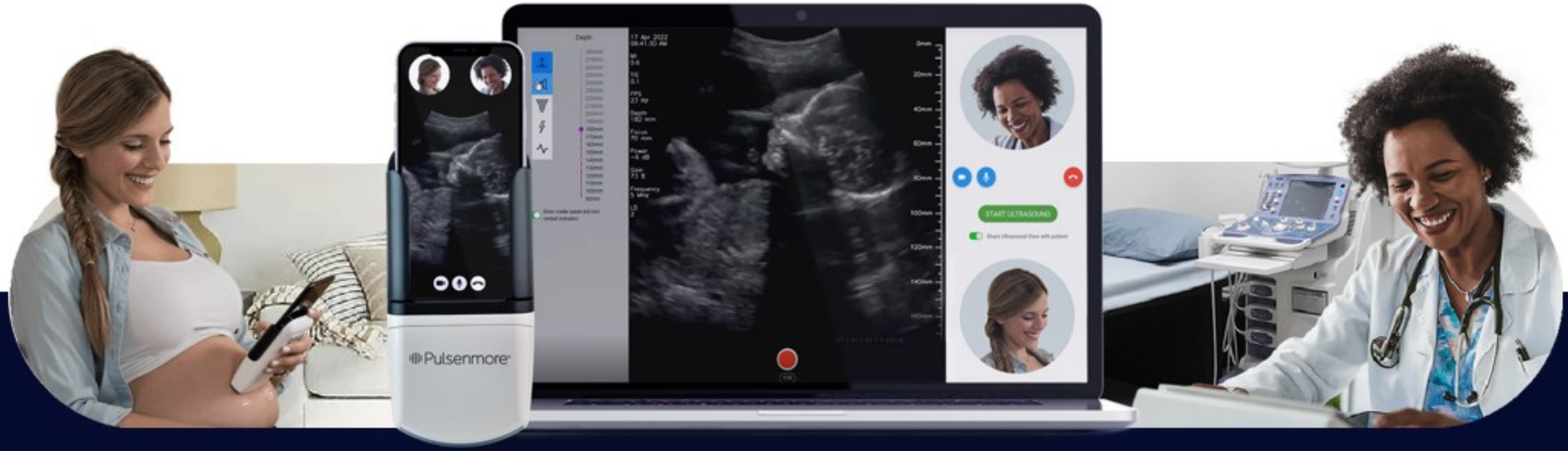
Pulsenmore™
Home Ultrasound

The Carnival is Over Let's Register our Product in Brazil

Israel Citron MSc MBA
VP QA/RA
Pulsenmore Ltd.



March 19, 2024

Brazil - Here We Come

Today’s agenda

- Pulsenmore ES a short intro
- Health Market in Brazil
- ANVISA registration
- INMETRO Registration
- ANATEL registration
- The results
- Tips and tricks

Pulsenmore ES - a True Story with a Happy Ending

https://www.youtube.com/watch?v=oP6Yrt6vOLA

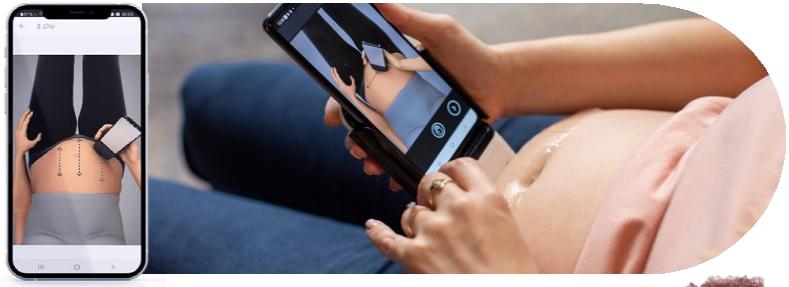
Self-Scan at Home, get Remote Clinical Diagnosis

Patient's Self-Scan Device

Docking with her personal smartphone

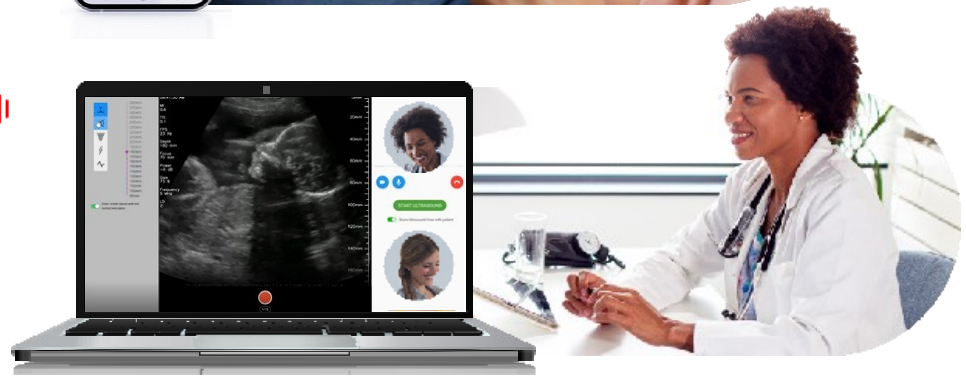
Mobile App

Step-by-step guidance



Clinician's Dashboard

Review scans and interact with patients



Home Ultrasound Benefits

- Better pregnancy experience
- Less anxiety
- Greater access to care
- Better resource management
- Saving lives
- Strategic Partnerships

Clalit to offer pregnant members startup PulseNmore's at-home ultrasound kit

Israel's PulseNmore has developed a handheld tele-ultrasound device that enables pregnant women to perform ultrasound scans at home and get remote feedback from physician

By SHOSHANNA SOLOMON

11 August 2020, 11:07 am

Overcoming Challenges, Building Success

- Launched the service 2.5 years ago
- National diagnostic center
- >100,000 remote diagnoses to date!
- Average response time- 1 hour

Health Market in Brazil

- Approximately 214M people
- The total female population between ages 15-44 is approx. 48M / 22% of total population
- The total registered birth numbers is approx. 2.5M / 1.1% of total population
- Total number of pregnancies per year is approx. 2.67M
- Number of Gynecologists and Obstetricians: 37.727
- Hybrid Market: 75% public and 25% private
- Total Medical Consultations carried out (Public + Private in 2022): 860,285,300
- The health sector in Brazil is the 8th largest in the world. In 2022, the health, beauty and well-being sector grew 21.5%, reaching $47,362 billion

Health Market in Brazil

- The attention of pregnant women is made by:
  - Public hospitals and centers of health attention (predominant low social class)
  - Private hospitals and special clinics/offices, majority covered for private health insurance (medium and high classes)
  - Military hospitals (Armed Forces)
- Remote care solutions, such as Telehealth, home care, digital health, and others, are being implemented and regulated very fast.
- 7,5MM consultations performed by teleconsultation in 2022
- 52K doctors performing teleconsultation care
- In 2023, Brazil imported the equivalent of U$ 8.18 billion in medical devices.

Definition of a Medical Device in Brazil

ANVISA
Agência Nacional de Vigilância Sanitária

- **ANVISA** defines medical devices as : *"Health products, such as equipment, apparatus, material, item or system with a medical, dental, or laboratory use or application for prevention, diagnosis, treatment, rehabilitation and that does not use contraception and pharmacological, immunological or metabolic means to perform the main function in humans but can be assisted in their functions by such means."*

ANVISA Requirements

- All medical devices imported into or distributed within Brazil must first undergo registration with ANVISA.
- Once ANVISA makes its final decision on registration applications, the result is published in Brazil's Official Diary.
- Approved devices are then listed on ANVISA's public registration database.
- Aside from ANVISA registration, some products require additional certifications in Brazil such as
  - INMETRO
  - ANATEL
- ISO and CE certificate must be appended to the ANVISA device application.
- RESOLUTION – RDC No. 751, DATED SEPTEMBER 15, 2022

Medical Device Classifications and Grouping

Pulsenmore®

Medical devices in Brazil are classified in four classes based on the risk they pose to the human body.

Chapter II section I of the resolution

Risk Level	Classification
Low Risk	Class I
Medium Risk	Class II
High Risk	Class III
Very High Risk	Class IV

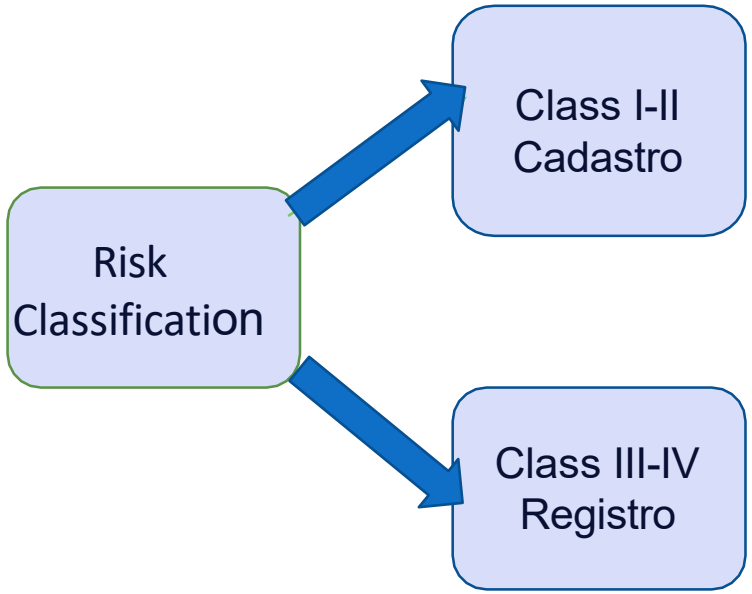
Medical devices also follow the 22 classification rules, which are largely similar to the rules outlined in the MDD /MDR

Attachment I of the resolution

Classification Rules	Rules Grouping
1-4	Non-invasive devices
5-8	Invasive devices
9-13	Active Devices
14-22	Special Rules

Example: Rule 11 is on Software

Registration Process for Medical Devices



Registration does not expire, it might be cancelled upon request

Registration is valid for ten years from the date of publication in the Brazilian Official Gazette and may be renewed for equal and successive periods.

Cadastro Registration Pathway

- Castrado pathway is applicable to “Class I and Class II” medical devices
- Includes a simplified subset of the registration required documents
  - Application form
  - LOA from foreign manufacturer to local license holder in Brazil (BRH)
  - Additional certifications of the product (INMETRO, ANATEL)
- A Technical Dossier prepared and kept by the Brazilian Registration Holder (BRH)
  - Market history
  - Risk management file
  - Essential principles checklist
  - Safety and EMC test reports
  - Usability and HF studies
  - Verification and validation summary reports
  - User manuals
  - Other documents (similar to EC TF)

Registro Pathway

- Registro pathway is applicable to all Class III and IV devices.
- The registro process requires a comprehensive level of technical and clinical information provided for ANVISA review.
- Prior to approval of registro applications, proof of compliance with BGMP is also required (similar to ISO 13485 and FDA QSR 820.
- Registro applications can be submitted without proof of BGMP compliance, the application will be approved once BGMP certificate has been obtained for all applicable manufacturing facilities.
- Class III and IV registrations are valid for 10 years.
- Renewal applications must be submitted at least 180 days prior to expiration date.

Registration Timeline

Registration Type	Registration Timeline
Registro	9-15 months
Cadastro	1- 3 months
Notification	20-30 days

The Registration number is published in ***Diário Oficial da União (DOU)*** issued periodically

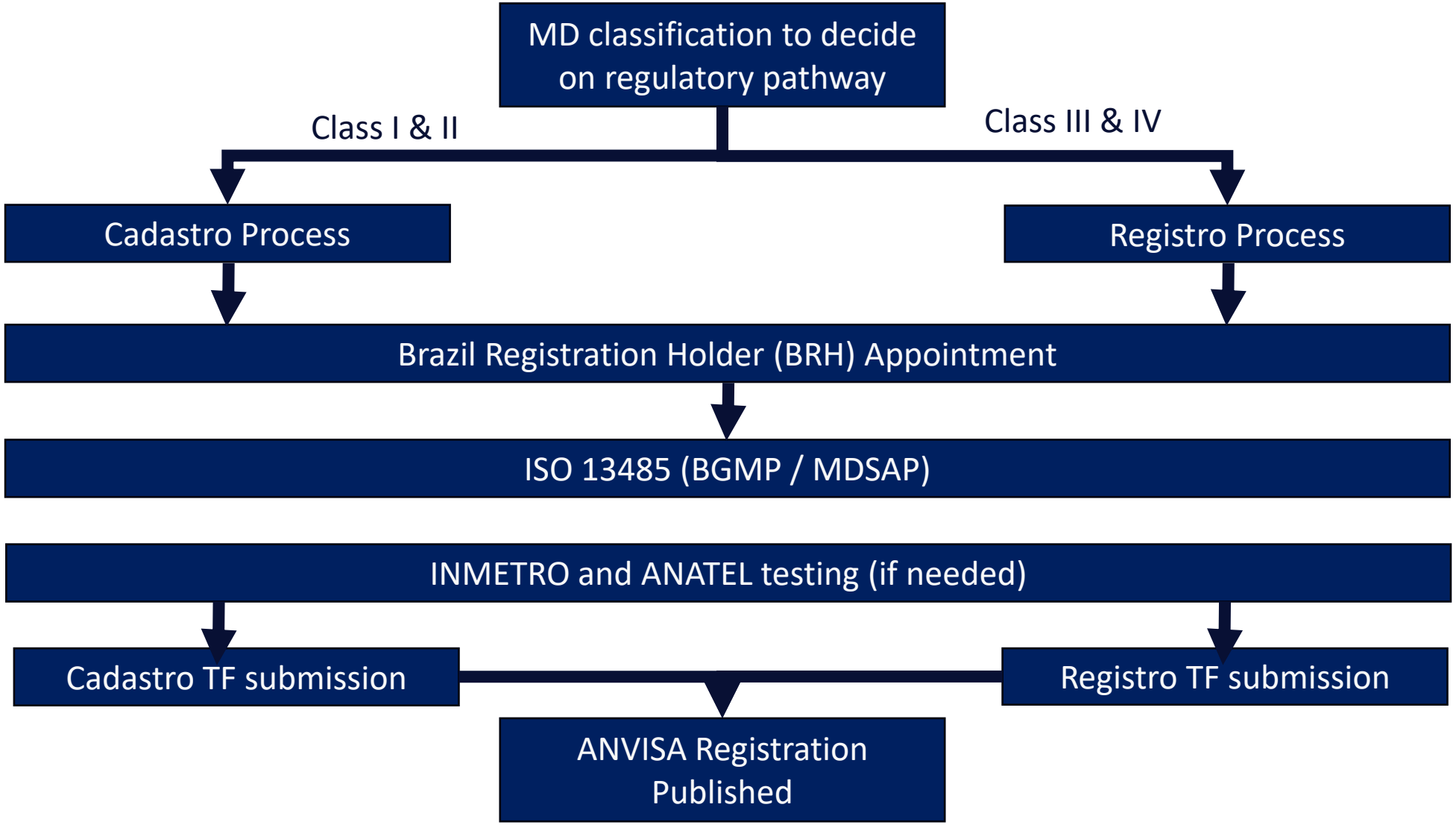
INMETRO Certification

- INMETRO certification is required for all electro-medical devices identified in Normative Instruction IN 04/2015, and is based on international test standards, e.g., IEC 60601 series testing.
- If manufacturers have already conducted testing through an International Laboratory Accreditation Cooperation (ILAC) laboratory and if the test report is less than two years old, there is no need for INMETRO certification testing.
- A certification audit at the manufacturing facility by the certification lab is required prior to INMETRO approval (similar to NRTL).
- An INMETRO label with the identification of the certification lab, must be affixed on the product and on the shipping box.
- INMETRO certificates are valid for five years assuming manufacturers continue maintenance efforts.
- INMETRO certification process takes 2-3 Month including auditing report

ANATEL Certification

- If the device has a wireless capability (Wi-Fi or BT) it must be tested and registered in Brazil by ANATEL.
- Radio testing in and ANATEL accredited test laboratory in Brazil are mandatory
- Samples of the Wi-Fi board together with a means to test it (test board) must be provided to the test laboratory together with a functioning device that includes the Wi-Fi board (similar to FCC testing).
- Once tests are successfully completed, a unique ID is provided, and must be affixed on the product and included in the IFU.
- License is valid for 5 years and needs to be renewed prior to expiration.
- Test and certification can take 2-4 Month, depends on test laboratory.

ANVISA Registration Process



Brazil Registration Tricks and Tips

- Brazilian Registration Holder – Distributor or Independent
- Product classification rules – Local regulatory consultant
- SW as medical device – accessory or stand alone
- Environmental safety standard IEC-60601-1-9
- INMETRO Accredited Test Laboratory – selection process
- ANATEL Test laboratory – selection process
- Apostille process – MOJ Court stamping
- Managing documents sent to regulatory agent – follow ups and status monitoring

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Questions?
Thank You!

Israel Citron, VP QA/RA, Pulsenmore Ltd.
israelc@pulsenmore.com
054-7299535