Agência Nacional de Vigilância Sanitária

Vision for Global UDI System

Medical Devices Webinar – Unique Devices Identification (UDI)
Thursday, January 20th, 2022
9:10 – 9:20 CT

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Vision for Global UDI System

Summary

Summary

UDI Starting Point and a Real Example
UDI System Implementation Worldwide
UDI System Implementation in Brazil
Concluding Remarks

Unique Device Identification

Starting Point - 2008

Post-market: challenge for manufacturers, users, and authorities

Corrective actions need good track and trace systems

machine readable device identification system available (e.g. GS1)

main purpose of these systems is the economical and logistical optimization

Safety of Medical Devices

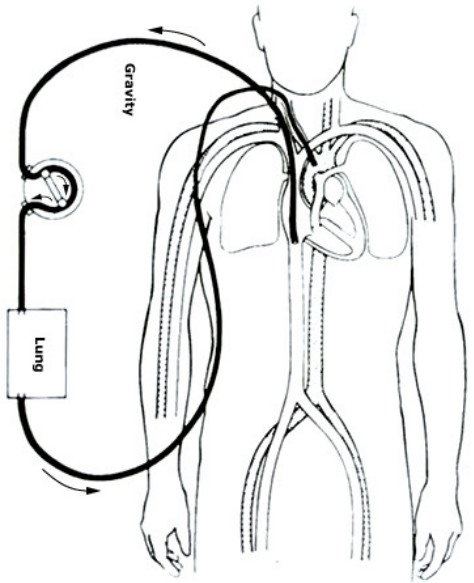
Optimize the processes in the public healthcare service

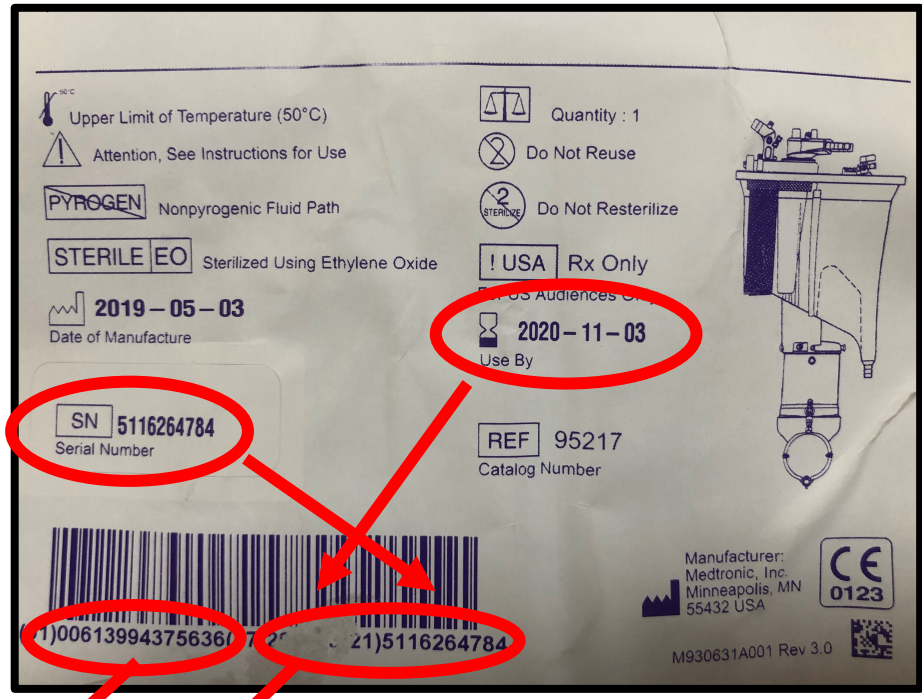
Reduce costs

Model for an efficient **global** medical devices surveillance system

Unique Device Identification

Real Example (Oxygenator)





UDI = UDI-DI + UDI-PI

Unique Device Identification around the Globe

Examples of UDI Systems in place:

China: https://udi.nmpa.gov.cn/
Europe: https://ec.europa.eu/tools/eudamed/
Japan: https://www.medis.or.jp/
Saudi Arabia: https://udi.sfda.gov.sa/.
Singapore: https://eservice.hsa.gov.sg/osc/portal/jsp/AA/process.jsp?eService=UDI
South Korea: https://udiportal.mfds.go.kr/udi
Taiwan: https://udid.fda.gov.tw/
United States of America: https://gudid.fda.gov/gudid/

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

July, 07th 2021 - September, 06th 2021

UDI Rules under Public Consultation

September, 2021 – December, 2021

Public Consultation Review

December, 2021

Anvisa's Board of Directors Deliberation on UDI Resolution

January, 4th 2022

UDI Resolution (591/2021)

Concluding remarks

Brazil is strongly committed to implementing UDI

Adherence to IMDRF UDI Guidance enforces a Global UDI System implementation

Most of the continents have at least one country implementing UDI

Manufacturers are building systems to submit UDI data elements to UDI databases of distinct jurisdictions at once

Medical device identification worldwide

Thank you

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