



USAN - UDI / Standards Adoption Network

Orlando, 31 March 2010





GS1 Healthcare Topics

- About GS1 Healthcare
- Standards Update
- Regulatory Update – Global
- Regulatory Update – Eucomed
- AIDC in Healthcare
- Questions





Standards and Regulatory Update

Ulrike Kreysa

Director Healthcare

GS1 Global Office



GS1 Healthcare

Voluntary, Global Healthcare User Group

To lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.



GS1 Standards in Healthcare ...

Our vision

GS1 Healthcare envisions a future where the healthcare sector utilises **GS1 global standards** for all items, locations, people and processes to drive **patient safety and supply chain efficiency improvements**-- starting with the manufacturer and ending with procedures or treatments for a specific patient.





Leading healthcare organisations pave the way...

Corporate members of the global user group



Leading healthcare organisations pave the way...

Healthcare providers and Group Purchasing Organisations going global



France



Germany



Netherlands



HONG KONG
HOSPITAL
AUTHORITY

Hong Kong



Switzerland



Germany



Germany



USA



Austria



USA



Ireland



Netherlands



France



USA

 **Healthcare Global work groups**

- AIDC Application Standards
- Global Data Synchronisation & Product Classification
- Traceability in Healthcare
- Public Policy

Meet bi-weekly via conference call
and 3 times per year in the global conferences.

Standards development continues, but global standards are ALREADY available to build on:

- 
- ✓ GTIN Allocation Rules for Healthcare
 - ✓ AIDC Application Standards for 90% of medical products
 - ✓ AIDC Application Standards for small instruments
 - ✓ Healthcare extension in next GDSN release
 - ✓ Global Traceability Standard for Healthcare

GS1 Healthcare

Voluntary, Global Healthcare User Group

To be the **recognised, open and neutral source** for regulatory agencies, trade organisations and other similar stakeholders **seeking input and direction for global standards** in healthcare for patient safety, supply chain security & efficiency, traceability and accurate data synchronisation.

GS1 Healthcare Increasing global recognition



And many more...



“When developing a bar code strategy, reviewing a company’s existing bar code strategy or changing packaging and labelling configurations, Eucomed recommends that its members consider the adoption, or increased use of GS1 standards.”

Eucomed Guidance Document, September 2007 (European association representing 24 national medical technology associations and 62 medical technology companies)



Eucomed and UDI

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



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

Eucomed and UDI

UDI - Industry Key Messages (1):

- ▶ UDI is a key development for the Medical Technology Industry. For electronic health systems to work (patient records, traceability, reimbursement, registration, etc.) a Unique Device Identification system must first be defined, to provide an identifier ('passport') for each medical device
- ▶ Medical Technology is a global industry and for UDI to work effectively identifiers must be globally unique. Globally accepted product identifiers are a key success factor; there should be NO local or national deviation as this would cause unacceptable fragmentation
- ▶ A risk-based approach is essential for machine-readable product identification (AIDC); not all medical devices need the same information at all packaging levels

Eucomed and UDI

Industry recommends the following UDI requirements (machine-readable identification of the product packaging)

	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 manufacture'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

Eucomed and UDI

UDI - Industry Key Messages (2):

- ▶ Implementation will be a vast undertaking for the healthcare industry and step-wise implementation is essential. At least 3 years is needed by manufacturers for the first step, starting with the highest risk class first; for which the globally harmonised risk classification system should be used
- ▶ UDID (Unique Device Identification Database) should be the single global database (probably a network of databases) for Core Product Identification Attributes. This can be used further for other purposes such as migration to, integration with or replacement of other currently un-harmonised databases

Eucomed and UDI

UDI - Industry Key Messages (3):

- ▶ There are suggestions that more data, than that needed for device identification, should be included in the data base. It is not clear how this can increase patient safety (for instance dynamic information, storage conditions etc.)
- ▶ The true benefit, in terms of patient safety, can only be achieved if **all stakeholders (from the manufacturer through to healthcare providers) use a harmonised UDI system**

Eucomed and UDI

UDI - Industry Key Messages (4):

- ▶ Legislation is being developed which is directed at the manufacturer. However to achieve the public health objective, authorities must ensure that healthcare providers are under an equivalent obligation. If this is not done the whole exercise and the vast cost to industry will have been largely wasted
- ▶ A thorough Impact Assessment must be carried out. This is essential because the costs in terms of investment and implementation will be significant for both industry and healthcare systems. This will be the only way to assess the full effect and to achieve the full benefit of UDI

Eucomed and UDI

UDI - Industry Key Messages (5):

- ▶ There is an increasing requirement, in the EU, for more languages, more symbols for material content (e.g. DEHP, LATEX...), addresses, human readable information etc.. The question “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?” needs to be addressed
- ▶ For very small packs there might not be sufficient space to include UDI; therefore it will have to be omitted from labelling until technology can provide a solution

Eucomed and UDI

UDI Database - Mandatory Core Attributes:

- ▶ From Eucomed's perspective, the following 8 (eight) attributes, described in the GHTF Discussion Paper, are focusing on identification and should therefore be defined as the Mandatory Core Attributes:
 - ✓ 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)

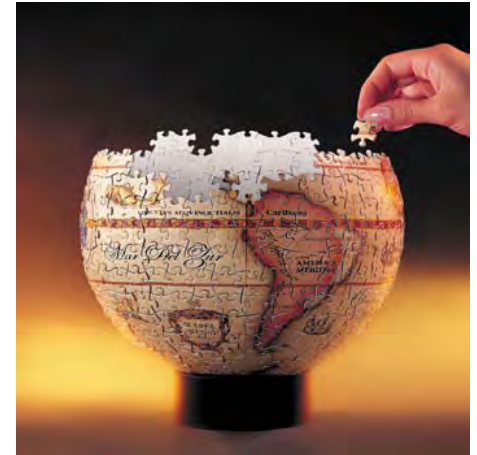
** There appear to be concerns about the use of GMDN in the Asia/Pacific region*

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





Enabling AIDC solutions in healthcare worldwide

Grant Hodgkins

Alcon Laboratories, Inc.





GS1 Healthcare Topics

- Background
- Where we are going
- Where we are today
- What this means to you
- Questions





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Automatic Identification & Data Capture (AIDC)

“Automatic Identification and Data Capture (AIDC) refers to the methods of **automatically identifying** objects, **collecting data** about them, and **entering those data** directly into computer systems (i.e., without human involvement).”

Wikipedia, 2009





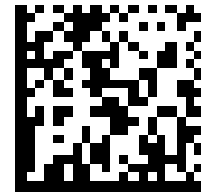
Healthcare AIDC Application Standards

Defines
the **data** to carry
using specific **data carriers**
for every healthcare **product**
at every **packaging level**



Data – a few examples:

- ✓ Global Trade Item Number (GTIN)
- ✓ Expiry Date
- ✓ Batch / Lot
- ✓ Serial Number



(01)07612345678900(17)100503

(10)AC3453G3 (21)123





(01) 0 0012345 67890 5



100000012345678905

**GS1-128 &
GS1 DataBar**



(01)07612345678900(17)100503

(10)AC3453G3

GS1 DataMatrix



EPC / RFID

Of course, UPC and EAN formats will continue for retail channels

Healthcare Scope: All healthcare products

Pharma / Vaccine / Nutritional



Medical devices



Retail

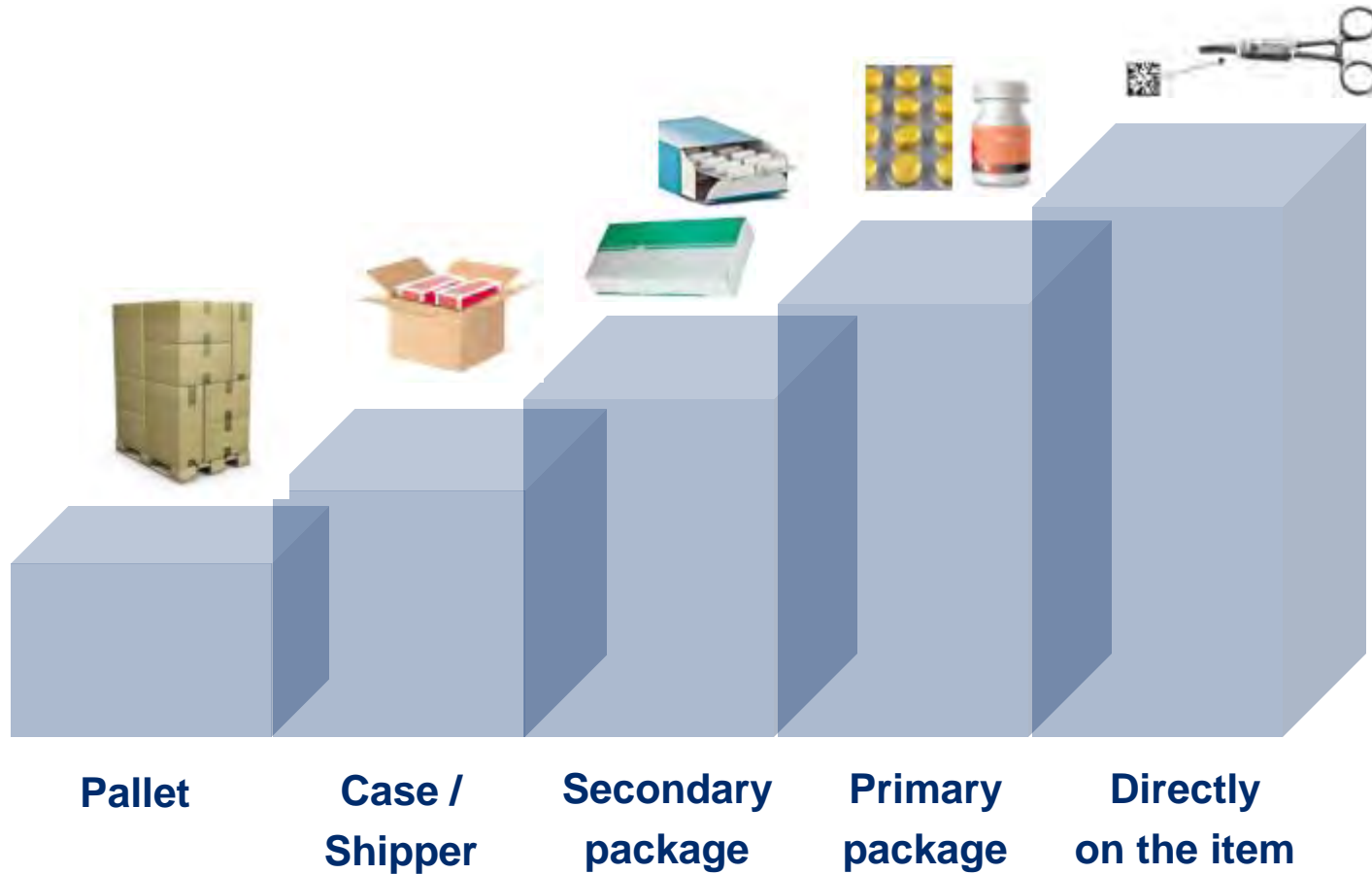


Non-retail





Healthcare Scope: All packaging levels





Healthcare

Scope: Risk-based solutions

AIDC Marking requirements

Highest

Enhanced

Minimum



Cotton balls, bandages, patient exam gloves, ...



Catheters, needles, ...



Pacemakers, hip replacements, ...



AIDC and the “5 Patient Rights”

The *right* patient



The *right* product



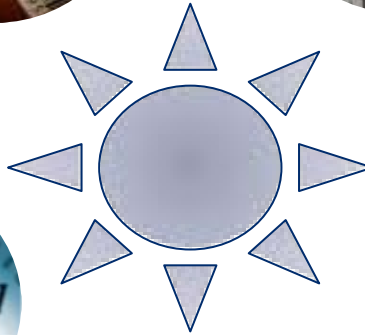
The *right* route



The *right* time



The *right* dose





AIDC and the “8 Patient Rights”





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Healthcare AIDC for Healthcare...Vision

EVERY item has
ONE set of key identification data carried in
ONE data carrier
able to be scanned by **EVERYONE**
at every key process step...





Healthcare Nice words...What do they mean?

My twin nephews, 11 weeks premature, in NICU...Mar. 1



Baby Brennan



Baby Collin



Healthcare **Putting it all together**

It often takes items from many companies,
sourced from all over the world,
to effectively treat ONE patient (or in this case, TWO)

Now, imagine a world where:

- EVERY item is uniquely identified
- ONE data carrier contained all the key identification information
- ONE globally accessible repository provides data describing the item
- Picking, receiving, dispensing, billing, invoicing, EHR entries—all completed electronically and without human error



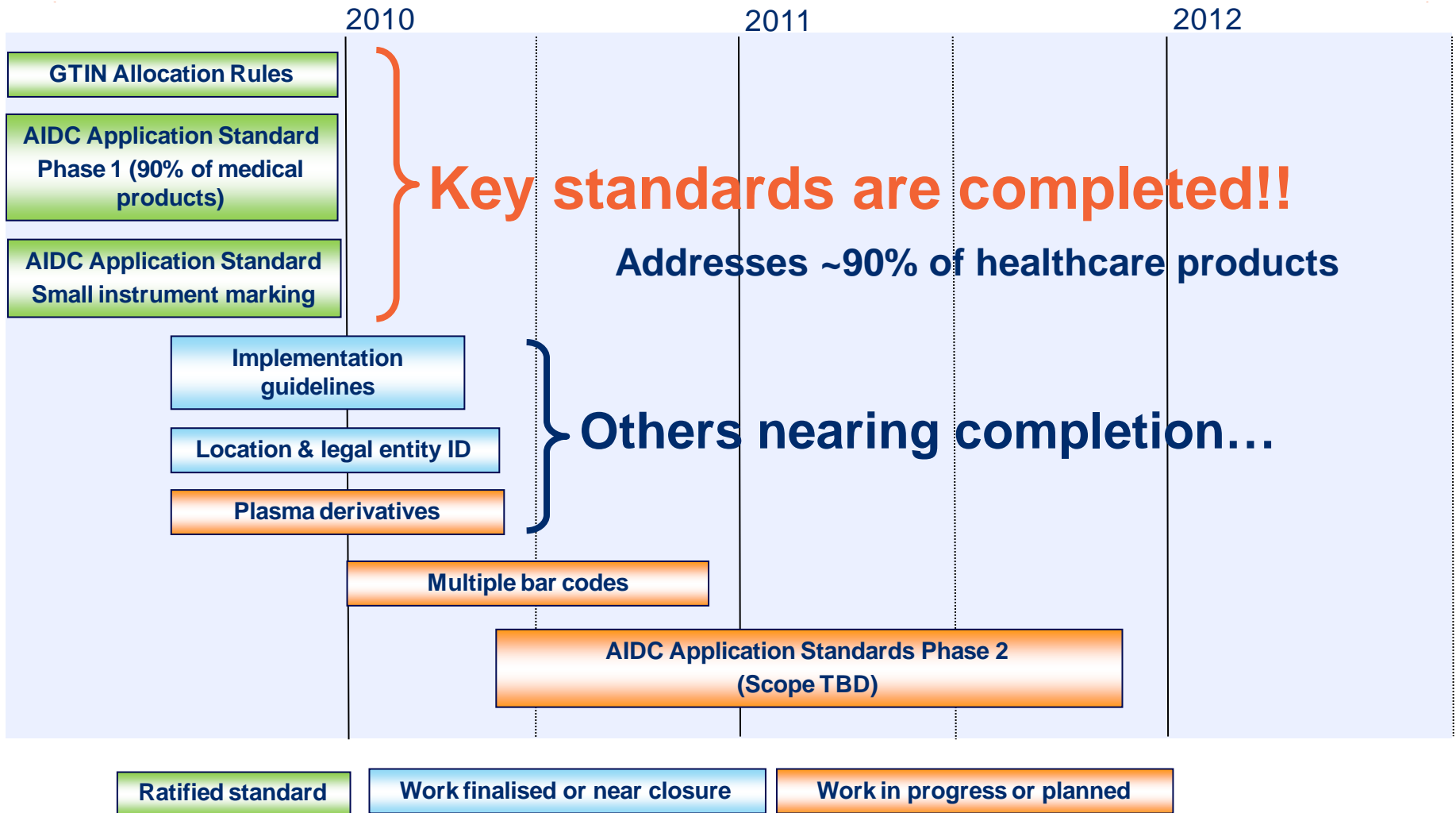
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Healthcare Roadmap to global standards





Healthcare

GS1 General Specifications

Revised!



The core standards document of the GS1 System

Now including AIDC Application Standards for Healthcare

And specific standards for marking re-usable surgical instruments

GS1 General Specifications

Version 10

Issue 1, Jan-2010

Contact your GS1 Member Organisation for your copy!





Healthcare AIDC Implementation Guide

In final draft!

**How to implement AIDC for
EVERY healthcare participant**

Coming VERY soon!!

AIDC Healthcare
Implementation Guide

Issue 1, Draft 10, 28-Jan-2010





AIDC Application Standards for Healthcare and Product Marking Grid

	MINIMUM Level of AIDC Marking (Retail)		MINIMUM Level of AIDC Marking (Non-Retail)		ENHANCED Level of AIDC Marking		HIGHEST Level of AIDC Marking	
	Pharmaceuticals Distributed and/or Sold Primarily Via Retail Channels	Medical Devices Distributed and/or Sold Primarily Via Retail Channels	Pharmaceuticals Distributed and/or Sold Primarily Via Non-Retail Channels	Medical Devices Distributed and/or Sold Primarily Via Non-Retail Channels	Medical Devices Distributed and/or Sold Primarily Via Retail Channels	Medical Devices Distributed and/or Sold Primarily Via Non-Retail Channels	Pharmaceuticals Distributed and/or Sold Via Retail and/or Non-Retail Channels	Medical Devices Distributed and/or Sold Primarily Via Non-Retail Channels
Description of the Example Product Hierarchy	DPM: 1 pill Primary Package: 1 pill in blisterpack of 12 pills Secondary Package: 3 blisterpacks of 36 pills in one carton Case: 24 cartons (864 pills) Pallet: 200 cases (172,800 pills)	DPM: 1 consumer bandage Primary Package: 1 bandage in pouch Secondary Package: 12 pouched bandages in one carton Case: 12 cartons (144 bandages) Pallet: 200 cases (28,800 bandages)	DPM: 1 pill Primary Package: 1 pill in blisterpack of 12 pills Secondary Package: 3 blisterpacks of 36 pills in one carton Case: 24 cartons (864 pills) Pallet: 200 cases (172,800 pills)	DPM: 1 empty syringe Primary Package: 1 empty syringe in blisterpack Secondary Package: 12 empty blisterpacked syringes in one carton Case: 12 cartons (144 syringes) Pallet: 200 cases (28,800 syringes)	DPM: 1 contact lens Primary Package: 1 contact lens in vial Secondary Package: 2 vials of 1 contact lens each in one carton Case: 12 cartons (24 contact lenses) Pallet: 100 cases (2,400 lenses)	DPM: 1 catheter (temporary) Primary Package: 1 catheter in blisterpack Secondary Package: 6 blisterpacked catheters in one carton Case: 24 cartons (144 catheters) Pallet: 200 cases (28,800 catheters)	DPM: 1 pill Primary Package: 1 pill in blisterpack of 12 pills Secondary Package: 3 blisterpacks of 36 pills in one carton Case: 24 cartons (864 pills) Pallet: 200 cases (172,800 pills)	DPM: 1 re-usable scalpel handle Primary Package: 1 re-usable scalpel handle in pouch Secondary Package: 6 pouched re-usable scalpel handles in one carton Case: 15 cartons (90 scalpel handles) Pallet: 200 cases (18,000 handles)
Direct Part Mark (AIDC marked directly onto a single, unpackaged, unlabeled item)	No marking 	No marking 	No marking 	No marking 	No marking 	No marking 	No marking 	GTIN Serial No. - Not for Implants Hospital: - 8003/8004 - optional
Primary Package (AIDC marked onto the first level of packaging, either on the packaging or on a label affixed to packaging. May consist of 1 single item, or a group of items for a single therapy such as a Kit.)	No marking (mark with GTIN if no Secondary Package) 	No marking (mark with GTIN if no Secondary Package) 	GTIN 	No marking (mark with GTIN if no Secondary Package) 	No marking (mark with GTIN if no Secondary Package) 	GTIN Lot Expiry 	GTIN Hospital: AI(01)+AI(21)+AI(7003) 	GTIN Lot Expiry Serial No. Potency (kits) Hospital: - 8003/8004 - optional
Secondary Packaging (AIDC marked onto the next level of packaging, containing one or more single items in their Primary Packaging)	GTIN 	GTIN 	GTIN Lot Expiry 	GTIN Lot Expiry 	GTIN 	GTIN Lot Expiry 	[Need 2 marks] GTIN Hospital: AI(01)+AI(21) + AI(7003) Expiry Serial No. Potency 	GTIN Lot Expiry Serial No. Potency (kits) Hospital: - 8003/8004 - optional
Case / Shipper (AIDC marked onto a shipping container. May contain one or more items in their Primary Packaging and/or Secondary Packaging.)	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry - Serial No. - Potency Logistics: - SSCC Hospital: AI(01)+AI(21) + AI(7003) 	Trade Item: - GTIN - Lot - Expiry - Serial No. - Potency Logistics: - SSCC
Pallet (AIDC marked onto a pallet. May contain one or more Case / Shippers.)	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry - Serial No. Logistics: - SSCC 	Trade Item: - GTIN - Lot - Expiry - Serial No. Logistics: - SSCC



Operating Room

Sterilisation Unit



Use



Case carts



Stock



Transport



Preparation

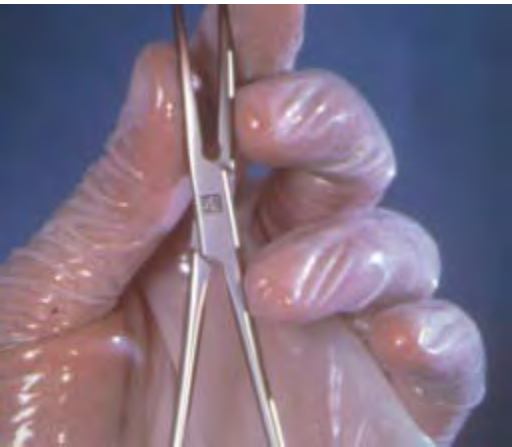
- ✓ Cleaning
- ✓ Dis-/assembling
- ✓ Maintenance
- ✓ Substitution
- ✓ Set configuration
- ✓ Completeness check



Sterilisation

- ✓ Creation of 'Steri Batches' (e.g. labels)
- ✓ Batch loading and release

Small instrument marking GS1 General Specifications



- Data carrier: **GS1 DataMatrix**
 - 2-D bar code
- Identification key: **GTIN**
 - Global Trade Item Number
- Attribute: **Serial number**



Small instrument marking GS1 General Specifications



- Data carrier: **GS1 DataMatrix**
 - Target useable mark area of 2.5mm x 2.5mm
 - One bar code on a single instrument
 - Though not limited to, laser etching is recommended
 - Mixed marking technologies within the same scanning environment should be avoided (ensures highest reading performance)
- Identification key: **GTIN**
 - GTIN (Global Trade Item Number) – preferred option
 - GTIN-12, -13 or -14 allowed
 - GRAI (Global Returnable Asset Identifier) or GIAI (Global Individual Asset Identifier) – in case of hospital legacy system
- Attribute: **Serial number**
 - AI(21) (Application Identifier) mandatory - Serial number





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A vertical image on the left side of the slide showing a globe made of puzzle pieces. One piece is missing, and a hand is shown placing a new piece into it. The background is a soft, light blue sky with clouds.

ONE global standard for **AIDC** in healthcare **now available**

Many countries have already adopted
GS1 Standards

Many more are following...





Putting the standards to work...





Healthcare **How Alcon got started**



- **Participated** in work groups to understand the issues
- Started a **gap analysis** of key items
 - Focused on medical devices for UDI compliance
 - And for pharma / devices in areas with active regulations (Brazil, France, Serbia, Korea, Turkey, etc)
- Preparing **action plan** by mfg. facility based on gaps
- Reviewing results with Auto-ID Steering Committee
- Requesting 2011 – 2015 **funding**
- Starting pathfinder projects to **'learn by doing'**
- Continuously improving our approach

Changing our world...ONE item at a time...



Healthcare How YOU can get started



1. Contact your local **GS1 Member Organisation** for guidance
2. **Get familiar** with the standards / guidelines
 - Attend breakout sessions this week!
 - Participate on GS1 implementation projects / team
3. Do a **gap analysis**...your items vs. GS1 Standards
 - Focus on key items and facilities...don't 'boil the ocean'
 - Build action plans, budgets, management approval
4. Implement your **action plan**
 - Start small, conduct Pilot Projects, “learn by doing”, “crawl before you walk / run”...

Global teams

- Implementation Guideline
- Blood / Plasma Derivatives
- Location and Legal Entity ID
- Patient and Caregiver ID
- Multiple Bar codes
- Bar code / EPC Interoperability
- Serialization
- Phase 2: AIDC Application Standards

Local teams

- Contact your local Member Organisation representative

Join Us!



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