



Eucomed and UDI

(Unique Device Identification)

Eucomed ETF (eBusiness Task Force)

May 2010

UDI : History and Players

- 09/2007 : US Congress asked FDA to develop a 'UDI-System'
- 10/2008 : GHTF (Global Harmonization Task Force) recognized global relevance



=



*partnership between regulatory authorities and the regulated industry (founded in 1992)
→ achieve greater uniformity between national medical device regulatory systems*

www.gh tf.org

► GHTF ad-hoc WG

- founded in 10/2008
- regul. bodies + industry trade assoc.
- assess FDA draft /
ensure global harmonization
- draft 'UDI Guidance' published 11/2009

EUROPE

- EU Commission (L. Selles, R. Munoz)
- MoH DE (M. Neumann)
- Eucomed (V. Zeinar - B. Braun)
- EDMA (C. Tarrajat)

USA

- FDA (J. Crowley)
- AdvaMed (J. Secunda, T. Werthwine)

ASIA

- China Shanghai FDA (L. Yan)
- JFMDA Japan (H. Ishikawa - Toshiba)
- AHWP (L. Tao, AHWP - J&J)

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The regulators intention :
Make the usage of auto-ID technology at Medical Devices mandatory!

To

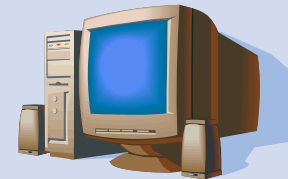
- ... improve patient safety
- ... enhance vigilance & market surveillance
- ... facilitate traceability
- ... support processes

Machine-readable Marking (AIDC)
packaging and/or product

Examples

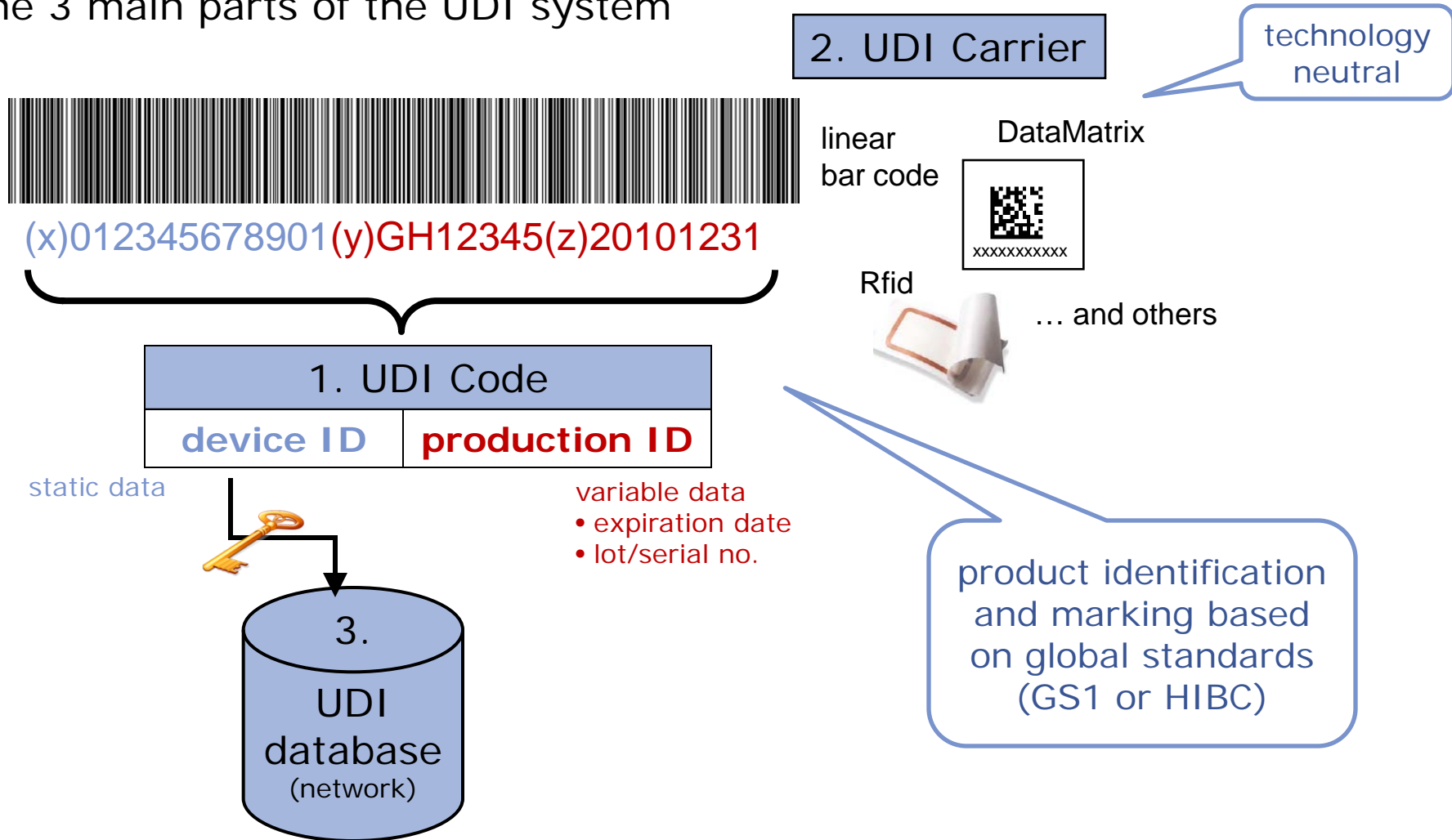


Database(s)



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The 3 main parts of the UDI system



product identification and marking based on global standards (GS1 or HIBC)

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What is Unique Device Identification?

at the beginning
**confusion about
the term 'unique'**

UDI (alone) **is not** Serialisation!

▶ **UDI** (*GTIN Static Data*)...

Will distinguish one type of device from one manufacturer with ***differing*** product or packaging characteristics



GTIN = AI(01)35019315050804



GTIN = AI(01)35019315050804

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GTIN = AI(01)3501931508695

GTIN = AI(01)3501931508695

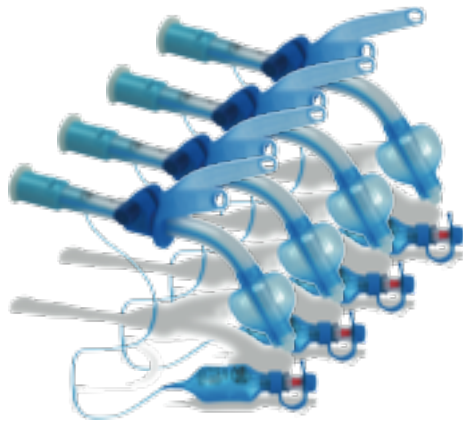
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What is Unique Device Identification?

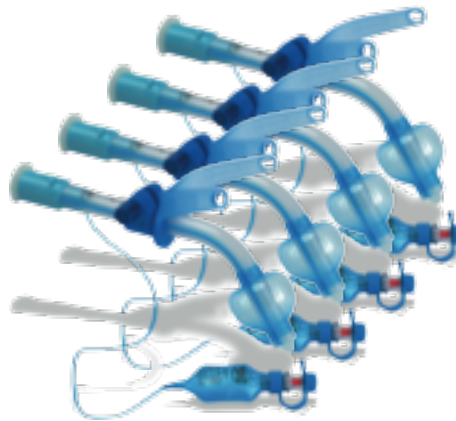
UDI (alone) **is not** Serialisation!

- ▶ **UDI** (*GTIN Static Data*) + **Batch/Lot Number** (*Production Data*)...

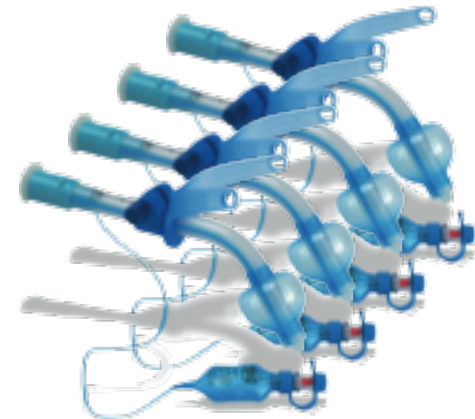
Will distinguish a device from a manufacturer with *identical* characteristics but manufactured in *different batches*



GTIN + AI(10)12345



GTIN + AI(10)67891



GTIN + AI(10)65439

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What is Unique Device Identification?

Serialisation is:

- ▶ **UDI** (*Static Data*) + **Serial Number** (*Production Data*)...

Will distinguish *individual* devices from a manufacturer with *identical* characteristics



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The latest definition of the main goals

Improve patient safety by :

- ▶ enhancing the identification of devices in case of adverse events
- ▶ facilitating traceability of devices in the event of a field safety correction

It is anticipated the UDI may facilitate the reduction of medical errors.

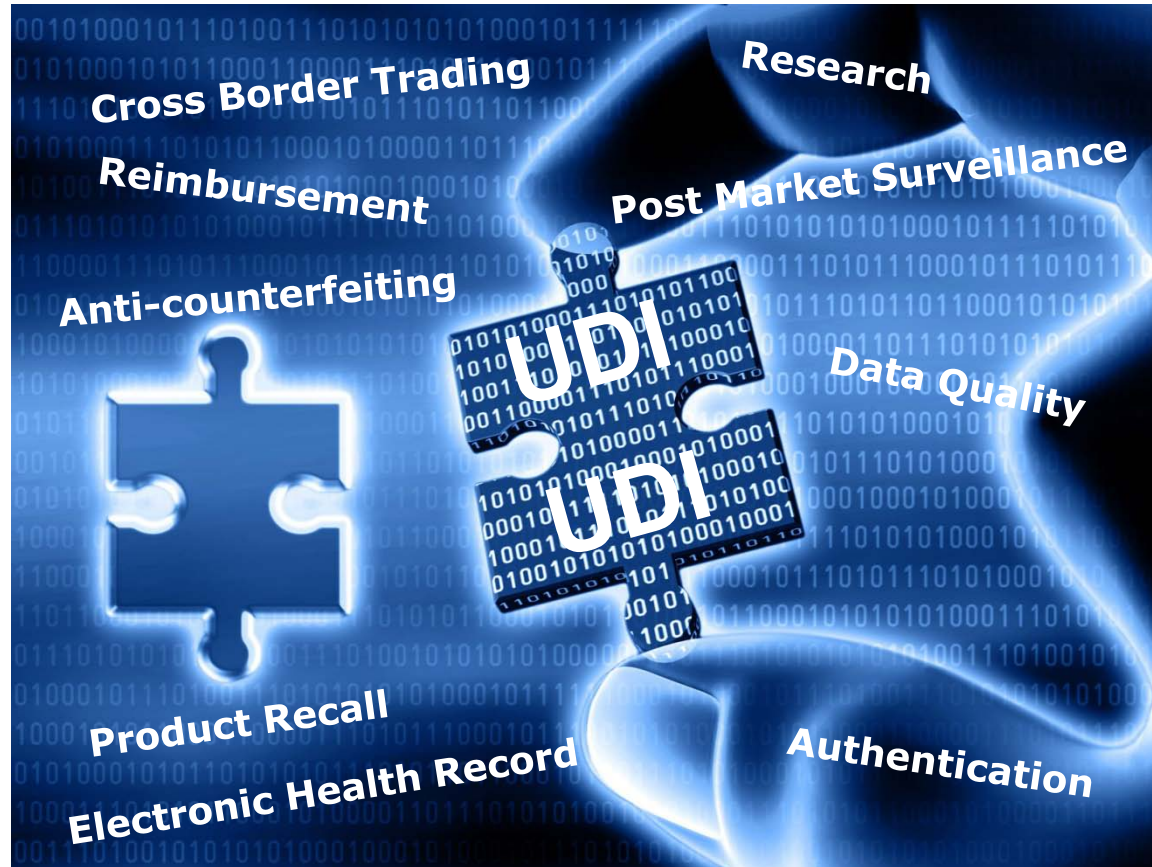
The former definition :

- reducing device related medical errors
- enhancing the identification of devices in case of adverse events
- facilitating traceability

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UDI is the foundation, leading to improved process for...

Traceability
???



UDI creates transparency, improves processes, increases efficiency and makes isolated systems interoperable

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UDI regulations/requests from around the world

→ not all are following a globally harmonized approach !

North America

US (FDA)
Canada

Europe / Mid.East

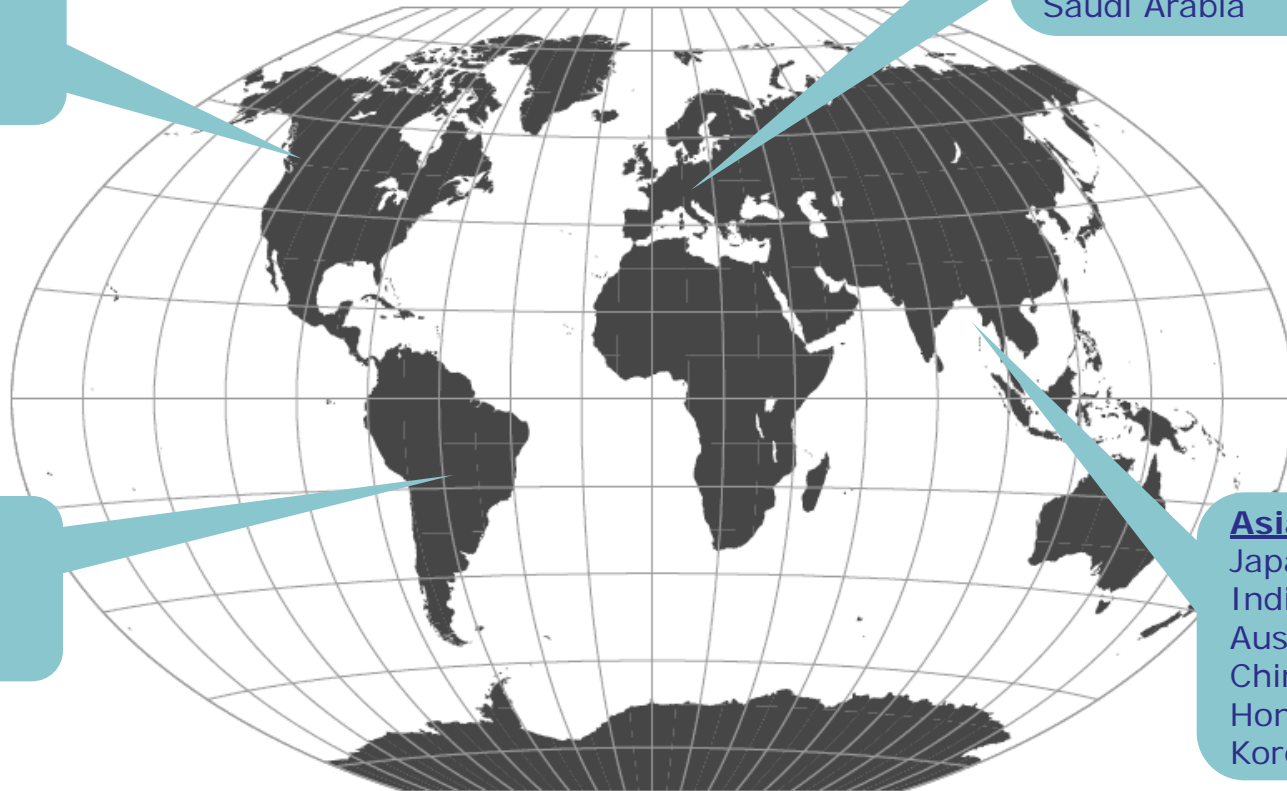
England
Spain (Andalusia)
Turkey
Italy
EU Com
Saudi Arabia

Latin America

Chile
Brazil

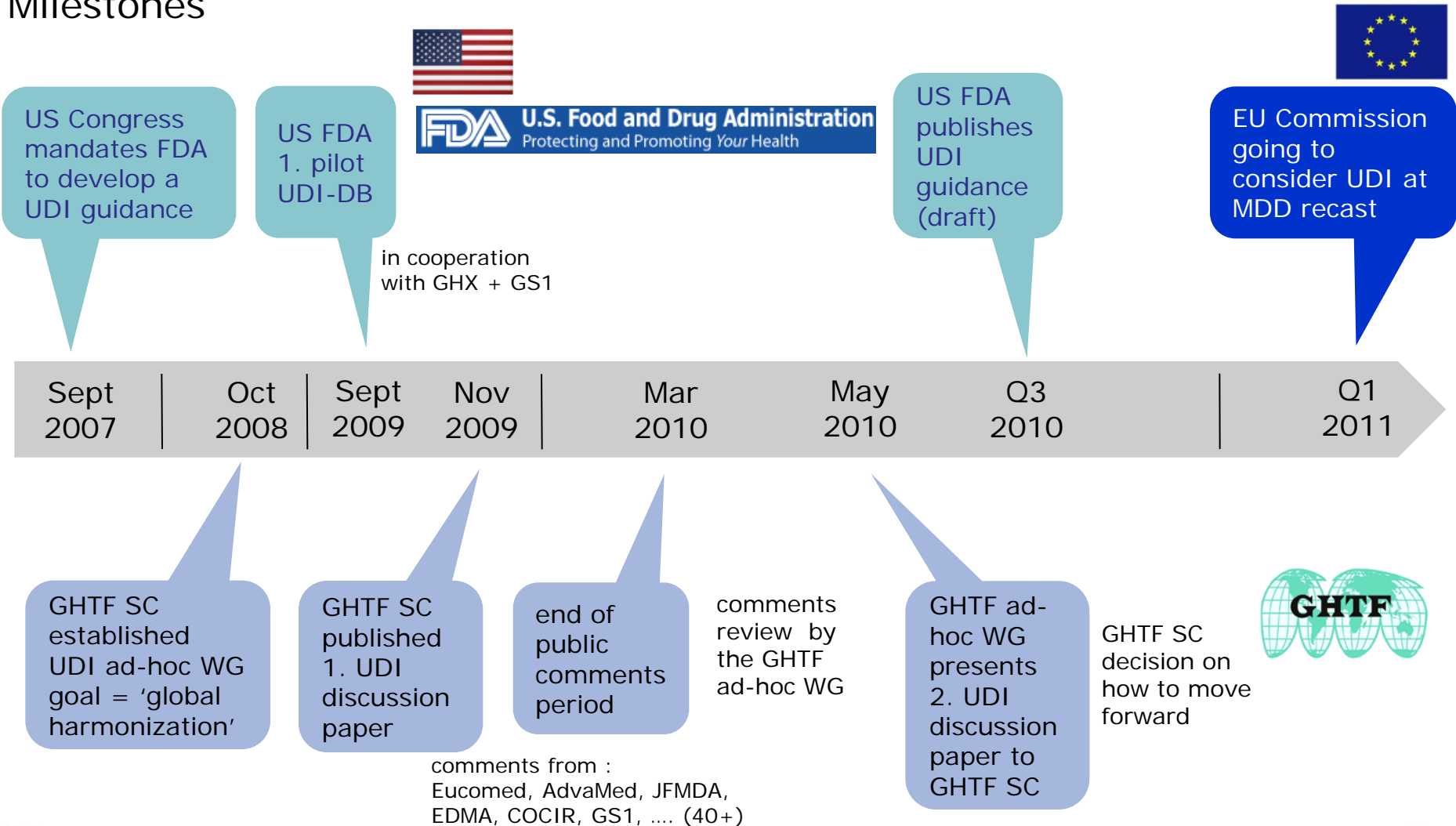
Asia Pacific

Japan
India
Australia
China
Hong Kong
Korea



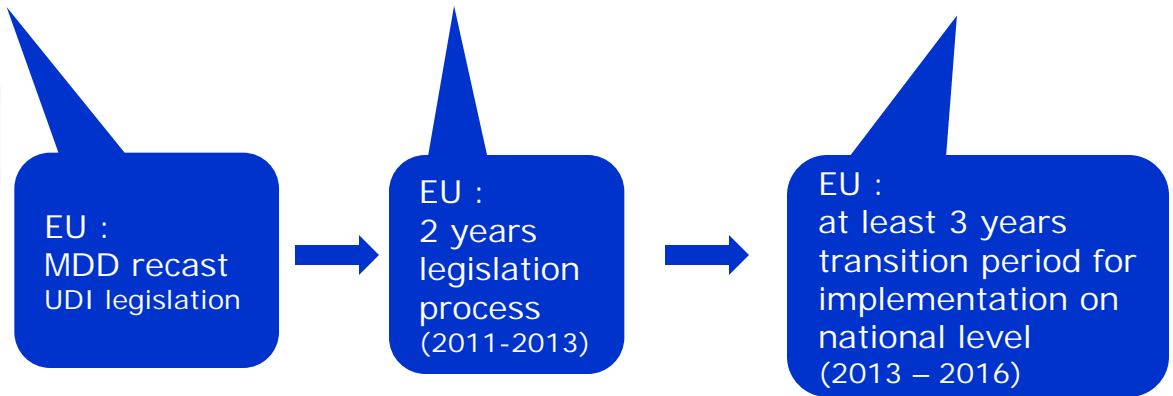
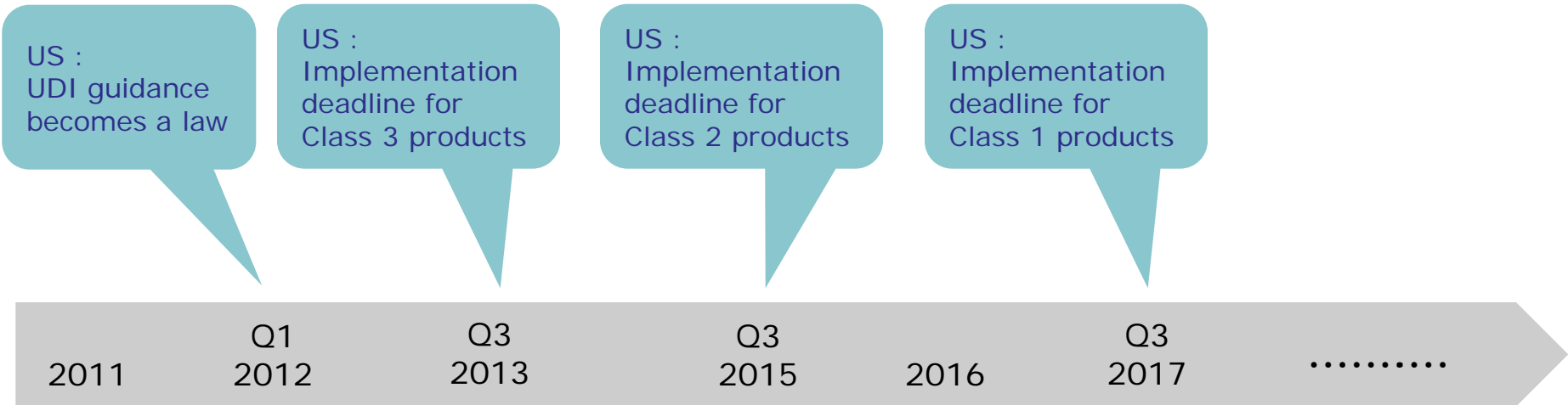
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Milestones



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Implementation Schedule (expected)



other regions worldwide ???

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- ▶ EU Com organised a meeting of Competent Authorities (17)
 - Madrid, March 2010
 - representatives from 17 member states
 - 1st introduction to UDI → great success
- ▶ Agreement between Industry + EU Com about the way forward
 - some MSs diverge
 - ‘realistic/practical’ approach versus ‘high-end’ approach incl. traceability
- ▶ The EU MedTech industry is working through the various medical device trade associations to put together a joint industry response

The EU MedTech industry is speaking with one voice !

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UDI - Industry Key Messages (1):

- ▶ UDI is a key development for the Medical Technology Industry
- ▶ A Unique Device Identification system must first be defined
 - for e-health systems to work (patient records, traceability, reimbursement, registration, etc.)
 - to provide an identifier ('passport') for each MedDev
- ▶ UDI identifiers must be globally unique → key success factor !
 - Med Tech is a global industry
 - NO local or national deviation → unacceptable fragmentation
- ▶ Step-wise implementation is essential
 - vast undertaking for the healthcare industry
 - at least 3 years is needed by manufacturers for 1. step
 - starting with the highest risk class first
 - based on a globally harmonised risk classification system

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regulators view ?

- risk-based impl. seque.
 - misidentification ?
- risk-based coding
 - granularity
 - class I + II
 - new marking grid

UDI - Industry Key Messages

- ▶ A risk-based approach is essential (AIDC);
 - not all MedDev need the same information at all packaging levels
- ▶ Industry recommendation (AIDC)

	Unit (consumption) Pack ⁽¹⁾ or Product itself (direct part marking)		Shelf Pack	
	Mandatory	Optional ⁽²⁾	Mandatory	Optional ⁽²⁾
Class I	/	GTIN ⁽³⁾	GTIN	Production Data
Class IIa	GTIN	Production Data ⁽⁴⁾	GTIN + Production Data	/
Class IIb	GTIN	Production Data	GTIN + Production Data	/
Class III	GTIN + Production Data	/	GTIN + Production Data	/

Note:

- (1) Technical feasibility prerequisite (space, substrate etc.)
- (2) At the manufacturer's discretion (e.g. for internal processes), but not to be used for regulatory purposes
- (3) GTIN = Global Trade Item Number (GS1 terminology) = UDI code, static data
Does not exclude the use of production data, which is at the manufacturer's discretion
- (4) Production Data = Expiry Date + Lot Number or Serial Number
It is at the manufacturer's decision whether the product is 'Lot Number' or 'Serial Number' controlled

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UDI - Industry Key Messages (3):

- ▶ UDID (UDI Database) should be the single global database for Core Product Identification Attributes
 - probably a network of DB's
 - can be used for other purposes (e.g. migration to, integration with or replacement of other currently un-harmonised databases)
- ▶ The Core Attributes from Eucomed's perspective
 - 8 attributes focusing on identification and should be mandatory
 - UDI code (static data)
 - Manufacturer name
 - Manufacturer contact information
 - Nomenclature (e.g GMDN)
 - Device name (generic name)
 - Trade name (brand name)
 - Device model number (REF number)
 - Regional authorised representatives (if applicable)
 - all other attributes should be optional
(not clear how e.g. 'storage conditions' can improve patient safety)

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list of attributes within the GHTF paper

main purpose
of the UDI system

	Attribute (GHTF draft)	reducing errors	enhancing identification	facilitating traceability
1	UDI code (static part) = KEY	Yes	Yes	Yes
2	Manufacturer name	No	Yes	Yes
3	Manufacturer contact information	No	Yes	Yes
4	Nomenclature (e.g. GMDN)	No	Yes	Yes
5	Device name (generic name)	No	Yes	Yes
6	Trade name (brand name)	No	Yes	Yes
7	Device model number (Ref no.)	No	Yes	Yes
8	Controlled by serial/lot no - manuf./expiry date	No	no	Yes
9	Quantity and packaging level	No	No	No
10	Size incl. units of measure	No	No	No
11	Storage conditions	Yes	No	No
12	Sterility (and sustainability)	Yes	No	No
13	Labeled as single use	Yes	No	No
14	Need to be sterilized before use	Yes	No	No
15	Restricted number of use	Yes	No	No
16	Labeled as containing allergens/materials of concern	Yes	No	No
17	Regional authorized representatives	No	Yes	Yes
18	URL for additional information	Yes	No	No
19	Special instructions for use	Yes	No	No



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What do we need first ?

Clear definition of the purpose of the UDI-database !

Know what the use cases will be !

Know what the expectations of the SC stakeholders are !

otherwise it's hardly possible to create a system !

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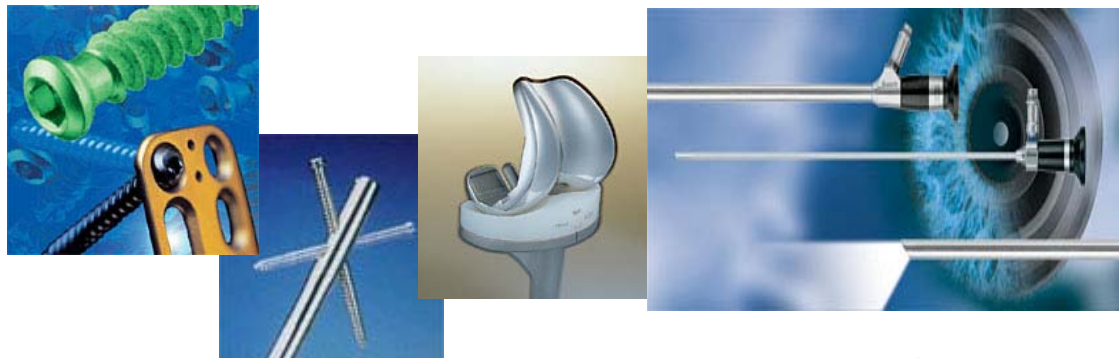
UDI - Industry Key Messages (4):

- ▶ Legislations directed at the manufacturer only !
- ▶ Authorities must ensure that healthcare providers are under an equivalent obligation
 - to achieve the public health objective
 - otherwise whole exercise + vast cost to industry will have been largely wasted
- ▶ A thorough Impact Assessment must be carried out
 - essential because the costs (investment and implementation) will be significant for both industry + healthcare systems
 - only way to assess the full effect and to achieve the full benefit of UDI

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UDI - Industry Key Messages (5):

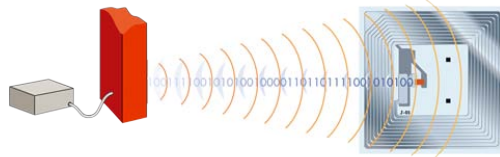
- ▶ How to handle space constraints or other physical limitations ?
- ▶ Increasing requirement, in the EU, for more languages, more symbols for material content (e.g. DEHP, LATEX...), addresses, human readable information etc.
 - what can be omitted from the labelling to meet the mandated UDI requirements for high risk devices, if there is insufficient space to include all this information?
- ▶ For very small packs/products there might not be sufficient space to include UDI; therefore it will have to be omitted from labelling until technology can provide a solution



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The risk of technical neutrality = 'AIDC Babylon'

- Bar Code (linear, 2D), Rfid
 - GS1 : EAN-13, GS1-128, DataMatrix, DataBar, composite, ..., Rfid
 - HIBC : Code39, Code128, Codablock, DataMatrix, QR, ..., Rfid
 - concatenated, non-concatenated, stacked, ...
- all versions would fulfill UDI
 → but could be a nightmare for HC providers !?
 → will this enhance adoption on HC prov. side ?



+A99912345/99015Y0X3C

Medtronic

05504SP
 Catheter Connecting Cable, 4 Conductor
 Câble de connexion de cathéter, 4 Conducteurs
 Katheteranschlusskabel, 4 Pol
 Cable de conexión de catéter, 4 Conductores
 Cavo di collegamento per cateteri, 4 Pini
 Kabel voor catheterverbinding, 4 - pins geleider
 Forbindelseskabel for kateter, 4 ledere
 Kabel für kateteranslutning, 4 ledere
 Cabo de ligação do cateter, 4 condutores
 Καλώδιο συνδεσης καθετήρα, 4-άκτινο

LOT H612 | 122 cm (4 ft) Length | STERILE R

Use By: 2009-01-15 (YYYY-MM-DD)
 Attention: See accompanying documents.

2007-01-15 (YYYY-MM-DD)
 Manufacturing Date

0130081490024464170501151010412 | PIN: 082104004

Manufactured for: Medtronic, Inc. Minneapolis, MN 55432 USA | USA R only

dextrus ENDOPATH[®]

Finger-Mounted Locking Forceps

REF FMF02 | LOT 1Q34
 080100 | QTY 4

(01) 2 081019001 002 4

(17)080100(10)1Q34

Manufacturer: T.A.G. Medical Products, Kibbutz Goston 25130 Israel
 EU representative: MEDONE GmbH, Borkstrasse 10 45163 Muenster, Germany
 Distributor: Ethicon Endo-Surgery Inc, Cincinnati OH 45242-2839 USA

STERILE R | Rx Only

Safil[®]

Polyglycolic acid, braided, coated, absorbable

VIOLET 5/0 sct.

HR22 | 70 cm | 28" | 1/2 c | 22mm Taper

REF 1048028

STERILE R | Rx Only

Mini-Spike Micro-Tip

50

YYYY-MM | BATCH | 4550510

STERILE R

B BRAUN

B. Braun Melsungen AG, Melsungen, Germany



BRAUN B BRAUN BE

Introcath Safety[®]-W
 Winged-FEP

24G x 0,55"
 (0,7 x 14 mm) **24G**
 26 ml/min

REF 4251609-02
 YYYY-MM
 YYYY-MM
 Batch.no.XXX.

US Safety IV Catheter
ES Catéter periférico de seguridad
FR Cathéter court de sécurité

US Single use only • Sterile in unopened undamaged package • Do not resterilize • Refer to instructions for use • Distributed by B. Braun Medical Inc., Bethlehem, PA 18018. Components made in U.S.A., Malaysia and Japan
Radiopaque • nonporous

CE 0123 Rx only 15327261/0509

B BRAUN
 B. Braun Melsungen AG
 34209 Melsungen
 Germany
 www.bbraun.com

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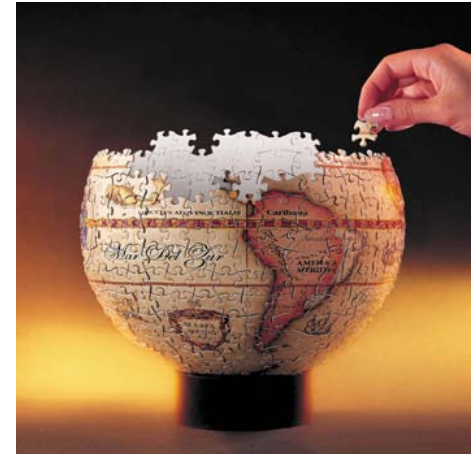
In Summary

UDI will bring great benefits for:

- ✓ PATIENT SAFETY
- ✓ IMPROVED VIGILANCE & MARKET SURVEILLANCE
- ✓ GLOBAL TRADE

BUT it is essential that

- ✓ A pragmatic (risk-based) approach is adopted
- ✓ Healthcare providers are fully resourced to respond
- ✓ Regional authorities co-operate to ensure a truly **GLOBAL** and **HARMONISED UDI** approach



Thank you very much for your attention !

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