Health Technology Regulation in Mexico

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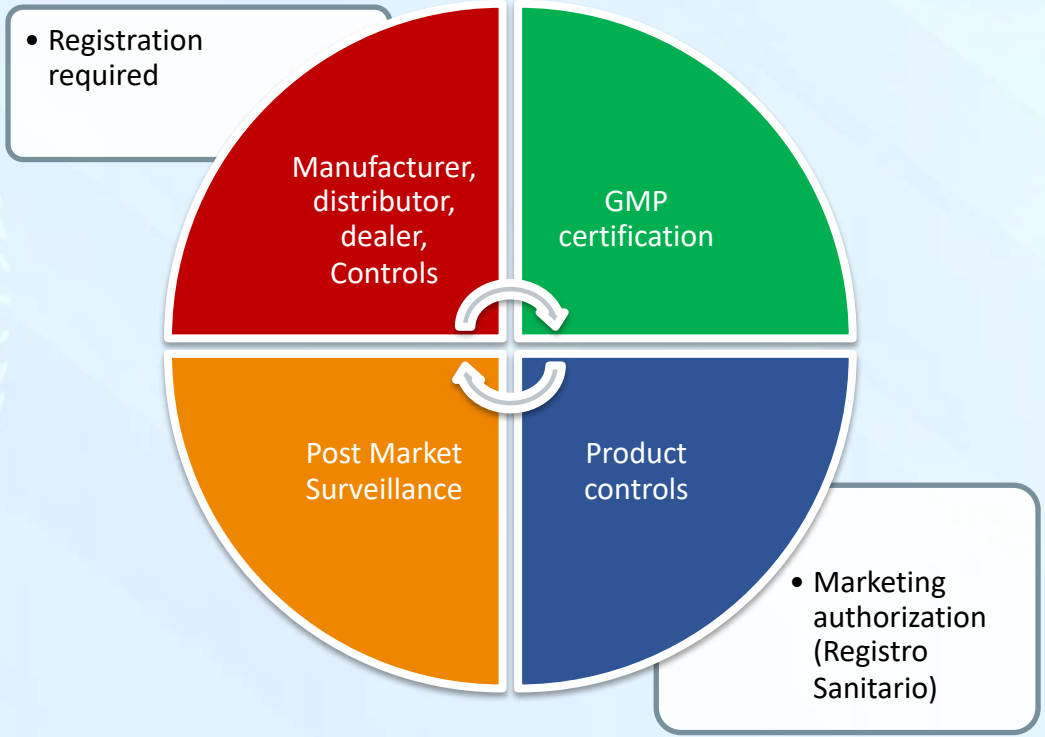
COFEPRIS
COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

REGULACIÓN SANITARIA

Regulatory Framework

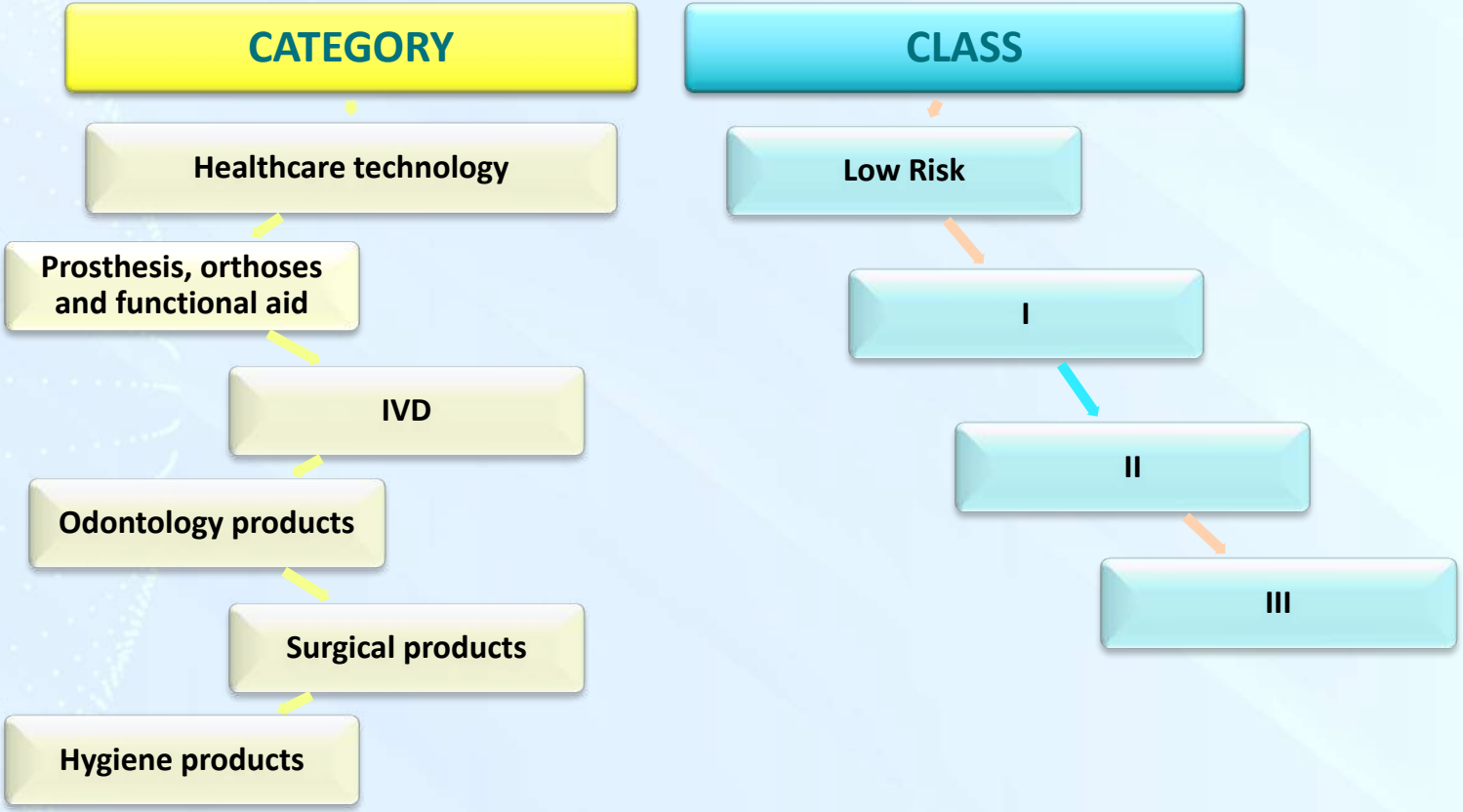
Regulatory controls in line with MD lifecycle



National and International Standards for Medical Devices

- ❑ Mexican National Standards
  - ➢ NOM-137-SSA1-2008. Labeling
  - ➢ NOM-001-SSA1-2010.Procedure for updating the Pharmacopeia
  - ➢ NOM-240-SSA1-2012. Post market surveillance
  - ➢ NOM-241-SSA1-2012, GMP for MD
  - ➢ NOM-012-SSA3-2012. Clinical trials
- ❑ Pharmacopeia for MD
- ❑ International standards
  - *IEC 60601- Medical Electrical equipment
  - *ISO 14155- Clinical investigation of medical devices for human subjects.
  - *ISO 13485- Medical devices -- Quality management systems
  - *ISO 14971- Risk Management
  - *IEC 62366- medical devices - Application of usability

Risk based Classification



Registro Sanitario, Marketing Authorization

Medical Device Classification and Category

Ordinary

Equivalency agreements

Low risk agreement

Equivalency Agreements

Equivalency agreement for USA and Canada MD; published 26/10/2010.

Equivalency agreement for Japan MD; published 25/01/2012.

REGISTRO SANITARIO , Marketing Authorization

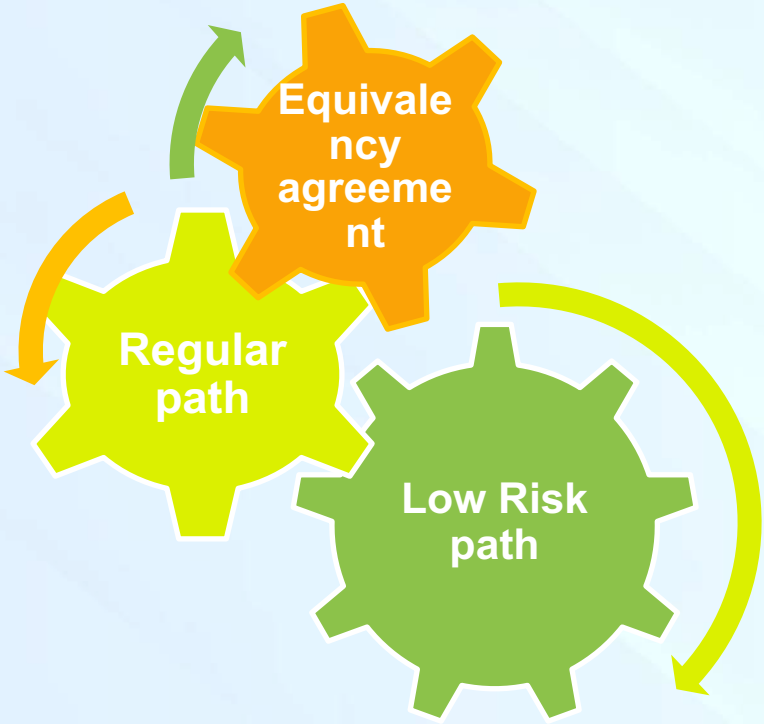
All Medical Devices require a marketing authorization issued by COFEPRIS **before** being manufactured, sold, distributed or used.(Art. 82 RIS)

- Issued by COFEPRIS for 5 years

  0865E2007 SSA

Allows:

- Administrative Modifications
- Technical Modifications
- Renewal



HT Regulation Challenges

Mexico's CE Challenges in Regulatory Requirements

Alignment with international requirements and standards

- Biomedical/Clinical Engineer CE as a Healthcare professionals
- National Standards involvement
  - Labeling
  - GMP
  - Technovigilance
- MDSAP (Medical Devices Standards Authorisation Process)
- Development of new MD

SALUD
SECRETARÍA DE SALUD

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Thank you

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