



Eucomed and UDI

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member of :

- Eucomed ETF (2004)
- GS1 Healthcare LT (2005)
- GHTF UDI AHWG (2009)

Medical Device Supply Chain Council
Orlando (FL) Oct. 22, 2009

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ETF (e Business & Supply Chain Task Force)

- ▶ Wide industry representation
 - Group has focused on Automatic Identification & Data Capture (AIDC) and Unique Device Identification (UDI) since 2003
- ▶ Objectives:
 - to monitor developments in AIDC as a tool for improved PATIENT SAFETY
 - to engage industry, healthcare professionals and the authorities
- ▶ 2005/06 the ETF forged an 'alliance' with GS1 Healthcare
- ▶ This relationship has enabled a global approach to the understanding, recommendation and adoption to standards

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Our main goals

Risk based approach

Avoid country-specific UDI regulations

Limit the number of UDI data bases

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The 'Risk Based' approach

- ▶ In a perfect world all device and/or packaging should carry a unique identifier
- ▶ Today a pragmatic approach is needed
- ▶ Start with devices where patient safety is the major consideration
- ▶ These would be MDD Class III or II b devices e.g. implants
- ▶ Many devices are too small to be marked individually
 - Therefore these devices need to be marked only at an appropriate level of packaging e.g. shelf pack
- ▶ Very significant costs to all stakeholders are anticipated

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Industry suggests the following UDI requirements

(machine-readable identification of the product packaging)

	Consumption Unit Pack ⁽⁴⁾		Shelf Pack	
	Mandatory	Optional	Mandatory	Optional
Class I	(not applicable)	GTIN ⁽⁵⁾	GTIN	Production Data
Class IIa	GTIN	Production Data	GTIN + Production Data	(mandatory)
Class IIb	GTIN	Production Data	GTIN + Production Data	(mandatory)
Class III	GTIN + Production Data	(mandatory)	GTIN + Production Data	(mandatory)

Note:

(4) Technical feasibility prerequisite (space, substrate etc.)

(5) Does not exclude the use of production data, which is at the manufacture's discretion

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

Reference:

Eucomed ETF Position Paper - Risk-based implementation of Unique Device Identification (UDI), June 2009

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Based upon GS1 GTIN Allocation Rules for Healthcare, this example does not meet the *current* 'local' UDI requirements for Andalusia (Spain) and Turkey

16G Dual Lumen Oocyte Recovery Set **wallace**™

de	16 G doppellumiges Eizellenentnahmebesteck	pt	Conjunto de colheita de oócitos de duplo lúmen de calibre 16
da	16G dobbeltl�bet oocyttudtagningss�t	sv	16 G h�mtningsset f�r oocyter med dubbellumen
es	Equipo de doble luz para recogida de ovocitos de 16 G	fi	16G Kaksi kanavainen munasolun ker�yspakkaus
fr	Jeu � double lumi�re pour r�cup�ration d'ovocytes 16 g	cs	Souprava k odb�ru oocyt� s dvoulumenovou jehlou 16 G
el	�et an�kthshs wokutt�rwn d�plou auλου 16G	pl	Dwukanaowy zestaw do pobierania oocyt�w 16 G
it	Set per prelievo oociti a doppio lume da 16G	hu	16G kett�s lumen� oocyta begy�jt� k�szlet
no	16G Dobbeltlumensett for uthenting av oocytter	tr	16G �ift L�menli Oosit Alma Seti
nl	16 G dubbellumenset voor het verzamelen van o�cyten	et	16G kahe valendikuga munarakkude kogumise kon
		ro	Set cu lumen dublu pentru recoltarea ovulelor, 16G
		bg	Набор за събиране на яйцеклетки с двоен лумен 16 G
		sk	Dvojl�menov� s�prava na odber oocytov 16 G
		it	16 G dvigubo spind,jo oocit� emimo sistema

REF DNS1633-500

Caution. Do not reuse. Latex free.
Do not use if package is damaged. Sterilised using ethylene oxide. **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

Smiths Medical International Ltd.
Hythe, Kent, CT21 6JL, UK.
Australian Representative:
Smiths Medical Australasia Pty. Ltd.
Brisbane, QLD 4113, Australia.
www.smiths-medical.com.

(01)15019315059926(17)101000(10)1111111

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smiths medical

example country-specific + local requirement.

problem : 14-digit GTIN

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What about the Healthcare Providers?

- ▶ If Patient Safety and other benefits are to be achieved the healthcare community must be able to interface effectively
- ▶ This is an even greater task than adoption in industry
- ▶ Governments must respond by ensuring that healthcare establishments are properly equipped and personnel trained
- ▶ Regional authorities (e.g. FDA, EU Commission, MHLW, SFDA...) must also address this

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close co-operation Eucomed & EU Com

- ▶ EU Com supports 'risk-based' implementation
- ▶ UDID : better to have more attributes to offset risk of further fragmentation
- ▶ EU Com recognise the massive task involved in educating and ensuring investment by HC providers
- ▶ Industry & EU Com work together to head off fragmentation in member states
- ▶ Eucomed : vital to be involved in GHTF phase 2 (UDID architecture, marking granularity, ...)

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In Summary

- ▶ UDI will bring great benefits for
 - PATIENT SAFETY
 - IMPROVED VIGILANCE AND MARKET SURVEILLANCE
 - GLOBAL TRADE BENEFITS

BUT it is essential that

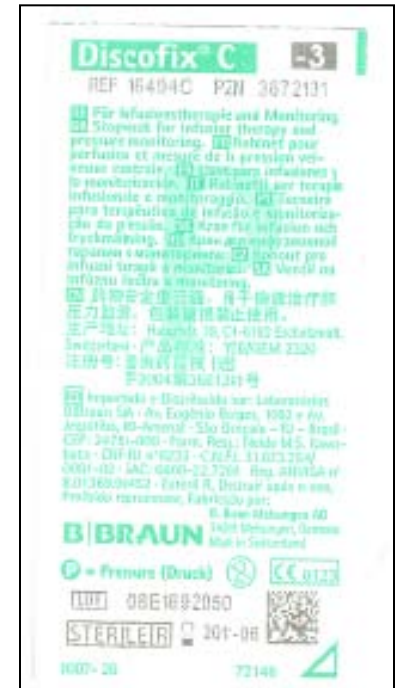
- ▶ A pragmatic (risk-based) approach is adopted
- ▶ Healthcare providers are fully resourced to respond
- ▶ Regional authorities co-operate to ensure a truly **global** and **harmonised** approach

B. Braun : current status



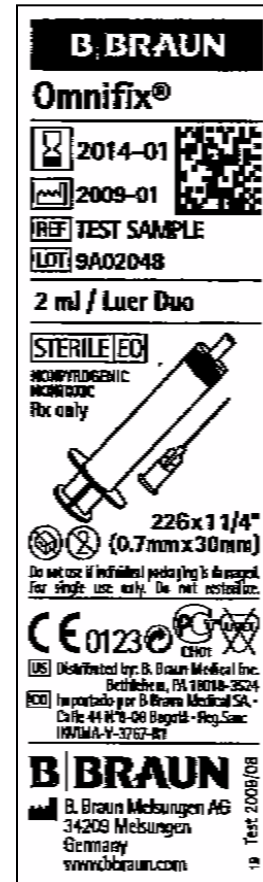
shelf pack / case

- linear GS1 bar code
- non-concatenated
- GTIN
- expiry, lot no



consumption unit

- GS1 DataMatrix
- GTIN, expiry, lot no
- in preparation



product

(DPM = Direct Part Marking)

- product ID + SN
- no GS1 standard
- 2.5 x 2.5 mm

Technical Challenges



DM-Code through the camera of the Verifier



DM-Code in comparison to a 2 Cent coin

- ▶ **CU level : time consuming learning period !**
 - limited space (DM size : 6x6 - 10x10 mm)
 - production speed
 - DM quality verification : ISO/IEC 15415 (final grade 1,5)
 - packaging material (Tyvek, coated/uncoated paper, ...)
 - translucent paper in use
 - printing technology (inkjet, thermo transfers, etc.)
 - only validated ink permitted
 - any change in production lines means re-validation
 - huge investments (packg. lines around the world), ...

**Central material master data base is in use since >5 years !
- good basis for UDID -**

Thank you very much for your attention !

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