UDI: US vs EU Requirements

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Agenda

- UDI Basics: US and EU
- US UDI Requirements
- EU UDI Requirements- Review of MDR/IVDR

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UDI Basics

US	UDI must be applied to labels and device packages of commercially sold medical devices
	UDI should be provided in a plain-text version and in a form that uses Automatic Identification and Data Capture (AIDC) technology
	Direct marking of UDI for reprocessed devices

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Key FDA requirements for UDI Compliance

UDI Rule

- Labels and packages of medical devices must bear a UDI as per § 801.20. It contains two parts:
  - the Device Identifier (DI) and
  - A Product Identifier (PI)

Format

- Dates on the labels of these devices must be formatted as required by § 801.18. (i.e. YYYY-MM-DD)

Submission

- Data for the devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.

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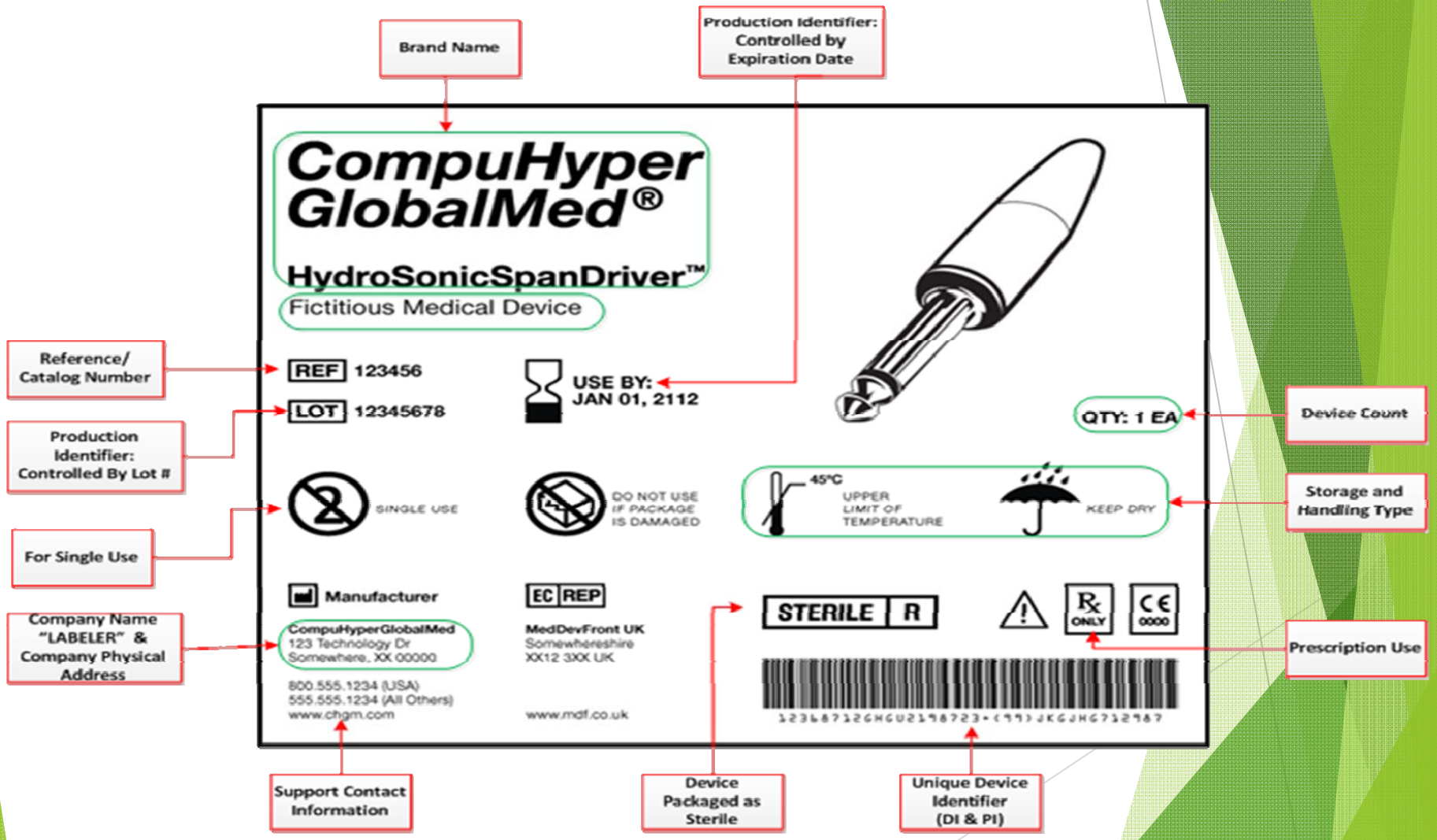
UDI Example



Reference: FDA UDI Guidance, 20August 2014

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FDA Compliance Dates

Device	*Label/GUDID/ Date Format*	*Direct Mark*
• Class III (including class III LS/LS) • Devices licensed under the PHS Act	September 24, 2014	• Class III LS/LS devices must bear a permanent UDI by September 24, 2015 • All other class III devices must bear a permanent UDI by September 24, 2016
Implantable (Class II, Class I & unclassified)	September 24, 2015	N/A
LS/LS (class II, class I & unclassified)	September 24, 2015	September 24, 2015
Class II (other than I/LS/LS)	September 24, 2016	September 24,2018
Class I or unclassified (other than I/LS/LS)	September 24, 2018	September 24,2020

LS/LS=Life-Supporting or Life Sustaining
I= Implantable

Lessons Learned from US UDI Implementation

- Early Gap Analysis of the existing products
- Understand global marketing plan for the devices
- Involve key stake holders as early as possible i.e Supply-chain, OEMs, consultants, commercial etc.
- Review Bar-Code Verifiers and label printing system
- Submit to GUDID as early as possible

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What does UDI mean in Europe?

- Definition: Unique Device Identification means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of a specific device on the market.

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UDI Basics

EU

All labels and device packages of commercially distributed medical devices must include a unique identifier (UDI) to facilitate identification and traceability of devices

Each UDI comprises of DI +PI.

Will be applied to highest level of packaging

Basic Identifier i.e. UDI-DI must appear on the Declaration of Conformity

Single Registration Number (SRN): Issued by the competent authority to identify the device manufacturer

Will be used by NB and CA and applied on CFS,DOC, and EUDAMED, NB certificates

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UDI Basics

EU

Issuing Agencies: GS1 AISBL,HIBCC, and ICCBBA.

The Notified Body will reference the Basic UDI-DI on the certificate issued

Before placing the device on the market the manufacturer must obtain the relevant NB certification and shall submit the device related information in the UDI database. (Refer to Annex V of IVDR/MDR)

For Class III implantable devices: Health institutions will store and keep electronic records of the UDI of the devices which they have supplied or they have been supplied

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EU Compliance Dates

IVD Classification	Compliance Date
Class D	1 year after date of application of the IVDR
Class C and B	3 years after date of application of the IVDR
Class A	5 years after date of application of the IVDR

Medical Device Classification	Compliance Date
Class III Implantable	1 year after date of application of the MDR
Class II a and III b	3 years after date of application of the MDR
Class I	5 years after date of application of the MDR
Reusable Devices (Direct Marking)	2 years after the date of application for its class of device.

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UDI Exceptions

US	EU
Shipping Container: UDI not required to be placed on shipping containers	Same as US
No exception in US	**Labeling exception for both AIDC and Human Readable if labeling constraints**
Device used solely for research, teaching, or chemical analysis: Not intended for clinical use	Same as US (devices under PE, RUO, and IUO)
Investigational Device and Custom Device	Same as US
Exported Device Intended for export from the United States	CFS should also have UDI
Software embedded in system	Same as US – only applicable for Stand alone software medical devices

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EUDAMED

UDI-DI

- There are 22 data attributes/core elements related to device DI

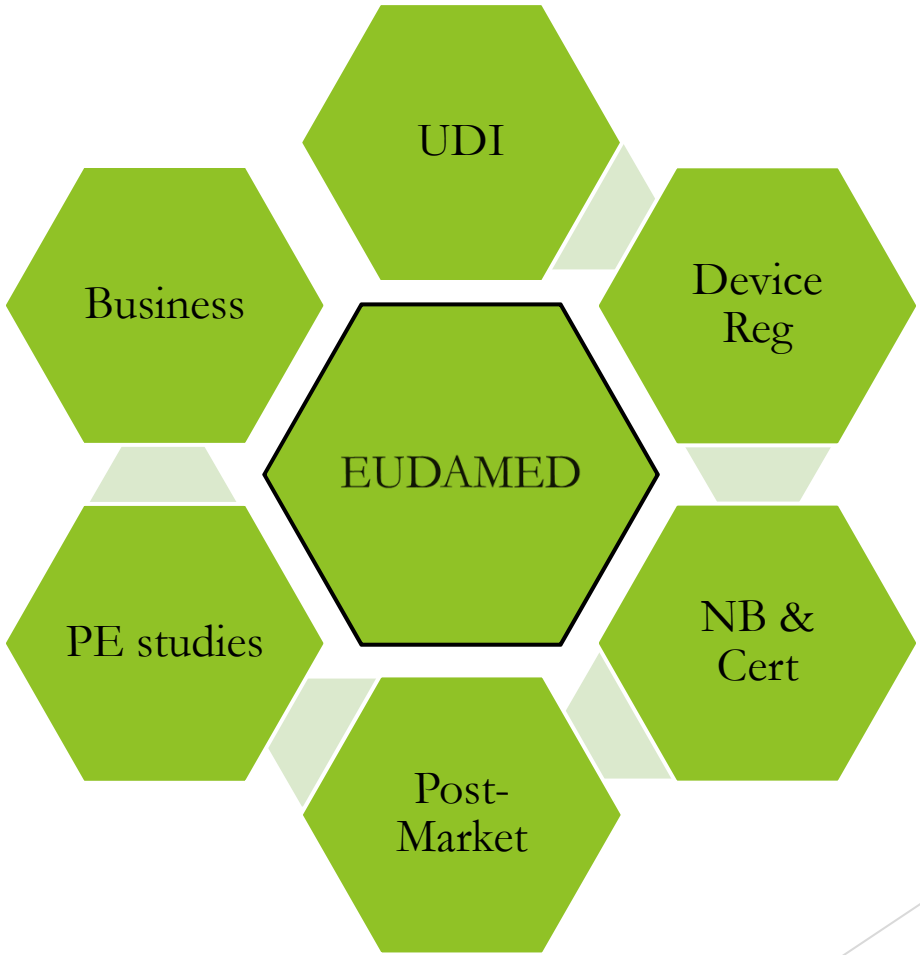
UDI-PI

- No production identifiers are included in the UDI database

Timeline

- Submit within 2 weeks of placing device on market
- Update record within 30 days of change to UDI

EUDAMED


UDI
Business
Device Reg
EUDAMED
PE studies
NB & Cert
Post-Market

Additional requirements for Class III implantable devices and Class C and D IVDs

- Clinical and safety performance data summary report - submitted to NB and will be public via EUDAMED:
  - UDI-DI and SRN (Single Registration Number)
  - Intended Use, IFU, contraindications, and target population
  - Device description
  - Possible diagnostic or therapeutic alternatives
  - Reference to harmonized standards and common specifications
  - Clinical Evaluation Summary and relevant post market clinical information
  - Suggested profile and training for users
  - Risk Profile information (including residual risks and warnings and precautions)

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EU UDI

Recap

UDI on DOC, NB Cert, and CFS

UDI records maintained by health institutions/suppliers/distributors

Only UDI-DI records to be submitted in EUDAMED

Add to Technical File documentation

Receive a SRN (single registration number) from AR

Apply UDI on label prior to NB conformity assessment

Enter info in EUDAMED (using SRN) within 2 weeks of placing device on market.

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EU vs US Recap

Requirement	EU	US
Direct Marking	Direct marking requirements include both AIDC and Carrier	Done either by AIDC or Carrier
Database	EUDAMED (Not yet established)	GUDID (Web interface vs. HL7/SL)
Issuing Agencies	GS1 AISBL,HIBCC, ICCBBA	GS1, HIBCC, ICCBBA
Data	22 Core UDI elements (DI portion only) and need SRN to submit	55 data attributes DI + PI
Class III/C/D IVDs	Additional requirements for submission of clinical safety data	No additional requirements
Traceability	Via manufacturers, EUDAMED, DOC, NB cert, and CFS etc.	Via manufacturer and GUDID
Export	UDI-DI on CFS	No UDI needed on devices for export use only

What about UDI in England?

- April 2014 NHS eProcurement Strategy Published
  - Use of GS1 System for product Coding
  - Requirement for suppliers to provide GTIN
  - Adoption of PEPPOL standard for purchasing and invoicing
- Excepted phase-in of UDI requirements with release of MDR/IVDR

Thank you!

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