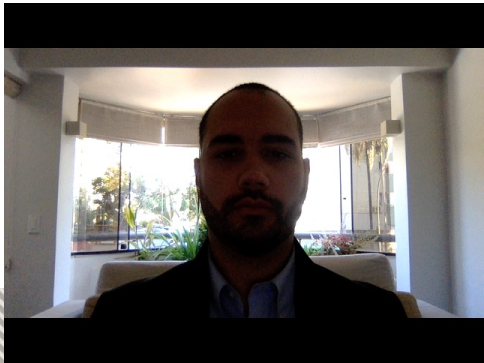
Agência Nacional de Vigilância Sanitária

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

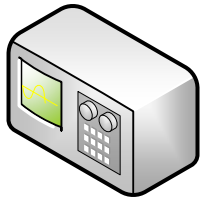
- *Emphasis on regulatory systems to enable use of UDI*
- *Focus on regional drivers of requirements and change triggers*

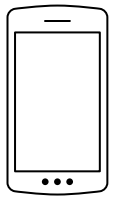
Summary

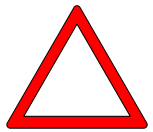
- *Core UDI Database Data Elements*
- *UDI Rules*
- *UDI Implementation in Brazil*
  - *Timeline and Schedule*

Unique Device Identification in Brazil

Core UDI Database Data Elements – Part I of II



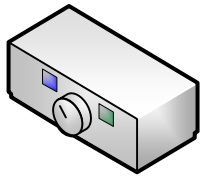




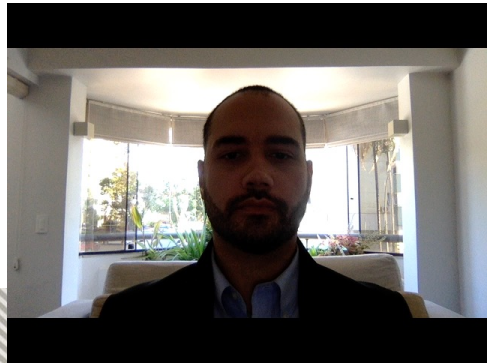
- Device Identification & Description:
  - Mandatory : UDI-DI and Issuing Entity, Brand name, Device model or version
  - Mandatory if applicable : UoU UDI-DI
  - Optional: Reference and/or catalogue number and additional product description
- Contact Information:
  - Mandatory: Manufacturer's name and 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

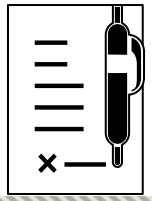


Unique Device Identification in Brazil

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

IMDRF UDI Guidance (Decembrer, 9th, 2013)

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

July, 7th, 2020

UDI announced as a priority at Anvisa

Anvisa's Internal Working Group on UDI Rules

October 13th, 2020 – April, 18th, 2021

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

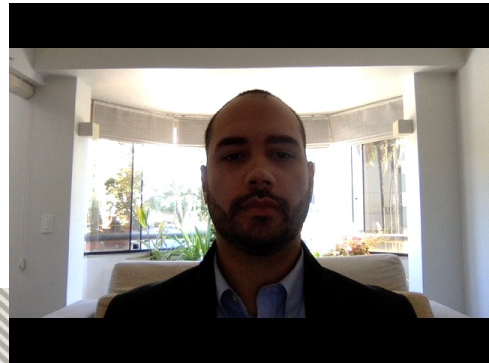
Public Consultation Review

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

D_0

UDI Resolution Publication Date

D_0 + 3 years

Class III Medical Devices

D_0 + 6 years

Class I Medical Devices

for reusable devices that shall bear the UDI carrier on the device itself, deadline shall apply two years after its respective class of device deadline

Class IV Medical Devices

D_0 + 2 years

Class II Medical Devices

D_0 + 4 years

Unique Device Identification in Brazil

UDI Implementation in Brazil – UDI Database Data Submission

D_0

Announcement date on
UDI Database readiness

D_0 + 3 years

Class III Medical Devices

D_0 + 6 years

Class I Medical Devices

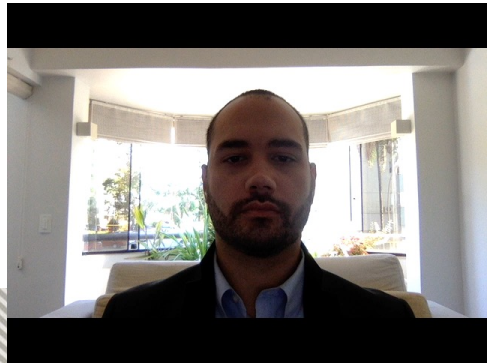
for reusable devices that shall bear the UDI carrier on the device itself, deadline shall apply two years after its respective class of device deadline

Class IV Medical Devices

D_0 + 2 years

Class II Medical Devices

D_0 + 4 years



Thank you

Hélio Bomfim de Macêdo Filho

Anvisa's Medical Device Office

Agência Nacional de Vigilância Sanitária - Anvisa
SIA Trecho 5 - Área especial 57 - Lote 200
CEP: 71205-050
Brasília - DF

www.anvisa.gov.br
www.twitter.com/anvisa_oficial
Anvisa Atende: 0800-642-9782

ouvidoria@anvisa.gov.br