Purpose
The purpose of this document is to assist brand owners, who have previously followed a different identification and marking standard for products, in their migration to GS1 Standards for identification and barcoding in the healthcare supply chain and support the U.S. FDA Unique Device Identification (UDI) regulation. A brand owner owns, and in most cases manufactures the trade item, making them responsible for: (1) allocating GS1 System numbering and barcode symbols on a given trade item as the administrator of a GS1 Company Prefix; (2) establishing the recognizable name to uniquely identify a line of products or services.

Quick Guide
- Obtain a GS1 Company Prefix
- Identify products at every level of packaging with a unique Global Trade Item Number® (GTIN®)
- Develop GTIN to former standard product identification cross reference in product data base
- Create GS1 barcodes with GTIN encoded
  - See Healthcare Supplier GTIN Tool Kit and GTIN Quick Start Guide (www.gs1us.org/hctoolkit)
- Verify labeling / GTIN
- Inform customers of transition to GS1 Standards

Process
1. Acquire a GS1 Company Prefix from GS1 US® or GS1 Member Organization
   - GS1 US provides a GS1 Company Prefix through its Partner Connections membership program. (www.gs1us.org/get-started/i-need-a-gs1-company-prefix)
   - There is an initial license fee and annual maintenance fee
   - GS1 Company Prefix capacity selection considerations are:
     - number of current items that need to be marked
     - future growth of new item introduction (recommend 5 year projection)
2. Implementation Considerations
   - Global Data Synchronization Network™ (GDSN®)
     - GDSN to FDA Global UDI Database (GUDID) interface
     - Select a data pool
     - Establish connection method, XML, GUI, file
     - Review GTIN Attributes for Healthcare Products attributes list (www.gs1us.org/hctools)
     - Establish map and field in internal system
     - Generate outbound files for data pool
   - GDSN Support
     - GDSN use cases: http://www.gs1.org/docs/healthcare/GDSN_Healthcare_Use_Cases.pdf
Medical Device Brand Owner Guide:
Transitioning to GS1® Standards In the U.S. for UDI

- Internal Company Catalog
  - Cross reference of former identification numbers to GS1 GTIN
  - Considerations
    - Unique GTIN assignments at every level of packaging
    - Maintenance of database cross reference for up to 5 years
    - Company catalog cross reference
    - GS1 to former standard identifier to catalog number
  - Education
    - Call center / sales / marketing training / internal communications
    - Customer communications on implementation
    - Current stock of preprinted labels
    - Change to ordering using GS1 standard identification
      - EDI, paper, fax

3. Implementation Consideration Barcode Symbol (Marking & Labeling)
   - Must use GS1 barcodes
     - E.g., GS1-128 and GS1 DataMatrix rather than generic 128 and data matrix
   - ISO/IEC 15416 symbol overall grade “C” (2.0/06/660) or better for U.P.C.; GS1-128; GS1 DataMatrix; GS1 DataBar™
     - GHTF now IMDRF (International Medical Device Regulators Forum) require GS1 Standards be followed if selected as UDI
   - Verification of ISO code
     - Statistical Process Control SPC/ sampling
     - Internal verify set up process
     - External verify (customer)
       - Detailed guidelines can be found in the GS1 US Solutions Center (www.gs1us.org/solutionscenter)

4. Secondary Item Information, Production Information, Application Identifiers (AIs)
   - Government regulation (i.e., FDA Unique Device Identification (UDI) proposed regulation and GUDID Database)
   - Device identifier
     - GTIN
   - Production identifiers
     - Lot/batch number AI 10 / Expiration date AI 17 / Serial Number AI 21

5. Other Considerations
   - Customer requirements
     - requirement for different /additional secondary information
   - Commercial Printing systems
     - Allow user to select generic or GS1 data carriers (barcode symbology)
     - Voluntary selection of GS1 Codes
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Common mistakes
- Former standard users select the same data carrier (barcode symbology) (generic 128 or Data matrix) and code in the GS1 data as before. This mistake removes the important FNC1 characters in the beginning of the string as well as separators between variable length fields
- GS1 128 barcodes can encode 48 characters not 128
- Application Identifier numbers (e.g., 01,10,17,) are included in character count
- Parenthesis in the human readable should not be encoded in the barcode
- Note that some label systems still call GS1-128 by their old names UCC-EAN 128

Scanning and upstream data collection
- GS1 data structures do not allow spaces and allow leading zeroes
- Some other standards may allow for the use of “space” characters so existing data collection systems may allow for spaces; Some other standards rely on variable length fields and often “trim” leading zeroes

GS1 US Implementation Support
GS1 US Partner Connections membership provides access to tools and resources needed to meet the barcoding requirements of your customers.

1. GS1 Healthcare US UDI Online Resource Site (www.gs1us.org/hcudi)
2. Verification Services
   - Have your barcode symbology verified to meet GS1 minimum standards
3. Data Driver® (www.gs1us.org/resources/tools-and-services/data-driver)
   - Easy-to-use online tool to create and manage your barcodes.
   - Creates new identification numbers for your barcodes (also known as Global Trade Item Numbers/GTINs) at every level of packaging.
   - Guides you with step-by-step instructions – no standards knowledge needed.
   - Provides bar code recommendations for your product based on your input.
   - Prints your U.P.C.; GS1-128; GS1 DataMatrix (soon) barcode labels.
4. Solutions Center (www.gs1us.org/solutionscenter)
   - Online reference library of supply chain standards
   - Latest implementation guidelines, “how-to” information, barcode and e-commerce standards, and essential tools such as the GTIN Allocation Rules guideline which provides detailed information on managing the assignment of GTINs.

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