MINISTRY OF HEALTH

AGREEMENT by which the requirements laid out in article 179 and 180 of the Regulation on Health Supplies and technical evaluation procedures carried out by the Federal Commission for the Protection against Sanitary Risks for the placement of products within the sanitary registry for health supplies, as specified in chapter IX of the second Regulation on Health Supplies, are recognized as equivalent to the requirements established by the Japanese Ministry of Health, Labour and Welfare for the authorization of trade in medical devices within national territory; and to tests and inspections carried out by the Japanese Agency on Pharmaceutical Products and Medical Devices, for the authorization of trade in medical devices within the national territory.

In the margin: a seal with the national Coat-of-Arms, with the words: United Mexican States.- Ministry of Health.

SALOMON CHERTORIVSKI WOLDENBERG, Minister of Health, with basis in articles 39, sections VII, XXI and XXIV of the Organic Law of Federal Public Administration; 4 and 69-C of the Federal Law of Administrative Procedures; 3, section XXII, 13, attachment A, section II, 17 b, sections IV and VI, 194, 194 b, 204 and 376 of the General Law on Health; 161 B of the Regulation on Health Supplies and 7 section XVI of the Internal Regulation of the Ministry of Health, and with the following

CONSIDERATIONS

That according to article 17b of the General Law on Health, the attributes of sanitary regulation, control and health promotion corresponding to the Ministry of Health as set out in the General Law on Health, the Organic Law of Federal Public Administration and other applicable ordinances relating to the evaluation, expedition or withdrawal of health supplies from the sanitary registry, are exercised by the Federal Commission for the Protection against Sanitary Risks;

That in terms of that laid out in articles 204 and 876 of the General Law on Health, the administration and sale of pharmaceuticals and other health supplies require the corresponding sanitary authorization, in the form of a sanitary registry;

That it is indispensable that Mexicans have access to medical equipment, prostheses, orthotics, functional aids, diagnostic agents, dental supplies, surgical materials, first aid materials, hygiene products and other devices of medical use (Medical Devices), with the latest worldwide advances in technology, as quickly as possible;

That a considerable quantity of the Medical Devices traded in Mexico was previously registered in Japan;

That article 161 B of the Regulation on Health Supplies states that the Ministry of Health may issue dispositions of a general nature as a means of recognizing that the requirements, tests, evaluation procedures and other such requirements administered by foreign health authorities to allow the sale, distribution and use of Supplies referred to in the Regulation on Health Supplies in their respective countries, are equivalent to those which the General Law on Health, the Regulation on Health Supplies and other applicable dispositions require for the assurance of quality, safety and efficacy with which said supplies must comply to obtain a sanitary registry in that country;

That the application of a mechanism to recognize equivalencies as set out in article 161 B of the Regulation on Health Supplies, allows the expedition of the aforementioned supplies' entry into the Mexican market, maintaining the same standards of quality, safety and efficacy granted to users by the evaluations of the Federal Commission for the Protection against Sanitary Risks, the requirements for the inclusion of these health supplies in the sanitary registry, contained in the General Law on Health, the Regulation on Health Supplies and other legal dispositions as applicable;

That article 69-C of the Federal Law on Administrative Procedures establishes that the heads of the dependencies of the Federal Public Administration may, via general agreements published in the Official Bulletin of the Federation, establish minimum response times within the maximums set out in laws or regulations and not insist on the submission of data and documentation as stated in the respective dispositions, when the necessary information can be obtained from other sources;

That on September 3, 2010, the "Agreement for the establishment of general dispositions to be fulfilled for the Ministry of Health to issue the administrative agreements by which are recognized the requirements, tests, evaluation procedures and other requirements as required by foreign sanitary authorities for the authorization of the sale, distribution and use in their own countries of health products referred to in article 194 B of the General Law on Health, are equivalent to those required under the General Law on Health, the Regulation on Health Supplies and other applicable legal and technical dispositions, to assure the quality, safety and efficacy with which said supplies must comply in this country to obtain a place in the sanitary registry, the renewal of their registry or any change in the conditions under which they were registered";

That in the case of Medical Supplies already approved for sale in Japan by the Japanese Ministry of Health, Labor and Welfare (Hereafter MHLW), Mexican health authorities may have access to the relevant information regarding the safety and efficacy of the same via the documentation required of sanitary registry applicants holding the corresponding authorization in Japan under the terms set out in this Agreement;

That the Federal Commission for the Protection against Sanitary Risks, in terms of the Second numeral of the "Agreement for the establishment of general dispositions to be fulfilled for the Ministry of Health to issue the administrative agreements by which are recognized the requirements, tests, evaluation procedures and other requisites as required by foreign sanitary authorities for the authorization of the sale, distribution and use in their own countries of health products referred to in article 194 B of the General Law on Health, are equivalent to those required under the General Law on Health, the Regulation on Health Supplies and other applicable legal and technical dispositions, to assure the quality, safety and efficacy with which said supplies must comply in this country to obtain a place in the sanitary registry, the renewal of their registry or any change in the conditions under which they were registered," published in the Official Bulletin of the Federation on September 3, 2010, has carried out the necessary actions to assure that the requirements and controls established in the foreign regulations and documents cited in the Second numeral of this Agreement, comply sufficiently with the objectives of the Regulation on Health Supplies, given that they exist to ensure that the Medical Supplies are of good quality and function in conditions of safety and efficacy and under the terms set out by article 179 and 180 of the Regulation on Health Supplies; the aforementioned, for the following reasons:

I. Medical devices in Japan are classified into classes I to IV, in the terms set out in the Attachment to the current Agreement. The requirements for authorization of trade in these products in Japan increase progressively in vigor from class I to class IV.

II. In the United Mexican States Medical the Devices from Class I to Class III are subject to the requirements of articles 179 and 180 of the Regulation of Health Supplies to obtain a sanitary registry.

III. Medical devices in Class II with criteria established by the MHLW, named as "Designated Controlled Medical Devices," are subject to the following general controls established in article 23-2 of the Japanese Law on Pharmaceuticals (1960) as well as the dispositions of the Ordinance of Law on Pharmaceuticals (1961), form 64 of article 115, form 65 of article 118 and form 66 of article 118 of the Regulation of the Law on Pharmaceuticals (1961), the regulations on Good Clinical Practices (2004) and Good Vigilance Practice (2004) and Ordinance 169 on the System of Quality Control (2004), based on ISO 13485:2003, which guarantee the quality, safety and efficacy in a way which is compatible to that of the Mexican sanitary authorities:

(i) Application File

- **a.** Product Category
- **b.** Product Name, generic name
- **c.** Purpose, indications for use
- **d.** Configuration, structure and principles
- **e.** Materials and components with detailed information
- **f.** Design requirements
- **g.** Method of use
- **h.** Method of manufacture

i. Conditions for storage and expiry with detailed information

j. Detailed information on manufacturing premises and quality control system facilities.

k. Comments including the package insert

(ii) Summary Technical Documents (STED)

a. Product summary

i. General product information

ii. Discovery and development history

iii. Situation of use abroad

b. Essential principals for compliance based on the list by the Global Harmonization Taskforce (GHTF)

i. General principals and evidence of compliance

c. Description of the device

i. General Information

ii. Materials

iii. Specifications

iv. Storage methods and expiry date

v. Comparison with similar devices

d. Design verification and summary of validation

i. Declaration of compliance with standards

ii. Safety tests

iii. Physical/chemical properties

iv. Electrical safety and electromagnetic compatibility

v. Biocompatibility

vi. Radiation

vii. Mechanical safety

viii. Stability and durability

ix. Performance tests

x. Efficacy tests

xi. Clinical evidence, where applicable

e. Label and package inserts

f. Risk analysis based on ISO 14971

g. Methods of manufacture and control processes

IV. Class II medical devices without established criteria (hereafter Class II), Class III and Class IV in Japan are subject to the following general controls established in article 14 of the Japanese Law on Pharmaceuticals (1960), as well as in the dispositions of the Ordinance of the Law on Pharmaceuticals (1961), form 22 of article 38, form 23 of article 46, form 24 of article 48, form 53 of article 102 and forms 55 and 56 of article 111 of the Regulation on the Law on Pharmaceuticals (1961), the regulation on Good Clinical Practices (2004) and on Good Vigilance Practices (2004) and Ordinance 169 on the System of Quality Control (2004) based on ISO 13485:2003, which guarantee the quality, safety and efficacy in a way which is compatible to that of the Mexican sanitary authorities mentioned in the previous numeral and presenting in addition the following:

(i) Supporting documentation

a. Experience abroad

b. Essential compliance requirements

c. Stability/durability

d. Information on product specifications and performance

e. Critical risks and dangers analysis system

f. Manufacturing control (processing and facilities), sterilization methods and quality control

g. Clinical information, where applicable

That the Federal Commission for the Protection against Sanitary Risks, in terms of the Second numeral of the "Agreement for the establishment of general dispositions to be fulfilled for the Ministry of Health to issue the administrative agreements by which are recognized the requirements, tests, evaluation procedures and other requisites as required by foreign sanitary authorities for the authorization of the sale, distribution and use in their own countries of health products referred to in article 194 B of the General Law on Health, are equivalent to those required under the General Law on Health, the Regulation on Health Supplies and other applicable legal and technical dispositions, to assure the quality, safety and efficacy with which said supplies must comply in this country to obtain a place in the sanitary registry, the renewal of their registry or any change in the conditions under which they were registered," published in the Official Bulletin of the Federation on September 3, 2010, has carried out the necessary actions to ensure that the technical and scientific evaluation procedures carried out by foreign health authorities, in accordance with the regulations and documents cited in this instrument and their consistent results in the Certification of Designated Controlled Medical Supplies issued by the Registered Certification Organisms, the Approval Letters for Medical Devices classes II, III and IV and Certificates of Free Sale issued by the Japanese Ministry of Health, Labor and Welfare and the Exportation Notification prepared by the industry and sealed by the Japanese Ministry of Health, Labor and Welfare, offer a degree of compliance with the objectives of quality, safety and efficacy contained in the General Law on Health and the Regulation on Health Supplies, equivalent to the technical evaluation procedures carried out by the Federal Commission for the Protection against Sanitary Risks to grant sanitary registry to a Medical Device in accordance with the Regulation on Health Supplies, for the following reasons:

I. The Japanese MHLW and a Registered Certification Organism verifies the compliance of controlled medical devices with the requirements and controls in the regulations and documents mentioned in the Second numeral of this Agreement, via the following actions:

(i) The MHLW establishes the performance criteria for the designation of controlled medical devices.

(ii) The MHLW establishes the review criteria which the Registered Certification Organism must then follow.

(iii) The Registered Certification Organism receives the application and documentation mentioned in numeral III of paragraph 10 of the Considerations, and conducts a review in conformance with review criteria, appropriate risk management, chemical and physical data on biocompatibility, sterilization, labeling, quality control, design, manufacturing and evaluation controls on site.

(iv) In the event that all the established requirements have been met, the Registered Certification Organism will grant the Certification to the applicant.

(v) The Registered Certification Organism will include a routine inspection program to the producing establishment to be certified with the purpose of following up on the certificate granted.

II. The MHLW and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) verifies the compliance of Class II medical devices, except in the case of designated medical devices, classes III and IV with the requirements and controls of the regulations and documents mentioned in the Second numeral of this Agreement, via the following actions:

(i) The applicant holds an interview with the PMDA for the purposes of presenting the product which will be submitted for commercial approval in Japanese territory and answers questions.

(ii) The PMDA assigns a team of application reviewers to the corresponding file.

(iii) A review of scientific information is carried out and the reliability of data presented is evaluated.

(iv) Where no prior data is available on compliance with the Quality Control System of the site in question, PMDA and local governments carry out inspections for the purposes of certifying compliance.

(v) In the event that the PMDA's reviewing team has doubts of a medical and/or technical nature, it will consult with external experts (academics, health professionals, health institutions, etc.).

(vi) The PMDA sends its review judgment to MHLW.

(vii) Where necessary, MHLW will consult with the Japanese Council on Pharmaceutical, Health and Safety Matters.

(viii) The MHLW sends a Letter of Approval or Non-Approval to the applicant.

That the technical equivalency analysis contained in the preceding paragraphs, as well as the power vested in the sanitary authorities of this country to revoke the sanitary registry of health supplies at any time, as well as decree the safety measures applicable to a named health risk, justify the recognition of technical equivalency referred to in the Second numeral of this Agreement,

That class I medical devices in Japan do not require technical evaluation by Japanese authorities, and are therefore not covered by this Agreement, and should be presented for registry in accordance with that established in the relevant, current Mexican regulations, I have seen fit to issue and order the publication in the Official Bulletin of the Federation the following:

AGREEMENT

FIRST. For the purposes of the present Agreement, the following will be defined:

Agreement on General Dispositions: "Agreement for the establishment of general dispositions to be fulfilled for the Ministry of Health to issue the administrative agreements by which are recognized the requirements, tests, evaluation procedures and other requisites as required by foreign sanitary authorities for the authorization of the sale, distribution and use in their own countries of health products referred to in article 194 B of the General Law on Health, are equivalent to those required under the General Law on Health, the Regulation on Health Supplies and other applicable legal and technical dispositions, to assure the quality, safety and efficacy with which said supplies must comply in this country to obtain a place in the sanitary registry, the renewal of their registry or any change in the conditions under which they were registered," published in the Official Bulletin of the Federation on September 3, 2010.

Procedural Agreement: "Agreement by which are made known the procedures and services, as well as the forms applied by the Ministry of Health, via the Federal Commission for the Protection against Sanitary Risks, entered in the Federal Registry of Procedures and Services of the Federal Commission for Regulatory Improvement," published in the Official Bulletin of the Federation on January 28, 2011; as well as the Amendment Agreement to the same, published in the Official Bulletin of the Federation on June 22, 2011.

"COFEPRIS": Federal Commission for the Protection against Sanitary Risks.

Medical Devices: Medical equipment, prostheses, orthotics, functional aids, diagnostic agents, dental supplies, surgical materials, first-aid materials, hygiene products and other devices for medical use, referred to in Chapter IX Second Title of the Regulation on Health Supplies.

Law: General Law on Health.

MHLW: The Japanese government entity named the Ministry of Health, Labor and Welfare.

PMDA: The Japanese government entity named the Pharmaceuticals and Medical Devices Agency.

Regulation: Regulation on Health Supplies.

SECOND. Recognition of equivalency with the requirements established in articles 179 and 180 of the Regulation and the procedures carried out by COFEPRIS for the granting of sanitary registries for Class I, II and III Medical Devices in accordance with criteria established in article 83 of the Regulation is given to:

(i) The requirements established in articles 14 or 23-22 of the Japanese Law on Pharmaceuticals (1960), as well as the dispositions of the Ordinance of Law on Pharmaceuticals (1961), the Regulation of the Law on Pharmaceuticals (1961), the regulation on Good Quality Practices (2004) and on Good Vigilance Practices (2004) and Ordinance 169 on the System of Quality Control (2004), based on ISO 13485:2003; and

(ii) to the tests and inspections carried out by the Japanese MHLW and the PMDA to allow trade in Medical Devices in Japanese territory.

This equivalency applies only to those medical devices classified in Japan as designated controlled; such as those in classes II, III and IV, and not with regard to class I, which will be subject to normal procedures applicable in this country.

Regardless of the classification of medical devices according to the documents mentioned in this numeral, COFEPRIS will classify Medical Devices in accordance with criteria established in article 83 of the Regulation.

THIRD. COFEPRIS will require of applicants for the sanitary registry of Medical Devices who choose to present their application in terms of the current Agreement and who hold a Letter of Approval signed by the MHLW or the Certificate given by the Japanese Registered Certification Organism, the following information and documentation:

I. For controlled medical devices designated in Japan:

(i) The official forms, in accordance with that set out in the Procedural Agreement, accompanied by the proof of payment of corresponding fees.

(ii) Notice of functionality or the most recent modification.

(iii) Certification granted by the Registered Certification Organism, including the sheets specifying the rubric outlined below, translated to Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation:

a. Description.

b. Indications for use.

c. Formula and/or composition, where applicable

d. Stability where applicable

e. Sterile period, where applicable

f. Primary and secondary packaging, where applicable

(iv) Notice of Export translated to Spanish, in terms set out in article 153 of the Regulation, with the following specifications:

a. Description.

b. Indications for use.

c. Presentations with code (catalog number, part number, etc.) including accessories.

d. Formula and/or composition, where applicable

e. Stability where applicable

f. Sterile period, where applicable

g. Primary and secondary packaging, where applicable

(v) Original Certificate of Free Sale with code and no more than one year since issue, translated into Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation.

(vi) Original Letter of representation, where the applicant is a non-affiliate, translated into Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation.

(vii) Label project for trade in Mexico in conformance with the applicable and current legal dispositions.

(viii) Instructions for use for trade in Mexico in conformance with applicable and current legal dispositions.

II. For medical devices Classes II, III and IV in Japan:

(i) The official forms, in accordance with that set out in the Procedural Agreement, accompanied by proof of payment of the corresponding fees

(ii) Notice of functionality or the most recent modification.

(iii) Approval Letter issued by MHLW, including sheets specifying the rubric outlined below, translated to Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation:

a. Description.

b. Indications for use.

c. Formula and/or composition, where applicable

d. Stability where applicable

e. Sterile period where applicable

f. Primary and secondary packaging, where applicable

(iv) Notice of Export translated into Spanish, in terms set out in article 153 of the Regulation, with the following specifications:

a. Description.

b. Indications for use.

c. Presentations with code (catalog number, part number, etc.) including accessories.

d. Formula and/or composition, where applicable.

e. Stability, where applicable.

f. Sterile period, where applicable.

g. Primary and secondary packaging, where applicable.

(v) Original Certificate of Free Sale with code and no more than one year since issue, translated into Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation.

(vi) Original Letter of representation, where the applicant is a non-affiliate, translated into Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation.

(vii) Label project for trade in Mexico in conformance with the applicable and current legal dispositions.

(viii) Instructions for use for trade in Mexico in conformance with applicable and current legal dispositions.

FOURTH. The registries granted under the terms of the present Agreement may be renewed with submission of the following to Mexican sanitary authorities:

I. For controlled medical devices designated in Japan:

(i) The official forms, in accordance with that set out in the Procedural Agreement, accompanied by proof of payment of the corresponding fees.

(ii) Simple copy of the sanitary registration under request for renewal.

(iii) Notice of functionality or the most recent modification.

(iv) Report on Technical Supervision per product in terms of applicable Mexican regulations.

(v) Certification issued by the Registered Certification Organism, including sheets specifying the rubric outlined below, translated into Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation:

a. Description.

b. Indications for use.

c. Formula and/or composition, where applicable

d. Stability where applicable

e. Sterile period, where applicable

f. Primary and secondary packaging, where applicable

(vi) Notice of Export translated into Spanish, in terms outlined in article 153 of the Regulation, with the following specifications:

a. Description.

b. Indications for use.

c. Presentations with code (catalog number, part number, etc.) including accessories.

d. Formula and/or composition, where applicable

e. Stability where applicable

f. Sterile period, where applicable

g. Primary and secondary packaging, where applicable

(vii) Original Certificate of Free Sale with code and no more than one year since issue, translated into Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation.

(vi) Original Letter of representation, where the applicant is a non-affiliate, translated into Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation.

(vii) Label project for trade in Mexico in conformance with the applicable and current legal dispositions.

(viii) Instructions for use for trade in Mexico in conformance with applicable and current legal dispositions.

(xi) Document assigning a legal representative with premises in the United Mexican States.

II. For Medical Devices Class II, III and IV in Japan:

(i) The official forms, in accordance with that set out in the Procedural Agreement, accompanied by proof of payment of the corresponding fees.

(ii) Simple copy of the sanitary registration under request for renewal.

(iii) Notice of functionality or the most recent modification.

(iv) Report on Technical Supervision per product in terms of applicable Mexican regulations.

(v) Letter of Approval issued by MHLW, including sheets specifying the rubric outlined below, translated into Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation:

a. Description.

b. Indications for use.

c. Formula and/or composition, where applicable

d. Stability where applicable

e. Sterile period, where applicable

f. Primary and secondary packaging, where applicable

(vi) Notice of Export translated into Spanish, in terms outlined in article 153 of the Regulation, with the following specifications:

a. Description.

b. Indications for use.

c. Presentations with code (catalog number, part number, etc.) including accessories.

d. Formula and/or composition, where applicable

e. Stability where applicable

f. Sterile period, where applicable

g. Primary and secondary packaging, where applicable.

(vii) Original Certificate of Free Sale with code and no more than one year since issue, translated into Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation.

(viii) Original Letter of representation, where the applicant is a non-affiliate, translated into Spanish by a certified translator and legalized, in terms set out in article 153 of the Regulation.

(ix) Label project for trade in Mexico in conformance with the applicable and current legal dispositions.

(x) Instructions for use for trade in Mexico in conformance with applicable and current legal dispositions.

(xi) Document assigning a legal representative with premises in the United Mexican States.

FIFTH. Applications for renewal should be submitted at least fifty-five calendar days before the expiry of the current registry.

Upon notification of the resolution regarding the application for renewal, the party named in the registry should submit to the notifier the original sanitary authorization and, where applicable, its modifications. Where the original sanitary registry is unavailable, the original report of loss or theft made to the Public Ministry should be submitted.

SIXTH. Registries granted under the auspices of the present Agreement may only be modified concerning changes in the site of production of the domestic or foreign producer in the event of changes between subsidiary companies, affiliates or factories.

SEVENTH. Applications for modifications to the conditions of registry and registry renewal of Medical Devices awarded in accordance with the current Agreement should be presented accompanied by the documents established in applicable legal dispositions.

EIGHTH. Except in the cases listed in the following paragraph, COFEPRIS will not require any further documentation other than that applicable according to the terms of the Third numeral of this Agreement, for the processing of applications for sanitary registry submitted based on this Agreement, regardless of the country of origin of the Medical Device for which the registry is being sought.

In the case of medical devices which use sources of radiation, the applicant should submit a copy of the corresponding license issued by the Ministry of Energy (Nation Commission for Nuclear Safety and Safeguards), and in the case of diagnostic agents which COFEPRIS considers as needing proof of efficacy in the target population, due to questions of genetics or other characteristics of the population, as well as in the case of condoms being a public health issue, a certification of analysis by an authorized third party or auxiliary control laboratory may be required to satisfy the sanitary regulations of the Ministry of health, in addition to the applicable documentation outlined in the Third numeral of this Agreement.

NINTH. COFEPRIS must reach a decision regarding the application for sanitary registry or renewal of sanitary registry of a Medical Device which has been granted under the terms of the current agreement in a period not exceeding 30 business days from that following the date on which the applicant submits the relevant documentation in accordance with the Third numeral of this Agreement.

In cases where the documentation submitted is incomplete, COFEPRIS will advise the applicant within a period not exceeding one third of the time allotted to reach a decision on the application, where the documentation required is of an administrative nature, and two thirds, where the documentation required is of a technical nature, in terms outlined in article 156 of the Regulation.

The make-up period for missing documentation will be established by COFEPRIS in accordance with that set out in article 17-A of the Federal Law on Administrative Procedures.

TENTH. The period specified in the first paragraph of the Ninth numeral of this Agreement will be suspended where the Ministry notifies the applicant, expressly and in writing, documents, clarifications, or missing information and will be reinstated on the business day following the date on which the applicant submits this information, documents or makes the relevant clarifications. Where the applicant fails to provide the requested missing documents, information or clarifications within the allotted time, the application will be taken to be withdrawn.

In any event, the applicant for sanitary registry who provides the registries, permits, approvals or licenses mentioned in the Third numeral of this Agreement, may choose to submit to the ordinary procedure described in articles 179 and 180 of the Regulation.

ELEVENTH. This Agreement does not exempt importers, distributers and traders in products granted a sanitary registry of a Medical Device in accordance with this Agreement from compliance with the requirements established in article 131 of the Regulation of from any other requirement or specification necessary to keep their sanitary registry, in accordance with applicable legal dispositions, nor from any other requirement in addition to the sanitary registry for trade in the Medical Device in Mexican territory in accordance with any other regulation or other applicable disposition.

TWELFTH. COFEPRIS may revoke or cancel the sanitary registry of registered Medical Devices in accordance with the current Agreement, in accordance with articles 376 and 380 of the Law and other applicable legal dispositions.

Furthermore, COFEPRIS, or any other competent authority, will have at all times the power in accordance with its attributes to immobilize or confiscate products registered in accordance with this Agreement, as well as to suspend trade and order their withdrawal in accordance with that established in articles 404 section X and 414 of the General Law on health and other applicable legal dispositions.

Holders of sanitary registries, as well as importers and traders of Medical Devices registered in accordance with this Agreement, must notify COFEPRIS and any other competent authority regarding the revocation, cancelation or suspension of the Letter of Approval issued by MHLW or the Certificate issued by the Registered Certification Organism of which they may be aware; in the same way, they must comply with that established in article 38 of the Regulation.

The grant of a sanitary registry in terms of this Agreement will not represent an obstacle for COFEPRIS to exercise its powers in matters of sanitary vigilance and sanitary control, in accordance with applicable legal dispositions.

THIRTEENTH. No disposition in this Agreement may be interpreted in any way which restricts the entry of products granted a sanitary registry by COFEPRIS in accordance with the current Agreement, for the simple fact of having obtained their registry via recognition of established technical equivalency. Both at the point of entry and during its transport and trade within national territory, Medical Devices registered in accordance with the current Agreement should be afforded the same treatment given to products registered through ordinary COFEPRIS procedures.

PROVISIONAL CLAUSE

FIRST.- The current Agreement will enter into effect 30 calendar days after its publication in the Official Bulletin of the Federation.

SECOND.- Applications for sanitary registry, renewal or any modification to the condition under which Medical Devices are registered with COFEPRIS before the effective date of this Agreement, should be submitted under the ordinary procedure described in the Regulation.

THIRD.- Applications will be submitted using the Open Application Form until the forms and procedures have been added to the "Procedural Agreement."

Issued in Mexico City, on January 13, 2012.- **Salomón Chertorivski Woldenberg**-. Minister of Health,.- Rubric.

ATTACHMENT ONE

Classification of Medical Devices in Japan

Class	Category	Approval or Certification
I	General Medical Devices	Notification to PMDA (Self-declaration)
II	Designated Controlled Medical Devices	Application for Certification made to the Registered Certification Organism
II	Controlled Medical Devices	Approval of application by MDA/MHLW
III	Highly Controlled Medical Devices	Approval of application by MDA/MHLW
IV	Highly Controlled Medical Devices	Approval of application by MDA/MHLW