Unique Device Identification: Unambiguous, Standardized and Harmonized

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2011- Year of the Rabbit

- Metal Rabbit - Calm and gentle, but persistent.
- One of the most cautious signs in the Chinese zodiac – they are the chess players who take their sweet time before making a move.
- Famous Rabbits include: Albert Einstein, Leon Trotsky, Frank Sinatra, Pope Benedict XVI, Angelina Jolie, Brad Pitt, Johnny Depp, David Beckham, Tiger Woods, Whitney Houston.

2011- Year of the Device

- UDI Development – slow, thoughtful, thorough
- Devices cover a very wide range of medical products – from the simplest to the most complicated
- Needs to be flexible, adaptable, and scaleable
- Includes other issues such as GMDN, HL7 SPL, development of UDID
- Information associated with the device in the UDID is critical to safe distribution and use

Current Device Identification

- Non-standard device identification systems; standards used in different ways
- Not necessary unique or unambiguous
- Does not include all necessary levels of uniqueness
- Manufacturers' own number/catalogue number
- Distributors' – apply different, proprietary number; lot or serial number not captured
- Hospital – yet different identification number/code
  - Information on use not usually captured
  - Control numbers rarely captured

Future Device Identification

Develop a system to identify medical devices, which is:

- Consistent
- Unambiguous (differentiates among all dimensions)
- Standardized
- Unique at all levels of packaging
- Harmonized internationally

And facilitates the:

- **Storage,**
- **Exchange, and**
- **Integration of data and systems**

UDI brings… Global Visibility

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion (location systems)
- Comparative effectiveness (e.g., registries)
- Disaster/terror preparation and shortages/substitutions
- Reduce medical errors
- Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
- Sentinel Initiative - strengthening FDA's ability to query data systems for relevant device information

FDA Amendments Act of 2007

September 27, 2007, the FDAAA signed into law:

> The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.

GHTF UDI ADWG

- Formed October 2008
- EC Chair (Laurent Selles)
- Members US (FDA, AdvaMed), Europe (EC, Eucomed, EDMA), Japan, Canada
- AHWP recently joined (China)
- Washington April 2010; Brussels June 2010; Ottawa September 2010; May 2011
- Guidance submitted to Nov 2010 SC meeting
- Public Document – available at: http://www.ghtf.org/ahwg/ahwg-proposed.html Comments due by 30 April 2011.

Establishing a UDI System

Combination of 4 distinct steps:

1. Develop a standardized system to develop the unique device identifiers (UDI)
2. Place the UDI in human readable and/or AutoID on a device, its label, or both
3. Create and maintain the UDI Database
4. Adoption and Implementation

1st – Developing the UDI

- Develop UDI code according to ISO 15459 [GS1, HIBCC]
- Created and maintained by the manufacturer
- Concatenating Device and Production Identifier
- Device Identifier (DI): [static] Manufacturer, make, model [i.e., each catalogue number]
- Production Identifier (PI): [dynamic] however product is currently controlled – serial, lot number; expiration, manufacturing date

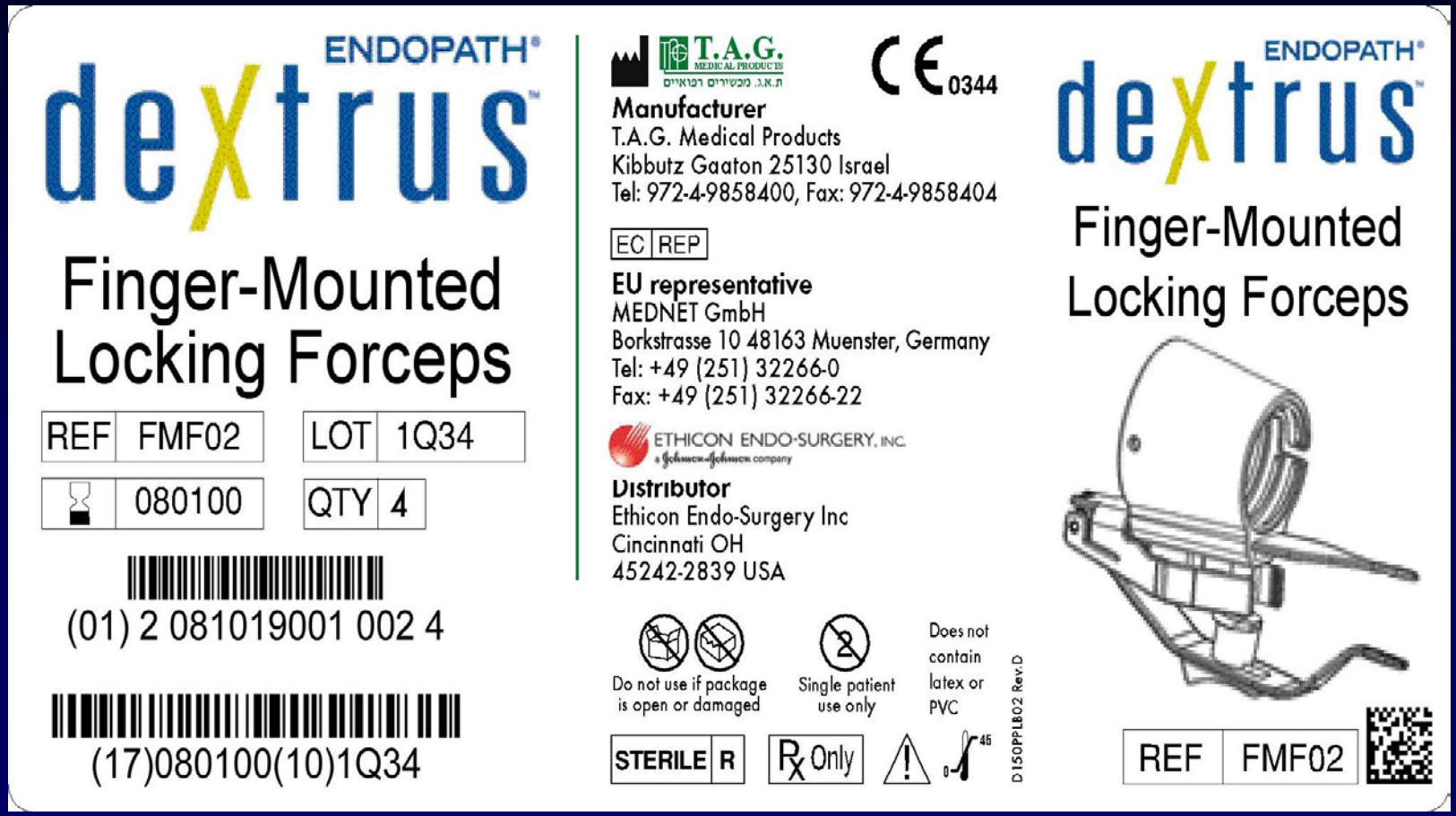
2nd – UDI Application

- Unique UDI applied to all levels of packaging, down to the lowest level (patient use/ unit of use)
- Human readable and/or encoded in a form of automatic identification technology
- No specific technology would be identified (technology neutral)
- Identify a series of standards (linear barcode, 2-dimensional barcode, RFID)
- Direct Part Marking (DPM) for some devices

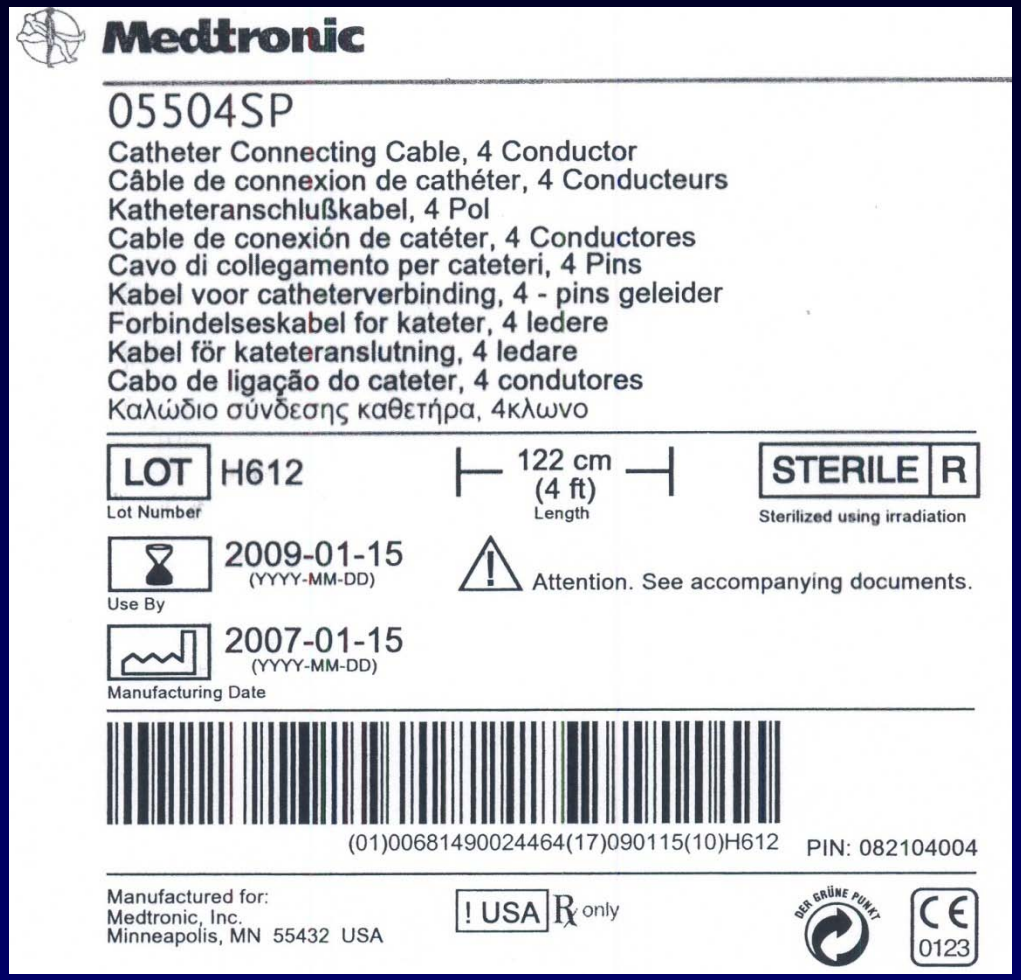
Risk-based Approach

- Production identifier reflects current control (label) – not requiring serialization.
- Granularity of marking based on risk of device - UDI for some devices on multi-packs or higher levels of packaging
- Not all devices require production identifiers
- Take into account realities of retail environment
- Robust alternative placement and exception processes

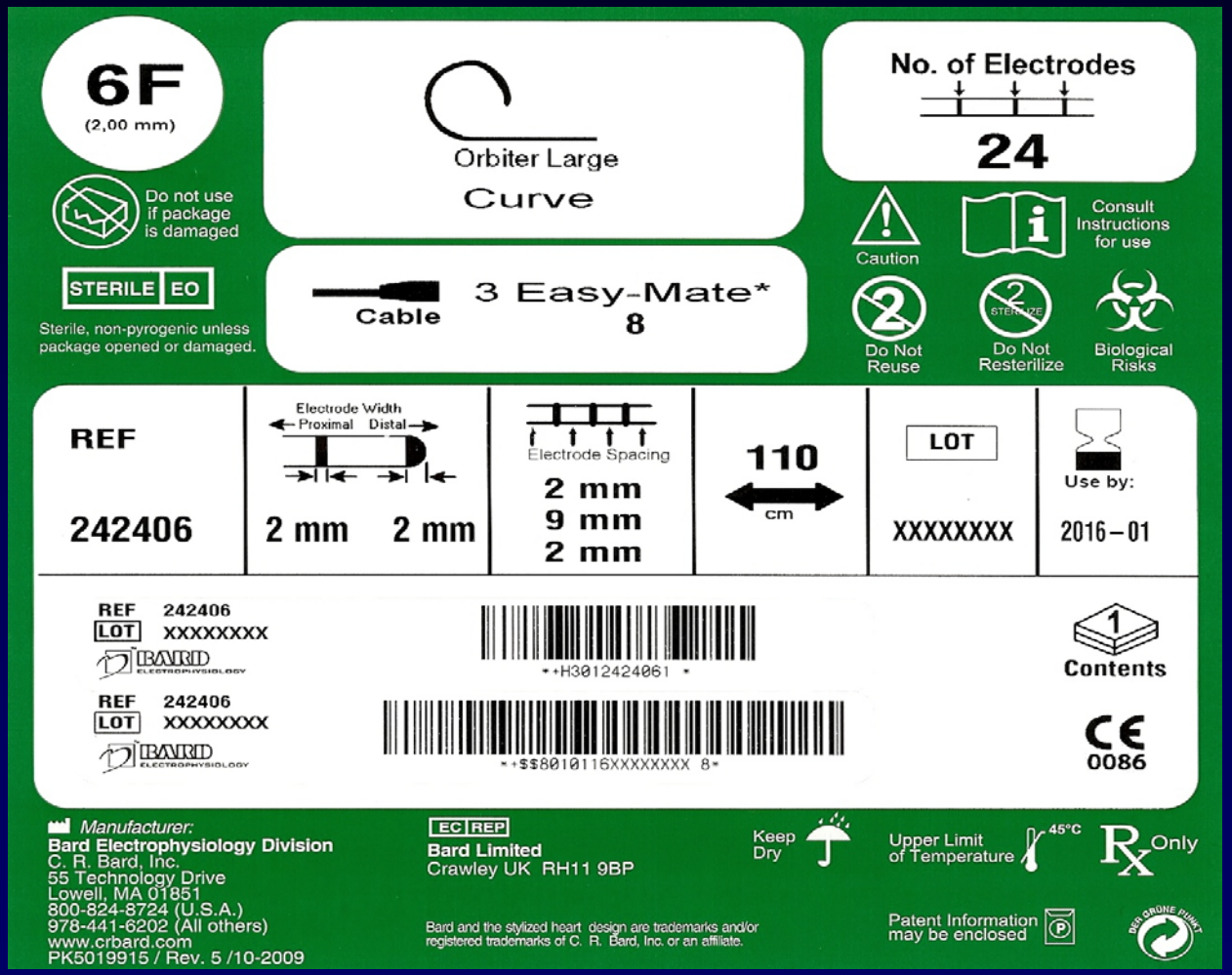
UDI Application Example



UDI Application Example



UDI Application Example



Combination Products and Kits

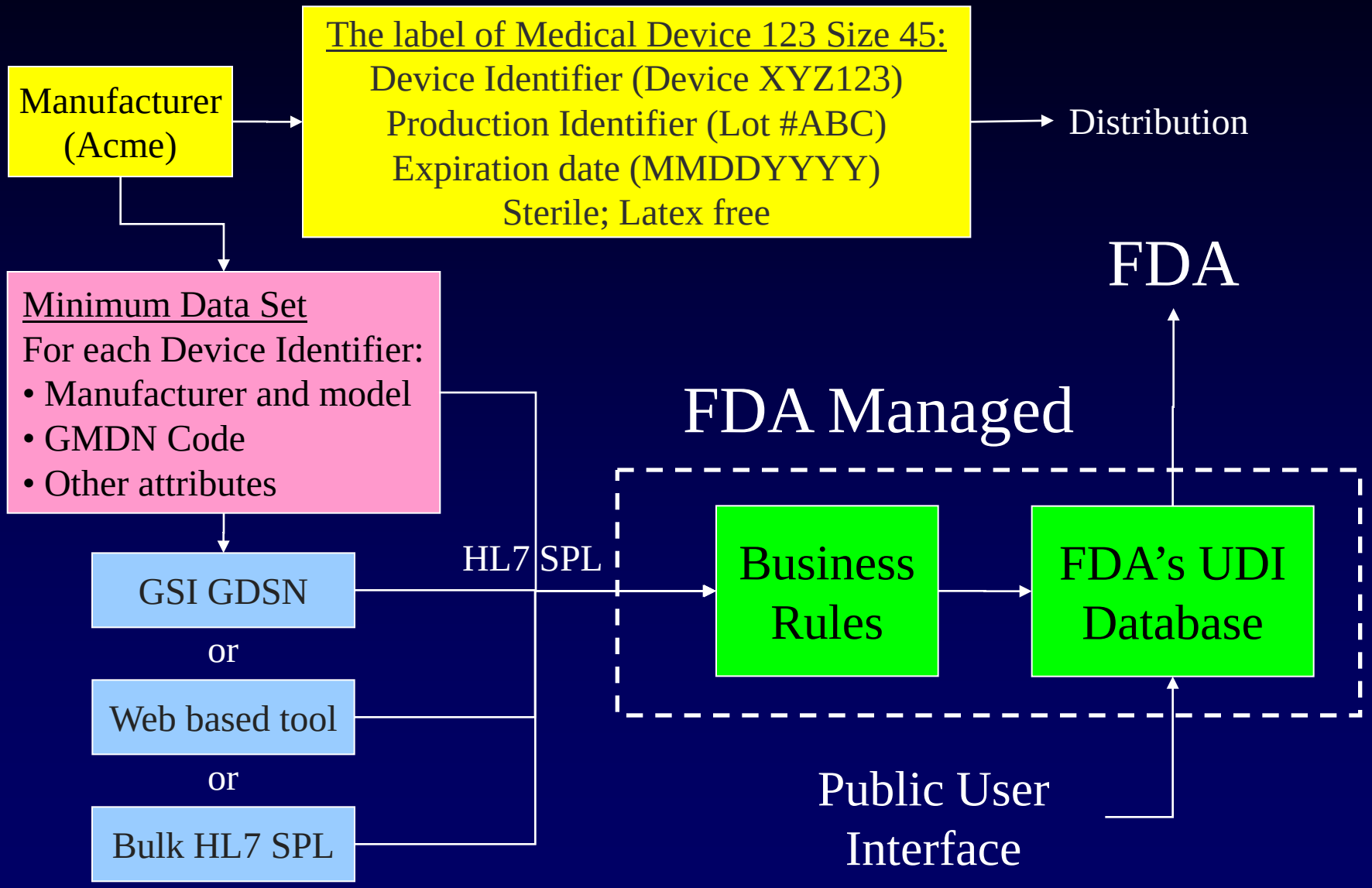
Like other devices – intended to facilitate identification:

- Combination product (device) has its own UDI; each device should have its own UDI.
- Each kit (devices only) has its own UDI; each device in a kit should also have its own UDI.

3rd – Global UDI Database

- Device Identifier Type/Code [GTIN, HIBCC]
- Make/model; Brand/Trade Name; Size; Description
- Device model number (or reference number)
- Unit of Measure/Packaging level/quantity
- Controlled by – Lot and/or Serial Number; Exp. Date
- Contact name, phone, email
- GMDN Classification code/term
- Storage condition; Single Use; Sterility
- Contains known, labeled allergen (e.g., latex)
- FDA premarket authorization (510k, PMA)
- FDA Listing Number

FDA's UDI Database



Implementation

- Based on premarket risk class:
  - class III – 12 months after final rule
  - class II – 36 months after final rule
  - class I – 60 months after final rule
- Allows stakeholders to jointly learn and for mid-course corrections
- Phase out national numbering system (NDC/NHRIC)
- Robust alternate placement and exception process
- Expect manufacturers and groups of manufacturers to submit requests – results of which will posted.

4th – Adoption and Implementation

- Facilitate distributor uptake and use
- Facilitate hospital uptake and use
- Facilitate use of UDI throughout device lifecycle
- Drive integration – MMIS-Clinical
- Drive appropriate use of UDI in EHRs – and use of EHRs for registries and other postmarket activities

HL7 SPL

- HL7 SPL r5 models UDI GHTF data elements
- Definitions
- Representation of Various Product combinations
- Identifying a Product without packaging
- Defining System requirements for UDID and internal FDA Product Information Database
- Accept , Store and Transmit HL7 SPL message

GMDN

- Development of global nomenclature to support regulatory and research activities.
- Preferred terms provide high degree of specificity
- Used for signal detection and device comparisons during data surveillance and analyses
- New governance model and activities in place
- Sustainable funding model under development
- Used with UDI/UDID to provide multiple levels of use (general → specific)

Unique Device Identification

www.fda.gov/MedicalDevices/
DeviceRegulationandGuidance/
UniqueDeviceIdentifiers

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