Healthcare

Point-of-Care Scanning for Surgical Implants
Implementation Guidance

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About GS1

GS1® is a neutral, not-for-profit, global organization that develops and maintains the most widely-used supply chain standards system in the world. GS1 Standards improve the efficiency, safety, and visibility of supply chains across multiple sectors. With local Member Organizations in over 110 countries, GS1 engages with communities of trading partners, industry organizations, governments, and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 Standards.

About GS1 US

GS1 US®, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely-used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers, and distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US® in the United States.

About GS1 Healthcare US

GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.
1 Introduction

As medical device manufacturers mark their products with unique device identifiers (UDI) per the U.S. Food and Drug Administration’s (FDA) UDI Rule, these UDIs are available for point-of-care (POC) scanning by healthcare providers.

Many manufacturers have chosen to use GS1 Standards to implement the rule. Thus, for many healthcare providers, their first experience using GS1 Standards in their operations will come from the implementation of POC scanning systems to capture UDIs from implantable devices.

To support this effort, GS1 US® established the GS1 Healthcare US® Point of Care Scanning Workgroup to gather feedback from providers who have implemented or are in the process of implementing GS1 Standards for POC scanning, and solution providers of associated supporting systems (e.g., scanning, electronic health record (EHR), enterprise resource planning (ERP), device inventory management systems, POC, etc.). The Workgroup:

- examined key aspects of a POC scanning project,
- gathered implementation insights and lessons learned (e.g., challenges, issue resolution steps, key enablers, etc.), and
- identified key steps that can be used to plan an implementation project (e.g., assessment of current state, communication plan, data readiness, etc.).

The culmination of that work was the development of this guidance document to support healthcare providers implementing POC scanning systems using GS1 Standards.

Note: As with all GS1 Standards and solutions, this guidance is voluntary, not mandatory. It should be noted that use of the words “must” and “require” throughout this document relate exclusively to technical recommendations for the proper application of the standards to support the integrity of your implementation.

The GS1 System

The GS1 System is an integrated suite of global standards for identifying, capturing, and sharing supply chain information, including:

- globally-unique numbering formats (identification numbers) for identifying supply chain objects including products, business locations, and more;
- barcodes and radio frequency identification (RFID) for capturing identification numbers; and
- data synchronization and electronic information exchange for sharing data.

GS1 Standards are the most widely-implemented supply chain information standards in the world. They are used in business practices, supply chain tools and software solutions to facilitate the communication and sharing of information across those systems and among trading partners.

GS1 Standards help industries and companies leverage the power of information to move their business forward. They promote quality data in IT systems and make it possible for companies to speak the same language and connect with each other. The results are greater visibility, efficiency, security, and collaboration for their business and greater convenience, value, safety, and satisfaction for their consumers.

The GS1 System is widely used in healthcare, from pharmaceuticals to medical devices to many of the other products found in healthcare facilities and supplied by other business sectors. Preventing medical errors and combating counterfeiting are top-of-mind concerns facing the healthcare sector, and GS1 Standards are helping to solve these issues.
2 U.S. FDA UDI Rule

On September 24, 2013, the U.S. FDA published a rule establishing a unique device identification system for medical devices ("the UDI Rule"). Under the rule, the healthcare community and the public will be able to identify a device through a Unique Device Identifier (UDI) that will appear on the label and package of a device in both plain-text format and a format that can be read by automatic identification data capture (AIDC) technology (e.g., a barcode). A device will also bear a permanent marking providing the UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. In addition, device labelers will submit device information to an FDA database called the Global Unique Device Identification Database (GUDID). The GUDID will provide critical information about medical devices, and the UDI will provide the key for accessing device information from the GUDID.

A UDI is a unique numeric or alphanumeric identification code assigned to medical devices by the labeler (e.g., manufacturer) of the device. A UDI includes two segments: a “device identifier” and a “production identifier”:

- **Device Identifier (DI):** a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device
- **Production Identifier (PI):** a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device: (i) lot or batch number; (ii) serial number; (iii) expiration date; (iv) date of manufacture; and (v) for an HCT/P regulated as a device, the distinct identification code

According to the UDI Rule, a **device identifier** is always present in a UDI. However, a **production identifier** is only required if it otherwise appears on the device label. Therefore, UDIs can be comprised of either DI only, or DI+PI. Because most implants include at least one piece of production information on the label, most implant UDIs would include a production identifier.

3 GS1 Standards for UDI

The UDI Rule requires medical devices to be labelled with a UDI issued under a system operated by an FDA-accredited “issuing agency.” GS1 is one of three FDA-accredited Issuing Agencies for UDI, and GS1 Standards are being used to implement UDI by a majority of device manufacturers.

When GS1 Standards are used to implement UDI:

- The **device identifier** is represented by the GS1 Global Trade Item Number® (GTIN®).
- The **production identifiers** are represented by GS1 Application Identifiers (AIs).
- The presentation of UDI on device labels is accomplished using GS1 Barcodes.

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2 Using ICCBBA standards for human cellular or tissue-based products

Table 3-1 GS1 Standards for U.S.FDA UDI

<table>
<thead>
<tr>
<th>UDI Requirement</th>
<th>GS1 Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labeling (AIDC and plain text format)</td>
<td>GS1 Barcodes</td>
</tr>
<tr>
<td>Device Identifier (DI)</td>
<td>GTIN</td>
</tr>
<tr>
<td>Production Identifier (PI)</td>
<td>AI (10) Batch/lot number</td>
</tr>
<tr>
<td></td>
<td>AI (11) Production/manufacturing date</td>
</tr>
<tr>
<td></td>
<td>AI (17) Expiration date</td>
</tr>
<tr>
<td></td>
<td>AI (21) Serial number</td>
</tr>
</tbody>
</table>

4 POC Scanning Implementation Overview

A POC scanning system relies on two types of data, and coordination of various provider systems.

4.1 Types of data

POC scanning leverages two types of data: data from a barcode and product master data from supply chain systems. The GTIN is what connects them. The GTIN is encoded in the barcode as the DI, and is stored in supply chain systems as a key for accessing information about that product.

4.1.1 Barcode data (UDI)

The first type of data used by a POC scanning system is barcode data. This data is entered into the system by the scan. The data elements that may be encoded in a UDI barcode are:

- Device identifier (DI)
- Batch/lot number
- Production/manufacturing date
- Expiration date
- Serial number
- HCT/P distinct identification code

Not every UDI barcode will carry all of these data elements because the PI required for a device can vary. However, the DI will always be included. The figure below illustrates a UDI barcode using GS1 Standards.
4.1.2 Product master data (attributes)

The second type of data used by a POC scanning system is product master data (which are also known as “attributes” in the GS1 System). The POC scanning system accesses this data from the hospital’s ERP item master (which is the authoritative database where this information is stored). The DI/GTIN is part of that data set, and it serves as the lookup key for accessing information about that product from the database. Examples of product master data often used in POC scanning include:

- Product Description
- Catalog Number
- Manufacturer Name
- Functional Name

4.2 Provider systems

POC scanning systems rely on the coordination of certain provider systems. Together, these systems provide the backbone for POC scanning functionality and data needs. Three key provider systems for POC scanning are:

- Supply Chain System (ERP): the EPR item master serves as the authoritative data source for product master data
- Device Inventory Management/Point-Of-Use (POU) System: supports implant/device inventory management and various point of use functionalities (e.g., POC scanning; recall alert; expiration date management; etc.)
- EHR System: patient record incorporating procedure and device information
4.3 **Essential implementation efforts**

As described above, a POC scanning system relies on two types of data and coordination of various provider systems. Because of that, implementation of POC scanning involves two core efforts:

- Data Readiness – data acquisition/sources, data storage, data interfaces
- System Readiness – assessment and gap analysis, hardware and software readiness, interoperability

5 **Data Readiness**

Data readiness is essential for POC scanning. Implementation efforts to promote data readiness focus on:

- Data Sources
- Data Storage
- Data Interfaces

The data readiness efforts needed for both types of data used for POC scanning are examined below.

5.1 **Barcode data (UDI)**

To accommodate all possible DI+PI variations, representing a UDI in an EHR would ideally include a field for the Device Identifier, and a field for each of the 5 possible Production Identifiers. (Note: every field will not be populated for every device UDI.) For example:

<table>
<thead>
<tr>
<th>UDI:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier:</td>
</tr>
<tr>
<td>Batch/Lot Number:</td>
</tr>
<tr>
<td>Expiration Date:</td>
</tr>
<tr>
<td>Production Date:</td>
</tr>
<tr>
<td>Serial Number:</td>
</tr>
<tr>
<td>HCT/P Distinct ID Code:</td>
</tr>
</tbody>
</table>

Some provider EHR systems cannot support this today (e.g., the system does not have fields to support serial number and/or batch number). To get around this, those providers leverage their device Inventory Management/Point of Use (POU) system to support POC scanning for UDI. Providers can also use POU systems with EHR systems that can support UDI. Therefore, there are two different paths by which UDIs can be captured and recorded for POC scanning:

- Capture directly into EHR system
- Capture in Inventory Management/Point of Use systems and then record in EHR

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4 ICCBBA is a UDI PI, and therefore is included as a recommended field above. However, it is not a GS1 Standard. (It is a standard administered by ICCBBA for human tissue/cell products.)
### Table 5-1 Data readiness considerations for barcode data (UDI)

<table>
<thead>
<tr>
<th>Data readiness consideration</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Source</td>
<td>UDI barcode</td>
</tr>
</tbody>
</table>
| Data Storage                | 2 Options:  
|                             | • Directly in Electronic Health Records (EHR)  
|                             | • In Inventory Management/Point of Use systems  
|                             | See Appendix A for GS1 standards about how to store each data element in databases and IT systems |
| Data Interfaces             | If using an Inventory Management/Point of Use systems: an interface to record the UDI from the POU in the EHR patient record  
|                             | 2 options:  
|                             | • If EHR can support UDI, direct feed of UDI from POU to EHR  
|                             | • If EHR cannot support UDI, interface that can add an attachment to the EHR with the UDI from the POU |

### 5.2 Master data

Providers implementing POC scanning need to assure that the master data needed to support POC scanning is available in their systems. To support that, the Workgroup reviewed GS1 standardized product attributes and identified 20 attributes they considered “required” to support a POC scanning system (e.g., GTIN, Item Description, Catalog Number, Manufacturer Name, etc.). In addition, the group also identified additional attributes which they “recommend” as useful for supporting POC scanning as well as other applications (e.g., Brand Name, Target Market Code, Depth, Height, Weight, Width, UNSPSC, etc.). All of the attributes identified by the Workgroup are listed in Appendix E with definitions and guidance.

Product master data is stored in the provider’s ERP item master, which should serve as an authoritative database from which provider systems pull that data. Providers can obtain master data from a variety of sources, including the manufacturer, the GS1 Global Data Synchronization Network™ (GDSN®), FDA GUDID, and their Group Purchasing Organization (GPO).

### Table 5-2 Data readiness considerations for product master data (attributes)

<table>
<thead>
<tr>
<th>Data readiness consideration</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Data Source                 | Various options available:  
|                             | • Manufacturer  
|                             | • GDSN  
|                             | • GUDID  
|                             | • GPO (for pricing and other attributes) |
| Data Storage                | ERP item master serves as the authoritative database where this information is stored |
| Data Interfaces             | Interface to pull master data from ERP into other systems (POU and/or EHR) |

### 5.3 Data Flow

In order to prepare your systems, it is essential to understand the data flow needed to enable POC scanning. To assist with that, the Workgroup reviewed prepared data flow maps to illustrate POC data scanning flow across the three provider systems that support POC Scanning:

- ERP system
- Medical Device Inventory Management/Point of Use (POU) system
- EHR system
POU systems are commonly used by healthcare providers to support a variety of implant/device management needs (e.g., POC scanning; inventory management; recall alert; expiration date management; etc.). Providers can leverage their POU system to support POC scanning, which is especially helpful for providers whose EHR system cannot currently support UDI capture (e.g., the system does not have fields to support serial number and/or batch number).

Therefore, there are two different system configurations commonly found for POC scanning:

1. ERP >> EHR system
2. ERP >> Inventory Management/Point of Use System >> EHR system

A separate diagram is provided below to illustrate the POC data flow under each system configuration.

**Note:** The data flow diagrams include the process that hospitals should follow to address and resolve unscannable barcodes. It includes an investigation to determine whether the problem stems from an issue on the provider’s side or the manufacturer’s side, and a defined communication path for reporting issues to the manufacturer.

### 5.4 ERP >> EHR system

**Point of Care Scanning – Data Flow between systems – ERP to EHR system**
## 5.5 ERP >> Inventory Management/Point of Use System >> EHR system

### Point of Care Scanning – Data Flow between systems – ERP to Inventory Management to EHR system

<table>
<thead>
<tr>
<th>Healthcare Provider Supply Chain</th>
<th>Clinical</th>
<th>Support – Clinical and Supply Chain</th>
<th>Manufacturer Supply Chain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Start</strong></td>
<td><strong>Data from GPO/Manufacturer/GS1/GTIN</strong></td>
<td><strong>Data Normalization by GS1 Data Pool or other solution provider</strong></td>
<td><strong>Items approved by hospital item Master/Value Analysis/New product committee</strong></td>
</tr>
<tr>
<td><strong>Items Data loaded to ERP (Item Master File)</strong></td>
<td><strong>Items Data loaded to ERP (Item Master File)</strong></td>
<td><strong>Define implant (I) vs Supply (S) Criteria</strong></td>
<td><strong>Charging related attributes (CMM Code) added, additional data normalization</strong></td>
</tr>
<tr>
<td><strong>Select items sent downstream from Item Master</strong></td>
<td><strong>Inventory Management/Point of Use System capture GTIN, Lot Number, Serial number and Expiration Date</strong></td>
<td><strong>Preference Cards Update process (for implants, tissues)</strong></td>
<td><strong>Preference Cards Management Step: (All preference cards have DI added to them)</strong></td>
</tr>
<tr>
<td><strong>Items Scanned and Documented in EHR System (Lot, Serial, Expiration, GTIN)</strong></td>
<td><strong>Issue Management – issues with barcodes or data quality reported to the manufacturer</strong></td>
<td><strong>Process to capture Non-scannable products (Error check and resolution step)</strong></td>
<td><strong>Issue Management – Internal Feedback from clinical to supply chain (to sustain data quality)</strong></td>
</tr>
<tr>
<td><strong>End</strong></td>
<td><strong>Manufacture determines steps for data quality issue</strong></td>
<td><strong>Manufacturer receives notification of data quality issue and resolves issue</strong></td>
<td></td>
</tr>
</tbody>
</table>

### 6 System Readiness

The second core effort in a POC scanning implementation is system readiness. It is essential to examine each of the systems that support your POC scanning implementation (i.e., ERP system, POU system, EHR system). Key considerations are:

- Assessment and Gap Analysis
- Hardware and Software Readiness
- Interoperability

To support system readiness efforts, the remainder of this chapter provides checklists of capabilities and tasks that providers need to assess to support system readiness in each system.

**Note About Scanning Hardware:** Traditional laser scanners can only read linear barcodes. Camera-based scanners can read both linear barcodes and two-dimensional (2D) barcodes. Work with your suppliers to understand the barcodes they are using for the products you purchase, and assess your scanner needs in light of the barcodes you will be receiving.
6.1 **Step 1: Supply Chain/ERP System**
- Master data is maintained in the ERP item master file
  - Possible Data Sources: GDSN, GUDID, GPO (for pricing and other attributes)
- Items are approved by Value Analysis Committees, and then GTIN and other necessary attributes are added to item master by supply chain team
  - See Appendix B for attribute list.
- Data normalization (e.g., attribute enhancement, description cleansing, value added tasks) provided by third-party solution providers
- Data interface to send to data to POU system, EHR system, and/or Operating Room (OR) modules which have capability to capture UDI data
- Surgical preference card templates are updated with DI/GTIN and correct master data
- Surgeons update their preference cards with the new templates

6.2 **Step 2: Point-of-Use System**

**Common capabilities of POU systems that can be leveraged for POC Scanning**
- Define the tracking method at the item-level (serial or lot)
- Support the identification of item types (e.g., supply, implant, tissue, etc.) as determined by provider
- POC scanning
  - See Appendix A for GS1 Standards for how to store UDI barcode data
- Expiration management
- Tracking logs (data directly flowing to EHR)
- Real-time integration with systems (e.g., GUDID, FDA recall database)
- Package Integrity check
- Recall check
- Expiration check

**Interfaces / Integration**
- Receive device master data from ERP (e.g., GTIN, Description, Manufacturer Name, etc.)
Send replenishment orders to the ERP at the line level where each order is for a specific location and item (e.g., item, quantity, UOM, location, GTIN)

Receive Surgical / Case scheduling from the EHR to receive case schedule (which will be used to create the procedure and the associated patient and physician records if needed)

Send case consumption details to the EHR (e.g., case, item, quantity, unit of measure (UOM), GTIN, lot, serial, expiration)

Document UDI from scan at point-of-care
  - Accommodate UDI barcode data (e.g., GTIN (DI), lot, serial number, expiration date, etc.)
    - See Appendix A for GS1 Standards for how to store UDI barcode data

Send UDI to EHR
  - If EHR can accommodate UDI, send directly
  - If EHR cannot accommodate UDI, send attachment with UDI information to EHR

### 6.3 Step 3: EHR systems

**Capabilities when UDI recorded directly in EHR**

- Receive master data from ERP
- Store procedure scheduling data
- Store procedure documentation
  - Requirements – device data available in EHR
  - Important Device attributes: GTIN, Description, UOM, Package Level, Manufacturer, Internal Product ID (ERP Item ID), Inventory Location ID (for replenishment), RFID Tag Number
- Document UDI from scan at point-of-care
  - Accommodate UDI barcode data (e.g., GTIN (DI), lot, serial number, expiration date, etc.)
  - See Appendix A for GS1 Standards for how to store UDI barcode data

**Capabilities when UDI recorded in POU systems and sent to EHR:**

- Send case schedule to the POU for Surgical / Case scheduling (which will be used to create the procedure and the associated patient and physician records if needed)
- Receive case consumption details from POU (e.g., case, item, quantity, UOM, GTIN, lot, serial, expiration)
- Receive case details from POU systems
- Receive UDI from POU
  - If EHR can accommodate UDI, receive directly
  - If EHR cannot accommodate UDI, receive attachment with UDI information

### 7 Steps for POC Scanning Implementation

The Workgroup identified key steps that can be used to plan an implementation project, including assessing current state, preparing a communication plan, and analyzing data readiness.
7.1 **Step 1: Establish Executive Support**

The goals in this step are to inform and educate executive management on POC scanning, and to obtain executive approval to proceed with implementation. As with any project that will impact the business processes of the organization, the support of senior management is critical.

- Cite the benefits to patient safety and supply chain management.
- Include language to speak to specific stakeholders as necessary.
- Deliver a POC scanning presentation and implementation plan to senior management.
- Secure approval to initiate the project and form the needed team.

7.2 **Step 2: Form a UDI Implementation Team**

The goal in this step is to establish a cross-functional implementation team. Formation of a multi-disciplinary team including members from clinical, supply chain, and IT functions promotes buy-in, supports communication efforts, and assures proper input from the areas most impacted by implementation.

- Identify and select team members. The team should include members from clinical, supply chain and IT functions.
- Establish the role of each participant.
- Update job descriptions to reflect the new responsibilities of the team members.
- Provide education and training.

7.3 **Step 3: Develop Project Communication**

The goal in this step is to inform your internal and external community. Utilize internal communication tools such as newsletters, intranet, websites and vendor letters. Communication topics include:

- Implementation schedule and progress.
- Pilot test planning and partnerships.
- Supplier feedback about the barcodes they are using for UDI.

7.4 **Step 4: Assess Information Systems (ERP, POU and EHR)**

The goal in this step is to evaluate the readiness of your information systems, and make the appropriate system changes required to support POC scanning.

- Use the data flows and system readiness information provided in this document as a checklist and guidance.
- Meet with your IT system experts, internal and external (including different disciplines within the IT department), to review implementation strategy and understand implications for your information systems.
- Establish a collaborative plan to make the necessary changes and prepare information systems.

7.5 **Step 5: Identify/Obtain Device Master Data**

The goal in this step is to gather GTINs and the associated master data for each of the devices used/purchased at your facility. Hospital databases (ERP) already contain many GTINs and associated master data. Therefore, this effort will encompass assessing the GTINs and master data you already have in your ERP, and defining your plan for obtaining any GTINs and data you do not currently have.
Device master data is available from various sources (e.g., supplier, GDSN, GUDID, GPO, etc.). Examine the data and data sharing mechanisms available for each option.

- Select your master data source(s).
- Evaluate system requirements for uploading the data from that source to your systems.
- Create a plan for making any necessary technical accommodations for uploading the data.
- Upload the data.

### 7.6 Step 6: Engage Suppliers for Pilot Testing

The goal in this step is to identify partner(s) the supplier community for pilot testing. Collaboration and communication with your supplier community is critical to implementation success. So, now that an implementation plan and initial database has been established, engage strategic suppliers in a process of communication about your organizational plans.

- Explain implementation and process.
- Determine supplier capabilities.
- Analyze impact to operations and staff.

### 7.7 Step 7: Conduct Pilot Testing

At this point, you are ready to conduct pilot tests. The goal is to successfully scan a device UDI at point-of-care and record it in your EHR. The testing process will provide validation of information system capabilities and operational impact. It is recommended that providers first perform this step with their top/key suppliers.

- Document critical success factors.
- Make adjustments as identified.
- Communicate with community.

### 7.8 Step 8: Create Standard Operating Procedures

The goals in this step are to document standard operating procedures for POC scanning and obtain sign off, both internally and externally. Following testing and the implementation of the necessary adjustments, it is necessary to prepare standard operating procedures for internal and external staff to document use of your POC scanning system as well as any on-going maintenance and support procedures.
8 Appendix A: GS1 Standards for Data Storage

The table below presents GS1 data storage specifications for each UDI segment when expressed with GS1 Standards.

Table 8-1 UDI Segments when represented by GS1 Standards

<table>
<thead>
<tr>
<th>UDI Identifiers</th>
<th>GS1 Standard</th>
<th>Data Storage Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier</td>
<td>GTIN</td>
<td>fixed-length text field of 14 characters</td>
</tr>
<tr>
<td>Batch/Lot Number</td>
<td>AI (10)</td>
<td>variable-length text field with a minimum of 20 characters</td>
</tr>
<tr>
<td>Manufacturing / Production Date</td>
<td>AI (11)</td>
<td>fixed-length text field of six characters as YYMMDD where:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• YY = the tens and units of the year (e.g., 2014 = 14).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• MM = the number of the month (e.g., March = 03).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• DD = the number of the day of the relevant month (e.g., second day = 02)</td>
</tr>
<tr>
<td>Expiration Date</td>
<td>AI (17)</td>
<td>fixed-length text field of six characters as YYMMDD where:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• YY = the tens and units of the year (e.g., 2014 = 14).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• MM = the number of the month (e.g., March = 03).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• DD = the number of the day of the relevant month (e.g., second day = 02)</td>
</tr>
<tr>
<td>Serial Number</td>
<td>AI (21)</td>
<td>variable-length text field with a minimum of 20 characters</td>
</tr>
</tbody>
</table>
Appendix B: GDSN Attributes to Support POC Scanning

The Workgroup reviewed GS1 standardized product attributes and identified those considered "required" to support a POC scanning system. In addition, the group also identified additional attributes which they "recommend" as useful for supporting POC scanning and other applications. All are listed below.

<table>
<thead>
<tr>
<th>HC Common Name</th>
<th>GDSN Attribute Name</th>
<th>Description from Attribute Explorer</th>
<th>POC Scanning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit GTIN</td>
<td>globalTradeItemNumber</td>
<td>Trade Item Identification for a TradeItem</td>
<td>Required</td>
</tr>
<tr>
<td>Unit Descriptor</td>
<td>tradeItemUnitDescriptorCode</td>
<td>Describes the hierarchical level of the trade item. TradeItemUnitIndicator is mandatory. Examples: &quot;CASE&quot; , PALLET</td>
<td>Required</td>
</tr>
<tr>
<td>Name of Information Provider</td>
<td>informationProviderOfTradeItem / NameOfInformationProvider</td>
<td>Name of the party providing the information about the trade item</td>
<td>Required</td>
</tr>
<tr>
<td>GLN of Information Provider</td>
<td>informationProvider</td>
<td>Global Location Number (GLN) of the party providing the information about the trade item</td>
<td>Required</td>
</tr>
<tr>
<td>Target Market Code</td>
<td>targetMarketCountryCode</td>
<td>The code that identifies the target market. The target market is at country level or higher geographical definition and is where a trade-item is intended to be sold.</td>
<td>Recommended</td>
</tr>
<tr>
<td>Brand Name</td>
<td>brandName</td>
<td>The recognizable name used by a brand owner to uniquely identify a line of trade item or services. This is recognizable by the consumer.</td>
<td>Recommended</td>
</tr>
<tr>
<td>Global Product Classification Code</td>
<td>gpcCategoryCode</td>
<td>Code specifying a product category according to the GS1 Global Product Classification (GPC) standard</td>
<td>Recommended</td>
</tr>
<tr>
<td>Is Trade Item an Orderable Unit?</td>
<td>isTradeItemAnOrderableUnit</td>
<td>An indicator identifying that the information provider considers this trade item to be at a hierarchy level where they will accept orders from customers. This may be different from what the information provider identifies as a despatch unit. This may be a relationship dependent based on channel of trade or other point to point agreement</td>
<td>Required</td>
</tr>
<tr>
<td>Is Trade Item a Base Unit?</td>
<td>isTradeItemABaseUnit</td>
<td>An indicator identifying the trade item as the base unit level of the trade item hierarchy.</td>
<td>Required</td>
</tr>
<tr>
<td>Catalogue or Model Number Code (Part 1)</td>
<td>additionalTradeItemIdentificationTypeCode (type)</td>
<td>Code specifying an additional trade item identification type. Allowed code values are specified in GS1 Code List AdditionalTradeItemIdentificationTypeCode</td>
<td>Required</td>
</tr>
<tr>
<td>Catalogue or Model Number Code (Part 2)</td>
<td>additionalTradeItemIdentification (value)</td>
<td>Alternative means to the Global Trade Item Number to identify a trade item.</td>
<td>Required</td>
</tr>
<tr>
<td>HC Common Name</td>
<td>GDSN Attribute Name</td>
<td>Description from Attribute Explorer</td>
<td>POC Scanning</td>
</tr>
<tr>
<td>----------------------------</td>
<td>---------------------------</td>
<td>------------------------------------------------------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Manufacturer Name</td>
<td>manufacturerOfTradeItem</td>
<td>Name of the manufacturer of the trade item</td>
<td>Required</td>
</tr>
<tr>
<td>Manufacturer GLN</td>
<td>manufacturerGLN</td>
<td>GLN of the manufacturer of the trade item</td>
<td>Required</td>
</tr>
<tr>
<td>Product Description</td>
<td>additionalTradeItemDescrip</td>
<td>Additional variants necessary to communicate to the industry to help define the product. Multiple variants can be established for each GTIN. This is a repeatable field, e.g. Style, Color, and Fragrance. Allows for the representation of the same value in different languages but not for multiple values</td>
<td>Required</td>
</tr>
<tr>
<td>Functional Name</td>
<td>functionalName</td>
<td>Describes use of the product or service by the consumer. Should help clarify the product classification associated with the GTIN. Allows for the representation of the same value in different languages but not for multiple values</td>
<td>Required</td>
</tr>
<tr>
<td>Trade Item/Package Depth</td>
<td>depth (value + UOM)</td>
<td>The depth of the unit load, as measured according to the GS1 Package Measurement Rules, including the shipping platform unless it is excluded according to the Pallet Type Code chosen</td>
<td>Recommended</td>
</tr>
<tr>
<td>Trade Item/Package Height</td>
<td>Height (value + UOM)</td>
<td>The height of the unit load, as measured according to the GS1 Package Measurement Rules, including the shipping platform unless it is excluded according to the Pallet Type Code chosen</td>
<td>Recommended</td>
</tr>
<tr>
<td>Trade Item/Package Width</td>
<td>Width (value + UOM)</td>
<td>The width of the unit load, as measured according to the GS1 Package Measurement Rules, including the shipping platform unless it is excluded according to the Pallet Type Code chosen</td>
<td>Recommended</td>
</tr>
<tr>
<td>Trade Item/Package Gross Weight</td>
<td>grossWeight (value + UOM)</td>
<td>Used to identify the gross weight of the trade item. The gross weight includes all packaging materials of the trade item. At pallet level the trade item, grossWeight includes the weight of the pallet itself.</td>
<td>Recommended</td>
</tr>
<tr>
<td>Is Trade Item a Consumer Unit?</td>
<td>isTradeItemAConsumerUnit</td>
<td>Identifies whether the trade item is to be taken possession of or consumed/used by an end user or both, as determined by the manufacturer. The end user could be, but is not limited to, a consumer as in items sold at retail, or a patient/clinician/technician in a healthcare setting, or an operator for foodservice such as restaurants, airlines, cafeterias, etc.</td>
<td>Recommended</td>
</tr>
<tr>
<td>HC Common Name</td>
<td>GDSN Attribute Name</td>
<td>Description from Attribute Explorer</td>
<td>POC Scanning</td>
</tr>
<tr>
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</tr>
<tr>
<td>Is Trade Item an Invoice Unit?</td>
<td>isTradeItemAnInvoiceUnit</td>
<td>An indicator identifying that the information provider will include this trade item on their billing or invoice. This may be relationship dependent based on channel of trade or other point to point agreement.</td>
<td>Recommended</td>
</tr>
<tr>
<td>Is Trade Item a Despatch Unit</td>
<td>isTradeItemADespatchUnit</td>
<td>An indicator identifying that the information provider considers the trade item as a despatch (shipping) unit. This may be relationship dependent based on channel of trade or other point to point agreement.</td>
<td>Recommended</td>
</tr>
<tr>
<td>Is Trade Item a Variable Unit?</td>
<td>isTradeItemAVariableUnit</td>
<td>Indicates that an article is not a fixed quantity, but that the quantity is variable. Can be weight, length, volume, trade item is used or traded in continuous rather than discrete quantities.</td>
<td>Recommended</td>
</tr>
<tr>
<td>Is Trade Item Returnable?</td>
<td>isPackagingMarkedReturnable</td>
<td>Trade item has returnable packaging. This is a yes/no (Boolean) where yes equals package can be returned. Attribute applies to returnable packaging with or without deposit.</td>
<td>Recommended</td>
</tr>
<tr>
<td>Quantity of Children</td>
<td>quantityOfChildren</td>
<td>Value indicates the number of unique next lower level trade items contained in a complex trade item. A complex trade item can contain at least 2 different GTINs.</td>
<td>Required</td>
</tr>
<tr>
<td>Total Quantity of Units Contained</td>
<td>totalQuantityOfNextLowerLevelTradeItem</td>
<td>This represents the Total quantity of next lower level trade items that this trade item contains (Use this for Unit Quantity if lower level packaging exists)</td>
<td>Required</td>
</tr>
<tr>
<td>Next Lower Level GTIN</td>
<td>gTIN (child)</td>
<td>A trade item in the item hierarchy level immediately below</td>
<td>Required</td>
</tr>
<tr>
<td>Quantity of Next Lower Level GTIN</td>
<td>quantityOfNextLowerLevelTradeItem</td>
<td></td>
<td>Required</td>
</tr>
<tr>
<td>Unit Quantity</td>
<td>quantityOfInnerPack</td>
<td>Use this for Unit Quantity if Lower Level Packaging exists with no GTIN (Indicates the number of non-GTIN assigned inner-packs of next lower level trade items within the current GTIN level.)</td>
<td>Required</td>
</tr>
<tr>
<td>Item in Inner Pack Quantity (No GTIN Assigned)</td>
<td>quantityOfNextLevelTradeItemWithinInnerPack</td>
<td>Indicates the number of next lower level trade items contained within the physical non-GTIN assigned each or inner-packs (inner-pack).</td>
<td>Required</td>
</tr>
<tr>
<td>HC Common Name</td>
<td>GDSN Attribute Name</td>
<td>Description from Attribute Explorer</td>
<td>POC Scanning</td>
</tr>
<tr>
<td>------------------</td>
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<td>--------------</td>
</tr>
<tr>
<td>Net Content</td>
<td>netContent (value + UOM)</td>
<td>The amount of the trade item contained by a package, usually as claimed on the label. For example, Water 750ml - net content = &quot;750 MLT&quot;; 20 count pack of diapers, net content = &quot;20 ea.&quot;. In case of multi-pack, indicates the net content of the total trade item. For fixed value trade items use the value claimed on the package, to avoid variable fill rate issue that arises with some trade item which are sold by volume or weight, and whose actual content may vary slightly from batch to batch. In case of variable quantity trade items, indicates the average quantity. Allows for the representation of the same value in different units of measure but not multiple values.</td>
<td>Required</td>
</tr>
<tr>
<td>UNSPSC (Part 1)</td>
<td>additionalClassificationAgencyName</td>
<td>GS1 Code List. Use &quot;5&quot; for UNSPSC. Code specifying the applied additional trade item classification scheme (or system). Allowed values are specified in GS1 code list &quot;Additional Trade Item Classification Code List Code&quot;. (additionalTradeItemClassificationSystemCode).</td>
<td>Recommended</td>
</tr>
<tr>
<td>UNSPSC (Part 2)</td>
<td>additionalClassificationCategoryCode</td>
<td>Category code of the trade item based on the alternate classification schema chosen in addition to GS1 classification schema. (additionalTradeItemClassificationValue/additionalTradeItemClassificationCodeValue). Use the appropriate 8-digit UNSPSC Code. These values can be found by visiting <a href="http://www.UNSPSC.org">www.UNSPSC.org</a>.</td>
<td>Recommended</td>
</tr>
<tr>
<td>Trade Item Status</td>
<td>TradeItemStatus</td>
<td>Indicates if the trade item has been added for the first time (ADD), changed (CHN) or corrected (COR) by the information provider.</td>
<td>Recommended</td>
</tr>
<tr>
<td>Effective Date/Time</td>
<td>EffectiveDateTime</td>
<td>The date on which the information contents of the master data version are valid. This effective date can be used for initial trade item offering, or to mark a change in the information related to an existing trade item. This date would mark when these changes take effect. (effectiveDateTime)</td>
<td>Recommended</td>
</tr>
<tr>
<td>HC Common Name</td>
<td>GDSN Attribute Name</td>
<td>Description from Attribute Explorer</td>
<td>POC Scanning</td>
</tr>
<tr>
<td>------------------</td>
<td>------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Packaging Type</td>
<td>packagingTypeCode</td>
<td>The dominant means used to transport, store, handle or display the trade item as defined by the data source. This packaging is not used to describe any manufacturing process. Data recipients can use this data for: Space Planning, Data Accuracy (Tolerances), Supply Chain processes, Recycling process (In combination with packaging materials), Product buying/procurement decisions, Tax calculations/fees/duties calculation</td>
<td>Recommended</td>
</tr>
</tbody>
</table>
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