



**Agência Nacional de Vigilância Sanitária**

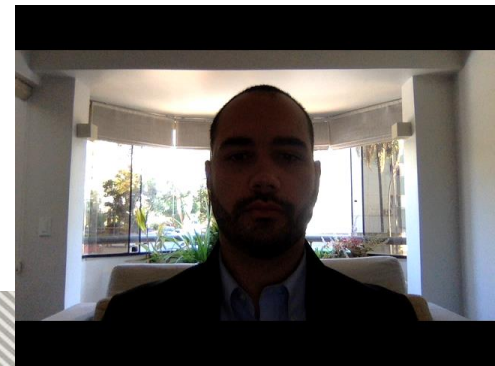
# **Implementation of UDI in Brazil**

**Current work overview**

**IMDRF-DITTA Joint Virtual Workshop on UDI**

**Thursday, September 9th, 2021**

**8:00PM KST**





# Unique Device Identification in Brazil

## Objectives and Summary

### Objectives

*Emphasis on regulatory systems to enable use of UDI*

*Focus on regional drivers of requirements and change triggers*



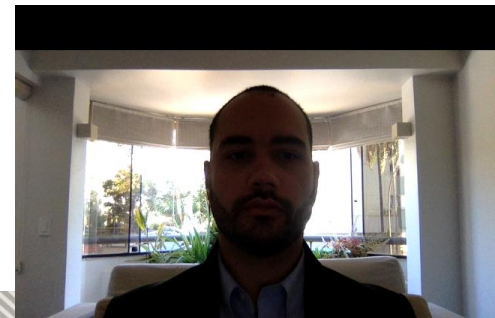
### Summary

*Core UDI Database Data Elements*

*UDI Rules*

*UDI Implementation in Brazil*

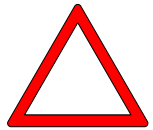
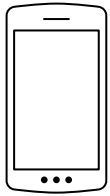
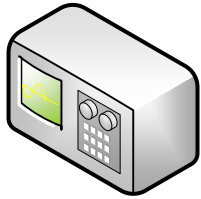
*Timeline and Schedule*



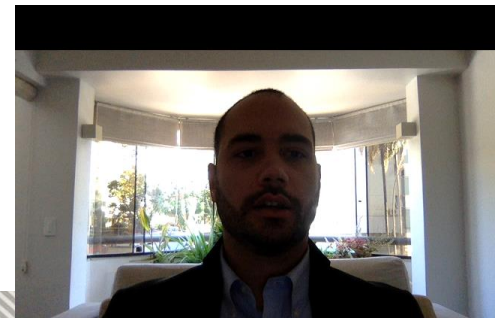


# Unique Device Identification in Brazil

## Core UDI Database Data Elements – Part I of II



- Device Identification & Description:
  - Mandatory : UDI-DI and Issuing Entity, Brand name, Device model or version
  - Mandatory if applicable : UoU UDI-DI
  - Optional: Reference and/or catalogue number and additional product description
- Contact Information:
  - Mandatory: Manufacturer's name and address
  - Optional: URL for additional information, e.g. electronic Instructions for use
- Device Packaging & Status:
  - Mandatory: UDI-DI, Date of discontinuance, and quantity per package configuration
- Licensing, Classification & Nomenclature:
  - Mandatory: Risk Class, GMDN preferred code, and Anvisa Product Code Name







# Unique Device Identification in Brazil

## Core UDI Database Data Elements – Part II of II

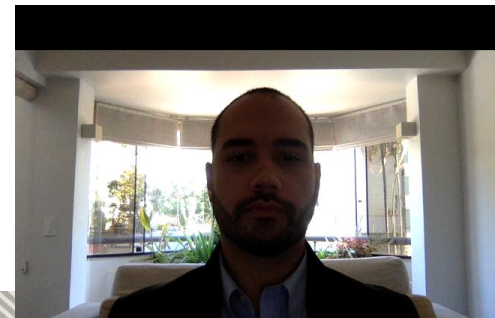
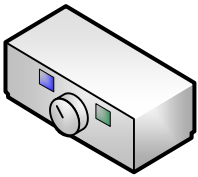
- Medical Device Characteristics:

- Mandatory

- How the device is controlled
    - Labeled as single use?
    - Labeled as sterile?
    - Need for sterilization before use?
    - Presence of Human tissues and Cells, as well as Animal tissues and Cells?

- Mandatory if applicable

- Clinical Size
    - Storage and Handling conditions
    - Maximum number of reuses
    - Method of sterilization
    - Critical warnings or contraindications
      - Containing Latex?
      - What MRI safety information does the labeling contain?
    - Information on substances
    - Clinical Trial Number





# Unique Device Identification in Brazil

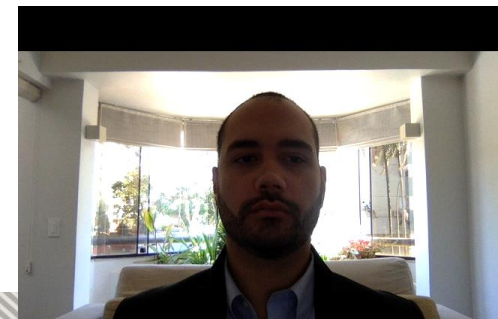
## UDI Requirements

- The UDI
  - New UDI triggers based on:
    - Brand Name
    - Device Model or Version
    - Clinical Size
    - Labeled as single use
    - Labeled as sterile
    - Need for sterilization before use
    - Quantity per package configuration
    - Critical warnings or contraindications
- UDI Carrier
- UDI Database General Principles
- Rules for specific device types

[IMDRF UDI Guidance](#)  
(December, 9th, 2013)



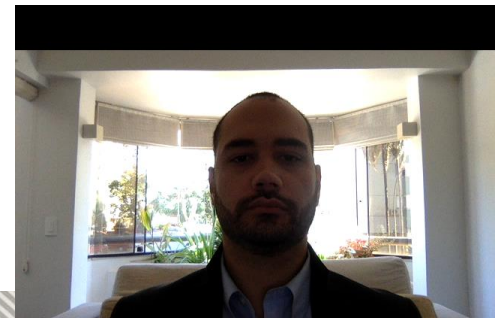
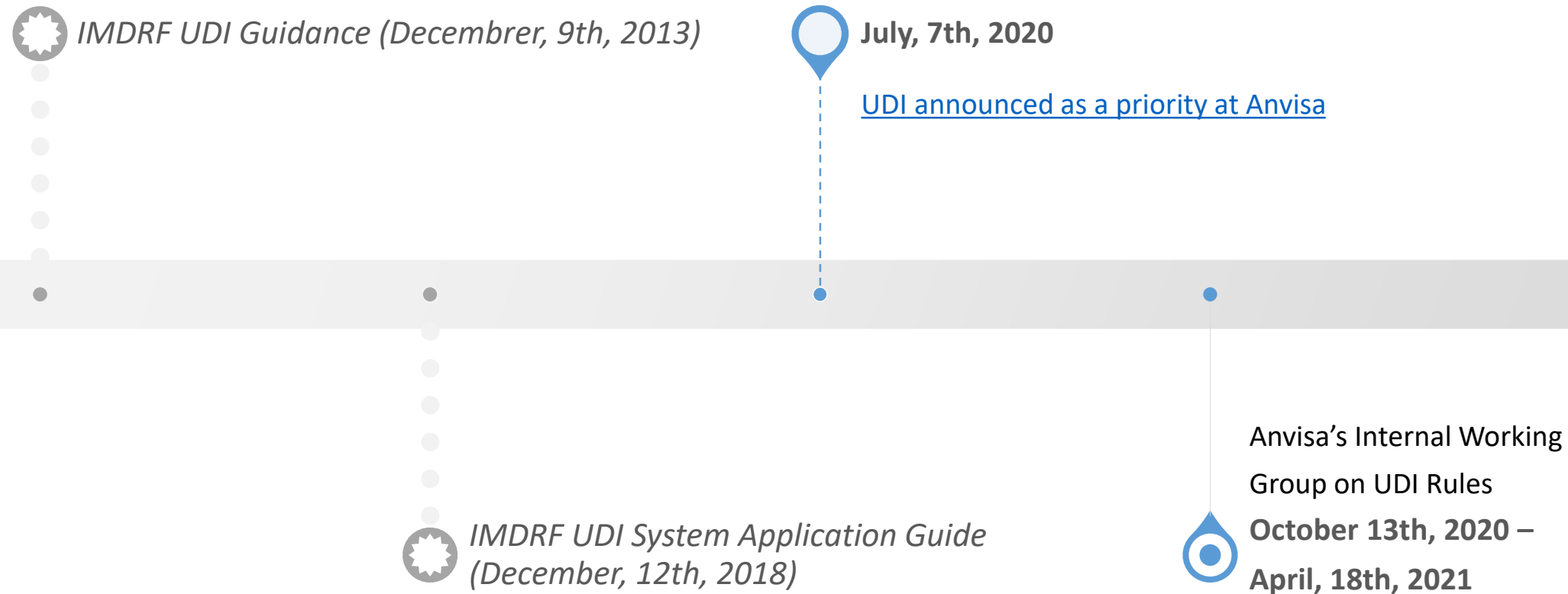
[IMDRF UDI System Application Guide](#) (December, 12th, 2018)





## Unique Device Identification in Brazil

Timeline – Part I of II







## Unique Device Identification in Brazil

Timeline – Part II of II

**April, 2021 – June, 2021**

Regulatory impact analysis exempted  
Brazilian Decree 10.411/2020, Article 4, Item VI  
Normative aimed at maintaining convergence to  
international standards

**September, 2021 – December, 2021**

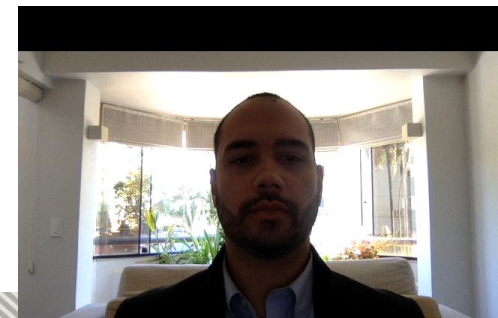
Public Consultation Review

UDI Rules under Public Consultation

**July, 07th 2021 - September, 06th 2021**

Anvisa's Board of Directors  
Deliberation on  
UDI Resolution

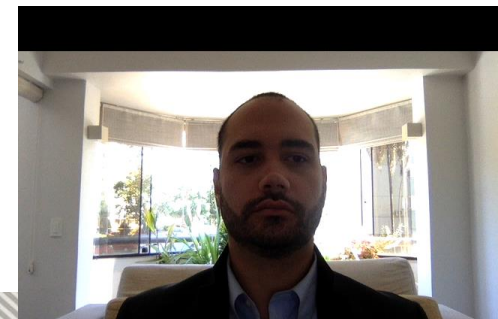
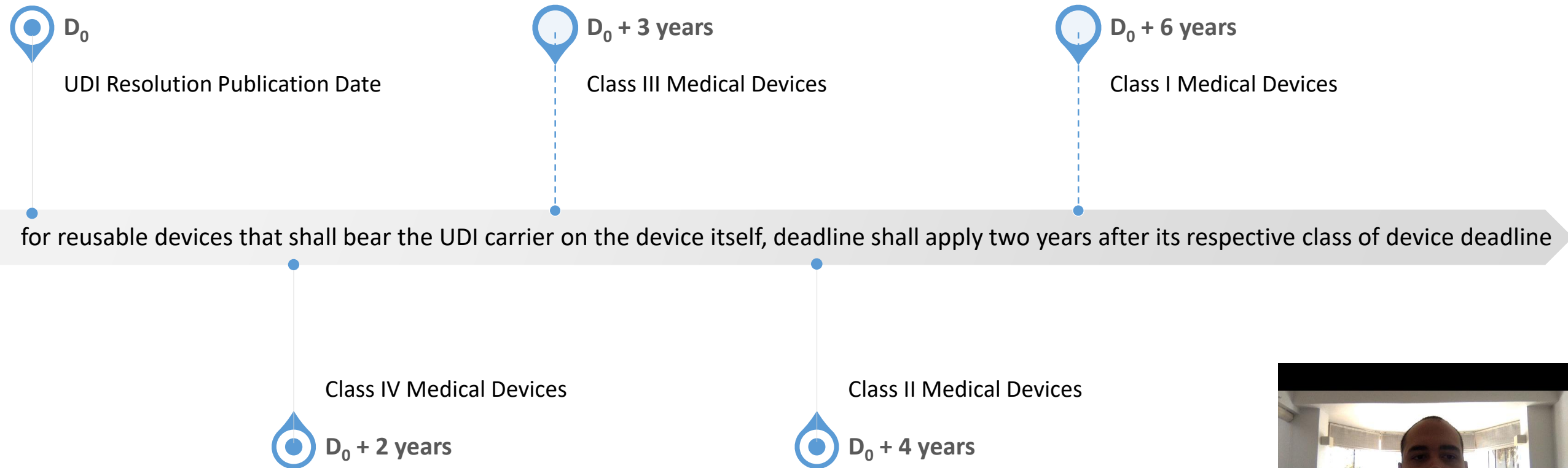
**December, 2021**





## Unique Device Identification in Brazil

UDI Implementation in Brazil – UDI Carrier on the label, on the device itself and on all higher levels of device packaging

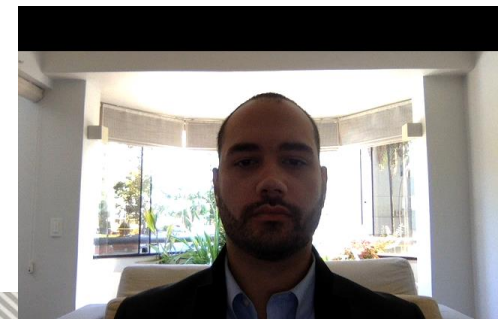
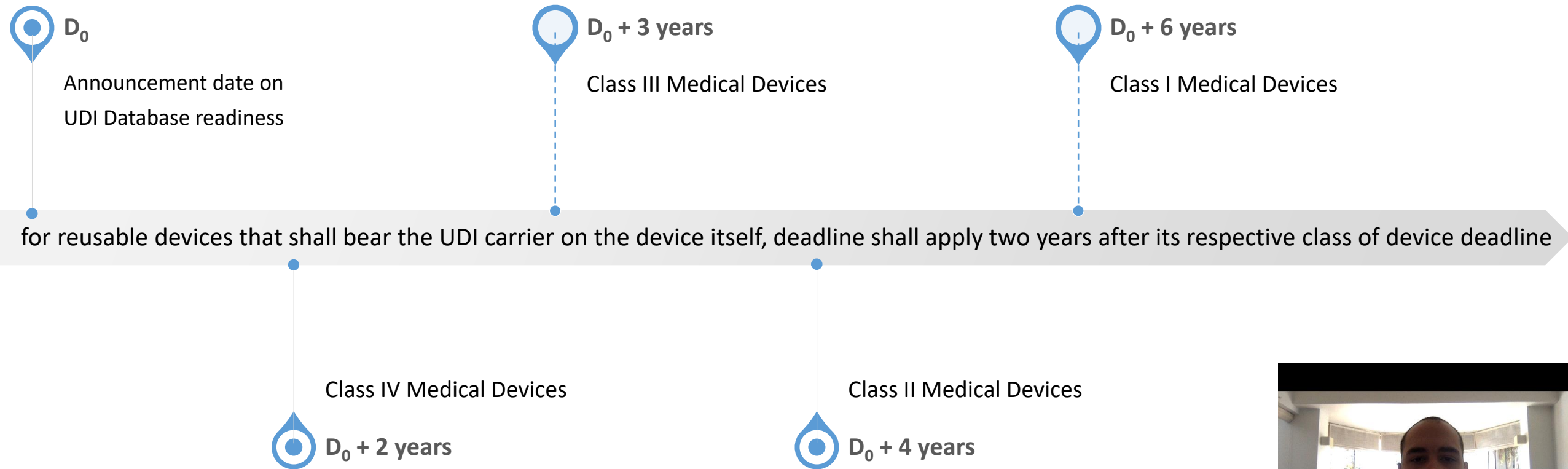






# Unique Device Identification in Brazil

## UDI Implementation in Brazil – UDI Database Data Submission





Thank you

Hélio Bomfim de Macêdo Filho

Anvisa's Medical Device Office

Agência Nacional de Vigilância Sanitária - Anvisa

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SAÚDE

