SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

"Regulatory Status of Premarket Submission and Approval Requirements in Mexico".

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Topics:

1. Strategies taken by the mexican goverment to streamline the process and reduce the regulatory burden.
2. Approval Requirements for the Ordinary Lane and Authorized Third Parties
3. Approval Requirements for the Equivalence Agreement FDA/HC
4. Approval Requirements for the Equivalence Agreement Japan
5. Agreement for Low Risk Medical Devices

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

LEGAL FRAMEWORK

Constitution of the Mexican United States

General Health Law (LGS)

Regulation of Heatlh Products (RIS)

Pharmacopoeia of the Mexican United States (FEUM)

Official Mexican Norms

Agreements

Guidelines

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

STRATEGIES TAKEN BY THE MEXICAN GOVERMENT TO STREAMLINE THE PROCESS AND REDUCE THE REGULATORY BURDEN ON THE APPROVAL OF MEDICAL DEVICES IN MEXICO

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Mexico has a Traditional Line to submit a medical devices dossier with the necessary information to comply with the Mexican Law, however, in the last 4 years strategies were designed to streamline the process and reduce the regulatory burden on the approval of medical devices :

- Equivalence Agreement FDA/HC (30 business days to obtain a Response)
- Equivalence Agreement with Japan (30 business days to obtain a Response)
- Agreement for Low Risk Medical Devices (reduce the regulatory burden for medical devices consider in Mexico to have Low Risk)
- Authorized Third Party (15 business days to obtain a Response, Pre-review)

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

REQUIREMENTS FOR THE APPROVAL OF MEDICAL DEVICES BY THE TRADITIONAL LINE AND AUTHORIZED THIRD PARTIES

SALUD
SECRETARÍA DE SALUD

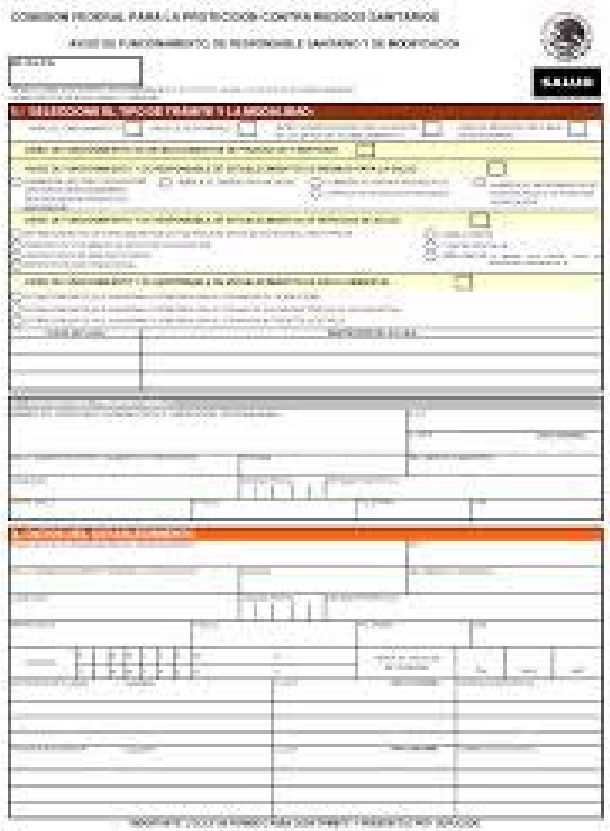
Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

ADMINISTRTIVE REQUIREMENTS:

1. Registration Application Form.

2. Proof of Payment of fees (Class I, II or III, as appropriate)

3. Copy of Notice of Reatil Operation in Mexico and Copy of Notice of Health Responsible.



SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

GENERAL REQUIREMENTS:

- Brand Name
- Generic Name
- Intended of Use.
- Description of the Medical Device.
- Category (art. 262 L.G.S.)
- Class I, II or III (Art. 83 RIS)
- Presentations (including codes and description)
- Project Tag according to the established in the NOM-137-SSA1-2008, “Labeling Medical Devices”

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

SCIENTIFIC AND TECHNICAL INFORMATION

- Insert of Use:

  ✓Description, intended of use, components, storage, warnings contraindications, adeverse events, etc.

- Opetrational Manual

  ✓Description, intended of use, components, operation, calibration, warnings, etc.

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

SCIENTIFIC AND TECHNICAL INFORMATION:

- Technical Drawings or diagram of functional parts
  - The drawing need to contain the material specifications and indicate the parts that come into contact with the patient

- Medical Devices with a Formula:

Quali-quantitative Formula

- Raw Material :

Information of the Active Ingredient that includes the chemical name, generic, physical and chemical structure, especifications, certificate of Analysis for the Raw Materials to demostrate that ensures the safety of the product.

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

SCIENTIFIC AND TECHNICAL INFORMATION:

•Manufacturing Flow Chart

•Certificate of Analysis of the product It's the report with results for a specific batch number(serial number) of the product, this document has to correlate with the Final release specifications and prove the safety and efficacy of the product, the CoA needs to be submitted on letterhead, signed by the person responsible of the quality (in the manufacturing site) and with translation to Spanish.

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

SCIENTIFIC AND TECHNICAL INFORMATION:

- Description of the sterility process
  - Complete Sterelization Process Protocol
  - Complete Protocol Validation for the Sterilization Process.
  - Certificate of Sterilization
- Stability
  - Complete Stability Studies in real time and accelerated, Issued by the manufacturer with wich endorses expiration date.
- Complete reports of biocompatibility studies conducted to the product or raw materials of the product, if applicable.

SCIENTIFIC AND TECHNICAL INFORMATION:

- Packaging information: Technical information regarding the packaging material (Primary and Secondary)
  - Must present the hermeticity test for sterile Medical devices in contact with the patient
- Report of Technolvigilance: information on adverse events that have been introduced during marketing or use, issued by the manufacturer on letterhead, signed by the person responsible of product quality (Manufacturing Site) with a simple Spanish translation.
- Complete clinical studies and a copy of the publication.

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

LEGAL DOCUMENTS

- Original or certified copy of the **Free Sale Certificate** issued by the health authority of the country of origin, which guarantees the product to be registered (and their codes), legalized (Apostille / consularized) and translated into Spanish (Legal translation).

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

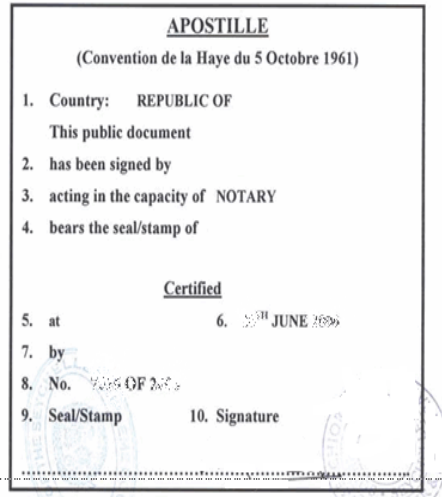
FREE SALES CERTIFICATE

1. Authenticated (Apostille/Consularized).
2. Legal translation
3. Original or Certified Copy


DEPARTMENT OF HEALTH & HUMAN SERVICES

CERTIFICATE TO FOREIGN GOVERNMENT

1


APOSTILLE

(Convention de la Haye du 5 Octobre 1961)

1. Country: REPUBLIC OF
This public document
2. has been signed by
3. acting in the capacity of NOTARY
4. bears the seal/stamp of

Certified

5. at 6. 5TH JUNE 20[illegible]
7. by
8. No. [illegible] OF 20[illegible]
9. Seal/Stamp 10. Signature

2

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

LEGAL DOCUMENTS

- Original or certified copy in original Certificate of Good Manufacturing Practices (ISO 13485, CE Mark) that endorses the actual manufacturing sites, duly legalized (Apostille / consularized) and translated into Spanish (Legal translation).

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

CERTIFICATE OF GOOD MANUFACTUTING PRACTICES

1. Authenticated (Apostille/Consularized).
2. Legal translation
3. Original or Certified Copy

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

LEGAL DOCUMENTS

- Original or certified copy of the **Letter of Representation** issued by the manufacturer's letterhead and signed sheet. It is very important that this letter specify that the Distributor in Mexico will market, distribute, import, and make the necessary arrangements with COFPRIS, and if necessary to be authorized renaming him or the products, properly legalized (Apostille / Consularization) and translated into Spanish (Legal translation)

SALUD
SECRETARÍA DE SALUD

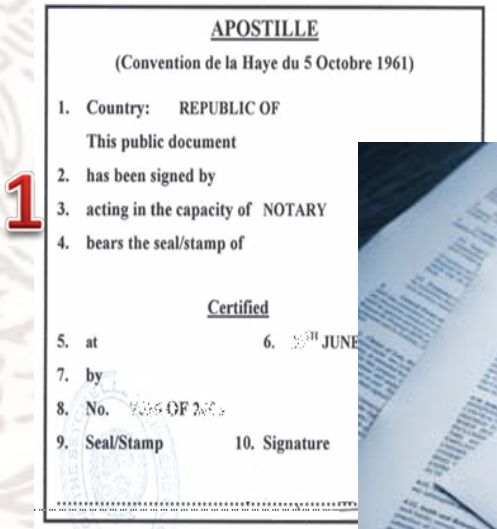
Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

LETTER OF REPRESENTATION

1. Authenticated (Apostille/Consularized).

2. Legal translation

3. **Original or Certified Copy**



1

2

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

EQUIVALENCE AGREEMENT FDA/ HEALTH CANADA

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

CLASSIFICATION IN ACCORDANCE TO THE COUNTRY OF ORIGIN OF THE APPROVAL

- FDA
  - Class 1
  - Class 2
  - Class 3

- Health Canada
  - Class 1
  - Class 2
  - Class 3
  - Class 4

Impotant: Class 1 of Health Canada is Not included in this Agreement

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

GENERAL REQUIREMENTS

1. Registration Application Form.
2. Proof of Payment of fees (Class I, II or III, as appropriate)
3. Copy of Notice of Reatil Operation in Mexico and Copy of Notice of Health Responsible.
4. Project Tag according to the established in the NOM-137-SSA1-2008, “Labeling Medical Devices”
5. Insert of Use / Operational Manual
6. Certificado de Análisis
7. Letter of Representation
8. Monography (Technical and Scientific Information)

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

MONOGRAPHY

1. Brand Name
2. Generic Name
3. Intended of Use.Description of the device
4. Presentations (including codes and description)
5. Technical Drawings or diagram of functional parts/ Formula Quali-Quantitative
6. Specifications of the product
7. Manufacturing Flow Chart

The intended of use and the Description of the Device must correspond to those authorized by FDA/HC

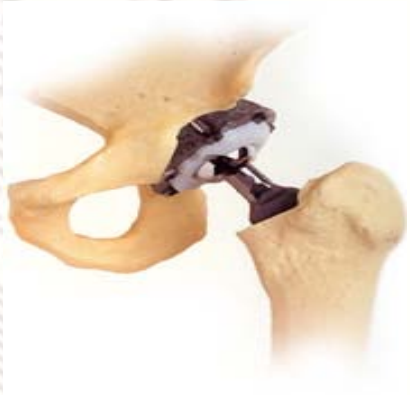
Health Canada
www.hc-sc.gc.ca

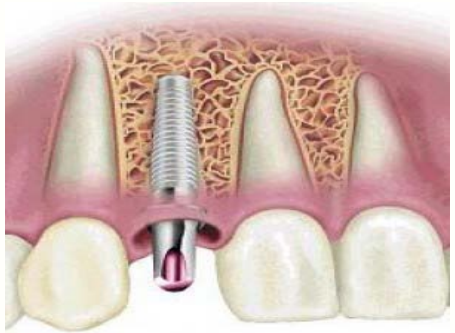
FDA

MONOGRAPHY

8. Summary of the Biocompatibility Studies.

Que incluya:





1. Protocol
2. Methodology
3. Results
4. Conclusions
5. Report Number and Date
6. Especify if the studie was made for the final product or for each raw material.

MONOGRAPHY

9. Sterilization Method:

- Summary of the Sterilization Method.
- Summary of the Sterility Validation Process
- Conclusions.

10. Packaging information: Technical information regarding the packaging material (Primary and Secondary)

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

MONOGRAPHY

11. Stability Studies (Shelf Life):
    - Summary with Results of the studies made in real time and/or accelerated that demostrate the shelf life proposed by the manufacturer

        - Methodology
        - Results
        - Conclusions

SALUD
SECRETARÍA DE SALUD

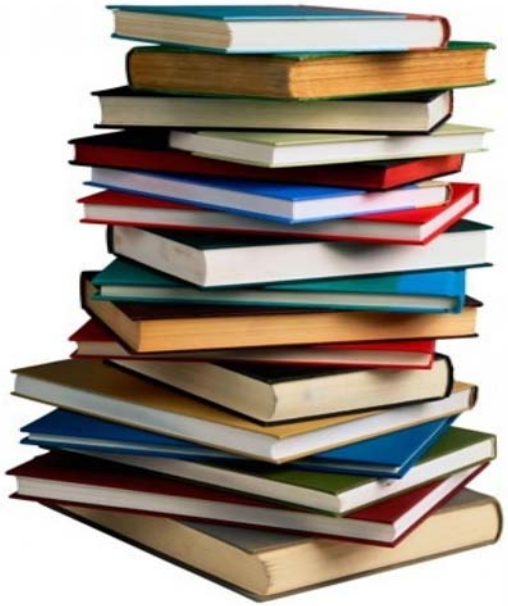
Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

MONOGRAPHY

12. Clinical Studies. (Current)

- Studies of Security and Efficacy:
  - Summary and conclusions of the published clinical studies.

13. Bibliography



SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

FDA

SPECIFIC REQUIREMENTS FOR MEDICAL DEVICES

FOOD & DRUG ADMINISTRATION (FDA)

• Certificate to Foreign Goverment - *CFG*

Including ALL the devices to register

• Codes

• Description

In force

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

Certificate No. XXX XXXXXXX

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List
(One Page)

Name of Manufacturer/Distributor, Address

Manufacturer:

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this ____ day of _____ month ____ year.

Establishment name and Address of place of manufacture

= Project Tag (Label)

= Inspection Report (EIR)

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

- Certificate to Foreign Goverment - *CFG*

1. Authenticated (Apostille).

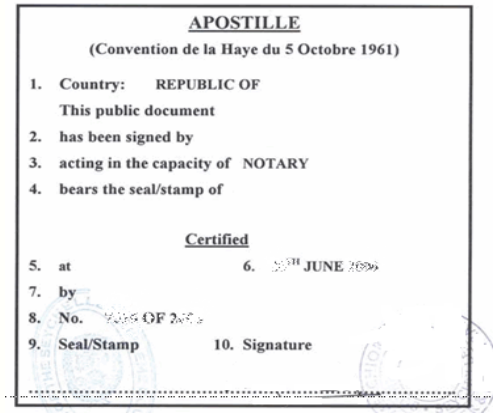
2. Legal translation

3. Original or Certified Copy


DEPARTMENT OF HEALTH & HUMAN SERVICES

CERTIFICATE TO FOREIGN GOVERNMENT

1


APOSTILLE

(Convention de la Haye du 5 Octobre 1961)

1. Country: REPUBLIC OF
This public document
2. has been signed by
3. acting in the capacity of NOTARY
4. bears the seal/stamp of

Certified

5. at 6. JUNE
7. by
8. No.
9. Seal/Stamp 10. Signature

2

SALUD
SECRETARÍA DE SALUD

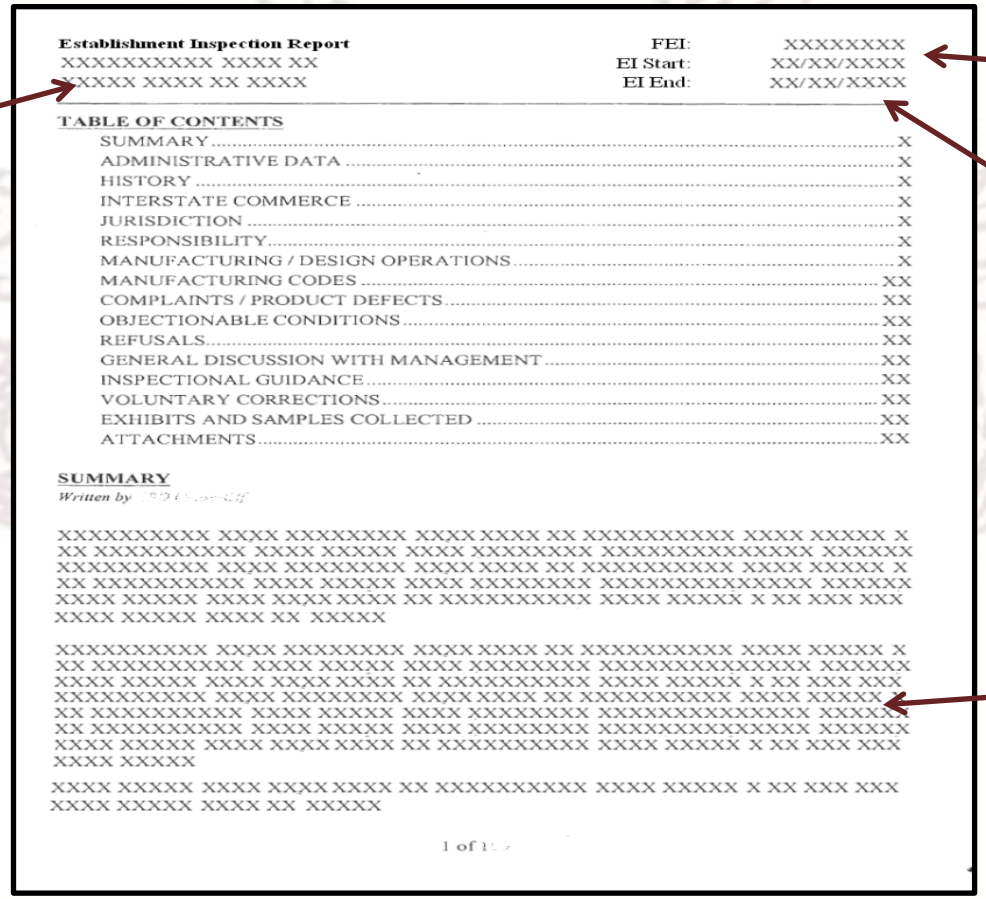
Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

• Establishment Inspection Report - *EIR*

Establishment name and Address of place of manufacture

= Tag

= CFG



Establishment Inspection Report
XXXXXXXXXX XXXX XX
XXXXX XXXX XX XXXX

FEI: XXXXXXXX
EI Start: XX/XX/XXXX
EI End: XX/XX/XXXX

TABLE OF CONTENTS

SUMMARY X
ADMINISTRATIVE DATA X
HISTORY X
INTERSTATE COMMERCE X
JURISDICTION X
RESPONSIBILITY X
MANUFACTURING / DESIGN OPERATIONS X
MANUFACTURING CODES XX
COMPLAINTS / PRODUCT DEFECTS XX
OBJECTIONABLE CONDITIONS XX
REFUSALS XX
GENERAL DISCUSSION WITH MANAGEMENT XX
INSPECTIONAL GUIDANCE XX
VOLUNTARY CORRECTIONS XX
EXHIBITS AND SAMPLES COLLECTED XX
ATTACHMENTS XX

SUMMARY
Written by

XXXXXXXXXX XXXX XXXXXXXX XXXX XXXX XX XXXXXXXXXX XXXX XXXXX X XX XXXXXXXXXX XXXX XXXXX XXXX XXXXXXXX XXXXXXXXXXXXXX XXXXXX XXXXXXXXXX XXXX XXXXXXXX XXXX XXXX XX XXXXXXXXXX XXXX XXXXX X XX XXXXXXXXXX XXXX XXXXX XXXX XXXXXXXX XXXXXXXXXXXXXX XXXXXX XXXX XXXXX XXXX XXXX XXXX XX XXXXXXXXXX XXXX XXXXX X XX XXX XXX XXXX XXXXX XXXX XX XXXXX

XXXXXXXXXX XXXX XXXXXXXX XXXX XXXX XX XXXXXXXXXX XXXX XXXXX X XX XXXXXXXXXX XXXX XXXXX XXXX XXXXXXXX XXXXXXXXXXXXXX XXXXXX XXXX XXXXX XXXX XXXX XXXX XX XXXXXXXXXX XXXX XXXXX X XX XXX XXX XXXXXXXXXX XXXX XXXXXXXX XXXX XXXX XX XXXXXXXXXX XXXX XXXXX XX XXXXXXXXXX XXXX XXXXX XXXX XXXXXXXX XXXXXXXXXXXXXX XXXXXX XXXX XXXXX XXXX XXXX XXXX XX XXXXXXXXXX XXXX XXXXX X XX XXX XXX XXXX XXXXX

XXXX XXXXX XXXX XXXX XXXX XX XXXXXXXXXX XXXX XXXXX X XX XXX XXX XXXX XXXXX XXXX XX XXXXX

1 of 1

Establishment name and Address of place of manufacture

Inspection number (FEI)

Most recent inspection date

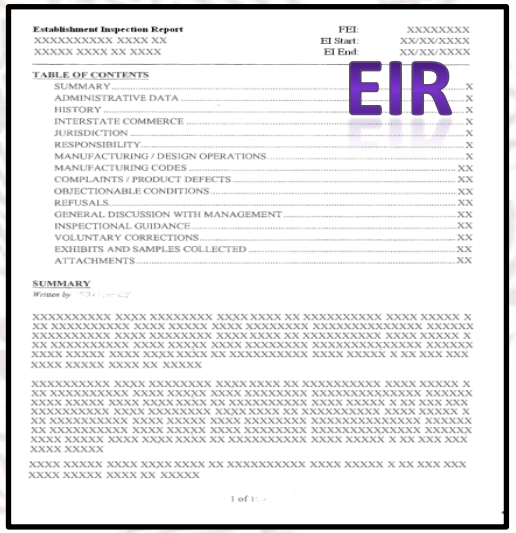
Observations and corrective actions

SALUD
SECRETARÍA DE SALUD

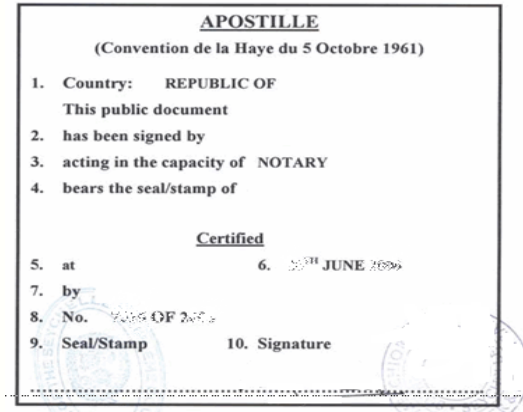
Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

- Establishment Inspection Report - *EIR*

1. Authenticated (Apostille).
2. Legal Translation.
3. Simple Copy



1


APOSTILLE

(Convention de la Haye du 5 Octobre 1961)

1. Country: REPUBLIC OF
This public document
2. has been signed by
3. acting in the capacity of NOTARY
4. bears the seal/stamp of

Certified

5. at 6. JUNE
7. by
8. No.
9. Seal/Stamp 10. Signature

2

- FDA approval
  a) Exempt to special controls
  b) 510(k)
  c) PMA

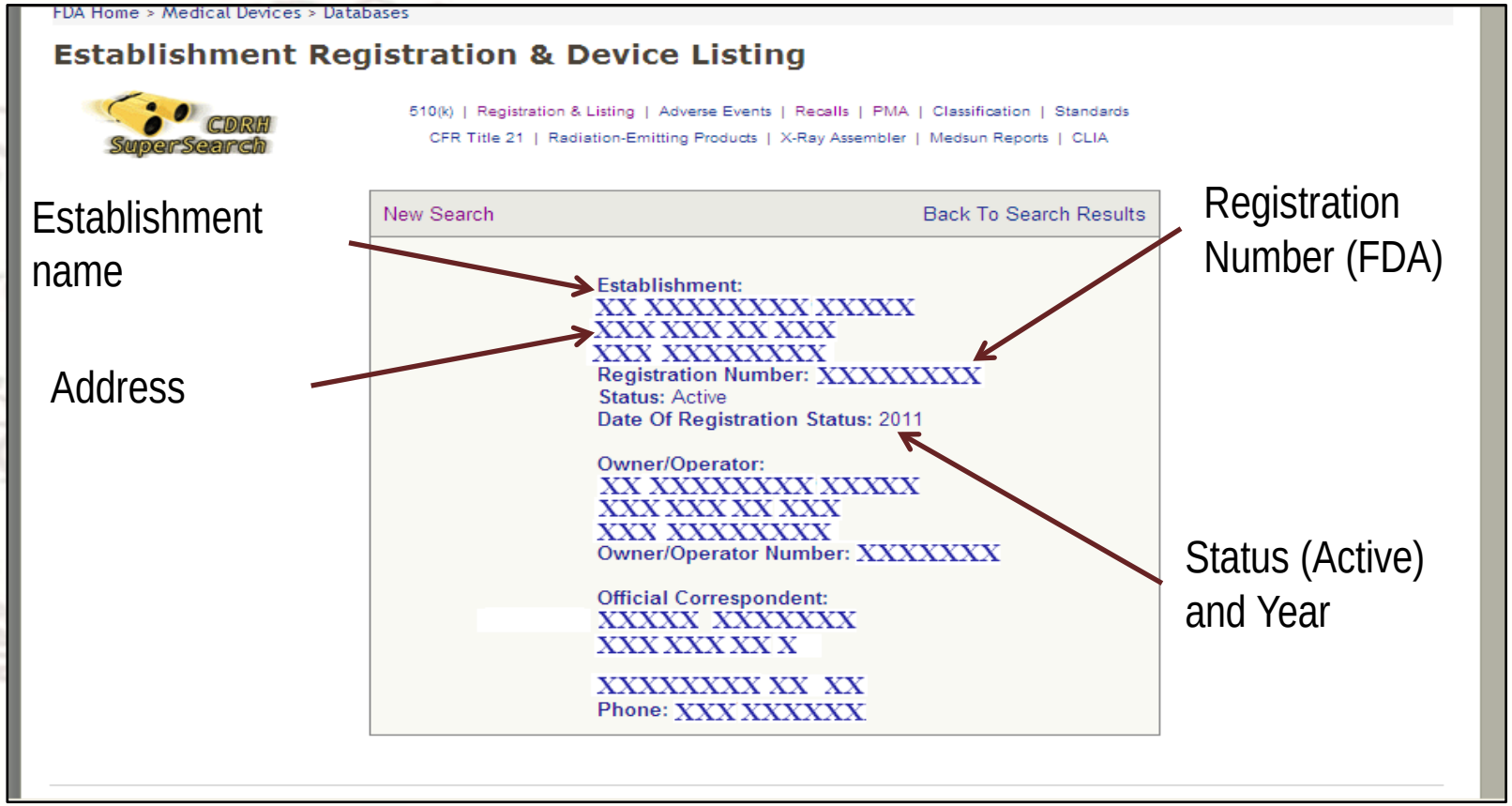
FDA
Approval as a Medical Device

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

- FDA Approval - EXEMPTS

Annual establishment registration with FDA and Device Listing.



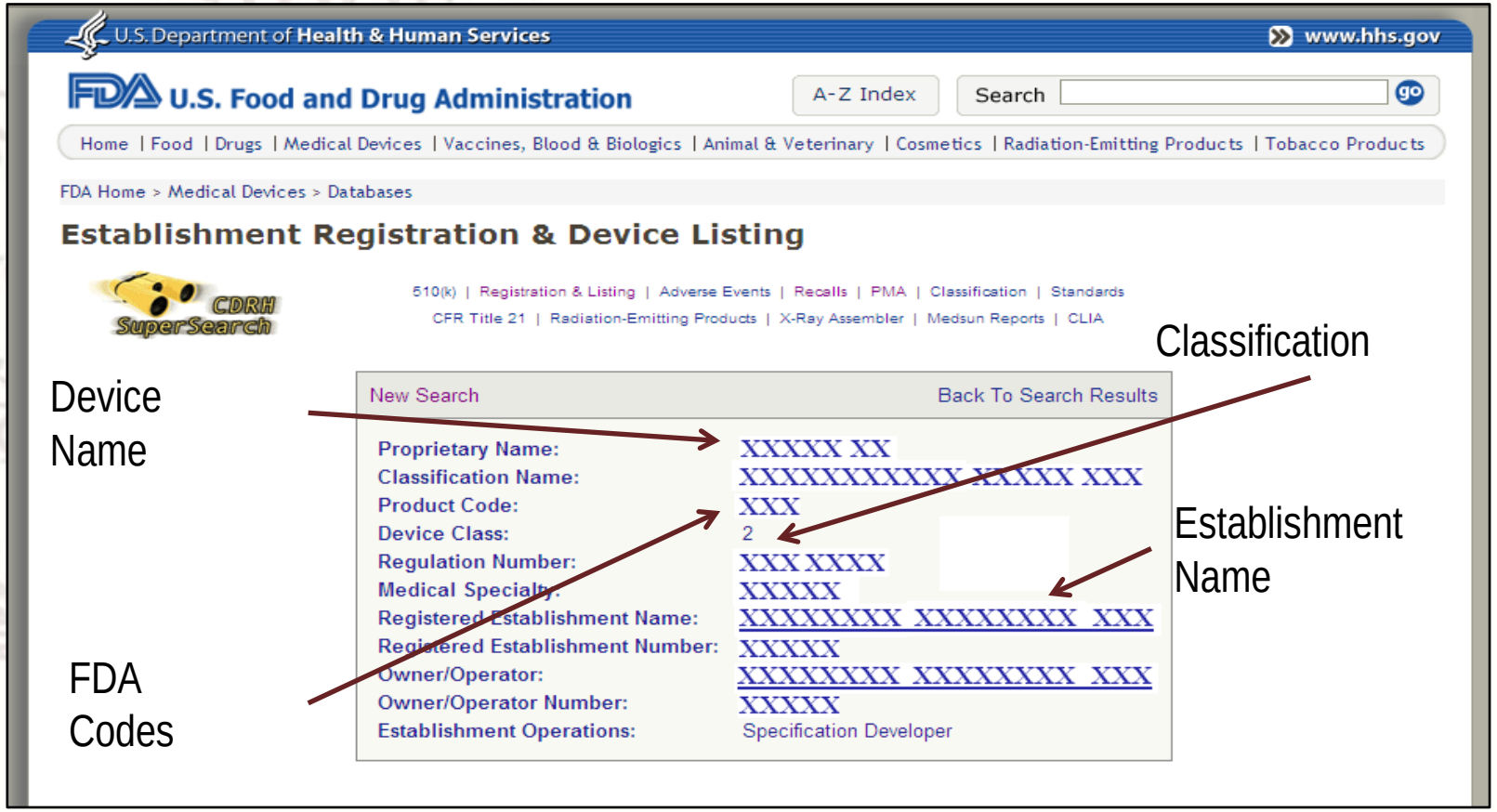
SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

- FDA Approval - EXEMPTS

Device information, classification y exempt status.

(Establishment Registration & Device Listing)



SALUD
SECRETARÍA DE SALUD

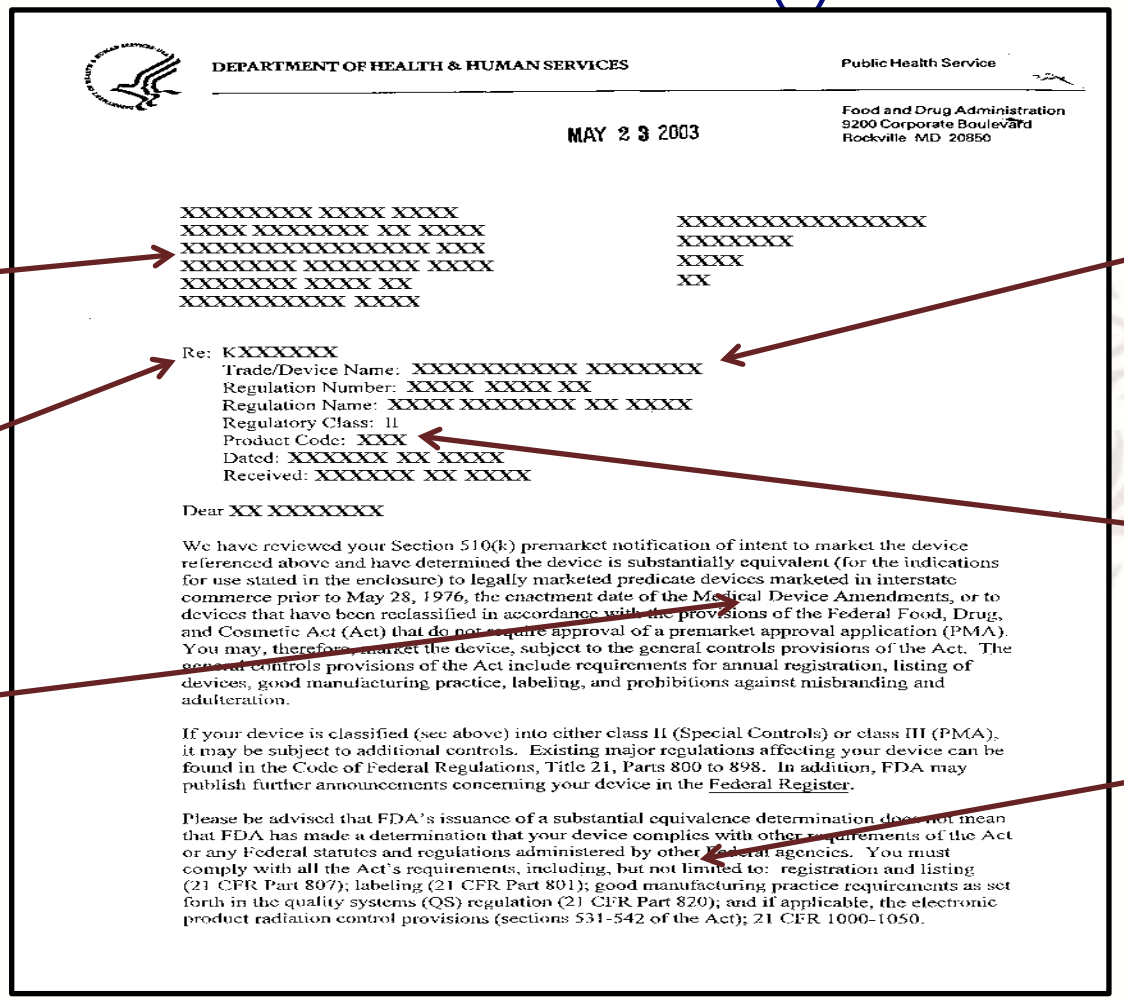
Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

- FDA Approval– Notification 510(k)

Establishment Name

No. 510(K)

Approval (Substantially Equivalent)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2003

XXXXXXXX XXXX XXXX
XXXX XXXXXXX XX XXXX
XXXXXXXXXXXXXX XXX
XXXXXXX XXXXXXX XXXX
XXXXXXX XXXX XX
XXXXXXXXXX XXXX

XXXXXXXXXXXXXX
XXXXXXX
XXXX
XX

Re: KXXXXXX
Trade/Device Name: XXXXXXXXXX XXXXXXX
Regulation Number: XXXX XXXX XX
Regulation Name: XXXX XXXXXXX XX XXXX
Regulatory Class: II
Product Code: XXX
Dated: XXXXXX XX XXXX
Received: XXXXXX XX XXXX

Dear XX XXXXXXX

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

Medical Device Name

Classification

Intended use of the device

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

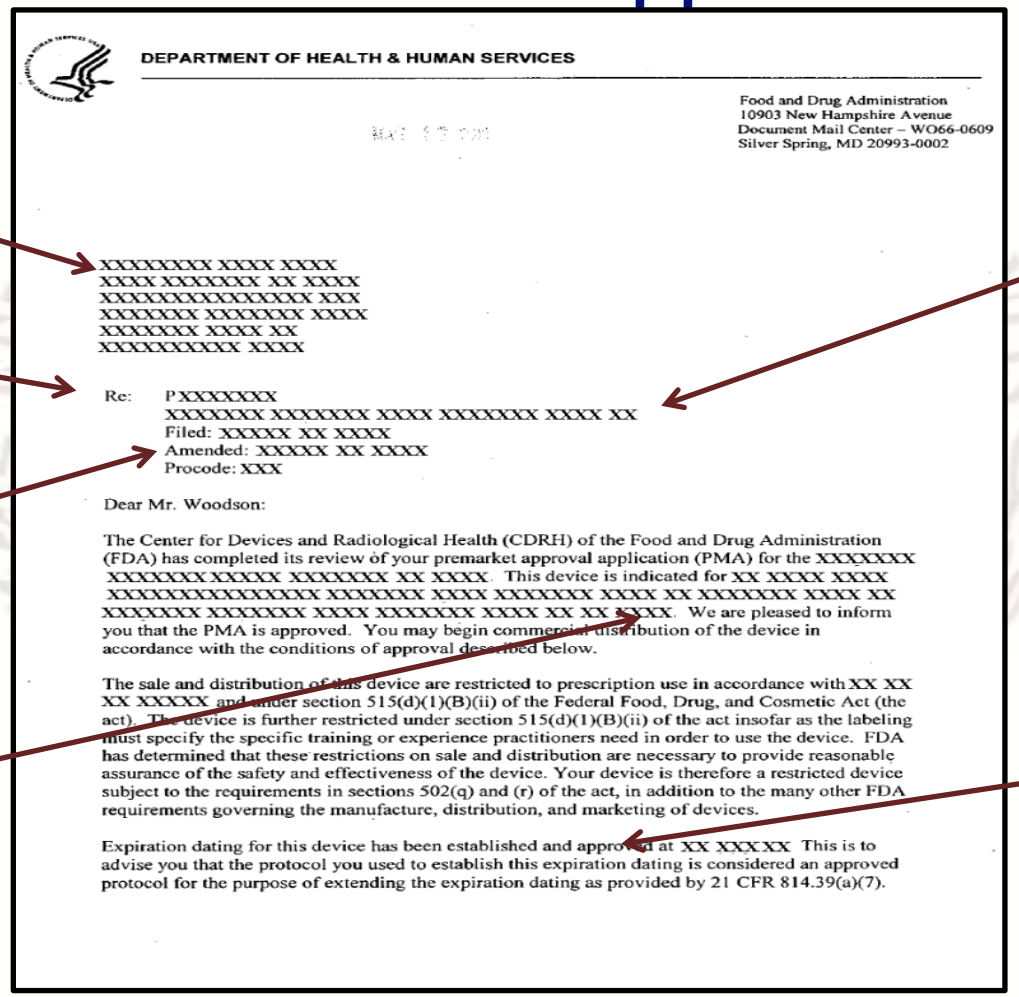
- # FDA Approval – Premarket Approval PMA

Establishment Name

PMA Number

Classification

Approval



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

XXXXXXXX XXXX XXXX
XXXX XXXXXXX XX XXXX
XXXXXXXXXXXXXX XXX
XXXXXXX XXXXXXX XXXX
XXXXXXX XXXX XX
XXXXXXXXXX XXXX

Re: PXXXXXXX
XXXXXXX XXXXXXX XXXX XXXXXXX XXXX XX
Filed: XXXXX XX XXXX
Amended: XXXXX XX XXXX
Procode: XXX

Dear Mr. Woodson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the XXXXXXX XXXXXXX XXXXX XXXXXXX XX XXXX. This device is indicated for XX XXXX XXXX XXXXXXXXXXXXXXX XXXXXXX XXXX XXXXXXX XXXX XX XXXXXXX XXXX XX XXXXXXX XXXXXXX XXXX XXXXXXX XXXX XX XX XXXX. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with XX XX XX XXXXX and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at XX XXX XX. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Name of Medical Device

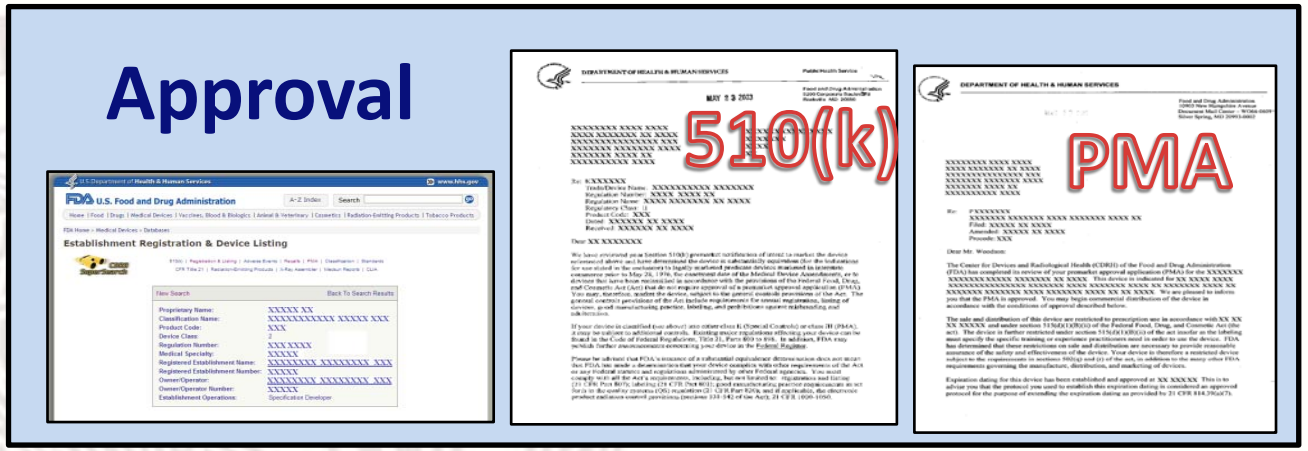
Intended use of the device

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

- FDA Approval

1. Authenticated (Apostille).
2. Legal translation
3. Simple Copy



1

APOSTILLE

(Convention de la Haye du 5 Octobre 1961)

1. Country: REPUBLIC OF
This public document
2. has been signed by
3. acting in the capacity of NOTARY
4. bears the seal/stamp of

Certified

5. at
6. JUNE
7. by
8. No.
9. Seal/Stamp
10. Signature

2

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

- **Technovigilance** (Only FDA class II and III)

  - Adverse Incidents.
  - Recalls
  - Corrective Actions and Conclusions
  - Declaration if not existent
  - Signed by Manufacturer.

  - *"Postmarket Surveillance"*

- Technovigilance (Only FDA class II and III)

1. Issued by the manufacturer in letterhead and signed by responsible the quality of the product
2. Original or Certified Copy

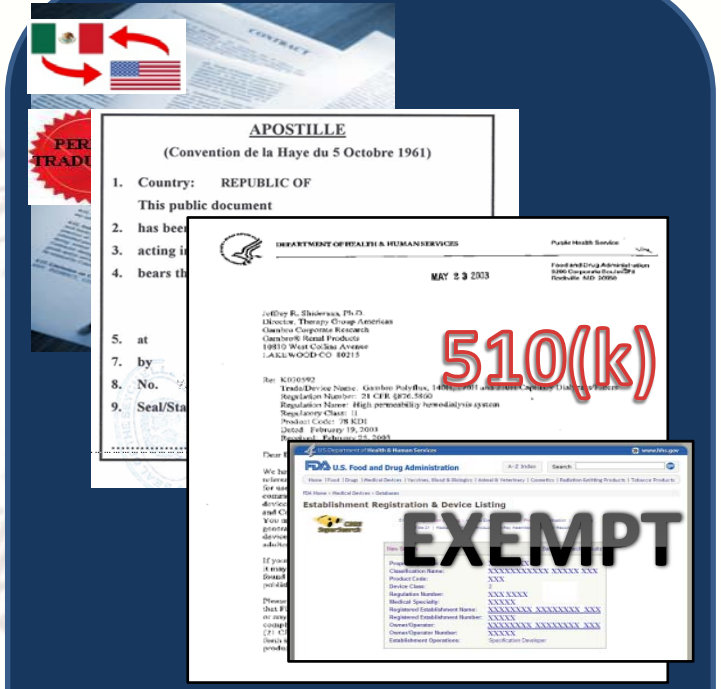
SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

FDA Requirements for CLASS 1 DEVICES

CFG

Establishment Inspection Report



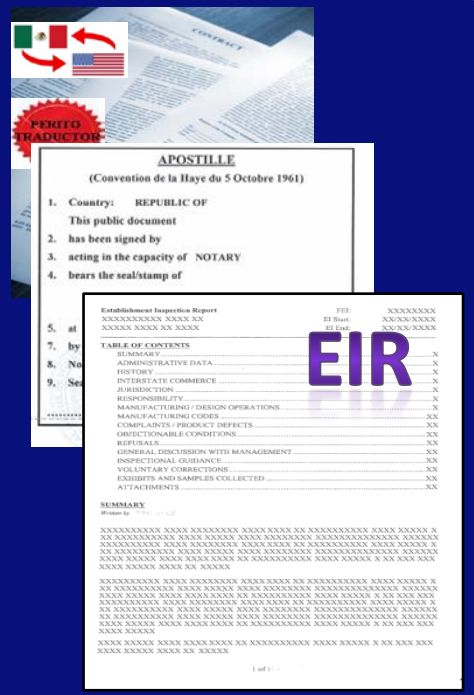
FDA Approval: ER&L, 510(k), PMA

SALUD
SECRETARÍA DE SALUD

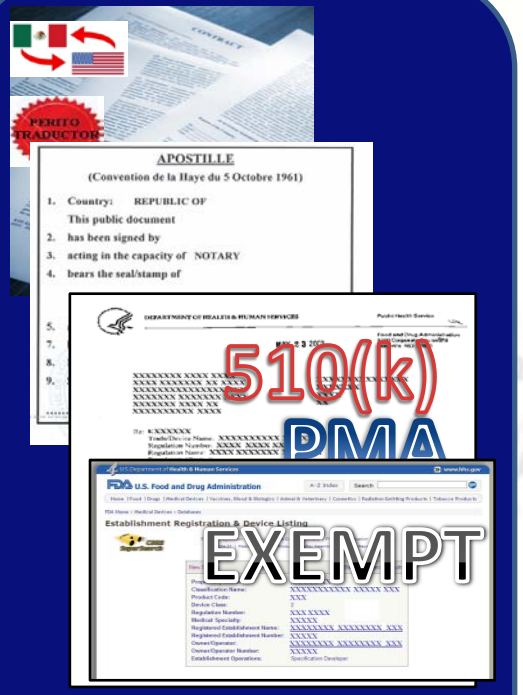
Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

FDA Requirements for CLASS 2 and 3 DEVICES

CFG



Establishment Inspection Report



FDA Approval: ER&L, 510(k), PMA

Technovigilance Report

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Health Canada
www.hc-sc.gc.ca

SPECIFYC REQUIREMENTS FOR MEDICAL DEVICES

HEALTH CANADA

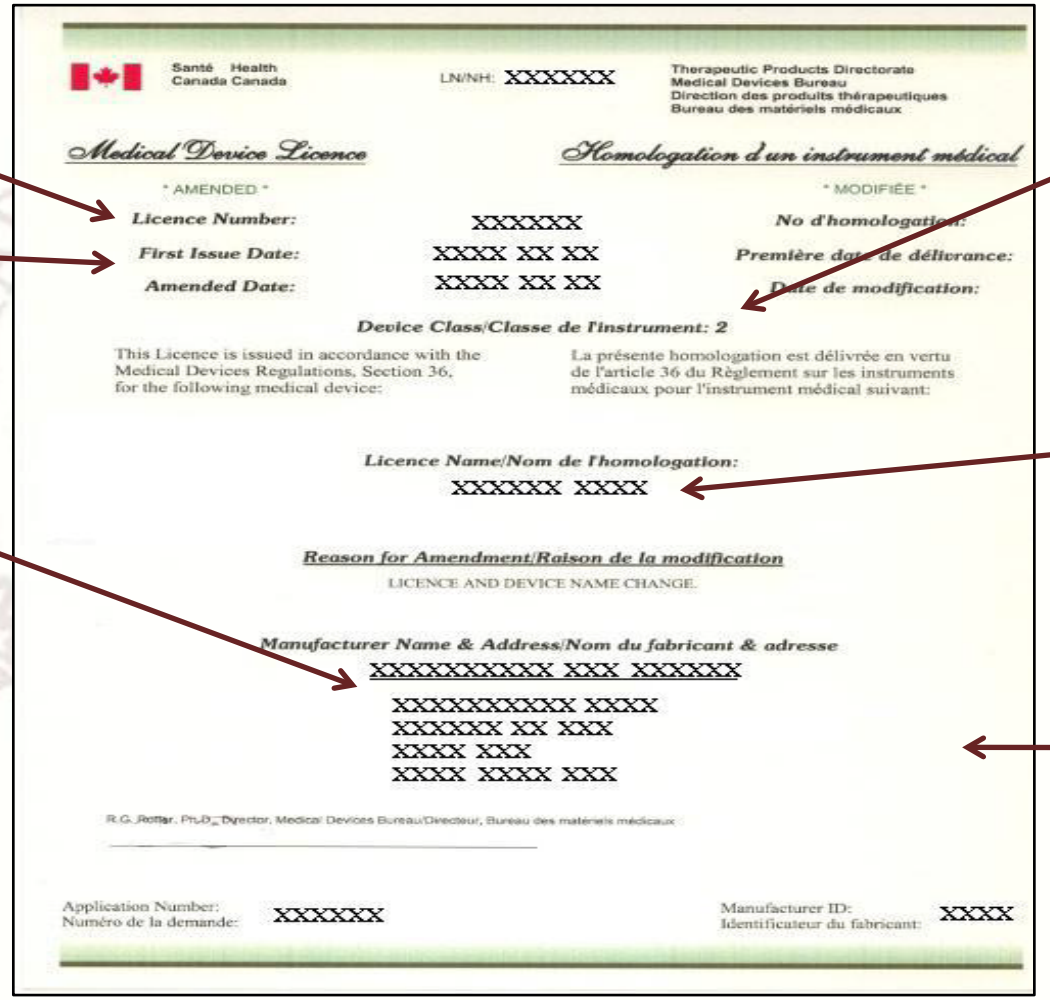
• Medical Device License

License number

Issuing Date

Establishment name and Address of place of manufacture

= Project Tag (Label)



Santé Health Canada Canada

LN/NH: XXXXXX

Therapeutic Products Directorate
Medical Devices Bureau
Direction des produits thérapeutiques
Bureau des matériels médicaux

Medical Device Licence — *Homologation d'un instrument médical*

" AMENDED " — " MODIFIÉE "

Licence Number: XXXXXX — **No d'homologation:**

First Issue Date: XXXX XX XX — **Première date de délivrance:**

Amended Date: XXXX XX XX — **Date de modification:**

Device Class/Classe de l'instrument: 2

This Licence is issued in accordance with the Medical Devices Regulations, Section 36, for the following medical device:

La présente homologation est délivrée en vertu de l'article 36 du Règlement sur les instruments médicaux pour l'instrument médical suivant:

Licence Name/Nom de l'homologation:
XXXXXX XXXX

Reason for Amendment/Raison de la modification
LICENCE AND DEVICE NAME CHANGE.

Manufacturer Name & Address/Nom du fabricant & adresse
XXXXXXXXXX XXX XXXXXX
XXXXXXXXXX XXXX
XXXXXX XX XXX
XXXX XXX
XXXX XXXX XXX

R.G. Reffar, Ph.D., Director, Medical Devices Bureau/Directeur, Bureau des matériels médicaux

Application Number: Numéro de la demande: XXXXXX

Manufacturer ID: Identificateur du fabricant: XXXX

Classification

Name of Medical Device

Including ALL devices to register

- Codes
- Description

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

- Medical Device License

1. Authenticated (consularized).
2. Legal Translation
3. Original or Certified Copy


Medical Device Licence
Homologation d'un instrument médical
Licence Number: XXXXXX
First Issue Date: XXXX XX XX
Amended Date: XXXX XX XX
Device Class/Classe de l'instrument: 3
Licence Name/Nom de l'homologation:
XXXXXX XXXX
Reason for Amendment/Raison de la modification
LICENCE AND DEVICE NAME CHANGE
Manufacturer Name & Address/Nom du fabricant & adresse
XXXXXXXXXX XXX XXXXXX
Application Number/Numéro de la demande: XXXXXX
Manufacturer ID/Identificateur du fabricant: XXXX

1


Consularized
No. XXXXXX
SERVICIO EXTERIOR MEXICANO

2

- Certificate CAN/CSA ISO13485:03

• Certificate CAN/CSA ISO13485:03

• Certificate number

Establishment name and Address of place of manufacture

= Project Tag (Label)

• Issuing Date

• Expiration Date

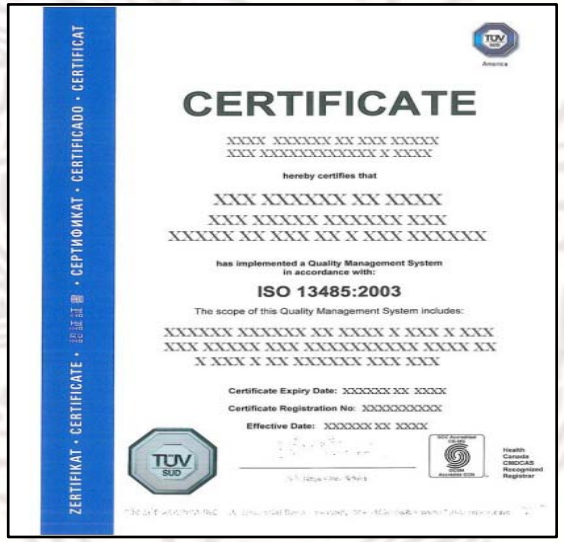
• Certification Standard (13485)

• Issued by Authorized Third ("Registrar")

•Standards Council of Canada Seal

- Certificate CAN/CSA ISO13485:03

1. Authenticated (Apostille / consularized).
2. Legal Translation
3. Simple Copy



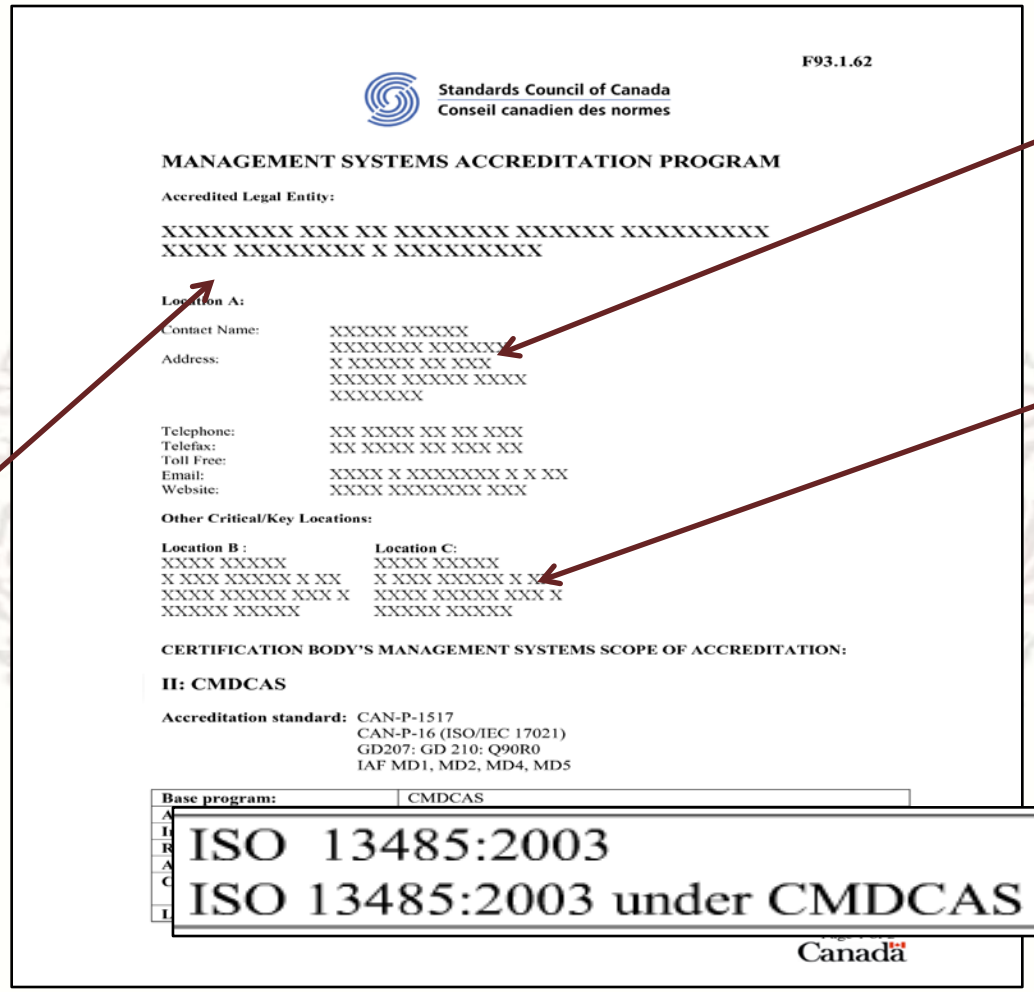
1

2

• ISO 17021 (Authorized Third)

Accreditation Program
Management Systems

• Issued by the Standards Council of Canada (SCC)



F93.1.62

Standards Council of Canada
Conseil canadien des normes

MANAGEMENT SYSTEMS ACCREDITATION PROGRAM

Accredited Legal Entity:

XXXXXXXX XXX XX XXXXXXX XXXXXX XXXXXXXXX
XXXX XXXXXXXX X XXXXXXXXX

Location A:

Contact Name: XXXXX XXXXX
XXXXXXX XXXXXX
Address: X XXXXX XX XXX
XXXXX XXXXX XXXX
XXXXXXX

Telephone: XX XXXX XX XX XXX
Telefax: XX XXXX XX XXX XX
Toll Free:
Email: XXXX X XXXXXXX X X XX
Website: XXXX XXXXXXX XXX

Other Critical/Key Locations:

Location B :
XXXX XXXXX
X XXX XXXXX X XX
XXXX XXXXX XXX X
XXXXX XXXXX

Location C:
XXXX XXXXX
X XXX XXXXX X XX
XXXX XXXXX XXX X
XXXXX XXXXX

CERTIFICATION BODY'S MANAGEMENT SYSTEMS SCOPE OF ACCREDITATION:

II: CMDCAS

Accreditation standard: CAN-P-1517
CAN-P-16 (ISO/IEC 17021)
GD207: GD 210: Q90R0
IAF MD1, MD2, MD4, MD5

Base program:	CMDCAS

ISO 13485:2003
ISO 13485:2003 under CMDCAS

Canada

• Authorized Third Address

• Other Addresses

• Legal Name of Authorized Third
= Certificate
ISO13485

• Accredited under ISO 17021 to issue certificates ISO 13485 (CMDCAS)

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

• Current Authorization (Authorized Third)

Certificate of Accreditation

•Issued by the Standards Council of Canada (SCC)

• Legal Name of Authorized Third

= Certificate ISO13485

CERTIFICATE OF ACCREDITATION

Standards Council of Canada
Conseil canadien des normes

CERTIFICAT D'ACCRÉDITATION

XXXXXXXXX XXX XXXXXXXX XXXXX XXXXXX XXXXXXXXXXX
XXXXXXX XXXXX XXXXXX XXXXX XXXX
XXX XXXXXXX XXXXX

having been assessed under the authority of the *Standards Council of Canada Act* and found to conform with the requirements established by the Council is hereby recognized as an

ACCREDITED MANAGEMENT SYSTEMS CERTIFICATION BODY

in specific subject areas and for key locations as identified in the scope of accreditation found under "Management Systems – Accredited Clients" on www.scc-ccn.ca

ayant été soumis à une évaluation selon la *Loi sur le Conseil canadien des normes* et ayant été trouvé conforme aux exigences établies par le CCN est de fait reconnu comme étant un

ORGANISME DE CERTIFICATION DE SYSTÈMES DE MANAGEMENT ACCRÉDITÉ

dans les domaines d'activité et pour les établissements clés indiqués dans la portée d'accréditation figurant à l'adresse : www.ccn-scc.ca sous la rubrique « Les Systèmes de management – Les clients accrédités ».

Accreditation number: / Numéro d'accréditation : XXXXXXXXX
Initial accreditation date: / Date de la première accréditation : XXXX XXX XXX
Reaccreditation date: / Date de la réaccréditation : XXXX XXX XXX
Accreditation expiry date: / Date d'expiration de l'accréditation : XXXX XXX XXX

Chairman (SCC) / Président (CCN)

To verify the validity of this accreditation, please see the Directory of Accredited clients on www.scc-ccn.ca

Pour vérifier la validité de l'accréditation, veuillez consulter le Répertoire des clients accrédités au www.ccn-scc.ca

This certificate is the property of the Standards Council of Canada (SCC) and must be returned on request; reproduction is prohibited except on written approval of the SCC.
Ce certificat est la propriété du Conseil canadien des normes (CCN) et doit lui être remis sur demande; toute reproduction est interdite sans l'autorisation écrite du CCN.

Canada

• Authorized Third Address

• Certificate Number

• Issuing Date

• Expiration Date

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

- Current Authorization (Authorized Third)

1. Authenticated (consularized).
2. Legal Translation
3. Original or Certified Copy

1

2

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Health Canada Requirements for CLASS 2,3 and 4 DEVICES

Medical Device License

ISO 13485:2003 Certificate

ISO 17021

Authorization Authorized Third

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

EQUIVALENCE AGRREMENT JAPAN

SALUD
SECRETARÍA DE SALUD

Cofepris
Somos COFEPRIS, somos ARN

=

厚生労働省
Ministry of Health, Labour and Welfare

Pmda Pharmaceuticals and Medical Devices Agency, Japan

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

MEDICAL DEVICES APLICABLES AL ACUERDO DE EQUIVALENCIAS CON JAPÓN
CLASIFICACIÓN JAPONESA

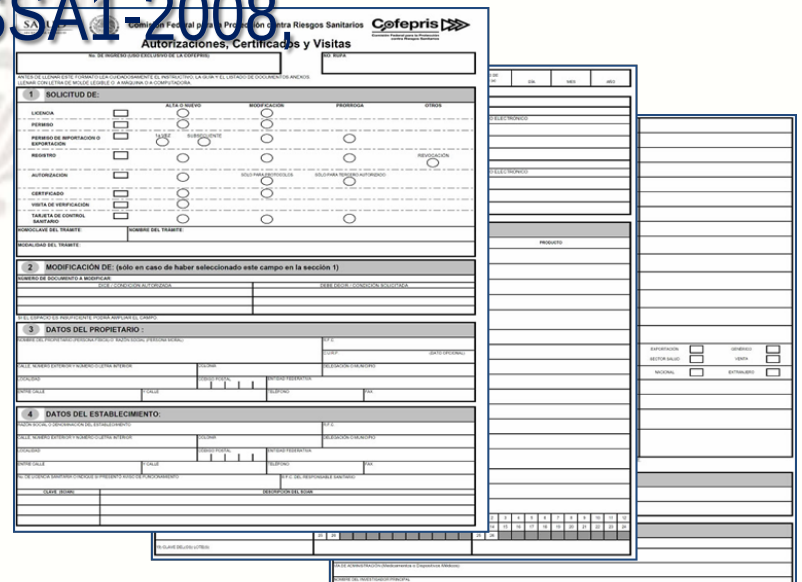
Clase	Categoría	Aprobación o Certificación
II	Designated Controlled Medical Device	**Certification Request to a Registered Certification Entity**
II	Controlled Medical Device	**Approval Request to PMDA/MHLW**
III	Highly Controlled Medical Device	**Approval Request to PMDA/MHLW**
IV	Highly Controlled Medical Device	**Approval Request to PMDA/MHLW**

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

GENERAL REQUIREMENTS

1. Registration Application Form.
2. Proof of Payment of fees (Class I, II or III, as appropriate)
3. Copy of Notice of Reatil Operation in Mexico and Copy of Notice of Health Responsible.
4. Project Tag according to the established in the NOM-137-SSA1-2008 “Labeling Medical Devices”
5. Insert of Use / Operational Manual
6. Letter of Representation



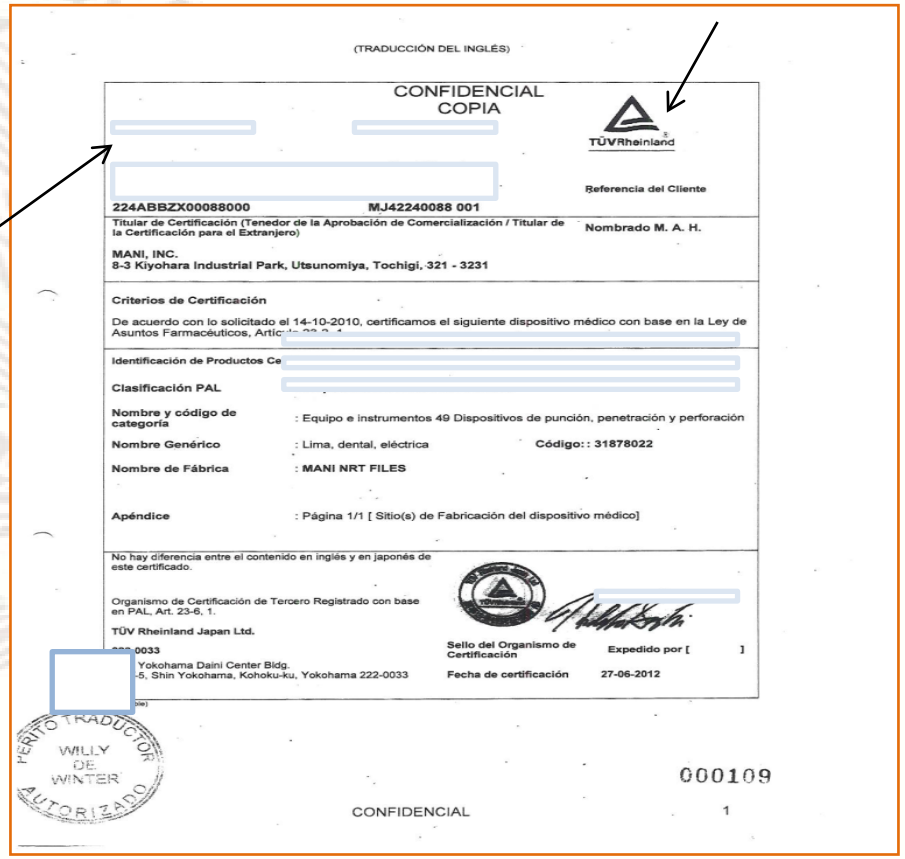
Designated Controlled Medical Devices Class II

- ***Certification*** *issued by the Registered Certification Entity, including the sheets where the following topics are specified:*

  ✓Description.
  ✓Intended of use.
  ✓Formula and/or composition. (if applicable)
  ✓Stability. (if applicable)
  ✓Sterility. (if applicable)
  ✓Primary and Secondary packaging information

Registered Certification Entity

Certification Number



(TRADUCCIÓN DEL INGLÉS)

CONFIDENCIAL
COPIA

TÜVRheinland

Referencia del Cliente

224ABBZX00088000 MJ42240088 001

Titular de Certificación (Tenedor de la Aprobación de Comercialización / Titular de la Certificación para el Extranjero) Nombrado M. A. H.

MANI, INC.
8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 321 - 3231

Criterios de Certificación

De acuerdo con lo solicitado el 14-10-2010, certificamos el siguiente dispositivo médico con base en la Ley de Asuntos Farmacéuticos, Artic

Identificación de Productos Ce

Clasificación PAL

Nombre y código de categoría : Equipo e instrumentos 49 Dispositivos de punción, penetración y perforación

Nombre Genérico : Lima, dental, eléctrica Código:: 31878022

Nombre de Fábrica : MANI NRT FILES

Apéndice : Página 1/1 [Sitio(s) de Fabricación del dispositivo médico]

No hay diferencia entre el contenido en inglés y en japonés de este certificado.

Organismo de Certificación de Tercero Registrado con base en PAL, Art. 23-6, 1.

TÜV Rheinland Japan Ltd.

0033
Yokohama Daini Center Bldg.
-5, Shin Yokohama, Kohoku-ku, Yokohama 222-0033

Sello del Organismo de Certificación Expedido por [ ]

Fecha de certificación 27-06-2012

PERITO TRADUCTOR WILLY DE WINTER AUTORIZADO

000109

CONFIDENCIAL 1

- ***Certification** issued by the Registered Certification Entity :*

CONFIDENCIAL
COPIA

TÜVRheinland

Apéndice

Certificación No. Nuestra Referencia

Página 1 / 1

Sitio(s) de fabricación

No hay diferencia entre el contenido en inglés y en japonés de este certificado.

Organismo de Certificación de Terceros Registrado con base en PAL, Art. 23-6, 1.

TÜV Rheinland Japón Ltd.

Sello del Organismo de Certificación

Expedido por [ ]

Fecha de certificación 2012-06-27

000108

CONFIDENCIAL 2

Medical Device Data

Manufacturer

Legal Translation

(TRADUCCIÓN DEL INGLÉS)

(16 112)

Certificado de gestión para fabricación y comercialización de conductor de dispositivos médicos designados

Nombre y código de categoría				
Nombre	Nombre Genérico			
	Nombre de Fábrica			
Objetivo de Uso	Consulte Anexo 1			
Configuraciones, estructura y princípios	Consulte Anexo 1			
Estructuras de materiales	Consulte Anexo 2			
Especificación	Consulte Anexo 3			
Instrucciones de uso o procedimientos de operación	Consulte Anexo 4			
Proceso de fabricación	Consulte Anexo 5			
Almacenamientos y duración de uso	--			
Sitio de fabricación y comercialización	Nombre	Dirección	Clasificación de Aprobación	No. de Certificado
	Consulte Anexo 5 Organigrama de fábrica			
Sitio de fabricación de materiales	Nombre	Dirección	Clasificación de Aprobación	No. de Certificado
Notas	Este producto es un producto no estéril y reutilizable. Instrucciones de uso: Consulte Anexo 6 Certificado No. para fabricación y comercialización de dispositivo médico Clasificación de Aprobación: Fabricación y venta de equipo médico de primera clase La ubicación del lugar principal de negocios: 8			

Por lo anterior, solicitamos un certificado de fabricación y venta de equipo médico.

Para TÜV Rheinland Japón Ltd.

Sección de Aseguramiento de Calidad: TAKATSUGU FUJIMOTO
TEL 028-667-1811
FAX 028-667-9267

000107

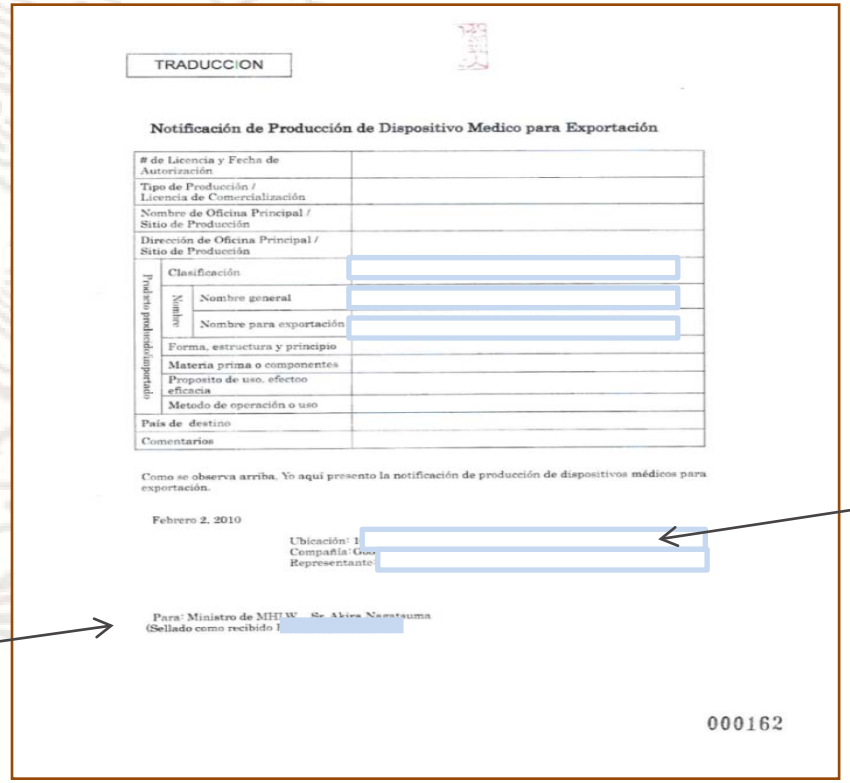
CONFIDENCIAL 4

Note: Authenticated (Apostille)

- ***Export Notification*** *with the following specifications:*

✓ Description.
✓ Intended of use.
✓ Presentations with codes (catalog number, part number, etc.) including accesories.
✓ Formula and/or composition.
✓ Stability. (if applicable)
✓ Sterility Period (If applicable)
✓ Primary and Secondary packaging information.

Medical Device Data



TRADUCCION

Notificación de Producción de Dispositivo Medico para Exportación

# de Licencia y Fecha de Autorización			
Tipo de Producción / Licencia de Comercialización			
Nombre de Oficina Principal / Sitio de Producción			
Dirección de Oficina Principal / Sitio de Producción			
Producto producido/importado	Clasificación		
	Nombre	Nombre general	
		Nombre para exportación	
	Forma, estructura y principio		
	Materia prima o componentes		
	Proposito de uso, efectoo eficacia		
	Metodo de operación o uso		
País de destino			
Comentarios			

Como se observa arriba, Yo aquí presento la notificación de producción de dispositivos médicos para exportación.

Febrero 2, 2010

Ubicación:
Compañía:
Representante:

Para: Ministro de MHLW Sr. Akira Nagatsuma
(Sellado como recibido

000162

Manufacturer Data

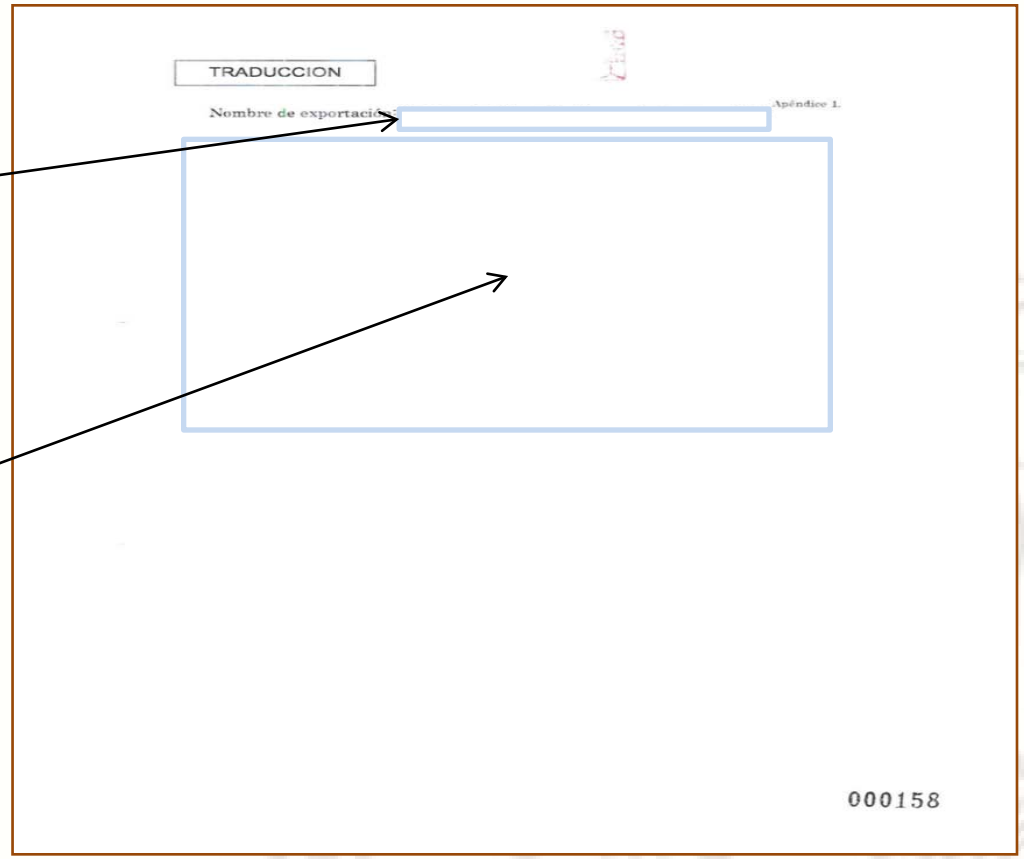
Seal by the Ministry of Health of Japan

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Brand Name of the Medical Device

Codes of the presentations of the product

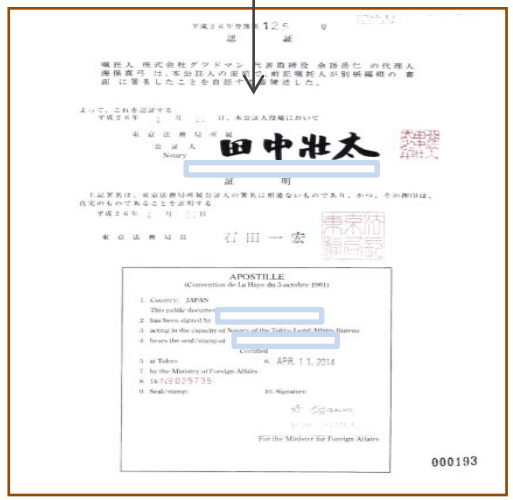

TRADUCCION

Nombre de exportación

Apéndice 1.

000158

Authenticated (Apostille)


APOSTILLE

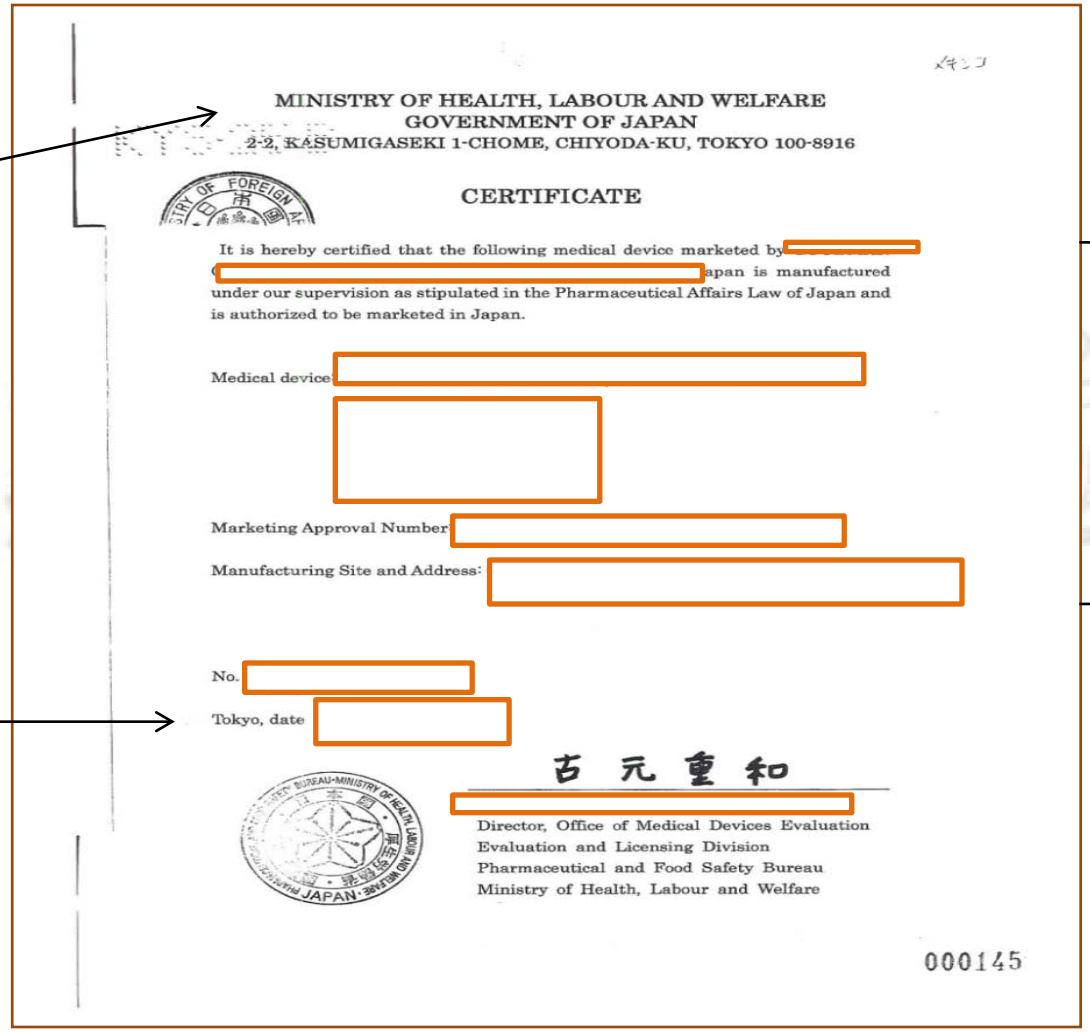
(Convention de La Haye du 5 octobre 1961)

000193

Note: Legal translation

- *Original or Certified Copy of the **Free Sales Certificate***
  No older than one year.

Issued by the Ministry of Health of Japan



MINISTRY OF HEALTH, LABOUR AND WELFARE
GOVERNMENT OF JAPAN
2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE

It is hereby certified that the following medical device marketed by [redacted] Japan is manufactured under our supervision as stipulated in the Pharmaceutical Affairs Law of Japan and is authorized to be marketed in Japan.

Medical device [redacted]

Marketing Approval Number [redacted]

Manufacturing Site and Address: [redacted]

No. [redacted]

Tokyo, date [redacted]

古 元 重 和

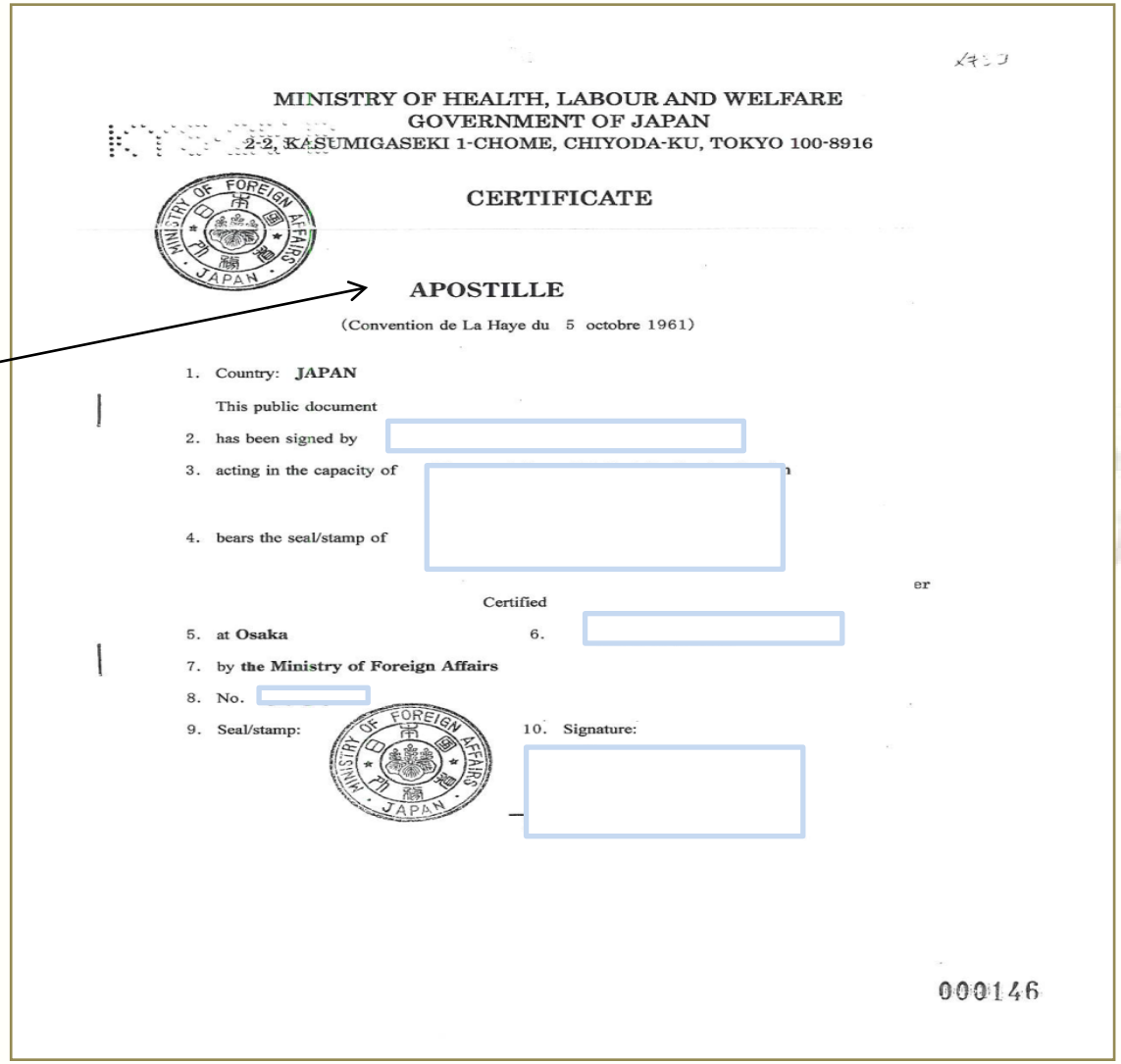
Director, Office of Medical Devices Evaluation
Evaluation and Licensing Division
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

000145

Medical Device Data

No older than one year

Authenticated
(Apostille)



MINISTRY OF HEALTH, LABOUR AND WELFARE
GOVERNMENT OF JAPAN
2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
This public document
2. has been signed by
3. acting in the capacity of
4. bears the seal/stamp of

Certified

5. at Osaka 6.
7. by the Ministry of Foreign Affairs
8. No.
9. Seal/stamp: 10. Signature:

000146

Note: Legal Translation.

SALUD

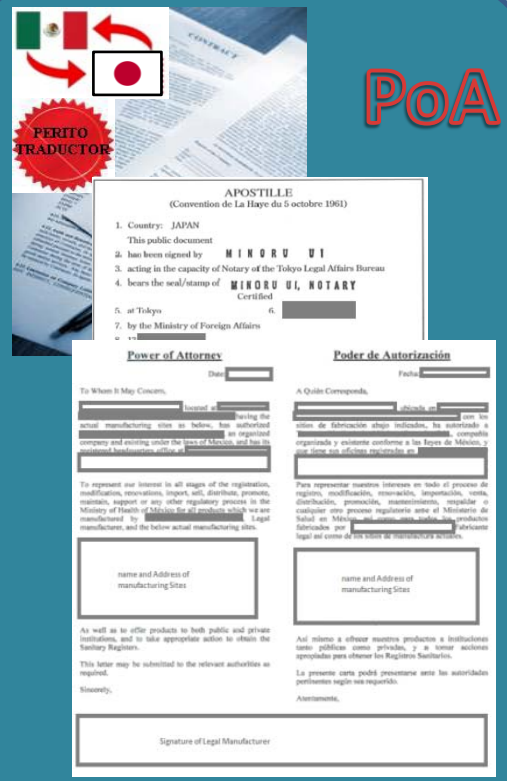
Cofepris

Designated Controlled Medical Devices (Class II in accordance with criteria established) with Certificate Issued by a Registered Certification Entity before the MHLW in Japan (COFEPRIS-04-001-G)

Certification issued by the Registered Certification Entity

Export Notification

Certificate of Free Sale



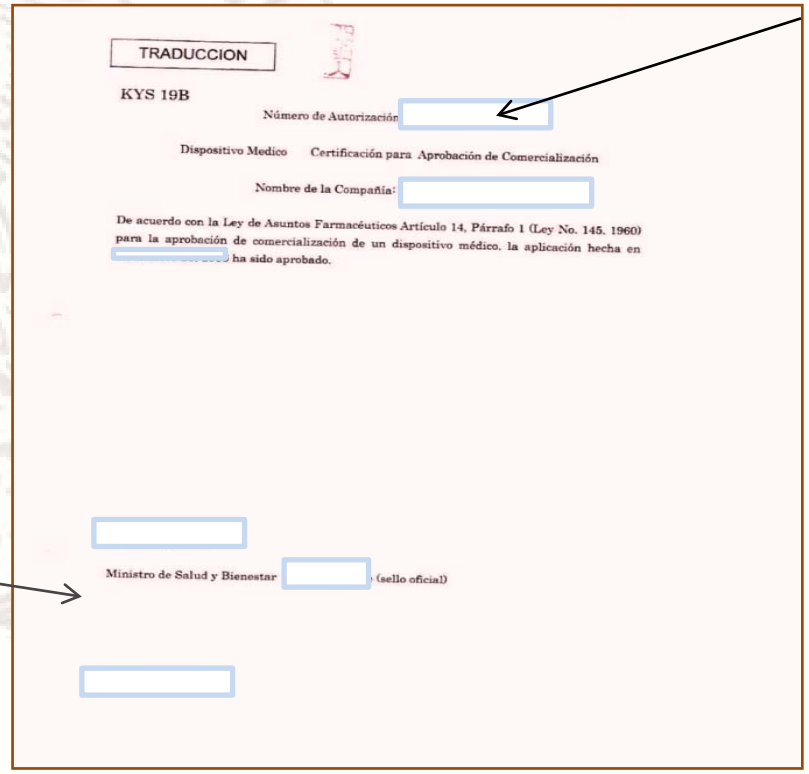
Letter of Representation

MEDICAL DEVICES WITH AN APPROVAL LETTER ISSUED BY THE MHLW, CLASE II, III Y IV

- ***Approval Letter*** *e issued by the MHLW of Japan, including the sheets where the following topics are specified:*

✓Description.
✓Intended of use.
✓Formula and/or composition. (if applicable)
✓Stability. (if applicable)
✓Sterility. (if applicable)
✓Primary and Secondary packaging information

Certification Number


TRADUCCION

KYS 19B

Número de Autorización

Dispositivo Medico Certificación para Aprobación de Comercialización

Nombre de la Compañía:

De acuerdo con la Ley de Asuntos Farmacéuticos Artículo 14, Párrafo 1 (Ley No. 145, 1960) para la aprobación de comercialización de un dispositivo médico, la aplicación hecha en ha sido aprobado.

Ministro de Salud y Bienestar (sello oficial)

Seal by the Ministry of Health of Japan

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

TRADUCCION

KYS 19 B

Solicitud para Aprobación de comercialización de Dispositivos Médicos

Clasificación		
Nombre	Nombre Genérico	
	Nombre comercial	
Uso pretendido, eficacia, y efectividad		
Forma, estructura y principio		
Materia prima o componentes		
Especificaciones		
Metodo de preparacion o uso		
Metodo de produccion		
Metodo de almacenamiento y vida de anaquel		

Productor del producto vendido	Nombre	Direccion	Categoria de aprobacion o acreditacion	No de aprobacion o acreditacion
Productor de materia prima	name	Direccion	Categoria de aprobacion o acreditacion	No de aprobacion o acreditacion
Comentarios				

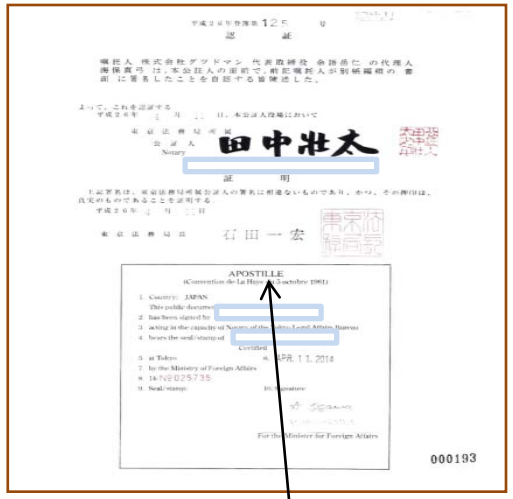
Como se observa arriba, Yo aquí solicito la aprobación de comercialización para dispositivo médico.
Noviembre 20, 2006
Ubicación:
Compañía:
Representante:

PARA: Ministro de Salud y Bienestar Hakuo Yanagisawa
(sellado como recibido Noviembre 20, 2006)

Brand Name

Manufacturer Data

Seal by the Ministry of Health of Japan

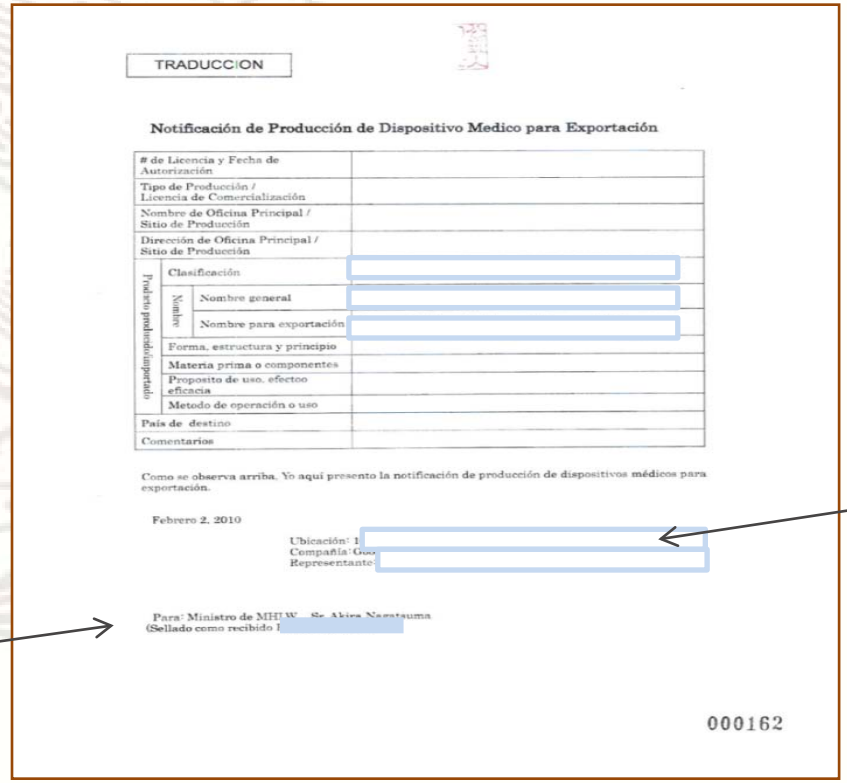


Authenticated (Apostille)

- *Export Notification with the following specifications:*

✓ Description.
✓ Intended of use.
✓ Presentations with codes (catalog number, part number, etc.) including accesories.
✓ Formula and/or composition.
✓ Stability. (if applicable)
✓ Sterility Period (If applicable)
✓ Primary and Secondary packaging information.

Medical Device Data



TRADUCCION

Notificación de Producción de Dispositivo Medico para Exportación

# de Licencia y Fecha de Autorización			
Tipo de Producción / Licencia de Comercialización			
Nombre de Oficina Principal / Sitio de Producción			
Dirección de Oficina Principal / Sitio de Producción			
Producto producido/importado	Clasificación		
	Nombre	Nombre general	
		Nombre para exportación	
	Forma, estructura y principio		
	Materia prima o componentes		
	Proposito de uso, efectoo eficacia		
	Metodo de operación o uso		
País de destino			
Comentarios			

Como se observa arriba, Yo aquí presento la notificación de producción de dispositivos médicos para exportación.

Febrero 2, 2010

Ubicación:
Compañía:
Representante:

Para: Ministro de MHLW Sr. Akira Nagatsuma
(Sellado como recibido

000162

Manufacturer Data

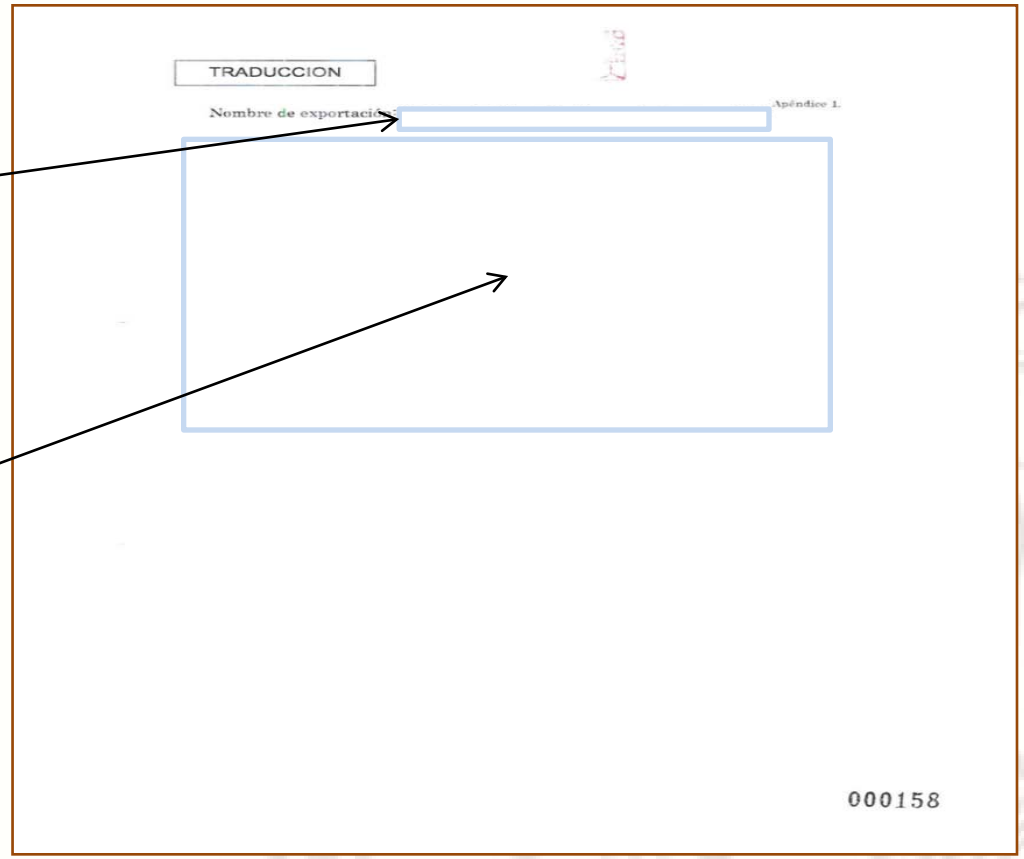
Seal by the Ministry of Health of Japan

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Brand Name of the Medical Device

Codes of the presentations of the product

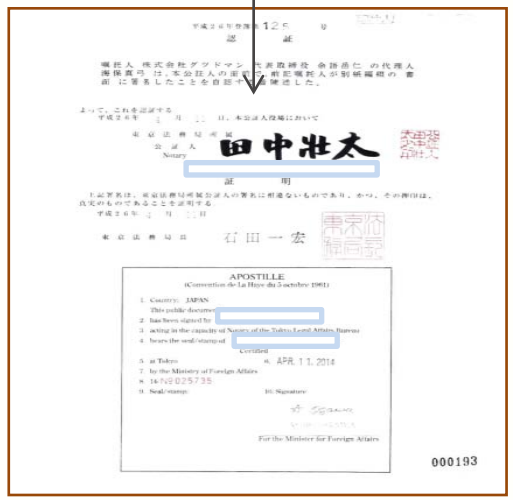

TRADUCCION

Nombre de exportación

Apéndice 1.

000158

Authenticated (Apostille)


APOSTILLE

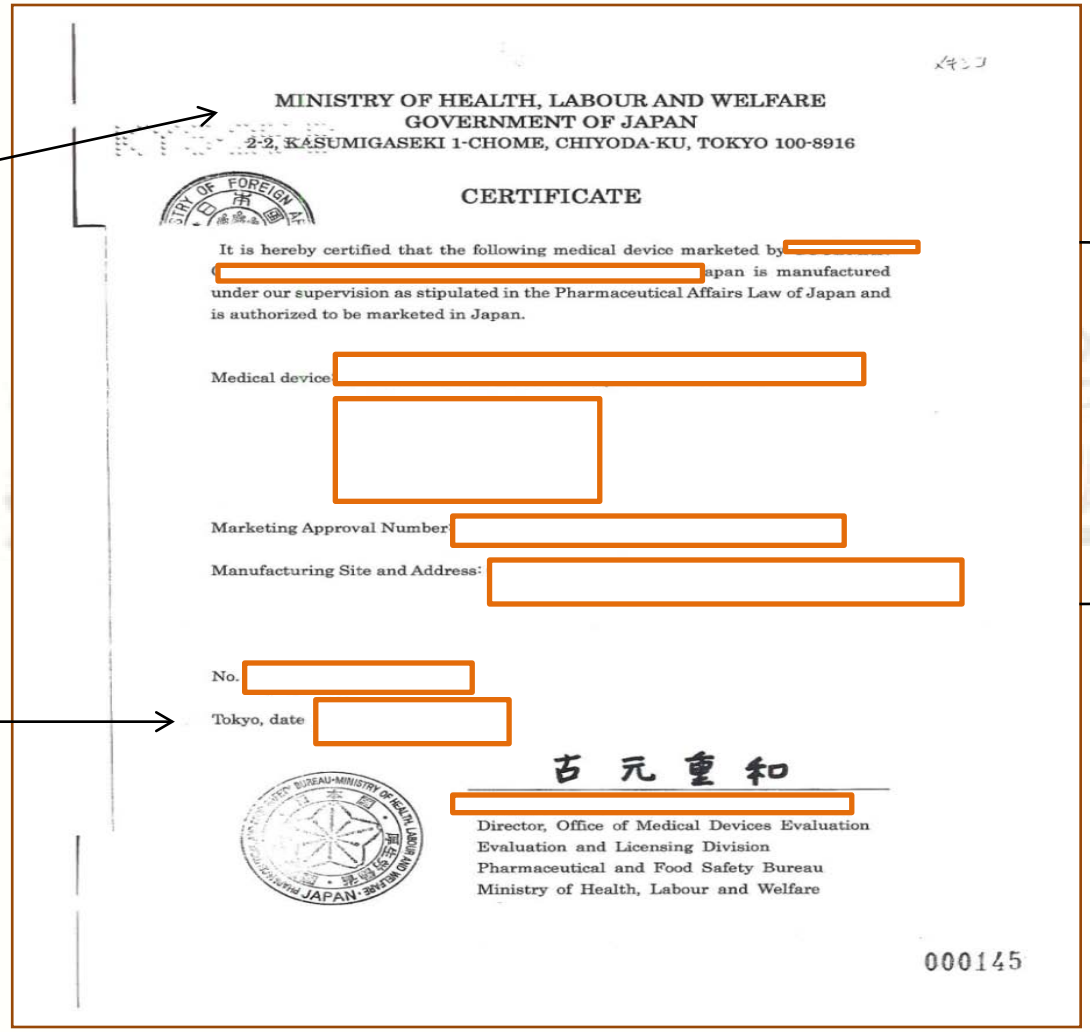
(Convention de La Haye du 5 octobre 1961)

000193

Note: Legal translation

- *Original or Certified Copy of the **Free Sales Certificate***
  No older than one year.

Issued by the Ministry of Health of Japan



MINISTRY OF HEALTH, LABOUR AND WELFARE
GOVERNMENT OF JAPAN
2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE

It is hereby certified that the following medical device marketed by [redacted] Japan is manufactured under our supervision as stipulated in the Pharmaceutical Affairs Law of Japan and is authorized to be marketed in Japan.

Medical device [redacted]

Marketing Approval Number [redacted]

Manufacturing Site and Address: [redacted]

No. [redacted]

Tokyo, date [redacted]

古 元 重 和

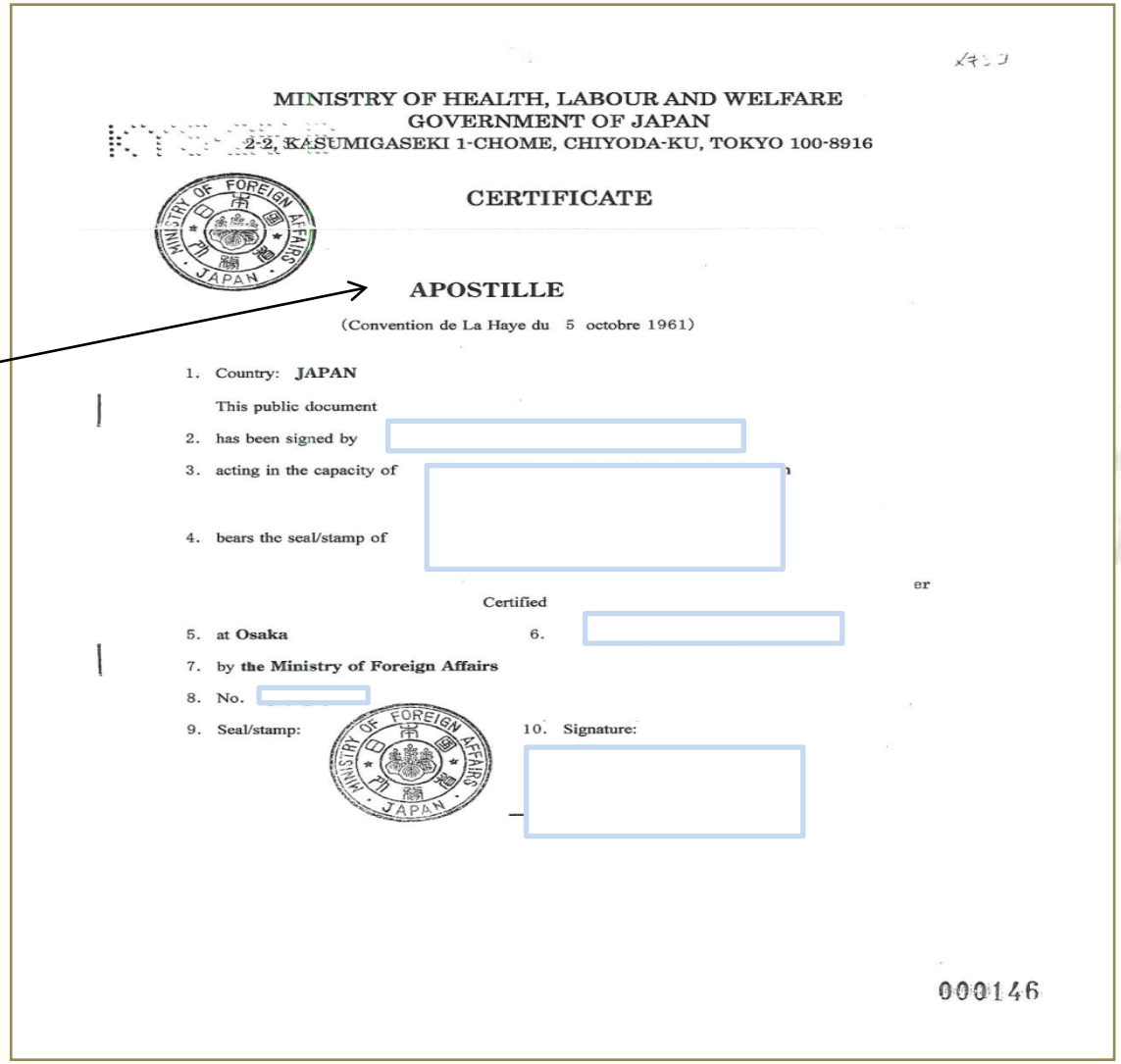
Director, Office of Medical Devices Evaluation
Evaluation and Licensing Division
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

000145

Medical Device Data

No older than one year

Authenticated
(Apostille)



MINISTRY OF HEALTH, LABOUR AND WELFARE
GOVERNMENT OF JAPAN
2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
This public document
2. has been signed by
3. acting in the capacity of
4. bears the seal/stamp of

Certified

5. at Osaka 6.
7. by the Ministry of Foreign Affairs
8. No.
9. Seal/stamp: 10. Signature:

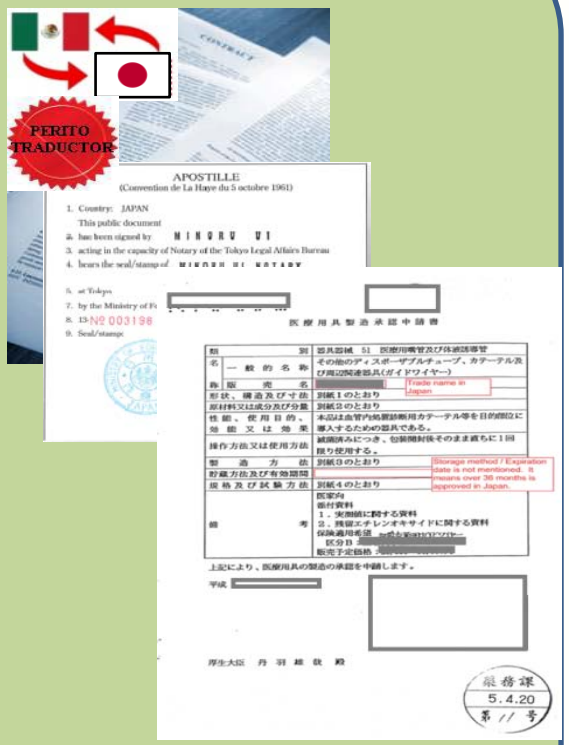
000146

Note: Legal Translation.

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

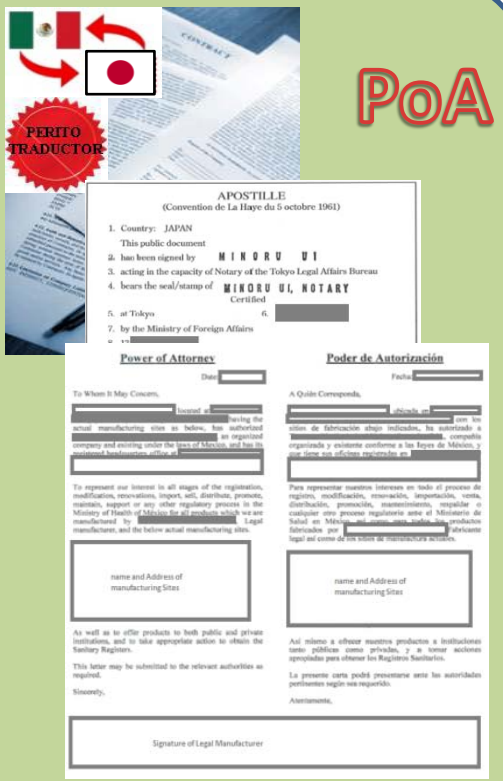
Class II Medical Devices (class II without criteria established in accordance), III and IV with Approval Letter Issued by the MHLW in Japan (COFEPRIS-04-001-H).



Letter of Approval issued by the MHLW

Export Notification

Certificate of Free Sale



Letter of Representation

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Agreement for Low Risk Medical Devices

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

CLASS IA SANITARY LOW RISK AND EXEMPT

- There is an Agreement that is given to know the list of health products considered at low risk for purposes of obtaining an Approval, and products that by their nature, characteristics and use are not considered devices for the health and therefore do not require authorization.

- ***Published in the Official Gazette on December 31, 2011***

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

CLASS IA SANITARY LOW RISK AND EXEMPT

- All devices that are now considered as low risk, have 5 years from the publication of the agreement to perform the procedure. (Appendix One)
- For those that are Exempts of an Approval the Ministry of Health will issued an Official Document of Exempt, this document don´t have an expiration date, however it can be updated if user require it. (Appendix Two)
- COFEPRIS is working with several Mexican Chambers (CANIFARMA, AMID, CANACITTRA, AMIC, etc) in order to update both Appendix.

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

Requirements for the Approval

Of MEDICAL DEVICES Import Products (Foreing Manufacture) Consider Low Risk

Requirements

1. Registration Application Form
2. Proof of Payment of fees Class IA
3. Notice of Retail Operation in Mexico and Notice of Health Responsible
4. Project Tag according to the established in the NOM-137-SSA1-2008, “Labeling Medical Devices”
5. Letter of Representation issued by the Manufacturer

SALUD
SECRETARÍA DE SALUD

Cofepris
Comisión Federal para la Protección contra Riesgos Sanitarios

THANKS