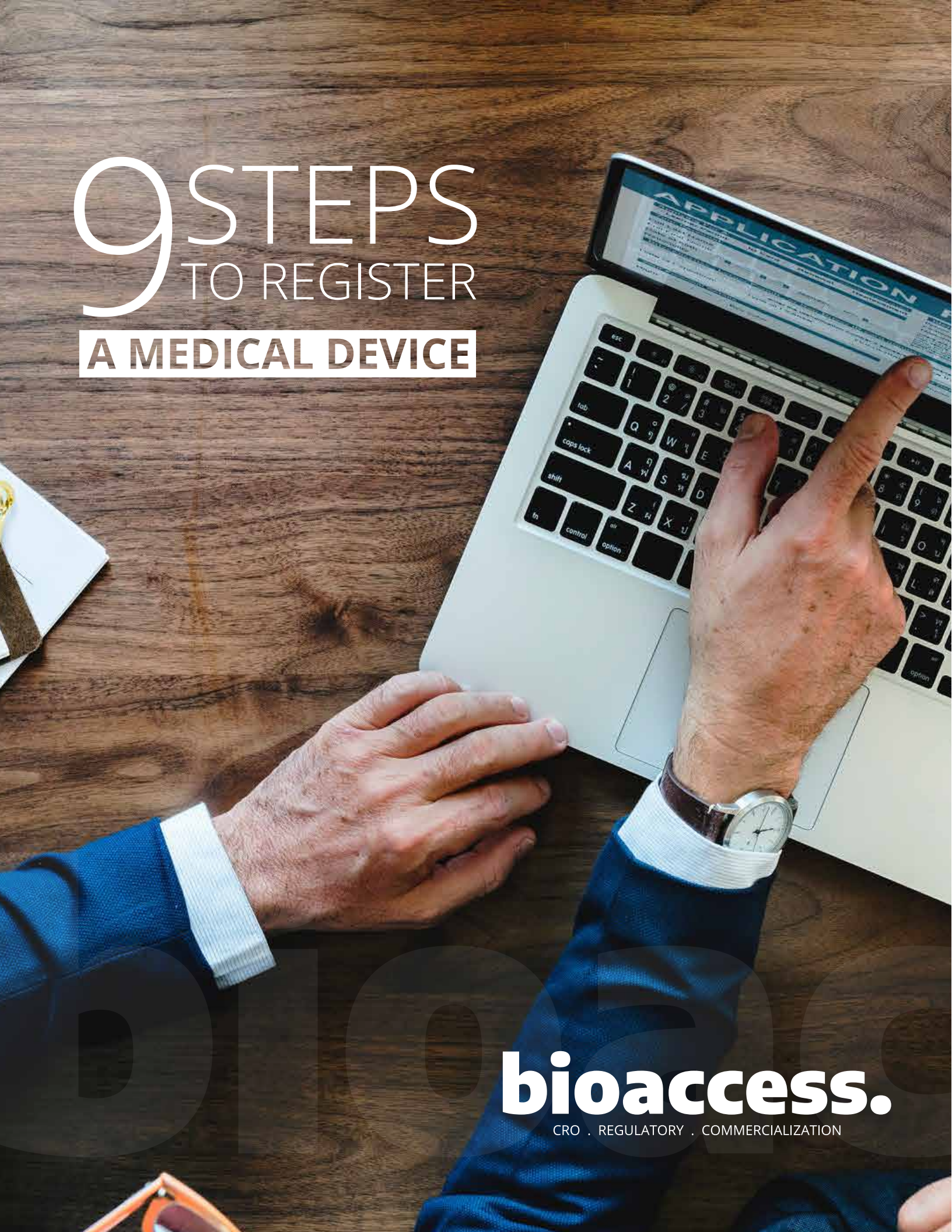
9 STEPS TO REGISTER A MEDICAL DEVICE



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1 Classification

Instituto Nacional de Vigilancia de Medicación y Alimentos (INVIMA) is the medical device regulator in Colombia. Colombia follows a four-tiered risk model (Class I, Class IIa, Class IIb and Class III) that is similar to the classification scheme used in Europe.

2 Registered Agent

Appoint a local registered agent as your legal representative who will submit your registration to INVIMA on your behalf. If you appoint a distributor, it may list itself as the owner of the registration for 10 years (not good). Your registered agent will manage your registration process form A to Z, and you will retain ownership and maintain control of the reigstration.

3 Certificate of free sale

Provide a Certificate of Free Sale (CFS) or Certificate to Foreign Government (CFG) to demonstrate that your device can be legally sold
in your home market or Australia, Canada, the European Union, Japan or the U.S.

4 Quality System

Provide proof of quality system compliance, such as an ISO 13485 certificate or proof of FDA QSR compliance. Have your prepare registration application dossier including detailed device information.

5 Test reports

Provide proof of quality system compliance, such as an ISO 13485 certificate or proof of FDA QSR compliance. Have your prepare registration application dossier including detailed device information.

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6 Translations & Submission

Your Colombia registered agent will translate all legal and technical documents to Spanish, will submit your application and dossier file to INVIMA, and will manage your medical device registration in Colombia.

7 Approval

INVIMA automatically approves Class I and IIa applications, so you can begin selling right away (you will receive your certificate in about eight (8) days). For class IIb and Class III, INVIMA must review and approve your application before you can begin selling the review takes about three (3) months.

8 Registration Certificate

Once approved, INVIMA will issue your registration certificate.

9 Market

You may begin marketing your device in Colombia. Registrations are valid for 10 years. Application renewals are due to INVIMA three (3) months before the expiration of your registration certificate.

NOTES:

You must appoint a) anINVIMA-licensed storage company inyour INVIMA application, and b) animporter of record. This is a simplified overview of theprocess. INVIMA may choose to audit your submissionand request more documents, which will add time to your approval. The time frames shownabove are typical for the majority of medical device submissions and assume that your medical device doesnot containanimal tissue, medicinal substances or employ entirelynovel technology. Your lengthof approval will depend onthequality and completeness of your technical documentationandhow muchtime youtake to address additional informationrequests from INVIMA after submission. YOUR SUBMISSION(S) MAY TAKE MORETIMETHAN WHAT ISSHOWN ABOVE. Registrations remainvalid for the time specified as longas youdonot makephysical changes to the medical device, intendeduse or indications foruse. Renewal documents are due to INVIMA three monthsprior to the expirationof the current registrationcertificate. We recommend startingthe re-registrationprocessno later than the timeperiod specified above to avoid any lapse inyour registration. More informationat www.latammarketaccess.com.