

FDA Public Meeting on Unique Device Identification



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Meeting on
Unique Device
Identification

Mass serialization

The world's leading manufacturer of printer inkjet produces over 300 million cartridges a year.

Each \$10 cartridge is coded with a unique identifier, utilizing 2D barcode. The cartridge manufacturer maintains a genealogy of each cartridge, from raw materials – to – retail outlet.



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If UDI can be applied to 100's of millions of inkjet cartridges,
why not medical devices ?



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Each of the 420 million airline passenger trips a year in the USA is mass serialized, with the support of the industry standards body, IATA.

Each airline ticket is a Unique Device Identifier:

009-7649465513

In 2006, 60 million vehicles are built in the world.

Over 13 Billion parts include unique identification numbers, with the support of an industry standards body, AIAG.

If UDI can be applied to Billions of automotive parts, why not medical devices ?

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We would like to offer the premise that creating and maintaining a unique identification (UDI) architecture in the USA is a relatively uncomplicated process.

The cornerstone for UDI is:

- Design of the identifier
- Utilization of prevailing technologies in Direct Part Marking (DPM)

Build it and they will come...

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Mass serialization - UDI

Since three UDI designs already exist, the only action to be taken is to mandate the use of one identification structure:

- DoD IUID
- AIAG
- EPCGlobal

The DoD IUID structure is the most mature structure and requires no investment in licensing, and requires no investment by member organization.

The AIAG UID structure is also mature and has wide adoption in the automotive sector.

EPCGlobal is less mature and requires member organizations to commit financially.

See next slide for structures...

No need to re-invent the wheel...

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Mass serialization - UDI

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DoD / OSD Structures

Construct #1

Issuing Agency Code: D

Enterprise Identifier (MFR Cage): 0CVA5

Serial Number: 786950

Example: D 0 C V A 5 7 8 6 9 5 0



Construct #2

Issuing Agency Code (IAC): UN

Enterprise Identifier (MFR Cage): 194532636

Orig. Part Number: 1234

Serial Number: 786950

Example: U N 1 9 4 5 3 2 6 3 6 1 2 3 4 7 8 6 9 5 0



EPCGlobal



01. 0000389. 000162. 000169740

Header	EPC Manager	Object Class	Serial Number
8 bits	28 bits	24 bits	36 bits

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The first step...

We respectfully recommend the medical device supply chain be compelled to agree on “one” of three UDI structures, within a prescribed timeframe.

Concurrently, establish the definition and listing of all items defined as ‘medical devices.’

There must be a definitive milestone path, or the process will drag for years...

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Mass serialization - devices

The second step...

Establish a rules and adjudication, self governing, body to facilitate classification arbitration.

There needs to be a permanent determining medical industry body that governs and updates the listing of items defined as 'medical devices.'

What is a medical device ?

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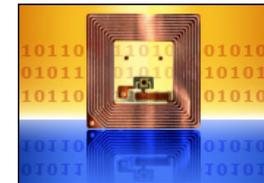
Mass serialization - DPM

Direct Part Marking (DPM)

Once establishing the architecture for serialization, the ability to efficiently apply the serial number requires the adoption of prevailing technologies.

The technologies existing today:

Technology	Application	Cost of Medical Devices	Cost of Technology
RFID	Non-line of sight	Med-High	High
2D barcode	Line of sight	Low	Low
Laser etch	Line of sight	Low-High	Medium
Inkjet serial no.	Line of sight	Low	Low



Does it matter which technology is utilized for medical device marking ?



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Mass serialization - technology

Considering that a variety of technologies exist today to facilitate the reading and recording of UDI, such as 2D barcode, smartvision, and RFID... there is little need to pre-define the form factor of the UDI.

It is generally accepted that product identification will continue to grow utilizing two basic paths:



- Low cost line-of-sight technologies such as 2D barcode...or even standard alphanumeric serialization....
- Higher cost RFID and versatility in non-line of sight technologies



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Technology exists today to manage serialization efficiently

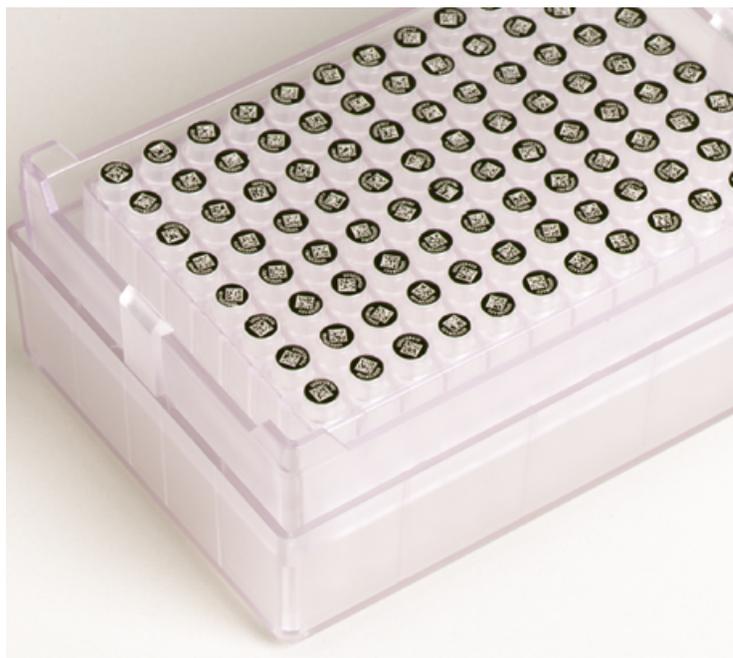


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Mass serialization - technology

Laser marking is available today on medical devices

- Serial number marked



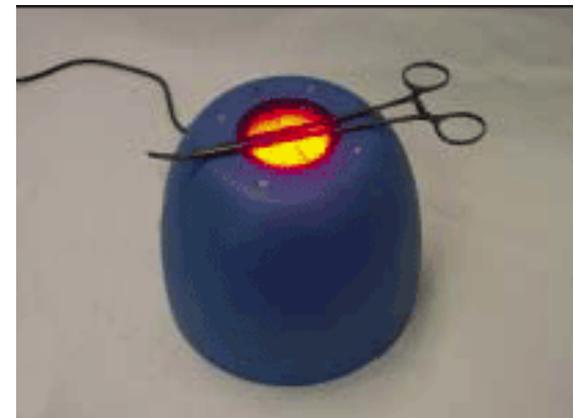
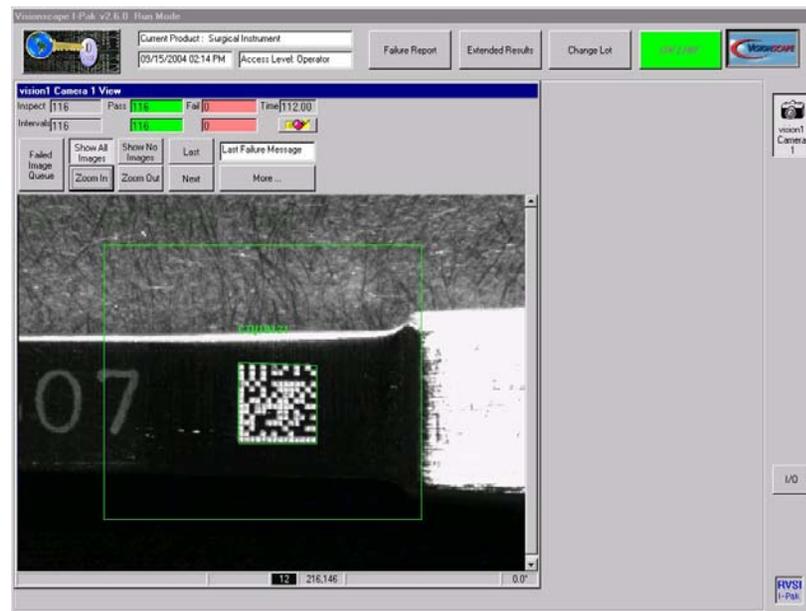
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Laser mark on surgical steel is mature

- Serial number marked



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Mass serialization - adoption

Once the UDI serial number architecture is defined, ratified and mandated....

....market forces will drive adoption and proliferation.

Technologies such as UPC product barcode, EDI and web services adoption were principally voluntary, once the infrastructure was defined

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Mass serialization - commitment

As one of the largest technology enterprises to the health sciences community, Siemens is committed to medical device identification.

Siemens can be found in every hospital and almost every clinic in the USA.

As a technical infrastructure provider, Siemens perceives medical device serialization as an integral part of the Siemens medical workflow offering.

Siemens investments in technologies to support UDI for medical devices include:

- 17 years of RFID experience
- Over 300,000 RFID readers and millions of devices sold, worldwide
- Innovation center in 2D barcode technology
- Prominent DPM competence center
- Serial number optical verification

Siemens is prepared to contribute in a leadership role to support the FDA and the health sciences community

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Medical Device Serialization (UDI)

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