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**DOF: 26/10/2010**

**AGREEMENT through which the equivalencies are recognized of the articles 179 and 180 of the Regulation of Health Products and of the procedures for technical evaluations conducted by the Federal Commissions for Protection against Sanitary Risks in order to grant the registration of health products, referred to in Chapter IX of the Second Title of the Regulation of Health Products, to the requirements established by the 510(k) and 514 sections of the Federal Food, Drug and Cosmetic Act and by Title 21, Chapter I, Subchapter H, of the Code of Federal Regulations of the United States of America, as established by the Food and Drug Act, and to the Medical Devices Regulations of Canada permitting the commercialization of medical devices in its territory, and to the tests and inspections conducted by the Food and Drug Administration of the United States of America and by Health Canada of Canada, in order to permit the commercialization of medical devices in their territory.**

**In the margin a seal with the National Emblem, which says: United Mexican States.- Ministry of the Economy.- Ministry of Health.**

BRUNO FERRARI GARCIA DE ALBA, Secretary of the Economy and JOSE ANGEL CORDOVA VILLALOBOS, Health Secretary, based on the articles 34 Sections I, II and XXXI and 39 Sections VII, XXI and XXIV of the Natural Law of the Federal Public Administration; 4 and 69-C of the Federal Law of Administrative Procedures; 4 Section III and 5 Section XIII of the Law of External Commerce; 3 Section XXIV, 13 Subsection A Section II, 17 bis Sections IV and VI, 194, 194 bis, 204 and 376 of the General Health Law; 161 bis of the Regulation of Health Products; 5 Section XVI of the Internal Regulation of the Secretary of the Economy and 7 Section XVI of the Internal Regulation of the Health Secretary, and

### **CONSIDERING**

That in agreement with articles 4 Section III and 5 Section XIII of the Law of External Commerce it is the responsibility of the Ministry of the Economy to establish and modify measures to regulate or restrict exportation and importation, of merchandise through the agreements issued by this Department, or in its case, together with the competent authorities, and to publish those measures in the Official Journal of the Federation;

That in agreement with article 17 bis of the General Health Law, the powers of health regulation, control and promotion correspond to the office of the Ministry of Health, in agreement with the General Health Law, the Natural Law of the Federal Public Administration and other applicable ordinances, among these responsibilities to evaluate, issue or revoke the sanitary registration of health supplies, which are exercised by the Federal Commission for Protection against Sanitary Risks;



That in the terms put forth by articles 204 and 376 of the General Health Law, medications and other health supplies, require for their sale or administration, to be in possession of the corresponding sanitary authorization, in the form of the sanitary registration;

That it is essential that the Mexican people have access to the medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical and healing materials, hygiene products and other devices for medical use (Medical Devices), with the latest technological advances in the world, in the most expedited form possible;

That a considerable part of the Medical Devices being commercialized in Mexico have previously obtained their registration in the United States of America and in Canada;

That article 161 bis of the Regulation of Health Products establishes that the Ministry of Health may issue provisions of a general character with the object of recognizing that the requirements, tests, evaluation procedures and other requirements requested by foreign health authorities in order to permit in their respective countries the sale, distribution and use of the Products referred to in the Regulation of Health Products, are equivalent to those of the General Health Law, the Regulation of Health Products and other applicable provisions to guarantee the quality, security and efficacy that those products should satisfy in order to obtain their sanitary registration in the country;

That the application of the mechanism of equivalency recognition provided in article 161 bis of the Regulation of Health Products, permits the more expedited entry into the Mexican market of the products previously mentioned, maintaining the same level of quality, security and efficacy that is granted to users by the evaluation conducted by the Federal Commission for Protection against Sanitary Risks, of the requirements to obtain the sanitary registration of those products, contained in the General Health Law, of the Regulation of Health Products and other applicable legal dispositions;

That the article 69-C of the Federal Law of Administrative Procedures establishes that the holders of offices of the Federal Public Administration can, through general agreements published in the Official Journal of the Federation, establish response times of less than the maximum provided in laws and regulations and cannot demand the presentation of information and documents provided in respective dispositions, when they can obtain said information through another corresponding method;

That on the 3<sup>rd</sup> day of September of 2010 in the Official Journal of the Federation establishing general provisions were provided that should be satisfied in order for the Ministry of Health to issue the administrative agreements through which would be recognized the requirements, tests, evaluation processes and other requirements requested by foreign health authorities, in order to permit in their respective countries the sale, distribution and use of the health products, referred to in article 194 bis of the General Health Law, as equivalent to those required by the General Health Law, the Regulation of Health Products and other technical and legal provisions applicable to the subject, in order to guarantee the quality, security and efficacy that should be satisfied by those products to obtain in our country their health registration, renewal of their registration or any modification to the conditions under which it was registered;

That in the case of Medical Devices that have been approved for sale in the United States of America and Canada by the Food and Drug Administration (henceforth referred to as the FDA, for its initials in English) and by Health Canada (henceforth HC, for its initials in English), respectively, the Mexican health authorities can access relevant information about the security and efficacy of the same through the documentation required of applicants for the health registration who have previously obtained the corresponding authorization in the United States of America and Canada in the terms provided in the present Agreement;



That the Federal Commission for Protection against Sanitary Risks, in the terms of the second numeral of the “Agreement by which are established the general provisions that should be satisfied in order for the Ministry of Health to issue the administrative arrangements through which the requirements, tests, evaluation procedures and other requirements requested by foreign health authorities, to permit in their respective countries the sale, distribution and use of health products referred to in article 194 bis of the General Health Law, are recognized as equivalent to those which are demanded by the General Health Law, the Regulation of Health Products and other legal and technical provisions applicable to the field, in order to guarantee the quality, security and efficacy that those products should satisfy to obtain in our country their health registration, renewal of their registration or any modification to the conditions under which they were registered”, published in the Official Journal of the Federation on the 3<sup>rd</sup> day of September of 2010, has conducted the necessary actions in order to ensure that the requirements and controls established in the regulations and foreign documents cited in the second numeral of the present Agreement, conform adequately with the objectives of the Regulation of Health Products, in such as they are oriented towards the aim that the Medical Devices are produced with quality, and function in conditions of security and efficacy in the terms provided by the article 179 of the Regulation of Health Products; the preceding, for the following reasons:

- I. Medical devices in the United States of America are classified in conformity with Annex I of the present Agreement, and in Canada they are classified in conformity with Annex II of the present Agreement, establishing in both countries, requirements for their commercialization that are stricter for Class I through Class III in the United States of America, and for Class II through Class IV in the case of Canada.
- II. In the United Mexican States Medical Devices of Class I through III are subject to the requirements of articles 179 and 180 of the Regulation of Health Products in order to obtain their health registration.
- III. Medical devices which are Class I in the United States of America are subject to the following general controls that guarantee their quality, security and efficacy in a manner that is measurable for the Mexican health authorities:
  - i) Establishment Registration, and
  - ii) Quality System Requirements for manufacturers of medical devices.
- IV. Medical devices which are Class II in the United States of America are subject to the following general controls that guarantee their quality, security and efficacy in a manner that is measurable for the Mexican health authorities:
  - i) Establishment Registration, and
  - ii) Quality System Requirements for manufacturers of medical devices.
  - iii) 510(k) premarket notification with information permitting the determination that the design, material, chemical composition, energy source, manufacturing process or intended use of the respective medical device, is substantially equivalent to that of the medical device now found in the United States market and that it was subject to Premarket Approval.
  - iv) Reference to the performance standards issued by the Department of Health and Human Services in accordance with the Federal Food, Drug and Cosmetic Act for each type of medical device, and to any voluntary standard which may be applicable, and information that is adequate to demonstrate that the



device conforms completely with these standards or information to justify the deviation from these standards, and

- v) Requirements for guides issued by the FDA specifically for each type of medical device.

V. Medical devices which are Class III in the United States of America are subject to the following general controls that guarantee their quality, security and efficacy in a manner that is measurable for the Mexican health authorities, as well as the requirements and controls for the Premarket Approval:

- i) Establishment Registration.

- ii) Quality System Requirements for manufacturers of medical devices.

- iii) Premarket Approval, including the following requirements and controls:

- a) Reports of all the information respecting the investigations that have been carried out to demonstrate that the device is secure and effective, including laboratory pre-clinical studies and clinical studies practiced on humans, with conclusions;
- b) Detailed description of the components, ingredients, properties, indications for use and operating principles of the device;
- c) Description of the methods, installations and controls used in the manufacturing, processing, packaging and installation of the device;
- d) Description of the practices and alternative procedures for treating the sickness or condition which the device deals with;
- e) Reference to some performance standard issued by the Department of Health and Human Services in accordance with the Federal Food, Drug and Cosmetic Act and with any voluntary standard which is applicable, and information that is adequate to demonstrate that the device conforms completely with these standards or information to justify the deviation from these standards;
- f) Samples of the device and of its components, and
- g) Any other information relevant to the application which the Department of Health and Human Services considers appropriate;

- iv) Post commercialization vigilance, and

- v) Requirements for guides issued by the FDA specifically for each type of medical device.

VI. Medical devices which are Class II in Canada are subject to the following controls that guarantee their quality, security and efficacy in a manner that is measurable for the Mexican health authorities:

- i) Manufacturer registration.

- ii) Description of the conditions, purposes and medical uses for which the device is manufactured.



- iii) List of standards to satisfy the requirements for safety and efficacy of the medical device that are complied with in its manufacturing, and
- iv) International standards of the quality system in the manufacturing of the medical device contained in the standard ISO 13485 issued by the International Standardization Organization (ISO), and incorporated in the standard CAN/CSA-ISO 13485:03, Medical Devices – Quality Management Systems – Requirements for Regulatory Objectives, and made obligatory by reference in the Medical Devices Regulations.

VII. Medical devices which are Class III in Canada are subject to the following controls that guarantee their quality, security and efficacy in a manner that is measurable for the Mexican health authorities:

- i) Manufacturer registration.
- ii) Description of the device and the materials used in its manufacturing.
- iii) Description of the functions of the device that permit it to be used for the conditions, purposes and medical uses for which it is manufactured.
- iv) List of standards to satisfy the requirements of safety and efficacy of the medical device that are complied with in its design and fabrication.
- v) Overview of all the investigations that have been completed to demonstrate that the device is safe and efficient, with conclusions.
- vi) Bibliography of all investigations of the use, safety and efficacy of the device, and
- vii) International standards of the quality system in the design and manufacturing of the medical device contained in the standard ISO 13485 issued by the International Standardization Organization (ISO), and incorporated in the standard CAN/CSA-ISO 13485:03, Medical Devices – Quality Management Systems – Requirements for Regulatory Objectives, and made obligatory by reference in the Medical Devices Regulations.

VIII. Medical devices which are Class IV in Canada are subject to the following controls that guarantee their quality, security and efficacy in a manner that is measurable for the Mexican health authorities:

- i) Manufacturer registration.
- ii) Description of the device and the materials used in its fabrication.
- iii) Description of the functions of the device which permit it to be used for the conditions, purposes and medical used for which it is manufactured.
- iv) Evaluation of the risks with analysis and evaluation of the risks and measurements for the reduction of risks adopted to satisfy the requirements of safety and efficacy.
- v) Quality Plan that specifies quality practices, resources and sequence of relevant activities for the device.
- vi) Specifications of the materials used in the manufacturing and packaging of the device.
- vii) Manufacturing process of the device.



- viii) List of standards to satisfy the requirements of safety and efficacy of the medical device which are complied with in their design and manufacturing;
- ix) Detailed information of all the investigations in which the manufacturer aids itself to ensure that the device complies with the requirements of safety and efficacy, including preclinical and clinical studies, process validation studies, written reports and, if applicable, software validation studies;
- x) Overview of all the investigations that have been completed to demonstrate that the device is safe and efficient, with conclusions;
- xi) Bibliography of all investigations of the use, safety and efficacy of the device, and
- xii) International standards of the quality system in the design and manufacturing of the medical device contained in the standard ISO 13485 issued by the International Standardization Organization (ISO), and incorporated in the standard CAN/CSA-ISO 13485:03, Medical Devices – Quality Management Systems – Requirements for Regulatory Objectives, and made obligatory by reference in the Medical Devices Regulations.

That the Federal Commission for Protection against Sanitary Risks, in the terms of the second numeral “Agreement by which are established the general provisions that should be satisfied in order for the Ministry of Health to issue the administrative arrangements through which the requirements, tests, evaluation procedures and other requirements requested by foreign health authorities, to permit in their respective countries the sale, distribution and use of health products referred to in article 194 bis of the General Health Law, are recognized as equivalent to those which are demanded by the General Health Law, the Regulation of Health Products and other legal and technical provisions applicable to the field, in order to guarantee the quality, security and efficacy that those products should satisfy to obtain in our country their health registration, renewal of their registration or any modification to the conditions under which they were registered”, published on the 3<sup>rd</sup> day of September of 2010, has performed the necessary actions to ensure that the procedures of technical and scientific evaluation conducted by foreign health authorities, in conformance with the regulations and documents cited in the second numeral of the present instrument and with its results consistent in the establishment registration, the 510(k) clearance and the marketing approval granted by the FDA of the United States of America, which are evidenced by the certificate to foreign government, as well as the medical device establishment license and the medical device license issued by HC of Canada, offer a degree of compliance with the objectives of quality, safety and efficacy of the Medical Devices contained in the General Health Law and the Regulation of Health Products, equivalent to the procedures of technical evaluation conducted by the Federal Commission for Protection against Sanitary Risks to grant the health registration of a Medical Device in conformity with the Regulation of Health Products, for the following reasons:

- I. The FDA of the United States of America verifies the compliance of medical devices Classes I, II and III, with the requirements and controls of the regulations and documents mentioned in the second numeral of the present Agreement, through the following actions:
  - i) Manufacturers of medical devices are inspected regularly (in periods of 2 to 4 years) by the FDA to verify the following points:
    - a) Quality System Management/Good Manufacturing Practices;
    - b) Commercialized device tracking;
    - c) Corrections and withdrawals from the market;



- d) Surveillance of establishment registration;
  - e) Good laboratory practices for pre-clinical laboratory studies;
  - f) Reporting conformance to the authority of adverse events and device dysfunctions;
  - g) Company flow-chart, including key position descriptions and capabilities of who occupies them;
  - h) Operating Procedures;
  - i) Degree of automation;
  - j) Calibration Procedures;
  - k) Production and Control Documents, and
  - l) Analytical capacity;
- ii) Manufacturers and commercializers of medical devices, as well as clinics and doctors must report adverse events and medical device dysfunctions (*medical device reports*) to the FDA;
  - iii) Manufacturers and commercializers of medical devices should notify the FDA about corrections and withdrawals from the market which have taken place for the medical devices, and
  - iv) The FDA maintains an obligatory registration of medical device withdrawals from the market;
- II. The FDA of the United States of America verifies the compliance of medical devices Class II with the requirements and controls of regulations and documents mentioned in the second numeral of the present Agreement, through the actions mentioned in section I above, and through post-marketing surveillance;
- III. The FDA of the United States of America verifies the compliance of medical devices Class III with the requirements and controls of regulations and documents mentioned in the second numeral of the present Agreement, through the actions mentioned in sections I and II above, as well as the following:
- i) Partial revision of some of the 17 specialized Panels of the Medical Devices Advisory Committee that are listed in Annex III, of the applications for Premarket Approval mentioned in Paragraph 11, Section V of the attached of the Considerings of the present Agreement, including the results of laboratory pre-clinical studies and of clinical studies practiced on humans, and
  - ii) Medical device sample tests conducts by some of the 17 specialized panels of the Medical Devices Advisory Committee that are listed in Annex III;
- IV. HC verifies the compliance of medical devices Classes II, III and IV with the requirements and controls of the regulations mentioned in the second numeral of the present Agreement, through the following actions:
- iii) Certificates of compliance to the standard CAN/CSA-ISO 13485:03, Medical Devices – Quality Management Systems-Requirements for Regulatory Objectives, issued by third parties authorized by HC;
  - iv) Granting of authorization to validly issue certificates in conformance to the standard mentioned in paragraph (i) preceding, to the certified auditors



(registrars) in accordance with the standard ISO 17021 Conformance Evaluation – Requirements for providers of auditing services and management systems certification, and

- v) Periodic inspections to the third parties by HC to issue certificates of compliance in accordance with the standard mentioned in paragraph (i) preceding; and

That the analysis of technical equivalency contained in the preceding paragraphs, as well as the powers of the health authorities in our country to revoke at any moment the sanitary registration of health products, as well as to decree the safety measurements that may be a health risk, justify the recognition of technical equivalence referred to in the second numeral of the present Agreement, we have been pleased to issue and order the publication in the Official Journal of the Federation the following:

## AGREEMENT

**FIRST.** For purposes of the current Agreement the following terms will be understood as:

**General Terms Agreement:** Agreement establishing the general provisions that must be met for the Ministry of Health to issue the administrative arrangements through which it is recognized that the requirements, tests, evaluation procedures and other documents requested by foreign health authorities, to allow in their respective countries the sale, distribution and use of health products referred to the Article 194 Bis of the General Health Law, are equivalent to those required by the General Health Law, the Regulation of Health Products and other legal and technical provisions that are applicable in the field, to ensure the quality, safety and efficacy that should be satisfied for such products to obtain their registration in our country, the extension of the registration or any amendment to the conditions under which they were registered, published in the Official Journal of the Federation on September 3, 2010.

**Procedures Agreement:** Agreement by which procedures and services are provided, such as the formats used by the Ministry of Health, through the Federal Commission for the Protection against Sanitary Risks, registered by the Federal Regulatory Commission in the Federal Procedures and Services Record, published in the Official Journal of the Federation on June 19, 2009.

**COFEPRIS:** Federal Commission for the Protection against Sanitary Risks

**Medical Devices:** Medical equipment, prosthetics, orthotics, functional aids, diagnostic agents, dental supplies, surgical and healing materials, hygiene products and other medical devices, referred to in Chapter IX of the Second Title of the Regulation of Health Products.

**FDA:** The United States government agency called the Food and Drug Administration.

**HC:** The Canadian Government Entity called Health Canada

**Law:** General Health Law

**PROFECO:** Federal Consumer Protection

**Regulation:** Regulation of Health Products



**SECOND.** The requirements established in Articles 179 and 180 of the Regulation and procedures for technical evaluation made by COFEPRIS are recognized as equivalent for granting health registration of medical devices classified as Class I, II and III according to the criteria established in Article 83 of the Regulation:

(i) For the requirements established by the 510(k) and 514 sections of the United States of America Federal Food, Drug and Cosmetic Act, and by the Title 21, Chapter I, Subchapter H of the Code of Federal Regulations, as established by the United States Federal Food and Drugs Act, and the Canadian Medical Devices Regulations, to allow the marketing of Medical Devices in its territory; and

(ii) Tests and inspections performed by the FDA in United States, and by HC in Canada, to allow the commercialization of Medical Devices in its territory.

Regardless of the classification of medical devices in accordance with the regulations and documents referred to in this paragraph, COFEPRIS will classify Medical Devices according to the criteria established in Article 83 of the Regulation.

**THIRD.** COFEPRIS will require applicants for registration of medical devices, that opt to submit the request according to the terms of this Agreement and that have the establishment registration or marketing approval [510(k) clearance] or premarket approval granted by the United States FDA, or the medical device license issued by the Canadian HC, the following information and documentation:

- I. In accordance with article 153 of the Regulation, the health registration will be requested on the official forms, according to the Procedures Agreement, accompanied by proof of payment of duties, the documents mentioned in articles 179, Sections II, II, and 180 Subsection II and IV of the Regulation, a copy of the establishment license, a copy of the license of the health official and of the cover page in accordance with the second paragraph of Article 153 of the Regulation, issued by the manufacturer and duly signed by the person responsible for quality assurance of the medical device, with the following information:
  - (i) Commercial Name;
  - (ii) Generic Name (if applicable);
  - (iii) Medical Device description and intended use;
  - (iv) Description or diagram of the structure, parts, materials, and functions (if applicable) or the quali-quantitative formula indicating the function of ingredients in the medical device (if applicable).
  - (v) Finished product specifications;
  - (vi) Overview of the manufacturing process or flow diagram of the manufacturing process;
  - (vii) Method of sterilization used (if applicable);



- (viii) Overview of atoxicity and biocompatibility tests (if applicable).
  - (ix) Expiration date and an overview of stability studies supporting it (if applicable);
  - (x) Characteristics of the primary and secondary packages;
  - (xi) Presentations, codes or models. An overview of laboratory pre-clinical studies and of clinical studies tested in humans with the conclusions (if applicable).
  - (xii) Bibliographic references, if they exist.
- II.** For the registration of medical devices categorized as Class I in the classification of the United States, in addition to the documents indicated in Section I, the following documentation that proves that the marketing of these Medical Devices is allowed in the United States of America should be delivered to COFEPRIS:
- (i) Original or certified copy of the certificate to foreign government issued by the FDA, translated into Spanish in accordance with the terms of article 153 of the Regulation;
  - (ii) The most recent establishment inspection report which has been performed for the medical device manufacturer, translated into Spanish in accordance with the terms of article 153 of the Regulation;
  - (iii) A copy of the document issued by the FDA approving the medical device, which mentions the classification of the same, translated into Spanish in accordance with the terms of article 153 of the Regulation;
- III.** For the registration of medical devices Class II and III in the United States, in addition to the documents mentioned in Section I, the following information proving that the marketing of these medical devices is allowed in the United States of America should be delivered to COFEPRIS:
- (i) Original or certified copy of the certificate to foreign government issued by the FDA, translated into Spanish in accordance with the terms of article 153 of the Regulation;
  - (ii) The most recent establishment inspection report which has been performed for the medical device manufacturer, translated into Spanish in accordance with the terms of article 153 of the Regulation;
  - (iii) Overview or record of the most recent techno-vigilance report or post-marketing surveillance of the product, translated into Spanish in accordance with the terms of article 153 of the Regulation;
  - (iv) A copy of the document issued by the FDA approving the medical device, which mentions the classification of the same, translated into Spanish in accordance with the terms of article 153 of the Regulation;
- IV.** Medical Devices that are Class I in Canada are excluded from this Agreement.
- V.** For the registration of medical devices categorized in Class II, III and IV of the Canadian classification system, in addition to the documents mentioned previously in Section I, the following information proving that the commercialization of these medical devices is permitted in Canada should be presented to COFEPRIS:



- (i) A certified copy of the current medical device license issued by HC to the manufacturer, translated into Spanish in accordance with the terms of article 153 of the Regulation;
- (ii) A simple copy of the current certificate according to the official standard CAN/CSA-ISO 13485:03, Medical Devices –Quality Management Systems- Requirements for Regulatory Objectives, translated into Spanish in accordance with the terms of article 153 of the Regulation;
- (iii) A simple copy of the current Certificate of compliance to the standard ISO 17021 Conformity Evaluation - Requirements for audatory and management systems certification service providers - from the registrar that provided the certificate referred to previously in subsection (ii), translated into Spanish in accordance with the terms of article 153 of the Regulation;
- (iv) Certified copy of the current authorization issued by HC to the third party (registrar) that issued the certificate referred to in subsection (ii), translated into Spanish in accordance with the terms of article 153 of the Regulation;

**FOURTH.** Except in the cases mentioned in the following paragraph, COFEPRIS will not require any additional documentation besides that mentioned in the previous article, in order to process the registration application that is submitted on the basis of this Agreement, regardless of the Medical Device country of origin, for whose health registration is being applied.

In the case of those medical devices that use radiation sources, the applicant shall submit a copy of the corresponding license issued by the Department of Energy (National Nuclear Safety and Safeguards), and in the case of diagnostic agents where COFEPRIS considers it necessary to prove its efficacy in the population that is being applied for, for genetic issues or other population characteristics, as well as in the case of condoms because it is a public health issue, a certificate of analysis performed by an authorized third party or an auxiliary control laboratory to the Ministry of Health regulations may be required, in addition to the documentation that is applicable based on the Third Article of this Agreement.

**FIFTH.** Applications for modifications to the registration conditions and for extension of the Medical Device Registration that were granted based on this Agreement, must present the documents established in the applicable legal provisions.

**SIXTH.** COFEPRIS should resolve sanitary registrations requests, and the modifications and extensions of the registration when the registration has been granted in accordance with the present agreement, within 30 working days starting the day following that in which the applicable documents, in conformance with the Third Article of this Agreement, were submitted. In the case that the submitted documents are not complete, COFEPRIS will notify the applicant within a time period equal to a third part of the time period granted to resolve the application, when the problem is of an administrative nature, and two thirds if of a technical nature, based on the terms of the article 156 of the Regulation.

In the case that COFEPRIS does not resolve the applications for Class I medical devices based on this agreement within the 30 days time period, the request will be considered as accepted.



**SEVENTH.** The timeframe discussed in the first paragraph of the sixth numeral of this agreement will be suspended when the Ministry of Health requires of the applicant, either verbally or in written form, documents, clarifications or missing information, and will be reinstated the day following that in which the applicant submitted the information, documents or makes pertinent clarifications. If the documents, clarifications or missing information are not provided on time, the request will be considered as unanswered.

In any case, any applicant for the registration in possession of the registrations, permits, approvals or licences mentioned in the third numeral of this Agreement, may opt to be subjected to the normal procedure described in the articles 179 and 180 of the Regulation.

**EIGHTH.** The current agreement does not exempt importers, distributors and dealers of products that receive a medical device sanitary registration based on the present agreement, from the requirements for conformance described in article 131 of the Regulation or any other necessary requirement or specification to maintain the health registration, according to the applicable legal dispositions, as well as any other additional requirement that they are obligated to comply with in order to commercialize the Medical Device in the Mexican territory in conformity with any law, regulation or other applicable dispositions.

**NINTH.** COFEPRIS may revoke or cancel medical device health registrations according to the present agreement, in accordance to the articles 376 and 380 of the Law and other applicable dispositions.

COFEPRIS, PROFECO or any other authority, will have the faculty to retain or keep all those products that are registered based on this agreement as well as suspend their commercialization and order their recall based on the articles 404 Section X and 414, established by the General Health Law, 25 bis of the Federal Consumer Protection Law and the other applicable dispositions.

The holders of health registrations, as well as importers and dealers of medical devices registered based on the current agreement, must report to COFEPRIS and PROVECO and any other competent authorities regarding the revocation, cancelation or suspension of the establishment registration, the 510(k) clearance or the pre-market approval, or of the Health Canada medical device license, of that information which they have or should have, in which regard they should conform based on article 38 of the Regulation.

The granting of the sanitary registration based on the present agreement will not be an obstacle to the ability of COFEPRIS to exercise its powers related to sanitary vigilance and sanitary control, based on the applicable legal dispositions.

**TENTH.** No disposition of the present agreement may be interpreted in a form that restricts the entry of products that obtain the COFEPRIS sanitary registration based on this Agreement, for the sole reason of having obtained their registration through the recognition of established technical equivalency. Both the ingress and during transportation and commercialization in the national territory those medical devices registered under this Agreement must be treated equally, as for products registered through the normal procedure with COFEPRIS.

## TEMPORARY CLAUSES



**FIRST.** - This agreement shall become active 30 natural days from the date of its publication in the Official Journal of the Federation.

**SECOND** .- Applications for sanitary registration, renewals or modifications of any kind to the established conditions in which the medical devices are registered, covered by this Agreement, will be requested on official forms in accordance with the provisions of the Procedures Agreement, and be accompanied by the proof of payment of duties.

**THIRD** .- Applications for health registrations, renewals or any modifications to the established conditions in which the medical devices are registered that have been submitted to the COFEPRIS prior to the activation of the present Agreement, will be submitted to the prescribed ordinary procedure of the Regulation.

**FOURTH** .- In order to avoid duplication of registrations, COFEPRIS will not receive sanitary registration applications concerning medical devices covered by this Agreement that have previously presented sanitary registration applications of the same medical device.

**FIFTH** .- Only all those Medical Devices described in the applicable legal provisions of the United States of Mexico, as stipulated in this Agreement, will be applicable to it.

Dated the City of Mexico, October 20, 2010 .- The Minister of Economy, **Bruno Ferrari García de Alba**.- Signature.

Dated the City of Mexico, October 6, 2010 .- The Secretary of Health **José Angel Córdoba Villalobos**.- Signature.



<b>ANNEX I</b> <b>Medical Device Classification of the United States of America</b> <b>In accordance with Federal Food, Drug, and Cosmetic Act of the United States of America</b>		
<b>Class I</b>	<b>Class II</b>	<b>Class III</b>
<ul style="list-style-type: none"> <li>• Authorized in the following sections 501, 502, 510, 516, 518, 519 y 520.</li> <li>• Subject to general controls when (i) They are sufficient to provide reasonable assurance device safety and effectiveness, (ii) or there is insufficient information to determine that special controls are needed.</li> </ul> <p>The device is not (i) indispensable (life-sustaining or (ii) necessary for life-supporting or (iii) the intended use is not vital for the prevention of the potential loss of human health and does not represent a potential risk of disease or illness.</p>	<ul style="list-style-type: none"> <li>• Is subject to special controls, because general controls (i) are not sufficient to provide reasonable assurance for safety and effectiveness of the device or (ii) there is enough information to determine that special controls are necessary.</li> <li>• Special controls include the introduction of performance standards, post-marketing vigilance and patent registration.</li> <li>• The device seems to be (i) indispensable (life-sustaining) or (ii) necessary for life-supporting.</li> </ul> <p>The commissioner is the individual who examines and identifies the special controls, and describes how they ensure safety and effectiveness.</p>	<ul style="list-style-type: none"> <li>• Pre market approval is required in accordance with section 515 FD&amp;C</li> <li>• There is insufficient information to determine (i) General controls or (ii) That special controls are sufficient to provide reasonable assurance of safety and efficiency</li> </ul> <p>In addition, the device is (i) indispensable (life-sustaining) or (ii) necessary for life-supporting or (iii) the intended use is vital for the prevention of the potential loss of human health and it does not represent a potential risk of disease or illness.</p>



**ANNEX II**

**Medical Device Classification of Canada**

**In accordance with Medical Device Regulations of Canada**

<b>Rule</b>	<b>Class II</b>	<b>Class III</b>	<b>Class IV</b>
<b>Invasive Device 1</b>	(1) Subject to sub-rules (2) and (3), all surgically invasive device	(2) A surgically invasive device that is designed to be absorbed by the body or to remain in the body for at least 30 consecutive days	(3) A surgically invasive device that is designed to diagnose, monitor, control or correct a defect in the central cardiovascular system or central nervous system or in a fetus or a uterus.
<b>Invasive Device 2</b>	(1) Subject to sub-rules (2) and (4), all surgically invasive devices that enter in the body through a bodily orifice or come into contact with the eye surface.	(3) A device described in sub-rule, (1) that is typically designed to remain within the body or in contact with the eye's surface for at least 30 consecutive days.	(4) A device described in sub-rule (1) which is designed to prevent transmission of infectious agents during sexual activity or to reduce the risk .
<b>Invasive Device 3</b>	Despite rules 1 and 2 (a) all dental materials, dental applications and accessories, and (c) all latex condoms		
<b>Non invasive Device 4</b>	Subject to sub-rules (2), all non invasive devices designed to enter in contact with injured skin.  14.		
<b>Non invasive Device 5</b>	A non-invasive device designed to transfer or store gases, liquids, tissues or bodily fluids, whose purpose is their introduction into		



	the body through infusion or other administrative methods		
<b>Non invasive Device 6</b>	(3) A device described in sub-rule (1) that is modified through centrifugation, gravity filtration, gas or heat exchange process	(1) Subject to sub-rule (2) and (3), Non invasive device designed for the modification of the chemical or biological composition of the blood or other body fluids, or liquids with the aim of introducing them into to the body through infusion or other administrative methods.	(2) A device described in sub-rule (1) whose characteristics are such that the modification process may introduce a foreign substance to the body that is or may be potentially dangerous, considering the nature and amount of substance.
<b>Non invasive Device 7</b>	A device described in sub-rule (a) if its designed to function as a calibrator, tester, or as an aid for quality control connected to an active device that is classified as Class II, III, or IV.		
<b>Active Device 8</b>	(2) A device described in sub-rule (1) that is designed for use in radiography	(1) ) Subject to sub-rule (2) and (3), An active device that is designed to emit ion radiation, including any device or software designed to control or monitor the device or directly influence its performance.  (3) Despite sub-rule (2), an active device that is designed to perform mammograms	
<b>Active Device 9</b>	(1) Subject to sub-rule (2) and (3), an active therapeutic device including any sensitive software designed to be used to administer or withdraw energy into or out the body.	(2) If the administration or withdrawal of energy through a device described in sub rule (1) is potentially dangerous, considering the nature of the administration or withdrawal, the intensity of energy and the body part in question.	(3) A device described in sub-rule (2) which is designed to control the treatment of a patient's condition through a closed system



	14.		
<b>Active Device 10</b>	(1) Subject to sub-rule (2) an active diagnostic device, including any software, which provides electricity for the purpose of imaging or monitoring physiological processes.	(2) A device described in sub-rule (1) that is designed to monitor, assess or diagnose a disease, a disorder, an abnormal physical state or pregnancy, if erroneous readings could result in immediate harm.	
<b>Active Device 11</b>	(1) Subject to sub-rule (2) and (3), an active device including any software, designed for the administration of medications, body fluids or other substances into the body, or to take them out of it.	(2) If the administration or withdrawal of a substance through a device described in sub-rule (1) is potentially hazardous, taking into consideration the nature of the substance administered and the body part in question.	(3) A device described in sub-rule (2) which is designed to control treatment of a patient's condition through a closed system
<b>Active Device 12</b>	Not Applicable	Not Applicable	Not Applicable
<b>Special Rules 13</b>	(b) Medical device for sterilization or disinfection.		A medical device that is designed to be used in: a) disinfecting or sterilizing blood, tissues or organs that are intended for transfusion and transplantation.
<b>Special Rules 14</b>			(1) Subject to sub-rule (2),  (a) A device that is manufactured or that incorporates human or animal cells, tissues or their derivatives.  (b) A device that is manufactured or incorporates a product produced through the use of recombinant DNA technology



<b>Special Rules 15</b>	Any device that is expected to be sold to a health professional or dealer for the purpose of setting or fixing a mold to meet the needs of an individual is classified in the class applied to the finished device	Any device that is expected to be sold to a health professional or dealer for the purpose of setting or fixing a mold to meet the needs of an individual is classified in the class applied to the finished device	Any device that is expected to be sold to a health professional or dealer for the purpose of setting or fixing a mold to meet the needs of an individual is classified in the class applied to the finished device
<b>Reglas especiales 16</b>			Breast implants and tissue expanders for breast reconstruction or breast augmentation



<b>ANNEX III</b>	
<b>Specialized review panels of the Food and Drug Administration</b>	
<b>Number</b>	<b>Panel Name</b>
1	Panel of Anaesthesiology and respiratory therapy Devices
2	Panel of Circulatory System Devices
3	Panel of Chemical and toxicology Clinical Devices
4	Panel of Dental Products
5	Panel of Otolaryngology Devices
6	Panel of Urology and Gastroenterology Devices
7	Panel of Plastic and General Surgery Devices.
8	Panel of Personal use and Internal medicine Devices.
9	Panel of Pathology and Haematology Devices.
10	Panel of Immunology Devices
11	Panel of Microbiology Devices.
12	Panel of Molecular genetics and clinical Devices.
13	Panel of Neurology Devices
14	Panel of Obstetric and Gynaecology Devices
15	Panel of Ophthalmology Device.
16	Panel of Orthopaedic and rehabilitation Device.
17	Panel of Radiology Devices