



CUSTOMER
& LOGISTICS
SERVICES

A Manufacturer's Perspectives on Unique Device Identification (UDI)

GS1 Healthcare Global

San Francisco, CA

Tom Werthwine | October 1, 2013

Johnson & Johnson: Global Presence

Global Leader in
Health Care

More than 250
Operating Companies
In 60 Countries

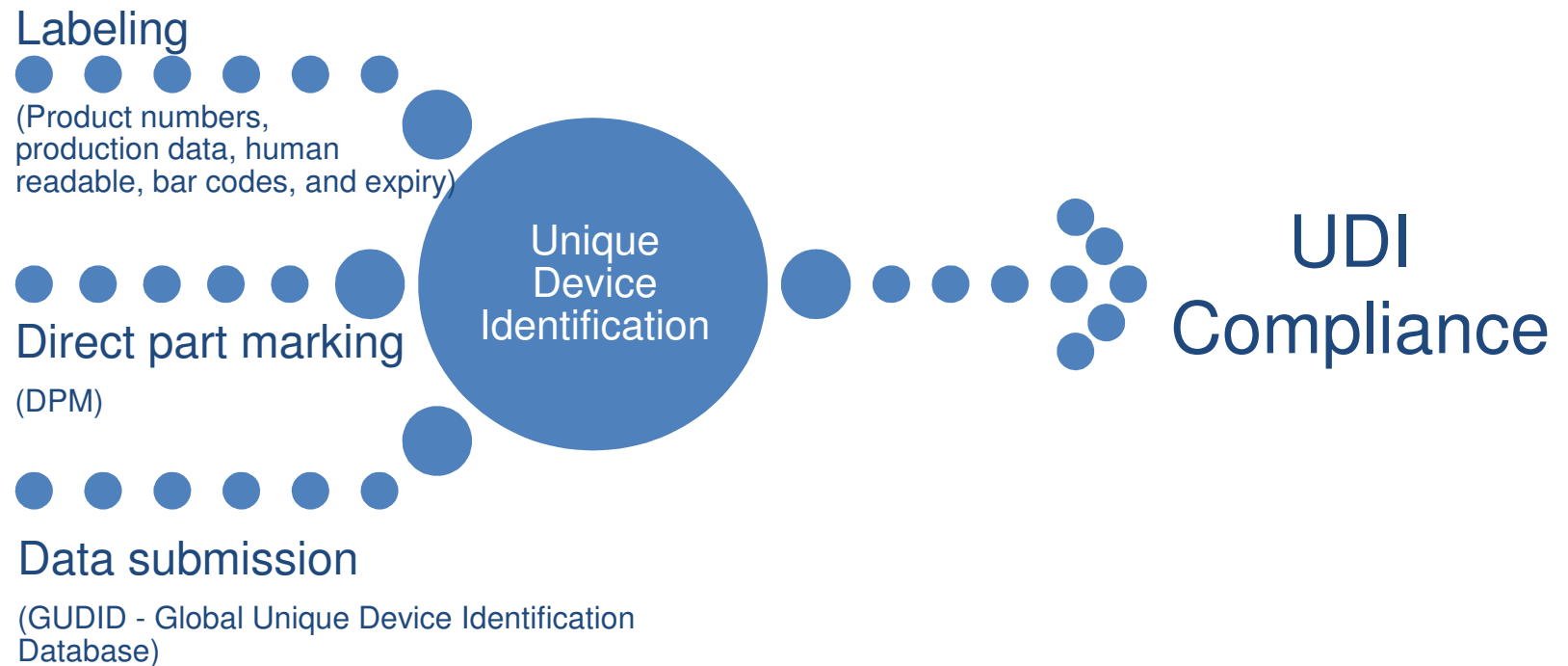
Selling Products in More
Than 175 Countries

128,000 Employees
Worldwide



Unique Device Identification

Three components required for UDI compliance



Unique Device Identification Bar Coding

REF 279751107 YYY-MM QTY 1
 LOT SAMPLE MATL SS/RADEL@SILICONE

EXPEDIUM® J SPINE SYSTEM
RATCHETING TEARDROP HANDLE
FOR EXPORT ONLY.

5.5 CE

NON STERILE

POIGNÉE PIRIFORME À CLIQUET
 TRÖPFENFÖRMIGER RATSCHENGRIF
 DRUPPELVÖRMIG HANDVAT MET RATEL
 IMPUGNATURA A GOCCIA CON ARPIGNISMO
 MANGO TIPO GOTA DE TRINQUETE
 CABO EM FORMA DE LÁGRIMA COM CATRACA
 DRÁBEFORMET SKRALDEHÄNDTAG
 SPÄRRANDE DRÖPPFORMAT HÄNDTAG
 RÁIKKÁPISARAKA-HVA
 ΔΑΚΡΥΟΞΗΜΗ ΛΑΒΗ ΜΕ ΚΑΙΤΑΝΙΑ
 RACSNIS. KÖNNYCSEPP ALAKÚ NYÉL
 OZUBENÁ SLZOVÁ KLIKA
 RĄCZKA ZAPADKOWA W KSZTAŁCIE ŁZY
 TÁREFORMET HÄNDTAK MED SKRALLE

Medos International SARL
 Chemin-Blanc 38
 2400 Le Locle, Switzerland

DePuy Spine, Inc.
 325 Paramount Drive
 Raynham, MA 02767, USA


DePuy Spine

For patent information about this product, go to
www.depuy.com/patentmarking

(01)10705034460581(20)99

(10)SAMPLE

REV. A

Testing Summary	
GS1 General Specifications for Linear Symbols tested environments:	
Not Assessed for Retail, Point of Sale Scanning	
Not Assessed for General Distribution and Logistics scanning	
Approved for Other Scanning Applications - Regulated Healthcare Non-Retail Consumer Trade Items Not Scanned in General Distribution	
Complies to GS1 Symbol Location	In/Out of Spec - Not Assessed (Comment on Business Critical Issue)
Recommendations	PASS
GS1 System Grade	ISO 3.1/10/660 (B) - PASS Example: ISO 4.00/06/660 (0.00 - 4.00) PASS/FAIL
ISO Symbol Grade	
Business Critical Comments	
生产日期: 2013-04-17 Model Number: 10033-901 序列号: 0033050293 GTIN: 10705037014163	
 (01) 1 0705037 01416 3 (11) 130417 (21) 0033050293	

GS1 US Verification Report

GS1 Linear 128 and Datamatrix

Unique Device Identification

Date Format YYYY-MM-DD

SKU: Reorder No. **4605**

Size: **5 ml**

Lot No.: R23T750

Exp. Date: 05.2014

Quantity: 6 sales units (Total 36 vials)

**THROMBIN TOPICAL (HUMAN)
EVITHROM***

For usage instructions and precautions, see complete prescribing information enclosed. For topical use only. Do not inject. Store frozen at -18°C or colder. Unopened vial can be stored at 2°C to 8°C for up to 30 days. Do not re-freeze once thawed.

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Wound Management
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P.O. Box 151, Somerville,
NJ 08876-0151 USA

omrix
Manufactured by:
OMRIX biopharmaceuticals Ltd.
MDA blood bank, Sheba Hospital,
Ramat-Gan.
POB 888, Kiryat Ono 55000 ISRAEL
U.S. License No. 1603
Art. No. 61TZ00M3D0

FOR TOPICAL USE ONLY
DO NOT INJECT

FOR TOPICAL USE ONLY
DO NOT INJECT

1 Vial of Evithrom
Thrombin (Human) solution
(5ml)
5 ml
EVITHROM®
THROMBIN
TOPICAL (HUMAN)

Reorder No. 4605

FOR TOPICAL USE ONLY
DO NOT INJECT

LOT: R23T750 EXP: 05.2014

1714053110R23T750

(01)10363713460057

0-11
8

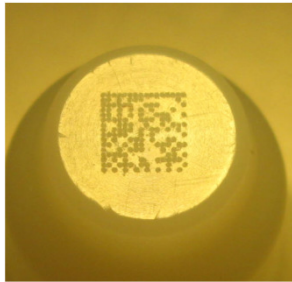
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MM-YYYY

Unique Device Identification

Direct Marking



Manufacturer must determine

1. Can the device be marked?
2. Can the bar code be read?
3. If not, note in Design History File
4. Does unpackaged, direct-marked device require its own GTIN/UDI Device Identifier?
5. Feed existence from shop floor to GUDID database

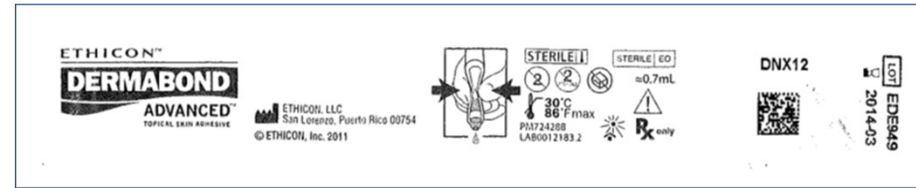
Sample 2D Bar Code Etches for DePuy Synthes



Unique Device Identification

GUDID Database Support

Field	Example
Submitter DUNS	884918947 (REED)
Labeler DUNS	002144145 (ETHICON)
RA Contact	TBD
Customer Contact	1-877-384-4266
UDI Issuing Agency	GS1
Primary UDI	10705031203532
Primary UDI Count	1 EA
Secondary UDI IA	HIBCC
Secondary Primary UDI	H206DNX121
FDA Authorization	K100423
FDA PROCODE	MPN
FDA PROCODE Name	Tissue adhesive



Field	Example
FDA Listing	FURLS
GMDN Code	TBD
GMDN Term	TBD
Brand Name	DERMABOND ADV
Model/REF	DNX12
Description	Topical Skin Adhesive
Market Status	Active
Combination Product	No
Contains Human Tissue	No

Unique Device Identification

Use in Other Processes

Adverse Event Reporting
Recall Notices

The screenshot shows the MAUDE - Manufacturer and User Facility Device Experience search interface. The page title is "MAUDE - Manufacturer and User Facility Device Experience". Below the title, there are navigation links: "FDA Home", "Medical Devices", and "Databases".

The main content area is divided into two sections:

- Introduction:** A text box stating "The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters ¹ (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers." It includes a "Learn More" link and a "Disclaimer" link.
- Search Database:** A search form with the following fields:
 - Product Problem (dropdown)
 - Product Class (dropdown)
 - Brand Name (text input)
 - Manufacturer (text input)
 - Event Type (dropdown)
 - 510K Number (text input, value: K)
 - PMA Number (text input, value: P)
 - Product Code (text input)
 - Date Report Received by FDA (mm/dd/yyyy) (text input, value: 01/01/2013) to (text input, value: 08/31/2013)

At the bottom of the search form, there are links for "Go to Simple Search", a "Records per Report Page" dropdown (value: 10), a "Clear Form" link, and a "Search" button.

On the right side, there is a section titled "Other Databases" with a list of links:

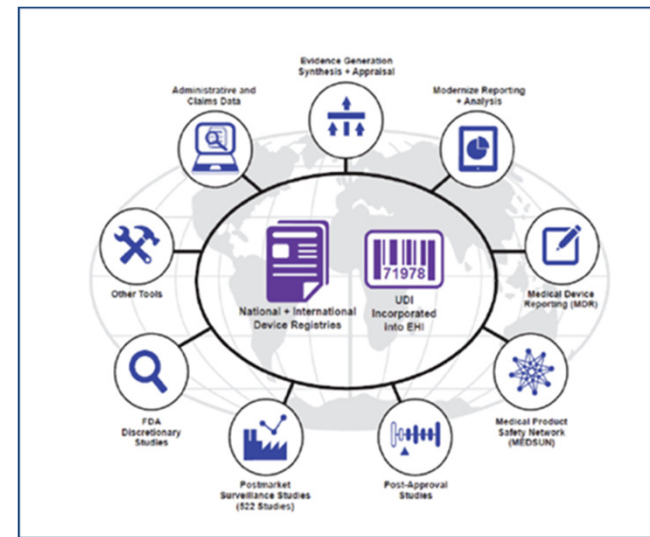
- 510(k)s
- Adverse Events (MAUDE)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- Inspections
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

At the bottom of the page, there is a paragraph of text: "Each year, the FDA receives several hundred thousand medical device reports (MDRs) of suspected device-associated deaths, serious injuries and malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The MAUDE database houses MDRs submitted to the FDA by mandatory reporters ¹ (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers."

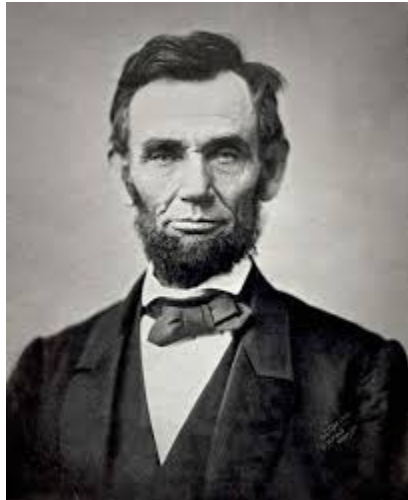
Unique Device Identification Opportunities

For manufacturers:

- Supporting customer need for data
- Globally unique product identification versus product selection by color, package size, etc.
- Support “perfect order”
- Support implant registries
- Support electronic health records
- Increase efficiencies for evidenced-based medicine



Closing Thought



“You cannot escape the responsibility of tomorrow by evading it today.”

Abraham Lincoln