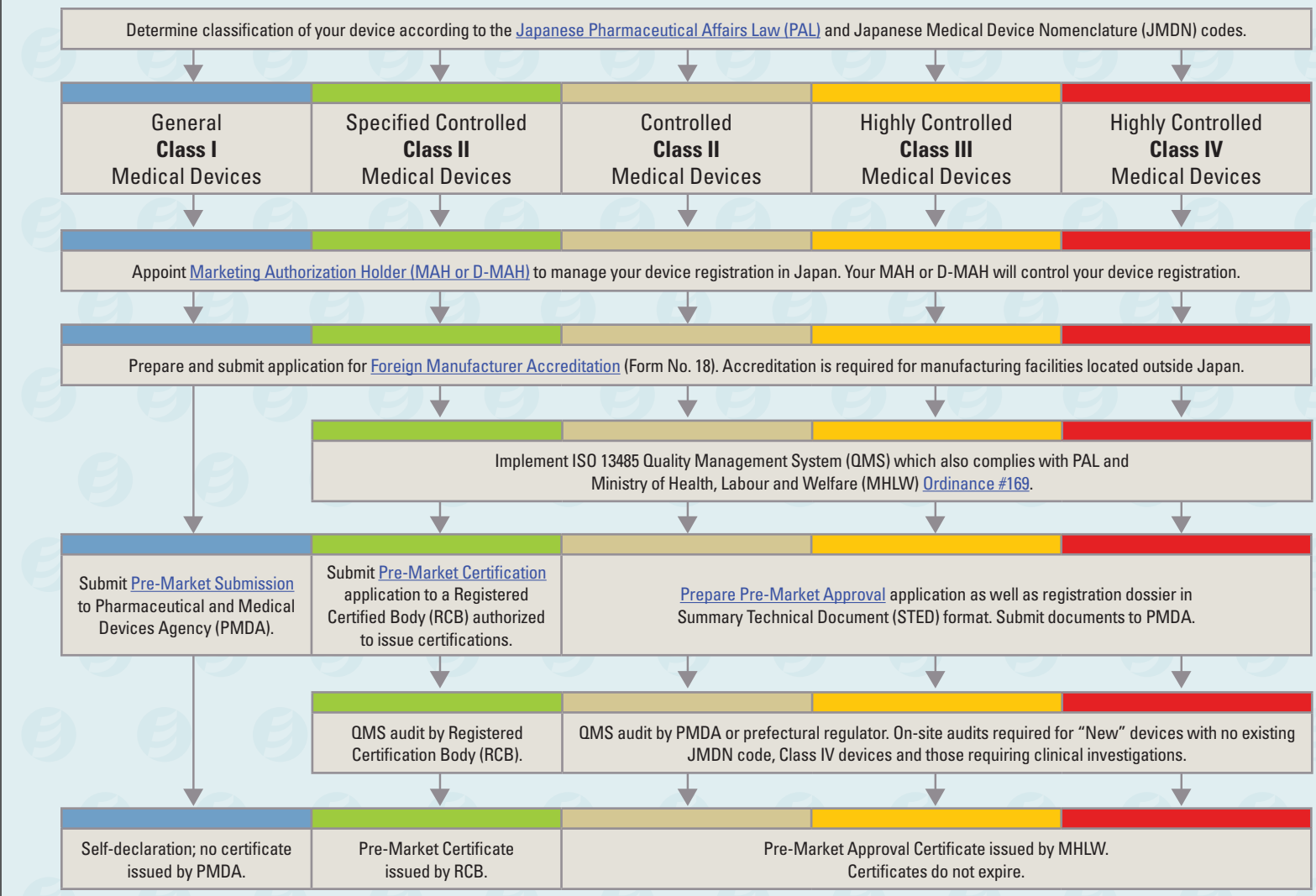
JAPAN

The medical device regulatory approval process



5000-0713

Learn more about Japan:

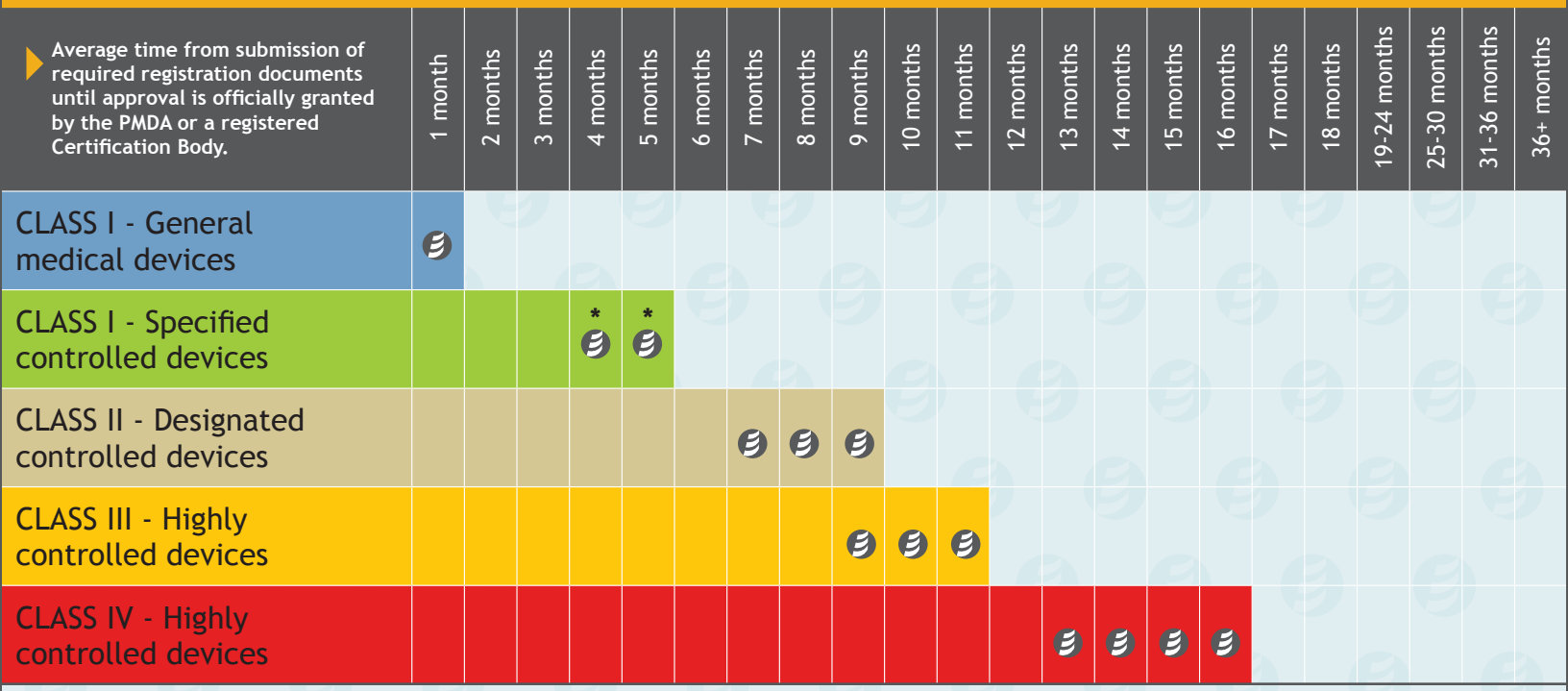
EmergoGroup.com/japan

EMERGO GROUP

JAPAN

Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by the PMDA or a registered Certification Body.



= Period during which approval may occur.

NOTE: The time frames shown above are typical for the majority of medical device submissions prepared by Emergo Group but assume that your device does not contain animal tissue or medicinal substances. Also, Japan considers whether a product is generic (exactly like another product), Improved (there is a JMDN code but it is not generic) or New (no JMDN code exists) when calculating review times. The time frames in this chart apply to "Improved" products. Time frames for "New" products are considerably longer. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, additional requirements/questions after submission, and how much time you take to address additional information requests. While many Ministries of Health publish internal goals for registration review time frames, those should generally be viewed as "best case" scenarios and often reflect working days, not calendar days. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

* Applications for Class II specified controlled devices are reviewed by Registered Certification Bodies (RCB). Approval times vary by RCB.

Learn more about Japan:

EmergoGroup.com/japan

EMERGO GROUP

The medical device regulatory approval process

See if your device is on the COFEPRIS list of deregulated devices. If not, determine classification of your device based on rules found in "Criteria for Medical Device Classification" published in Mexico's Official Diary.

Low Risk	Class I	Class II	Class III

If you have no local presence in Mexico, appoint a Mexico Registration Holder (MRH) as your in-country regulatory representative. Your MRH manages your device application and controls your medical device registration in Mexico.

Prepare Letter of Representation for your MRH and Letter of Appointment for your chosen distributor(s) in Mexico.

If your device is already registered with the US FDA (Class I, II or III), Health Canada (Class II, III and IV only) or Japan's PMDA (Class II, III, IV only), your device may qualify for an equivalency review process with COFEPRIS.

Submit application with basic company and device information.

If device qualifies for equivalency review:
Prepare Summary Dossier referencing prior registrations in the US, Canada or Japan, and include associated certificates, labeling and product technical documentation. CFS or CFG will be required. Include proof of QMS compliance from country you are trying to leverage for Mexico registration.

If device does NOT qualify for equivalency review:
Prepare a detailed Registration dossier which includes full product technical information, applicable testing results, labeling and instructions for use. Provide copy of ISO 13485 certificate. Proof of home country approval using a CFS will be required.

Include clinical and biocompatibility testing data in dossier submission. Clinical trials conducted outside Mexico will be accepted.

MRH submits Registration Dossier to COFEPRIS or Third Party Reviewer for review, along with payment for registration fees.

All devices must follow labeling requirements found in NOM-137-SSA1-2008. Labeling and instructions for use must be submitted in Spanish.

Certificate issued by COFEPRIS and confirmation of completed registration posted on Ministry of Health website. Registrations are valid for 5 years.

5038-0713

Learn more about Mexico:
EmergoGroup.com/mexico

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MEXICO

Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by COFEPRIS.	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months	13 months	14 months	15 months	16 months	17 months	18 months	19-24 months	25-30 months	31-36 months	36+ months
Low Risk			●	●																		
CLASS I - Third-Party Review				* ●																		
CLASS I - CA/JP/US Equivalency						** ●	** ●	** ●	** ●	** ●	** ●	** ●										
CLASS I - Standard				●	●	●	●	●	●	●												
CLASS II - Third Party Review				* ●																		
CLASS II - CA/JP/US Equivalency						** ●	** ●	** ●	** ●	** ●	** ●	** ●										
CLASS II - Standard						●	●	●	●	●	●	●	●	●	●	●						
CLASS III - Third Party Review				* ●																		
CLASS III - CA/JP/US Equivalency						** ●	** ●	** ●	** ●	** ●	** ●	** ●										
CLASS III - Standard						●	●	●	●	●	●	●	●	●	●	●						

● = Period during which approval may occur.

NOTE: The time frames shown above are typical for the majority of medical device submissions prepared by Emergo Group but assume that your device does not contain animal tissue or medicinal substances. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, additional requirements/questions from COFEPRIS after submission, and how much time you take to address additional information requests. Devices with existing approval in the US, Canada or Japan may qualify for an "equivalency" process which may shorten review times by COFEPRIS. Other restrictions apply for companies claiming US FDA equivalency. Also, while many Ministries of Health publish internal goals for registration review time frames, those should generally be viewed as "best case" scenarios and often reflect working days, not calendar days. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

* COFEPRIS has authorized certain "third party" companies to conduct registration reviews for Class I, II and III devices. These time frames apply only if you have elected to use a third party to review your submission.

** Companies which cannot claim "equivalency" and will not be using a third party reviewer are subject to COFEPRIS's standard review process.

Learn more about Mexico:

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RUSSIA

The medical device regulatory approval process

Search for equivalent medical devices already approved for sale in the Russian Federation. Confirm classification of your device using Roszdravnadzor Order No. 735 and Rosstandart 51609-2000. Define the type of the medical device according to Decree No. 4n

Class I	Class IIa	Class IIb	Class III

Appoint an Authorized Representative regulatory representative to coordinate your medical device registration in Russia.

Determine pre-submission testing requirements for your device. Medical devices need to have testing conducted in Russia even if the equivalent testing has been performed to international standards outside of Russia.

Get permission from Roszdravnadzor to import testing samples of your device. Valid for 6 months.

Have quality, safety and efficacy testing performed at Authorized Expertise Centers and Hospitals in Russia.

Prepare a Registration Dossier which includes all technical details about your device including testing results. Proof of home country approval must also be obtained using a CFS or CFG. Submit dossier and CFS or CFG to Roszdravnadzor. All technical documents must be submitted in Russian. Certificates must be notarized and apostiled.

Roszdravnadzor will review your Registration Dossier and issue a permit to conduct clinical trials if required. They will then temporarily suspend the registration process. Once the results of clinical trials are obtained, you or your authorized representative will submit the results to Roszdravnadzor and apply for continuation of the registration process.

If your dossier is approved, Roszdravnadzor issues a Registration Certificate. The registration certificate does not expire unless you make changes to your device, manufacturing facility address or contact details. After Registration Certificate is issued, approved medical devices are listed in the database on Roszdravnadzor website.

Apply for a Declaration of Conformity (DoC) certificate. which is a combined quality and product safety certificate. Your Registration certificate will be necessary to obtain the DoC certificate, which is valid for 1 or 3 years depending on the manufacturer's choice.*

After Declaration of Conformity certificate has been issued, Declaration of Conformity symbol must be placed on your device.

* Some manufacturers choose 1-year Declaration of Conformity certificates if they plan on making changes to their devices or business within 12 months.

5039-0713

Learn more about Russia:

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RUSSIA

Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by Roszdravnadzor.	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months	13 months	14 months	15 months	16 months	17 months	18 months	19-24 months	25-30 months	31-36 months	36+ months
CLASS I														*	*							
CLASS IIa														*	*							
CLASS IIb														*	*							
CLASS III																						

= Period during which approval may occur.

NOTE: The time frames shown above are typical for the majority of medical device submissions prepared by Emergo Group but assume that your device does not contain animal tissue or medicinal substances. The review times shown above are for devices WITH a predicate device already approved for sale in the Russian Federation. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, additional requirements/questions from Roszdravnadzor after submission, and how much time you take to address additional information requests. Also, while many Ministries of Health publish internal goals for registration review time frames, those should generally be viewed as "best case" scenarios and often reflect working days, not calendar days. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

* Class I and II devices WITH a predicate device already approved for sale in the Russian Federation qualify for an abbreviated review process with Roszdravnadzor and do not require additional testing. Devices WITHOUT a predicate device already approved for sale go through the normal review cycle with Roszdravnadzor and may require additional testing, even if equivalent testing has been already performed to international standards.

Learn more about Russia:

EmergoGroup.com/russia

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SAUDI ARABIA

The medical device regulatory approval process

Your medical device must be approved for sale in the US, Canada, Europe, Japan or Australia.

Low Risk	Medium Risk	High Risk
The classification of your medical device in your reference market will determine the classification of your device in the Kingdom of Saudi Arabia (KSA).		
Appoint a KSA Authorized Representative to manage your medical device registration in Saudi Arabia. Your representative must be licensed with the Saudi Food and Drug Authority (SFDA).		
Your KSA Authorized Representative obtains a license from the SFDA showing they will represent you in Saudi Arabia. Pay license fee. This license must be renewed each year.		
Your KSA Authorized Representative submits the Medical Device Market Authorization (MDMA) application to SFDA on your behalf. Pay registration fee.		
Once the MDMA application is submitted, you may begin marketing your Low Risk device in the KSA before formal approval is granted. However, this privilege is subject to revocation at any time by the SFDA.*	SFDA approval is required before marketing of your device may begin.	
Once your device is approved, the SFDA issues you an MDMA certificate. Your registration in KSA is valid for three years if your device is Class I in any market, or if it is based on CE Marking. In this case your KSA registration will expire once your CE Marking certificate expires.		

* If your device is Class I in any country, or a Class IIa device from Europe or Australia, or a Class II device from Japan, your device may be commercialized in the KSA prior to formal approval. Class II (in US) IIb, III, or IV devices to not qualify for this program.

5196-0713

Learn more about Saudi Arabia:

EmergoGroup.com/saudiarabia

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SAUDI ARABIA

Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by the SFDA.	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months	13 months	14 months	15 months	16 months	17 months	18 months	19-24 months	25-30 months	31-36 months	36+ months
Low Risk			●	●	●																	
Medium Risk			●	●	●																	
High Risk			●	●	●																	

● = Period during which approval may occur.

NOTE: The time frames shown above are typical for the majority of medical device submissions prepared by Emergo Group but assume that your device does not contain animal tissue or medicinal substances. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, additional requirements/questions from the SFDA after submission, and how much time you take to address additional information requests. Also, while many Ministries of Health publish internal goals for registration review time frames, those should generally be viewed as "best case" scenarios and often reflect working days, not calendar days. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

Learn more about Saudi Arabia:

EmergoGroup.com/saudiarabia

EMERGO GROUP

SOUTH KOREA

The medical device regulatory approval process

Determine classification of your device according to South Korea's Ministry of Food and Drug Safety (MFDS) Notification 2011-49.

Class I	Specially Class II Controlled	Class II	Class III	Class IV
If you have no local office in South Korea, you must appoint a Korea License Holder based in the country to manage your medical device registration with the MFDS.				
Prepare Pre-Market Notification including basic device information. All documents must be in Korean.		Prepare General Technical File OR Safety and Effectiveness Review (SER). Clinical data must be included in these submissions. The MFDS may accept clinical data obtained in other markets. All documents must be in Korean.		
		Submit device for Type Testing to independent lab such as the Korea Testing Lab OR submit existing equivalent testing results. Prior testing done in accordance with ISO or other international standards is usually acceptable.		
		Have your General Technical File or SER Technical File reviewed by the MFDS or a Third Party Reviewer.		
	Your company and your Korea License Holder must comply with Korea Good Manufacturing Practice (KGMP) quality system requirements. KGMP certification may include an on-site audit of foreign manufacturing facilities.			
	Certificate of Product Approval and KGMP Certificate issued by MFDS.			
Korea License Holder assists with clearing products through South Korean Customs. Product License and KGMP Certificate must be presented during importation. Product Approval certificates do not expire but KGMP certificates are valid for 3 years.				

5040-0713

Learn more about South Korea:

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SOUTH KOREA

Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by the KFDA.	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months	13 months	14 months	15 months	16 months	17 months	18 months	19-24 months	25-30 months	31-36 months	36+ months
CLASS I - Regular	●	●																				
CLASS I - Controlled		●																				
CLASS II				●	●	●																
CLASS III - Regular							●	●	●													
CLASS III - Safety effectiveness review										●	●	●	●	●	●							
CLASS IV - Regular							●	●	●													
CLASS IV - Safety effectiveness review										●	●	●	●	●	●							

● = Period during which approval may occur.

NOTE: The time frames shown above are typical for the majority of medical device submissions prepared by Emergo Group but assume that your device does not contain animal tissue or medicinal substances. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, additional requirements/questions from the KFDA after submission, and how much time you take to address additional information requests. Also, while many Ministries of Health publish internal goals for registration review time frames, those should generally be viewed as "best case" scenarios and often reflect working days, not calendar days. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

Learn more about South Korea:

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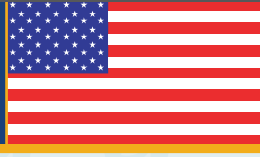
USA

The medical device regulatory approval process



Using the FDA classification database, determine the classification of your device by researching "Predicate Devices" already registered in the US market. Pay special attention to the three letter Product Code and seven digit Regulation Number associated with the predicate devices you identify. If no predicate found, use 513(g) or De Novo process.

Class I	Class II	Class III
Implement Quality Management System (QMS) which meets FDA Quality System Regulation (QSR) found in 21 CFR Part 820. This is also commonly known as FDA Good Manufacturing Practice (GMP).		
	Innovative Class II, and all Class III, devices will likely require clinical studies. Get "Pre-Submission (Pre-Sub)" feedback from the FDA.	
	If clinical studies will be required, apply for an Investigational Device Exemption (IDE). Develop clinical trial protocol and conduct studies.*	
	Prepare and submit 510(k) premarket notification application. Pay 510(k) review fee to FDA.	Prepare* and submit Premarket Approval (PMA) for completeness review. Pay PMA submission fee.
		FDA conducts facility inspections of all major suppliers involved in the design and production of your device. All parties must be compliant with FDA QSR.
	FDA issues 510(k) clearance letter.	FDA issues PMA approval letter.
If you have no local presence in the US, appoint an FDA US Agent representative as a local point of contact with the FDA.		
Register your device and company on the FDA website in accordance with 21 CFR Part 807. Specify your appointed US Agent.		
At this time, you must be in full compliance with the Quality System Regulations found in 21 CFR Part 820. The FDA will not inspect Class I or II device manufacturers for compliance prior to device registration but does conduct random inspections and can issue a Form 483 for non-compliance.		
You are now able to sell your device in the US. The FDA does not issue device approval certificates and your listing on the FDA website will serve as proof of compliance. Registrations do not expire as long as no changes are made to the indications for use, labeling or product design.		

* The process of supplying clinical study data in support of a PMA submission is far more complex than presented in this chart. This is an extremely simplified and high level view of the FDA requirements regarding clinical study data.

5002-0713

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USA

Typical approval time frames for medical devices

Average time from submission of required registration documents until approval is officially granted by the US FDA.	1 month	2 months	3 months	4 months	5 months	6 months	7 months	8 months	9 months	10 months	11 months	12 months	13 months	14 months	15 months	16 months	17 months	18 months	19-24 months	25-30 months	31-36 months	36+ months
Class I - Devices exempt from 510(k) process	*																					
Class II - Or any device subject to 510(k)																						
Class III - PMA or Class II devices without a predicate																		**	**	**		

= Period during which approval may occur.

NOTE: The time frames shown above are typical for the majority of medical device submissions prepared by Emergo Group but assume that your device does not contain animal tissue or medicinal substances. Your length of approval will depend on the quality and completeness of technical documentation used in the submission, additional requirements/questions from the US FDA after submission, and how much time you take to address additional information requests. Also, while the FDA publishes internal goals for 510(k) and PMA review time frames, those should generally be viewed as "best case" scenarios. YOUR SUBMISSION(S) MAY TAKE MORE TIME THAN WHAT IS SHOWN ABOVE.

* Most Class I devices do not need to be approved for sale by the FDA but do need to be registered via the FDA website. Once appropriate registration fees are paid and verified, you will be able to complete the registration of your Class I device online.

** Devices which the FDA has not previously classified based on risk are automatically placed into Class III by the FDA, regardless of the level of risk they pose. Some lower risk devices without a predicate device may qualify for the "de novo" process which may result in a Class I or II designation by the FDA.

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