IMDRF International Medical Device Regulators Forum

INMETRO

MINISTÉRIO DA INDÚSTRIA, COMÉRCIO EXTERIOR E SERVIÇOS

BRASIL GOVERNO FEDERAL

Brazilian System for Conformity Assessment (SBAC)

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National Institute of Metrology, Quality and Technology - Inmetro

Summary

- Inmetro and its activities
- Steps Technical Regulatory Implementation process
- Health Area Equipment

Summary

Mission

Provide **confidence** to the Brazilian society in measurements and products, through Metrology and **Conformity Assessment**, promoting harmonization in consumption relations, innovation and competitiveness of the country.

Main Activities

- National Institute of Metrology
- Focal Point of Technical Barriers to Trade Agreement of the World Trade Organization
- National Accreditation Body
- Unique Regulator in the field of Legal Metrology
- Regulator in the field of Consumers Health and Safety and Environmental Protection (in non-regulated areas or by delegation), Combat Deceptive Practices and Unfair Competition
- Coordinator of Conformity Assessment Programs under Brazilian Conformity Assessment System (SBAC)

Sinmetro

National System of Metrology, Standardization and Industrial Quality
Law nº 5.966, of December 11, 1973

Conmetro

National Council of Metrology, Standardization and Industrial Quality

10 Ministries
CNI
CNC
IDEC
ABNT

Inmetro: Executive Secretary and Policies Executor

CPCON

Technical Committees

- ***Brazilian Metrology Committee (CBM)***
- ***Brazilian Conformity Assessment Committee (CBAC)***
- ***Brazilian Standardization Committee (CBN)***
- ***Brazilian Codex Alimentarius Committee (CCAB)***
- ***Brazilian Regulatory Committee (CBR)***
- ***Brazilian Technical Barriers to Trade Committee (CBTC)***

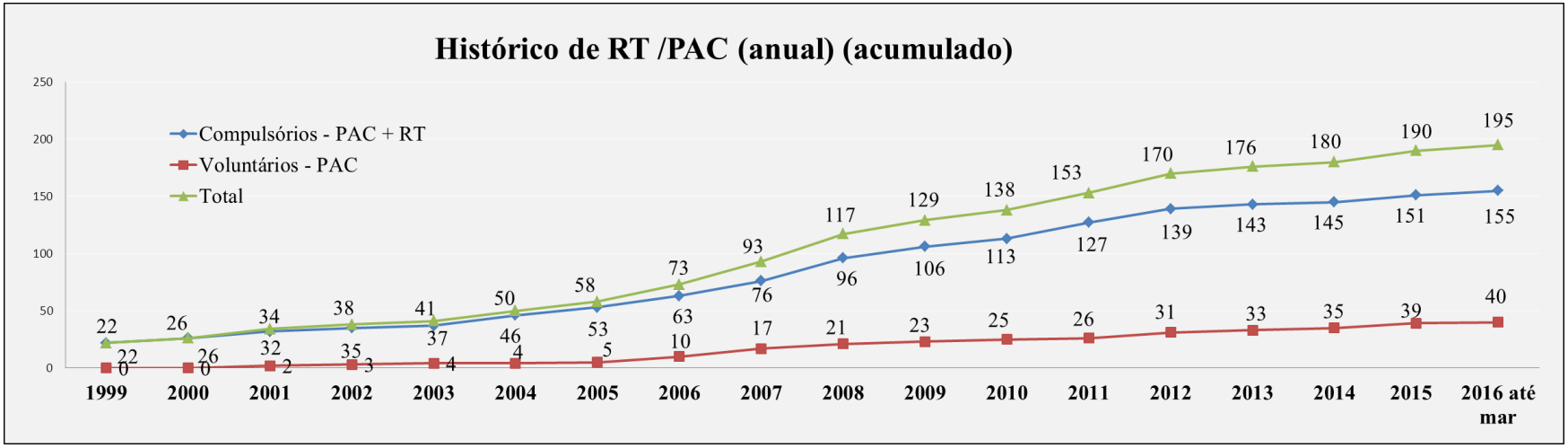
Conformity Assessment

The Conformity Assessment is a systematic process, with pre-established rules, monitored and evaluated, in order **to provide adequate degree of confidence** that a product, process or service, or a professional meets pre-established requirements in standards or regulations, **with the best cost-benefit ratio to society**.

Who ensures quality is the supplier of the product.

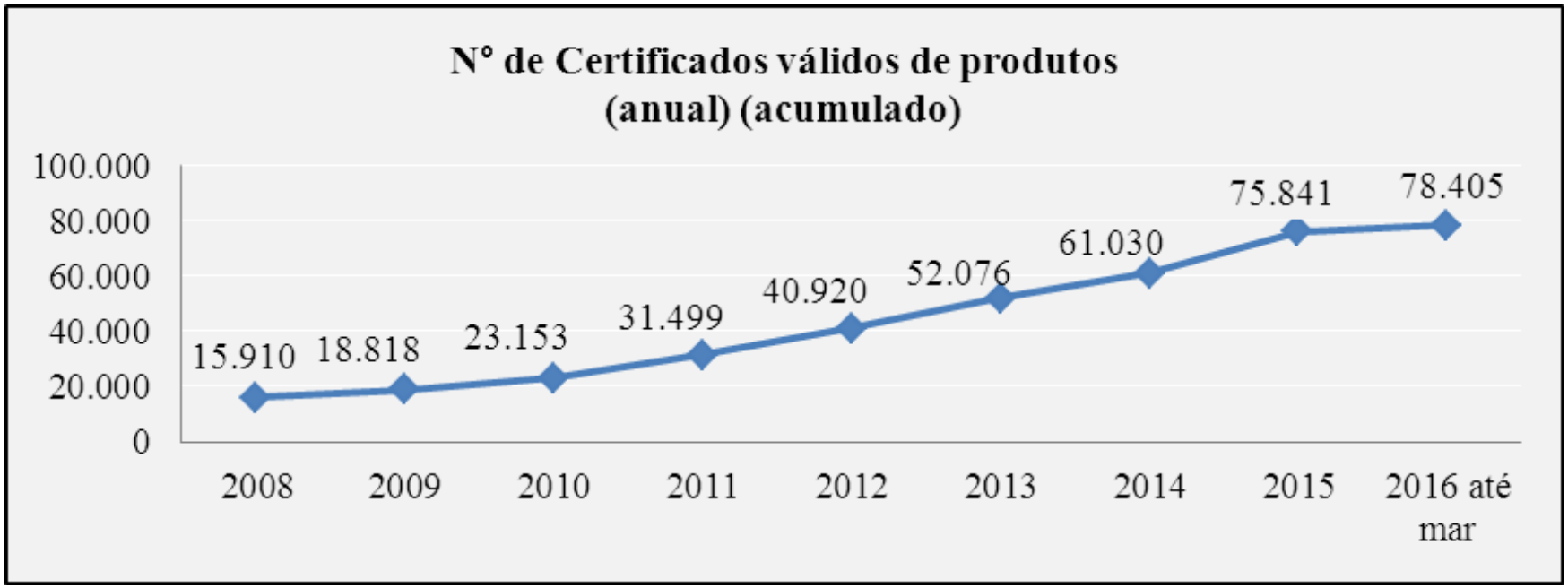
Activity Figures

Cumulative number of Technical Regulations and Programs developed, deployed and in implementation



Activity Figures

Number of valid product Certificates

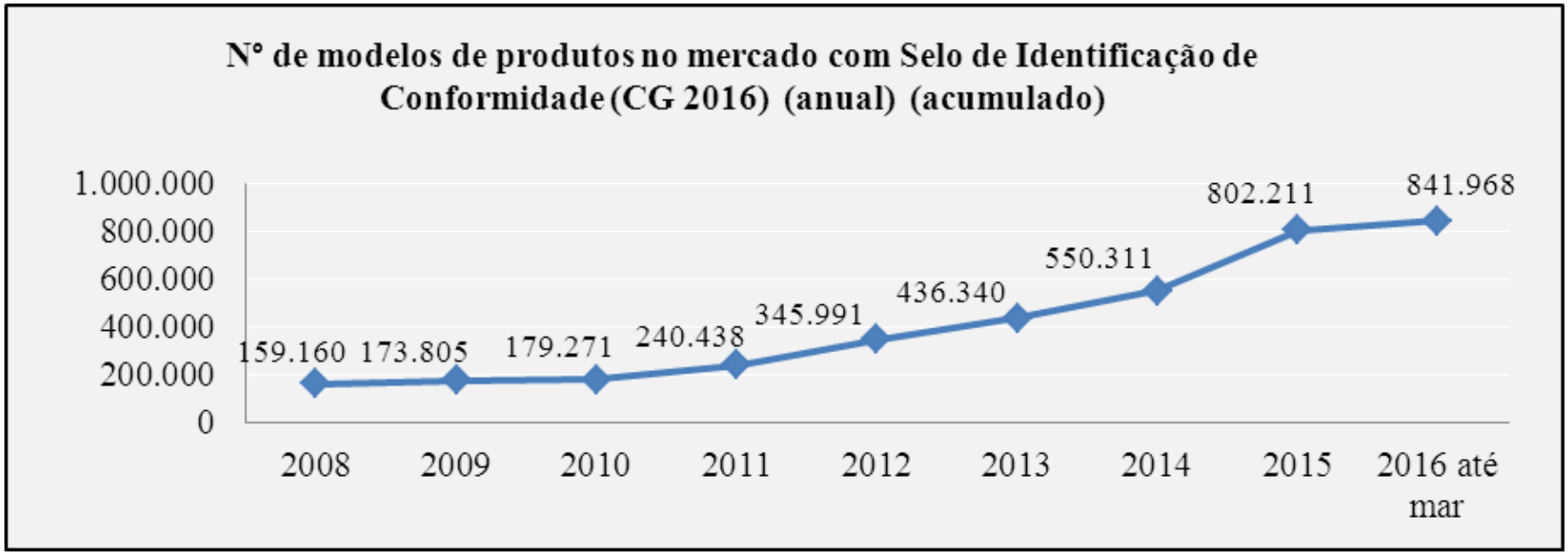


Activity Figures

Number of companies with objects subjected to Conformity Assessment

Activity Figures

Number of product models on the market with Compliance Identification Seal

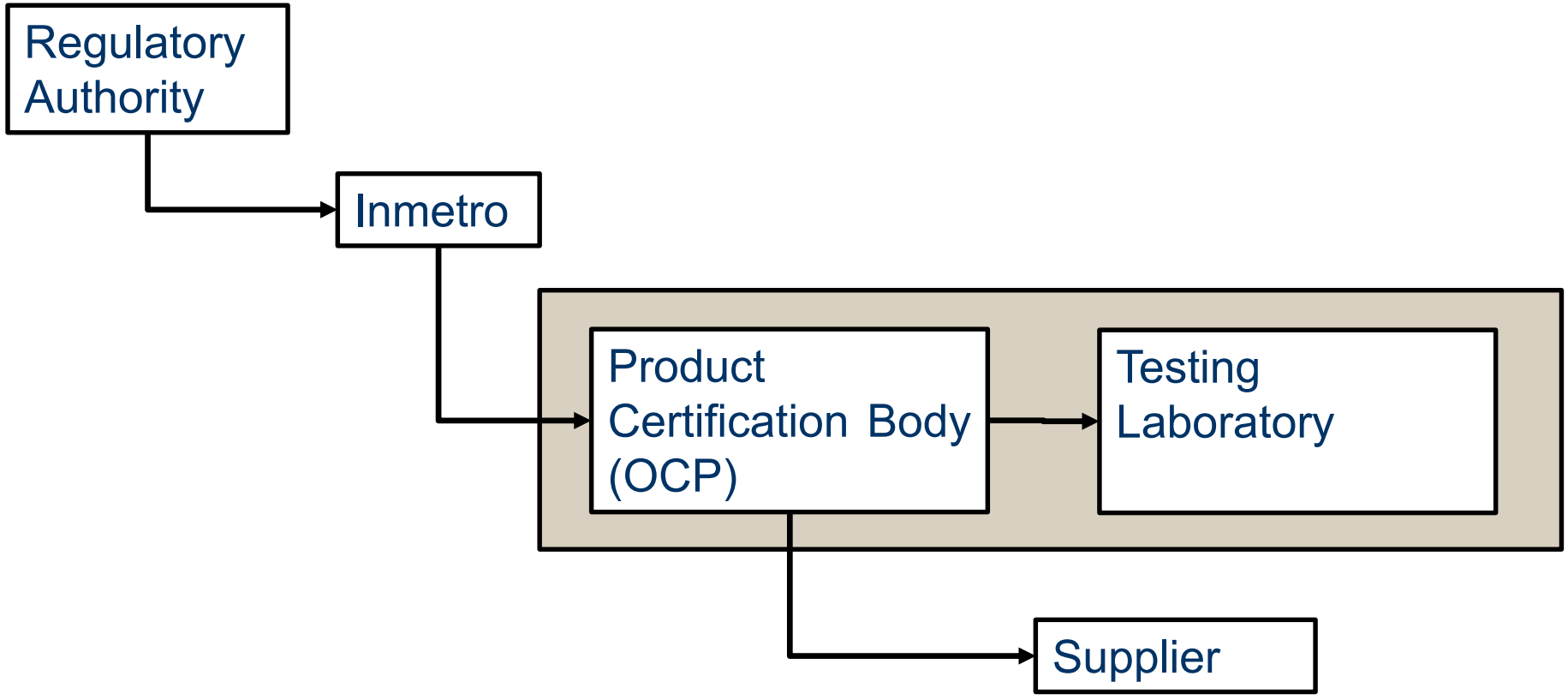


Activity Figures

Number of valid Certificates of Management Systems

- ABNT NBR ISO 9001: 12.038
- ABNT NBR ISO 14001: 1.512

Accreditation



Recognition of competence.

Accreditation

- Testing Laboratory: 990
  - (CLC) Clinical: 2
  - (CRL) Independent: 948
  - (CLF) Factory: 40

Chemical Tests: 561
Biological Tests: 461

- Calibration Laboratories: 374

- Product Certification Bodies: 107

Recognition of competence.

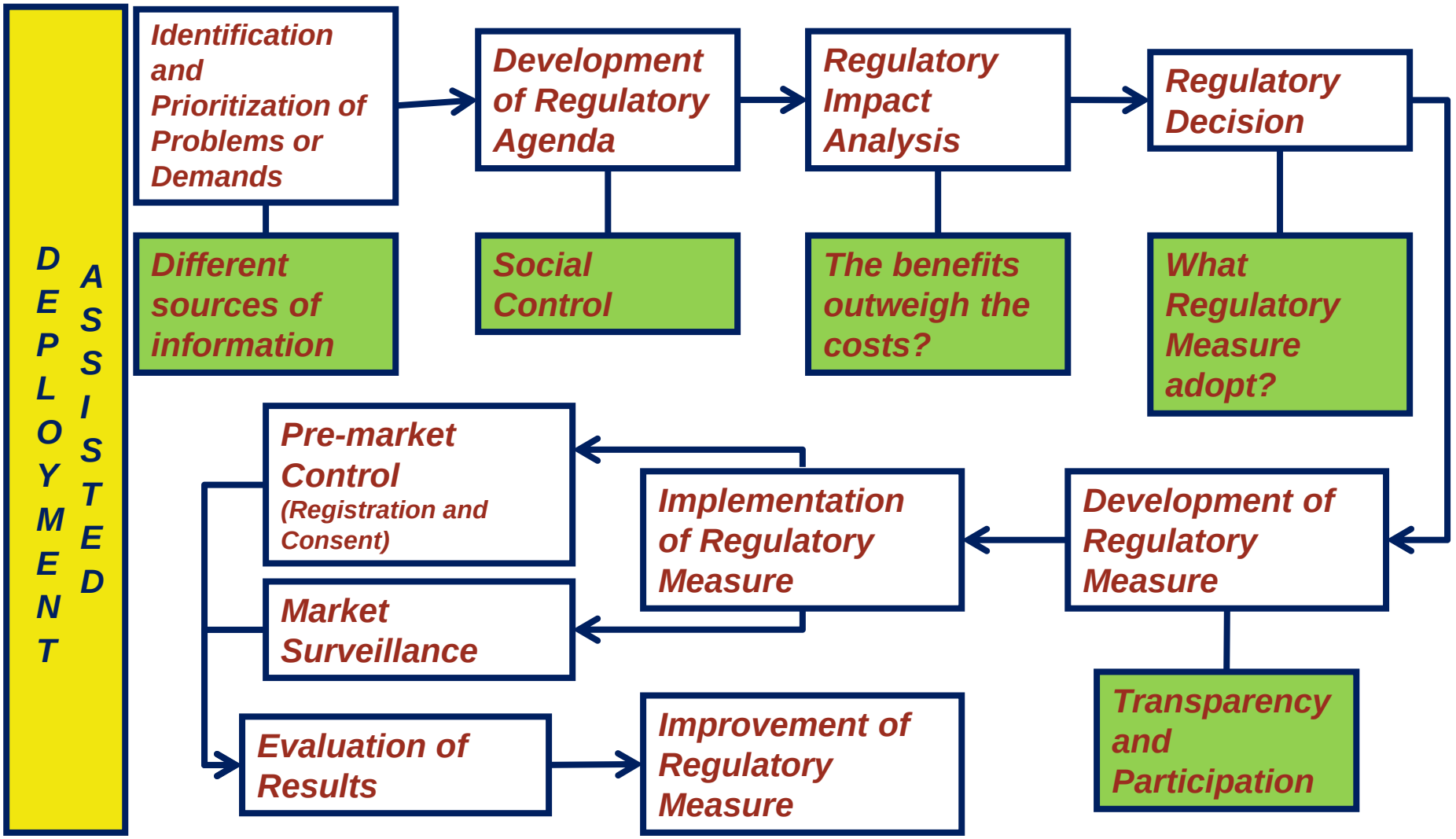
Summary

Inmetro and its activities

Steps Technical Regulatory Implementation process

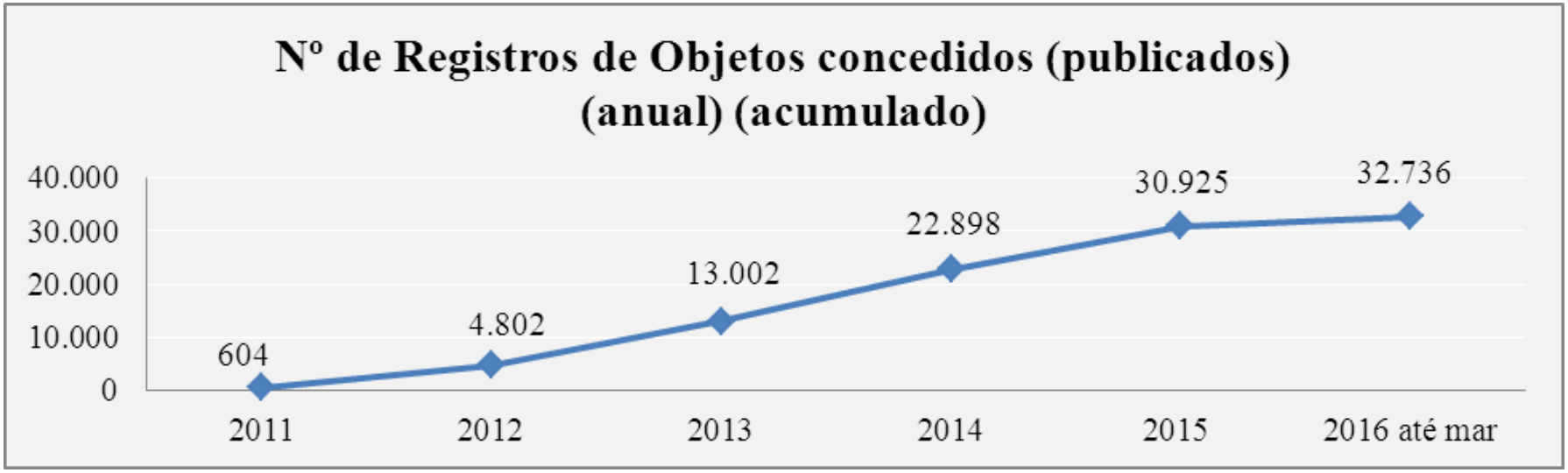
Health Area Equipment

Regulatory Process



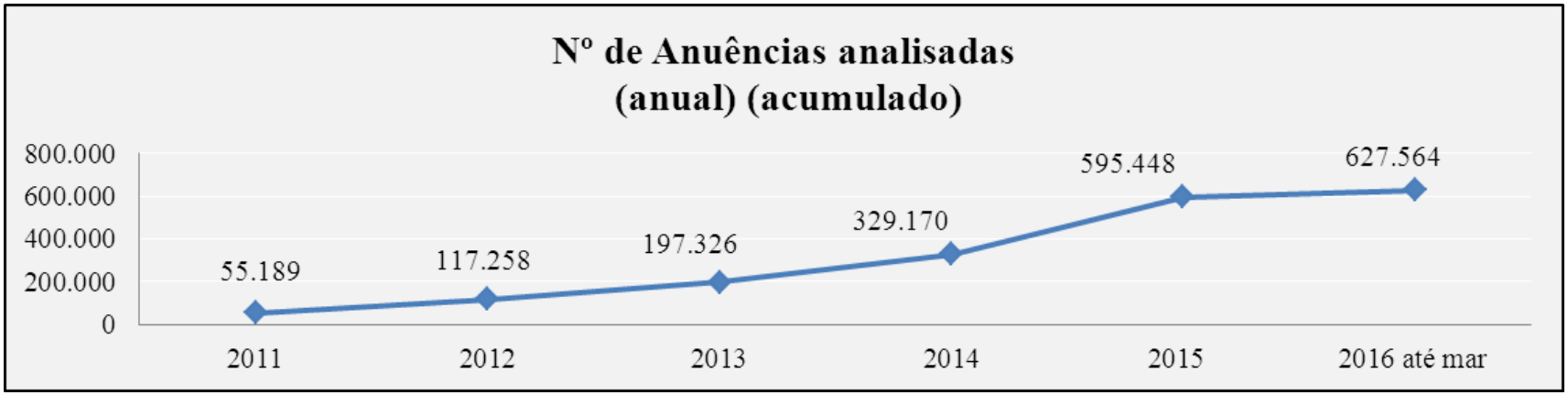
Activity Figures

Number of Registration granted



Activity Figures

Number of Analyzed Consents



Summary

Products

- Sterile hypodermic needles for single use and sterile gingival needles for single use
- Pacifiers
- Electrical Equipment under Sanitary Surveillance System
- Single Use Transfusion Equipos, Infusion Gravitational and Infusion for Use with Infusion Pump
- Breast Implants
- Surgical gloves and non-surgical procedure of natural rubber, synthetic rubber and mixtures of synthetic rubbers
- Bottles and bottle nipples
- Male condoms
- Sterile hypodermic Syringes for single use

Thank you

Leonardo Machado Rocha

http://inmetro.gov.br/ouvidoria

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