

## SIX STEPS TO UDI COMPLIANCE

### REACHING UDI COMPLIANCE BY 2016

Are you putting off developing a compliance program? Non-compliance is not an option. Refer to our chart and find your path to implementing a compliant Unique Device Identifier (UDI) program ...

#### 1 ID NEW REQUIREMENTS

Refer to the FDA/GS1 to identify new UDI requirements that apply to you. Appoint a UDI Champion and team within your organization and contact experienced vendors—such as Domino—to leverage their broad knowledge of the new requirements.

#### 2 SITUATIONAL ANALYSIS

Analyze your current situation: What compliance standards are in place? What are the capabilities and limitations of your current technologies? Ask for assistance—your suppliers know their equipment best. Also contact your issuing agency (GS1, HIBCC or ICCBBA) to determine your company's prefix and what standards you need to adopt.

#### EACH UDI WILL CONSIST OF TWO PORTIONS:

- 1 **Device identifier:** Corresponds to the specific version or model of the device and the labeler of the device.
- 2 **Production identifier:** More precisely identifies the specific device by providing variable information, such as the lot or batch, the serial number, expiration date, the date of manufacture.

#### 3 SURVEY CUSTOMERS

Engage customers and distributors to determine compliance expectations and concerns. Has your distributor already settled on a specific standard that you must meet? Again, partners such as Domino—who already supply serialized coding solutions around the world—are valuable assets.

#### 4 DEVELOP A SPREADSHEET

Set up a living spreadsheet of all your devices. Organize by labeler, class of service and compliance date. Include all information eventually needed to populate GUDID. Have a plan to address each level of packaging that requires UDI information.

#### 5 GAP ANALYSIS

Considering all input, your UDI team should identify gaps in your process. (If you'd like assistance finding a respected outside expert, please contact us.) The result should be a coherent and cost-effective plan to move forward on your compliance journey.

#### 6 PILOT PROJECT

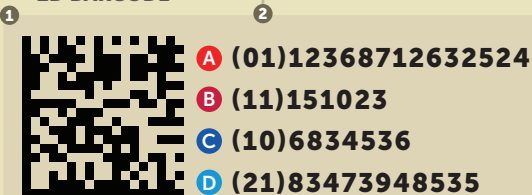
ASAP! Develop a pilot project to uncover gaps in your process. Experience shows this is the best way to increase organizational awareness and build momentum toward full UDI compliance.

Find up-to-date deadlines at:

<http://medicaldeviceacademy.com/6-udi-implementation-deadlines-need-remember/>

September 24, 2016 is the actual deadline for Class II devices  
September 24, 2018—the Class I deadline—will be here soon!

#### GS1 DATAMATRIX 2D BARCODE



#### HUMAN READABLE INTERPRETATION

- |   |  |
|---|--|
| A | (01) = GlobalTrade Identification Number |
| B | (11) = Date of Manufacture               |
| C | (10) = Lot Number                        |
| D | (21) = Serial Number                     |

CALL DOMINO AT  
**800.444.4512**  
TO RECEIVE A QUICK  
START GUIDE TO UDI  
COMPLIANCE.



**GET STARTED!  
GET TALKING!  
GET COMPLIANT!**



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