Johnson & Johnson 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

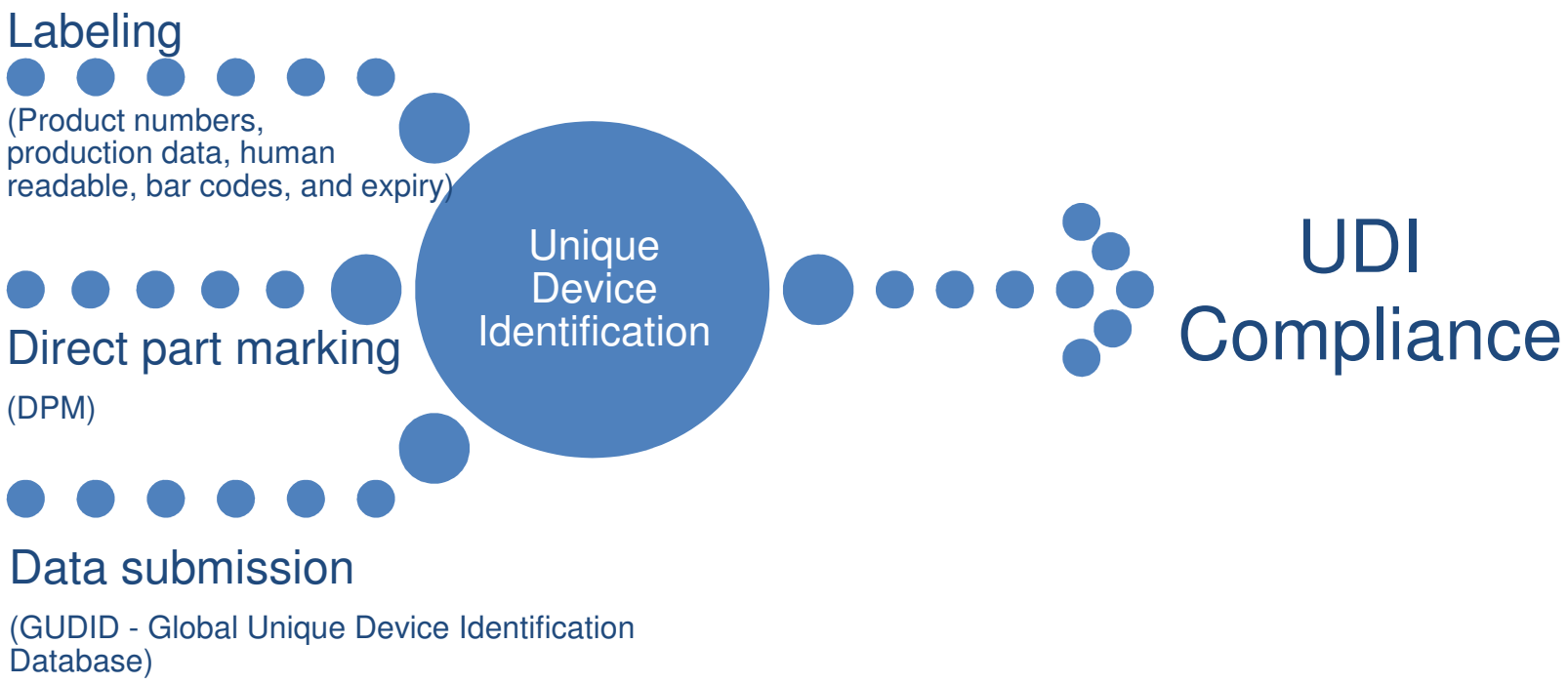
More than 250
Operating Companies
In 60 Countries

Selling Products in More
Than 175 Countries

128,000 Employees
Worldwide

Unique Device Identification

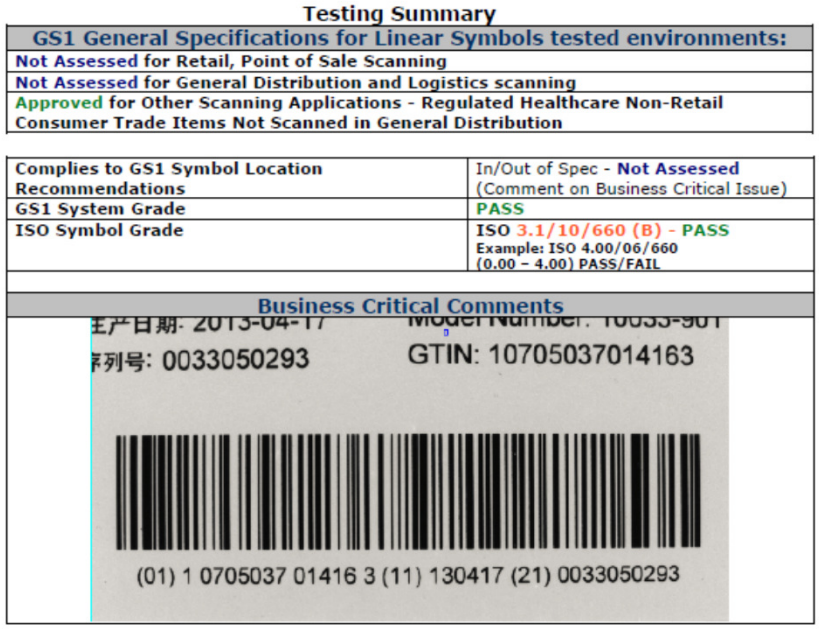
Three components required for UDI compliance



Unique Device Identification

Bar Coding

GS1 Linear 128 and Datamatrix



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 Recommendations	In/Out of Spec - Not Assessed (Comment on Business Critical Issue)
GS1 System Grade	PASS
ISO Symbol Grade	ISO 3.1/10/660 (B) - PASS Example: ISO 4.00/06/660 (0.00 – 4.00) PASS/FAIL

Business Critical Comments

序列号: 0033050293
GTIN: 10705037014163
(01) 1 0705037 01416 3 (11) 130417 (21) 0033050293

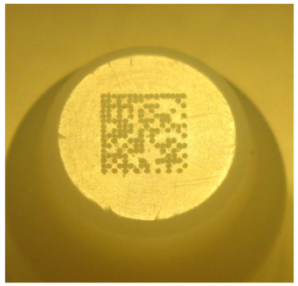
GS1 US Verification Report

Unique Device Identification

Date Format YYYY-MM-DD

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

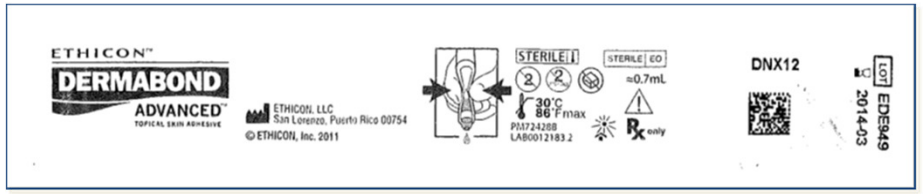
Sample 2D Bar Code Etches for DePuy Synthes

DePuy Synthes
COMPANIES OF Johnson & Johnson

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

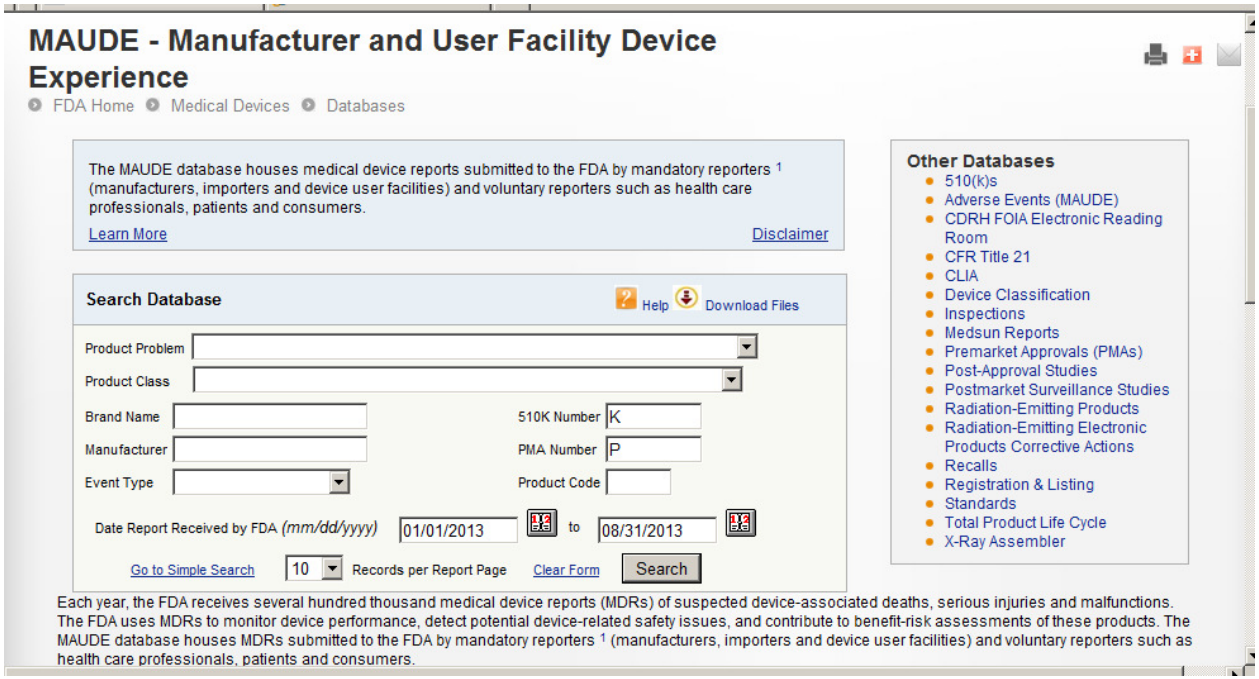


Field	Example
FDA Listing	FURLS
GMDN Code	TBD
GMDN Term	TBD
Brand Name	DERMABOND ADV
Model/REF	DNX12
Description	Topical Skin Adhesive
Market Status	Active
Combination Product	No
Contains Human Tissue	No

Unique Device Identification

Use in Other Processes

Adverse Event Reporting
Recall Notices

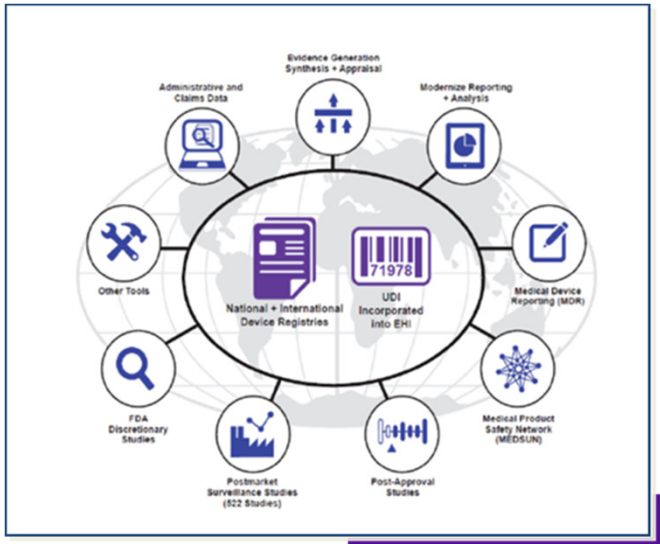


Unique Device Identification

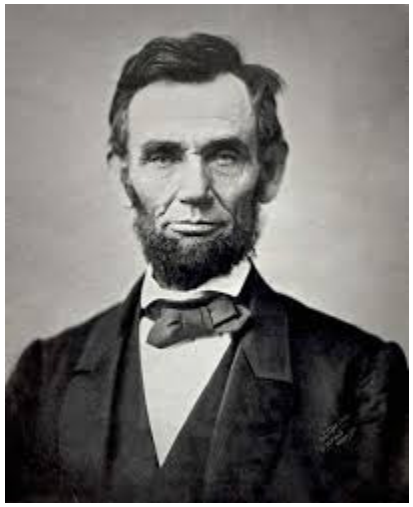
Opportunities

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