	DS 016 2011 SA GENERAL RULES	DS 040 2016 SA RULES FOR VACCINES SYRINGES AND NEEDLES PURCHASED THROUGH COOPERATION ORGANIZATIONS
REGISTRATION AND RE-REGISTRATION IN THE REGISTRY SANITARY OF BIOLOGICAL PRODUCTS	"**Article 104.- Requirements for the registration and re-registration of biological products:** For registration and re-registration in the sanitary registry of biological products, the interested party must submit the following requirements: 1 Application, with the character of affidavit; 2 Quality control documentation of the Active Pharmaceutical Ingredient - IFA, finished product and excipients (including technical specifications, analytical techniques, validation of analytical techniques, justification of specifications, batch analysis, characterization of impurities, excipients of animal or human origin, new excipients); 3 Certificate of release of lot issued by the Competent Authority of the country of origin, for imported products, as applicable; 4 Documentation containing the standards and reference materials of the Active Pharmaceutical Ingredient - IFA and finished product. 5. Description of the manufacturing process of the Active Pharmaceutical Ingredient - IFA and finished product and its validation; 6. Stability studies, as established in the corresponding regulations;	**Article 3.- Registration and re-registration in the Sanitary Registry of biological products (vaccines)** For registration and re-registration in the Sanitary Registry of biological products (vaccines), the following requirements must be presented: 1 Application with character of affidavit according to format established by the National Authority of Pharmaceutical Products, Medical Devices and Sanitary Products (ANM). 2 Technical specifications of the finished product, which is accredited with the Certificate of Analysis according to the technical standard of reference or the technical reports of the Expert Committee of the World Health Organization (WHO). 3 Summarized batch production and control protocol. 4 Certificate of release of lot issued by the competent Health Authority of the country of origin. 5 Stability studies of the finished product that endorses the useful life and storage conditions. 6 Certificate of pharmaceutical product or free trade certificate issued by the competent authority of the country of origin or exporter.

	7. Pharmaceutical product certificate or free trade certificate issued by the competent authority of the country of origin or of the exporter, preferably considering the Model of the World Health Organization (WHO), for imported products; 8. Certificate of Good Manufacturing Practices (GMP) of the national or foreign manufacturer issued by the National Authority of Pharmaceutical Products, Medical Devices and Sanitary Products (ANM). Only Certificates of Good Manufacturing Practices (GMP) from countries with high health surveillance and countries with which there is mutual recognition are accepted. In the case of the national or foreign manufacturer that has current BPM issued by the National Authority of Pharmaceutical Products, Medical Devices and Health Products (ANM), entering the manufacturer's BPM certificate number issued by the National Pharmaceutical Products Authority , Medical Devices and Health Products (ANM) in the application as an affidavit is enough; 9. Container-closure systems; 10. Characterization of the Active Pharmaceutical Ingredient - IFA and pharmaceutical development of the finished product; 11. Draft technical specifications and insert; 12. Projects of the labels in Spanish language of the immediate and immediate packaging; 13. Pre-clinical studies, when appropriate according to regulations; 14. Clinical studies; 15. Risk Management Plan;	7 Certificate of Good Manufacturing Practices (GMP) of the foreign manufacturer of the country of origin. In the case of human plasma derivatives, in addition to the requirements indicated above, a Certificate Suitability for HIV, Hepatitis B and C and others determined by the ANM must be presented. In the case of biological products (vaccines) derived from cattle, sheep and goats, in addition to the requirements indicated above, a Certificate Suitability for Bovine Spongiform Encephalopathy and others considered by the ANM must be presented.

	The national authority for pharmaceuticals, medical devices and sanitary products (ANM) proposes rules regulating particular details regarding the presentation and content of the required documents, depending on the type of biological product. For successive re-registration in the sanitary register of biological products, it won't be necessary to present the requirements of paragraphs 13 and 14 of this article, unless modifications have been made that warrant new studies on the safety or efficacy of the biological product. This provision is also applicable for the first re-registration in case the product has been registered with the requirements set out in this article. In the case of human plasma derivatives, in addition to the requirements for biological products, a certificate of negativity of HIV, Hepatitis B and C must be presented, and others determined by the National pharmaceutical Authority, Medical Devices and Sanitary Products (ANM) For biological products, the Pharmacopoeias referred to in article 40 of this regulation are used as reference.	
REGISTRATION AND RE-REGISTRATION IN THE REGISTRY SANITARY OF MEDICAL DEVICES	**In this point, the requirements for enrollment and re-enrollment in the sanitary registry under the general procedure depends on the level of risk of such medical devices. Such risk levels are:** **a) Low-risk** **b) Moderate risk** **c) High risk** **d) Risk critics** "**Article 122.-Sanitary Registration of medical devices**	**Article 4.- Enrollment and re-enrollment in the sanitary registry of medical devices (syringes and needles)**

	The sanitary registration of the medical devices is granted by common name, classification according to level of risk, manufacturer and country of the manufacturer, in addition it will be granted by group of devices (kit, set, system and family), name and country of the site of manufacture, trade name and/or brand if any, taking into consideration the documents of the International Medical devices regulators Forum-IMDRF. The aforementioned data must be endorsed by the certificate of free marketing. Exceptionally, the level of risk, common name, mark, family, as well as the components of the kit or set that are not detailed, may be endorsed by the manufacturer's letter with due sustenance. In the event that the declared manufacturer has a different manufacturing site that develops the medical device, its name or company name and address must also be informed, which must be guaranteed by the Free Commercialization Certificate. In the event that the declared manufacturer has a different site(s) for the manufacture of accessories, other than the medical device, the company name, address and country of said site(s) must be informed, data must be included in the Certificate of Free Marketing or letter from the manufacturer. If the combination of medical devices results in a device that is intended by the manufacturer to meet a purpose other than the individual medical devices that comprise it, the combination is a new medical device in its own right and must be classified according to the new use. provided.	For enrollment and re-enrollment in the Sanitary Registry of medical devices (syringes and needles), the following requirements must be presented: 1. Application as an affidavit according to the format established by the ANM. 2. Certificate of Good Manufacturing Practices (GMP) of the manufacturer of the country of origin or document that certifies compliance with quality standards specific to the type of medical device, for example, CE Certificate of the European Community, ISO 13485 in force, FDA or others according to the level of risk issued by the competent authority or entity of the country of origin. 3. Technical specifications of the medical device.

	If the combination of medical devices results in a device that is intended for the comfort of the user, but does not change the individual intended uses of the same that compose it, the classification assigned to the set of devices corresponds to that of the highest-risk device that It is included in it. Software that is not incorporated in a medical device, provided that it is independently framed within the definition of medical device, should be classified as follows: 1. When driving or exercising influence on the particular use of the medical device, it must be classified according to the intended use of the combination. 2. When it is found independently of any other medical device, it is classified taking into consideration the documents of the International Medical Devices Regulators Forum - IMDRF. 3. The software independently (to the extent that it corresponds to the definition of a medical device) will be considered as an active medical device. " **Article 124.- Requirements for the enrollment and re-enrollment of medical devices of Class I (low risk)** For the enrollment and re-enrollment in the sanitary registry of the medical devices of the Class I (under risk), the interested party must present: 1. Application as an affidavit; 2. Copy of the free trade certificate issued by the competent authority of the country of origin or exporter, for imported products. When the	

	certificate of free commercialization does not include the models, brand, code, dimensions of the device, components of the kit, set or system, or accessories when appropriate, a letter from the manufacturer that endorses their relationship is accepted; 3. Certificate of Good Manufacturing Practices (GMP) of the national or foreign manufacturer issued by the National Authority of Pharmaceutical Products, Medical Devices and Sanitary Products (ANM) or document certifying compliance with Quality Standards specific to the type of medical device, for example, CE Certificate of the European Community, ISO 13485 in force, FDA or others according to the level of risk issued by the Authority or Competent Body of the country of origin. In the case of the national or foreign manufacturer that has current BPM issued by the National Authority of Pharmaceutical Products, Medical Devices and Health Products (ANM), entering the manufacturer's BPM certificate number issued by the National Pharmaceutical Products Authority, Medical Devices and Health Products (ANM) in the Application as an affidavit is enough; 4. Technical report of the medical device which must contain the information provided in numerals 1 to 4 of article 130 of this regulation; 5. Technical studies and analytical checks. The requirement must be fulfilled with the presentation of the following documents issued by the manufacturer: a) Summary of design verification and validation documents.	

	b) Declaration of conformity of compliance with international reference standards; c) Certificate of analysis of the finished medical device if it had one. 6. Project of labeling of the immediate container and, mediate container as appropriate; 7. Instruction manual for use or insert, if any, translated into Spanish. For the case of instruments, present a copy of the catalog in the section where they are included. For imported products, it is required to present the documentation in the original language with its respective simple translation into Spanish. For the re-enrollment of the Class I medical devices that have been registered or re-registered in the Sanitary Registry complying with the requirements indicated in this article, the owner will be exempt from submitting the requirements indicated in numerals 4, 5, 6 and 7, the same that will be considered as presented by means of an affidavit stating that said technical information has not changed and if there have been changes, these are authorized . "For the enrollment and re-enrollment in the sanitary registry of the medical devices of the Class I (under risk), the interested party must present: 1. Application as an affidavit; 2. Copy of the free trade certificate issued by the competent authority of the country of origin or exporter, for imported products. When the certificate of free commercialization does not include the models, brand, code, dimensions of the device,	

	components of the kit, set or system, or accessories when appropriate, a letter from the manufacturer that endorses their relationship is accepted; 3. Certificate of Good Manufacturing Practices (GMP) of the national or foreign manufacturer issued by the National Authority of Pharmaceutical Products, Medical Devices and Sanitary Products (ANM) or document certifying compliance with Quality Standards specific to the type of medical device, for example, CE Certificate of the European Community, ISO 13485 in force, FDA or others according to the level of risk issued by the Authority or Competent Body of the country of origin. In the case of the national or foreign manufacturer that has current BPM issued by the National Authority of Pharmaceutical Products, Medical Devices and Health Products (ANM), entering the manufacturer's BPM certificate number issued by the National Pharmaceutical Products Authority, Medical Devices and Health Products (ANM) in the Application as an affidavit is enough; 4. Technical report of the medical device which must contain the information provided in numerals 1 to 4 of article 130 of this Regulation; 5. Technical studies and analytical checks. The requirement must be fulfilled with the presentation of the following documents issued by the manufacturer: a) Summary of design verification and validation documents. b) Declaration of conformity of compliance with international reference standards;	

	c) Certificate of analysis of the finished medical device if it had one. 6. Project of labeling of the immediate container and, mediate container as appropriate; 7. Instruction manual for use or insert, if any, translated into Spanish. For the case of instruments, present a copy of the catalog in the section where they are included. For imported products, it is required to present the documentation in the original language with its respective simple translation into Spanish. For the re-registrations of the Class I medical devices that have been registered or re-registered in the Sanitary Registry complying with the requirements indicated in this article, the owner will be exempt from submitting the requirements indicated in numerals 4, 5, 6 and 7, the same that will be considered as presented by means of an affidavit stating that said technical information has not changed and if there have been changes, these are authorized . " **"Article 125.- Requirements for the registration and re-registration of medical devices of Class II (of moderate risk)** For the registration and re-registration in the sanitary registry of the medical devices of the Class II (moderate risk), the interested party must present: 1. Application as an affidavit; 2. Copy of the free trade certificate issued by the competent authority of the country of origin or exporter, for imported products. When the	

	certificate of free commercialization does not include the models, brand, code, dimensions of the device, components of the kit, set or system, or accessories when appropriate, a letter from the manufacturer that endorses their relationship is accepted; 3. Certificate of Good Manufacturing Practices (GMP) of the national or foreign manufacturer issued by the National Authority of Pharmaceutical Products, Medical Devices and Sanitary Products (ANM) or document certifying compliance with Quality Standards specific to the type of medical device, for example, CE Certificate of the European Community, ISO 13485 in force, FDA or others according to the level of risk issued by the Authority or Competent Body of the country of origin. In the case of the national or foreign manufacturer that has current BPM issued by the National Authority of Pharmaceutical Products, Medical Devices and Medical Devices (ANM), entering the manufacturer's BPM certificate number issued by the National Pharmaceutical Products Authority, Medical Devices and Health Products (ANM) in the application as an affidavit is enough; 4. Technical report of the medical device which must contain the information provided in numerals 1 to 4 and 6 of article 130 of this Regulation. The requirement of numeral 6 of article 130 will be demanded as soon as the specific regulations referring to the essential conditions that medical devices must comply with enter into force; 5. Technical studies and analytical checks. The requirement must be fulfilled with the presentation of the following documents issued by the manufacturer:	

	a) Summary of design verification and validation documents. b) Declaration of conformity of compliance with international reference standards; c) Certificate of analysis of the finished medical device if it had one. 6. Project of labeling of the immediate container and, mediate container as appropriate; 7. Risk management report, according to the specific ISO standard in force; 8. Instruction manual for use or insert, if any, translated into Spanish. For the case of instruments, present a catalog copy in the section where they are included. For imported products, it is required to present the documentation in the original language with its respective simple translation into Spanish. For the re-registrations of the Class II medical devices that have been registered or re-registered in the Sanitary Registry complying with the requirements indicated in this article, the holder will be exempt from submitting the requirements indicated in numerals 4, 5, 6, 7 and 8, the same that will be considered as presented by means of an affidavit stating that said technical information has not changed and, in the case of having undergone changes, these are authorized. " **"Article 126.- Requirements for the registration and re-registration of medical devices of Class III (high risk)**	

	For the registration and re-registration in the sanitary registry of the medical devices of Class III (high risk), the interested party must present: 1. Application as an affidavit; 2. Copy of the free trade certificate issued by the competent authority of the country of origin or exporter, for imported products. When the certificate of free commercialization does not include the models, brand, code, dimensions of the device, components of the kit, set or system, or accessories when appropriate, a letter from the manufacturer that endorses their relationship is accepted; 3. Certificate of Good Manufacturing Practices of the national or foreign manufacturer issued by the National Authority of Pharmaceutical Products, Medical Devices and Sanitary Products or document certifying compliance with Quality Standards specific to the type of medical device, for example CE Certificate of the European Community, ISO 13485 current standard, FDA or others according to the level of risk issued by the Authority or Competent Body of the country of origin. In the case of the national or foreign manufacturer that has current BPM issued by the National Authority of Pharmaceutical Products, Medical Devices and Health Products (ANM), entering the manufacturer's BPM certificate number issued by the National Pharmaceutical Products Authority, Medical Devices and Health Products (ANM) in the application as an affidavit is enough; 4. Technical report of the medical device, according to article 130 of this Regulation. The requirement of numeral 6 of article 130 will be	

	demanded as soon as the specific regulations referring to the essential conditions that medical devices must comply with enter into force; 5. Technical studies and analytical checks. The requirement must be fulfilled with the presentation of the following documents issued by the manufacturer: a) Summary of design verification and validation documents; b) Declaration of conformity of compliance with international reference standards; c) Certificate of analysis of the finished medical device if it had one. 6. For sterile medical devices, copy of the validation reports of the sterilization process; 7. Project of labeling of the immediate container and, mediate container as appropriate. 8. Risk management report according to the specific ISO standard in force; 9. Clinical evaluation report; 10. Instruction manual for use or insert, as appropriate, translated into Spanish. For imported products it is required to present the documentation in the original language with its respective simple translation into Spanish. For the re-registrations of the Class III medical devices that have been registered or re-registered in the Sanitary Registry complying with the requirements indicated in this article, the owner will be exempt from submitting the requirements indicated in numerals 4, 5, 6, 7, 8, 9 and 10, the same ones that will be	

	considered as submitted by means of an affidavit stating that said technical information has not changed and if changes have been made, they are authorized. " **"Article 127.- Requirements for the registration and re-registration of Class IV medical devices (critical in terms of risk)** For the registration and re-registration in the sanitary registry of the medical devices of the class IV (critics in matter of risk), the interested one must present: 1. Application as an affidavit; 2. Copy of the free trade certificate issued by the competent authority of the country of origin or exporter, for imported products. When the certificate of free commercialization does not include the models, brand, code, dimensions of the device, components of the kit, set or system, or accessories when appropriate, a letter from the manufacturer that endorses their relationship is accepted; 3. Certificate of Good Manufacturing Practices (GMP) of the national or foreign manufacturer issued by the National Authority of Pharmaceutical Products, Medical Devices and Sanitary Products (ANM) or document certifying compliance with Quality Standards specific to the type of medical device, for example, CE Certificate of the European Community, ISO 13485 in force, FDA or others according to the level of risk issued by the Authority or Competent Body of the country of origin. In the case of the national or foreign manufacturer that has current BPM issued by the National Authority of Pharmaceutical Products, Medical Devices and Health Products (ANM), entering the	

	manufacturer's BPM certificate number issued by the National Pharmaceutical Products Authority, Medical Devices and Health Products (ANM) in the application as an affidavit is enough; 4. Technical report of the medical device, according to article 130 of this Regulation. The requirement of numeral 6 of article 130 will be demanded as soon as the specific regulations referring to the essential conditions that medical devices must comply with enter into force; 5. Technical studies and analytical checks. The requirement must be fulfilled with the presentation of the following documents, issued by the manufacturer: a) Summary of design verification and validation documents. b) Declaration of conformity of compliance with international reference standards; c) Certificate of analysis of the finished medical device if it had one. 6. For sterile medical devices, copy of the validation reports of the sterilization process; 7. Project of labeling of the immediate container and, mediate container as appropriate. 8. Risk management report according to the specific ISO standard in force; 9. Clinical evaluation report; 10. Instruction manual for use or insert, as appropriate, translated into Spanish. For imported products it is required to present the documentation in the	

	original language with its respective simple translation into Spanish. For the re-registrations of the Class IV medical devices that have been registered or re-registered in the Sanitary Registry complying with the requirements indicated in this article, the owner will be exempt from submitting the requirements indicated in numerals 4, 5, 6, 7, 8, 9 and 10, the same ones that will be considered as submitted by means of an affidavit stating that said technical information has not changed and if they have been changed, they are authorized. "	
DEADLINE FOR THE GRANT OF SANITARY REGISTRATION OR CERTIFICATE OF SANITARY REGISTRY	**Article 108.- Of the terms for the sanitary registration of biological products** The evaluation by the National Authority of Pharmaceutical Products, Medical Devices and Health Products of applications for registration and re-registration of vaccines and immunologicals has a term of up to one hundred and eighty (180) calendar days. For the rest of biological products, the term is up to twelve (12) months. **"Article 136.- Of the terms for the sanitary registration of medical devices** The evaluation by the National Authority of Pharmaceutical Products, Medical Devices and Health Products of the applications for registration and re-registration of medical devices is made, according to each level of risk, in the following terms: Class I (low risk): Up to thirty (30) calendar days. Class II (moderate risk): Up to sixty (60) calendar days.	**Article 7.- Period for granting Sanitary Registration or Sanitary Registration Certificate of biological products (vaccines) and medical devices (syringes and needles)** The ANM must issue a ruling regarding applications for Sanitary Registration or Health Registration Certificate of biological products (vaccines) and medical devices (syringes and needles) included in this Supreme Decree, within a period not exceeding seven (7) working days.

	Class III (high risk): Up to ninety (90) calendar days. Class IV (critics regarding risk): Up to ninety (90) calendar days ".	