GS1 AISBL APPLICATION

to the

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

for

Accreditation as an Issuing Agency for Unique Device Identifiers (UDIs)

GS1 hereby submits its application for accreditation as an Issuing Agency for the assignment of UDIs in the context of the U.S. FDA Unique Device Identification System. The information contained within this application demonstrates how GS1 meets the accreditation criteria established by the FDA.

GS1 is pleased to have the opportunity to apply for accreditation.

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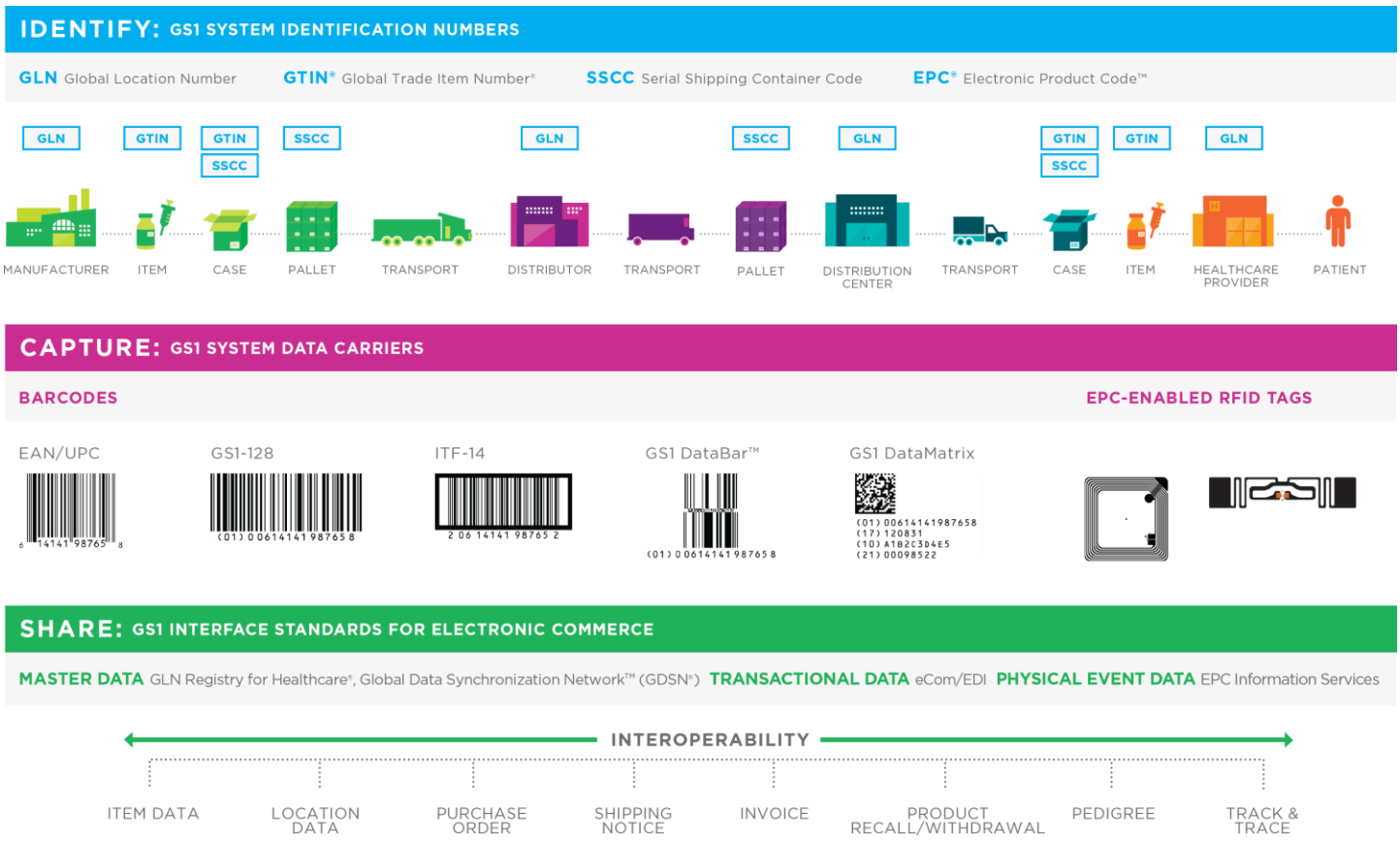
BACKGROUND INFORMATION ABOUT THE GS1 SYSTEM

To support this application, a brief description of the GS1 System and the GS1 Standards discussed in this document are provided below:

The GS1 System (formerly the EAN/UCC System) is an integrated suite of global standards that provides for accurate identification and communication of information regarding products, assets, services and locations. The system is designed to overcome the limitations of using company, organization or sector specific coding systems, and to make trading more efficient and responsive to customers. Using GS1 Identification Numbers (also referred to as GS1 Keys), companies around the world are able to uniquely and unambiguously identify physical things like trade items, assets, logistic units, shipments, and physical locations, as well as logical things like corporations or a service relationship between provider and recipient. GS1 Identification Numbers can be represented in bar code symbols to enable electronic data capture wherever required in business processes. In addition, the GS1 System provides for the encoding of supplementary information, such as expiration date, serial number, and batch/lot number to facilitate the communication of product-specific information wherever the bar code is scanned. GS1 Identification Numbers are also used in Electronic Data Interchange (EDI), Global Data Synchronization (GDSN), the Global Data Dictionary and GS1 Network Systems.

Graphic 1: GS1 Standards in Healthcare



The GS1 System is designed for use globally in any industry or trade sector, and any changes to the system are facilitated in the user-driven, user-focused standards development process known as the Global Standards Management Process (GSMP). The GSMP brings together users from all industries and from around the world to

identify needs for standards, gather business requirements, document best practices, obtain consensus on solutions, and then develop and implement the resulting standards. Changes take place only after wide consultation and are subject to a significant migration period so as not to negatively affect current users. The GSMP is an open and transparent process made possible by the participation of companies who seek to improve the efficiency of supply chains. It is the pre-eminent worldwide collaborative forum where GS1 Standards are built and maintained.

Global Trade Item Number® (GTIN®): The Global Trade Item Number® (GTIN®) is the globally unique GS1 Identification Number used to identify "trade items" (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain). GTINs are assigned by the brand owner of the product, and are used to identify products as they move through the global supply chain to the hospital or ultimate end user. The GTIN uniquely identifies a product at each packaging level (e.g., a box of 15 Brand X tissues; a carton of six boxes of Brand X tissues; etc.). The GTIN is the foundation of the GS1 System.

Global Location Number (GLN): The Global Location Number (GLN) is the globally unique GS1 Identification Number for locations and supply chain partners. The GLN can be used to identify a *functional entity* (like a hospital pharmacy or accounting department), a *physical entity* (like a warehouse or hospital wing or even a nursing station), or a *legal entity* (like a health system corporation). The attributes defined for each GLN [e.g., name, address, location type (e.g., ship to, bill to, deliver to, etc.)] help users to ensure that each GLN is specific to one unique location within the world.

GS1 Data Carriers: GS1 Data Carriers provide machine-readable representations of GS1 Identification Numbers that facilitate automatic identification and data capture (AIDC). AIDC is a term used to describe various technologies used to identify items, collect data about them and enter that data electronically into computer systems in a fully automated way. In order to accommodate a variety of environments and applications, the GS1 System supports eight AIDC data carriers: six bar code symbologies (i.e., GS1 BarCodes) and two RFID tags [i.e., GS1 Electronic Product Code / Radio Frequency Identification Tags (EPC/RFID Tags)]. Changes in the use of AIDC data carrier technology are made using a well-defined standards development process, taking into account the implementation impact of the changes.

GS1 Application Identifiers: In addition to the product identification number (i.e., GTIN), there may be certain *item-specific information* that manufacturers or supply chain partners want marked on products to enable communication of that information *wherever the bar code is scanned* (e.g., expiration date; lot/batch number; etc.). The GS1 System provides "Application Identifiers" to support this need. GS1 Application Identifiers (AIs) are a finite set of specialized identifiers encoded within bar codes to indicate the type of data represented in the various bar code segments. There are approximately 100 AIs, including an AI for each GS1 Identification Number (e.g., GTIN; SSCC; GLN; etc.) as well as AIs for various types of secondary information (e.g., expiration date; lot/batch number; etc.). GS1 AI's commonly used in healthcare include AI (10) for Lot/Batch Number, AI (17) for Expiration Date, and AI (21) for Serial Number. GS1 AIs are standard throughout the world and are familiar to IT system developers. GS1-128, GS1 DataBar (RSS), GS1 DataMatrix, and Composite Component can all carry AIs, and more than one AI can be carried in one bar code.

GS1 US GLN Registry: The GLN Registry is the single source of truth for healthcare location information, offering a comprehensive list of healthcare and healthcare-related facilities in the United States with corresponding Global Location Numbers (GLNs). The GLN is the globally recognized identification number used in the GS1 System to uniquely identify legal entities, trading partners, and customer locations in electronic commerce transactions. The GLN Registry enables subscribers to access up-to-date, reliable location information, validated by the U.S. Postal Service, for manufacturers, distributors, retailers, hospitals, clinics, as well as retail and mail-order pharmacies in order to improve the accuracy of their supply chain activities.

Global Data Synchronization Network (GDSN): The Global Data Synchronization Network (GDSN) provides an efficient and effective approach to (1) storing GS1 Identifiers with their associated attributes, (2) checking to make sure that the identifiers and attributes are properly defined and formatted, and (3) sharing that information with supply chain partners. The GDSN is a network of interoperable data pools connected by the GS1 Global Registry. The GDSN-certified Data Pools store and manage supply chain information for their users, and the GS1 Global Registry connects those data pools together. The GDSN offers a continuous, automated approach to data management that ensures that supply chain information is identical among trading partners, increasing data accuracy and driving costs out of the supply chain.

CONTACT INFORMATION

GS1

GS1 is a neutral, not-for-profit, international organization dedicated to the development and implementation of global standards and solutions to improve the efficiency and visibility of supply chains. The GS1 System of Standards is used by over 1 million companies worldwide. The Head Office of GS1 is located in Brussels (Belgium). GS1 has local Member Organizations in 111 countries, including the United States.

Contact Information:	Ulrike Kreysa, Vice President - Healthcare GS1 AISBL Avenue Louise 326 1050 Brussels T +32 2 788 78 37 M +32 473 633367 ulrike.kreysa@gs1.org
Not-for-Profit Information:	See Appendix A containing a publication from the Belgian Official Journal of Acts and Decrees "Moniteur belge" dated 13 July 2012. Under « Forme juridique », the publication reads "Association Internationale Sans But Lucratif " (which means international not-for-profit association).
Links:	GS1 website: http://www.gs1.org GS1 40th Anniversary website: http://www.40.gs1.org/ GS1 Healthcare website: http://www.gs1.org/healthcare GS1 webpage on UDI: http://www.gs1.org/healthcare/udi

GS1 US

GS1 US [formerly the Uniform Code Council (UCC)] is the Member Organization of GS1 that serves companies in the United States. As such, it is the national implementation organization of the GS1 System dedicated to the adoption and implementation of standards-based, global supply chain solutions in the United States. GS1 US currently serves over 300,000 U.S. member companies -- 16,000 of which are in healthcare. GS1 US will serve as the first point of contact for the FDA.

Contact Information:	Siobhan O'Bara, Senior Vice President - Industry Engagement GS1 US Princeton Pike Corporate Center 1009 Lenox Drive, Suite 202 Lawrenceville, NJ 08648 T (609) 620-8046 M (609) 216-3885 sobara@gs1us.org
Not-for-Profit Information:	See Appendix B containing a letter from the IRS indicating that GS1 US [(formerly the Uniform Code Council (UCC)] is a not-for-profit organization exempt under 501(c)(6) of the Internal Revenue Code.
Links:	GS1 US website: http://www.gs1us.org GS1 Healthcare US: http://www.gs1us.org/healthcare GS1 US webpage on UDI: http://www.gs1us.org/hcudi

STANDARDS AND CRITERIA GS1 WILL APPLY TO PARTICIPATING LABELERS

The standards and criteria that GS1 will apply to participating labelers will be the same as those applied to entities that use the GS1 System in general, and the GS1 Global Trade Identification Number® (GTIN®) in particular. (The GTIN is the foundation of the GS1 System.) The standards and criteria include the GS1 General Specifications, as well as ISO and ISO/IEC standards. By following the standards, architectural principles and guidelines of the GS1 System, users can design applications to automatically process GS1 System data.

GS1 GENERAL SPECIFICATIONS

Every organization using GS1 Standards is requested to conform fully to the GS1 General Specifications. The GS1 General Specifications provide detailed information and guidance with regard to syntax, identifier assignment, allocation, and AIDC standards within the GS1 System. The sections of the GS1 General Specifications are:

GS1 General Specifications Section	Description of Contents
Section 1 Basics & Principles	Provides an introduction to the core components of the GS1 System.
Section 2 Application Identification	Provides a definition for each GS1 application using a template format. Each application is uniquely identified and contains a description, the associated GS1 Key, its definition and links to relevant data structures and attributes, rules, carrier specifications, placement, and unique processing requirements.
Section 3 Application Identifier Definitions	Describes the meaning, structure, and function of the GS1 element strings so they can be correctly processed in users' application programs.
Section 4 Application Rules	Provides the rules for use of GS1 Keys in their application environments. Differences in industries are included as well as the data relationship rules for Application Identifier use.
Section 5 Data Carriers	Provides a detailed description of the data carriers that are endorsed by GS1. It includes symbol specification tables for use in the supply chain operational environment as well as the related bar code production and quality assessment required to achieve excellent scan rates.
Section 6 Symbol Placement Guidelines	Provides guidance on symbol placement as well as transport label standards and tag standards.
Section 7 AIDC Validation Rules	Provides rules for validating and processing GS1 Element Strings without human intervention. Check digit and calendar date algorithms are also included.
Section 8 GS1 Standards Glossary	

ISO AND ISO/IEC STANDARDS

The following ISO and ISO/IEC standards, which are required in the UDI Final Rule, are directly referenced within the GS1 General Specifications for use within the GS1 System:

- ISO/IEC 646 Information technology -- ISO 7-bit coded character set for information interchange
- ISO/IEC 15459-2 Information technology -- Unique identifiers -- Part 2: Registration procedures
- ISO/IEC 15459-4 Information technology -- Unique identifiers -- Part 4: Individual items
- ISO/IEC 15459-6 Information technology -- Unique identifiers -- Part 6: Unique identifier for product groupings

In addition to those standards, the following ISO and ISO/IEC standards are also directly referenced within the GS1 General Specifications:

- ISO 1073-2 Alphanumeric character sets for optical recognition -- Part 2: Character set OCR-B -- Shapes and dimensions of the printed image
- ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code symbol print quality test specification -- Two-dimensional symbols
- ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols
- ISO/IEC 15417 Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification
- ISO/IEC 15420 Information technology -- Automatic identification and data capture techniques -- EAN/UPC bar code symbology specification
- ISO/IEC 15424 Information technology -- Automatic identification and data capture techniques -- Data Carrier Identifiers (including Symbology Identifiers)
- ISO/IEC 15426-1 Information technology -- Automatic identification and data capture techniques -- Bar code verifier conformance specification -- Part 1: Linear symbols
- ISO/IEC 15426-2 Information technology -- Automatic identification and data capture techniques -- Bar code verifier conformance specification -- Part 2: Two-dimensional symbols
- ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification
- ISO/IEC 16390 Information technology -- Automatic identification and data capture techniques -- Interleaved 2 of 5 bar code symbology specification
- ISO/IEC 18004 Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification
- ISO/IEC 24723 Information technology -- Automatic identification and data capture techniques -- GS1 Composite bar code symbology specification
- ISO/IEC 24724 Information technology -- Automatic identification and data capture techniques -- GS1 DataBar bar code symbology specification

The following ISO/IEC standards are also important references to note when using the GS1 System:

- ISO/IEC 15418 Information technology -- Automatic identification and data capture techniques -- GS1 Application Identifiers and ASC MH10 Data Identifiers and maintenance
- ISO/IEC 15423 Information technology -- Automatic identification and data capture techniques -- Bar code scanner and decoder performance testing
- ISO/IEC 15459-1 Information technology -- Unique identifiers -- Part 1: Unique identifiers for transport units
- ISO/IEC 15459-3 Information technology -- Unique identifiers -- Part 3: Common rules for unique identifiers
- ISO/IEC 15459-5 Information technology -- Unique identifiers -- Part 5: Unique identifier for returnable transport items (RTIs)
- ISO/IEC 15459-8 Information technology -- Unique identifiers -- Part 8: Grouping of transport units
- ISO/IEC TR 24720 Information technology -- Automatic identification and data capture techniques -- Guidelines for direct part marking (DPM)
- ISO/IEC 29158 Information technology -- Automatic identification and data capture techniques -- Direct Part Mark (DPM) Quality Guideline

LINKS

- *GS1 General Specifications*: http://www.gs1.org/docs/gsmp/barcodes/GS1_General_Specifications.pdf
- Copies of ISO and ISO/IEC standards can be secured from ISO (the International Organization for Standardization) at http://www.iso.org/iso/home/store.htm

DESCRIPTION OF THE GUIDELINES THAT GOVERN ASSIGNMENT OF A UDI

A UDI comprises a Device Identifier (DI) and Production Identifier (PI). In the GS1 System, GTINs uniquely identify items that are traded in the supply chain, such as medical devices. GTINs can be utilized as the "Device Identifier" in a UDI. GS1 Application Identifiers (AIs) are used to communicate item-specific/production information in a bar code (e.g., batch/lot number, serial number, expiration date, etc.). GS1 AIs can be utilized as the "Production Identifier(s)" where required in a UDI. Thus, the GTIN and GS1 AIs can be used for UDI.

UDI Requirement	GS1 Standard	
Device Identifier (DI)	GTIN	
Production Identifier (PI)	AI (10)	Batch/lot number
	AI (11)	Production/manufacturing date
	AI (17)	Expiration date
	AI (21)	Serial number

ASSIGNMENT PROCESS

Upon joining a GS1 Member Organization, such as GS1 US, companies receive a GS1 Company Prefix. The GS1 Company Prefix is part of the data structure for all GS1 Identifiers (e.g., GTIN, GLN, etc.) and provides the foundation for generating all of the GS1 Identification Numbers. With membership, companies also receive full documentation on how to allocate GTINs (i.e., the "Device Identifier" of a UDI) to their products as well as how to utilize GS1 Application Identifiers (i.e., the "Production Identifier" of a UDI).

The GS1 System provides clear, structured data standards and allocation rules designed to ensure that GTINs are globally unique and in a consistent format. Manufacturers assign/allocate their own GTINs based on their GS1 Company Prefix, and the GS1 Standards and GTIN Allocation Rules. The GTIN should be unique to the product and variation (e.g., color, size, weight, count, formula, etc.).

Manufacturers who hold the specifications of a medical device must properly allocate and maintain their GTINs to enable trading partners to distinguish products effectively for regulatory, supply chain and patient safety concerns, and in accordance with FDA requirements. The integrity of these numbers throughout the item's lifetime is a key to maintaining uniqueness for manufacturers, wholesalers, distributors, hospitals, regulatory bodies and other supply chain stakeholders. A change to one aspect, characteristic, variant or formulation of a trade item may require the allocation of a new GTIN. GS1 GTIN Allocation Rules help manufacturers determine when a product should have a unique GTIN assigned.

SPECIFIC GUIDELINES

- *GS1 Healthcare GTIN Allocation Rules* have been tailored to meet the specific needs of Healthcare. While all GS1 Standards are voluntary, the rules are intended to drive consistent implementation in the Global Healthcare Community. National, federal or local regulations will take precedence over this voluntary guideline.

- *GS1 AIDC Healthcare Implementation Guide* provides specific guidance for using GS1 Keys in a Healthcare environment along with procedures for recognizing if additional data is required for types of products, needs for traceability, and marking requirements.

NOTICE RE: CHANGES TO UDI-RELATED APPLICATION IDENTIFIERS

GS1 will notify the FDA well in advance of any changes to any GS1 Application Identifier (AI) related to UDI, and will propose that the FDA participate in the development of any new AIs related to UDI.

LINKS

- *GS1 Healthcare GTIN Allocation Rules*:
  http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf
- *GS1 AIDC Healthcare Implementation Guide*:
  http://www.gs1.org/sites/default/files/docs/gsmp/healthcare/AIDC_Healthcare_Imp_Guide.pdf

PROCESS TO DETERMINE WHETHER A LABELER MAY USE THE GS1 UDI SYSTEM

Labelers who wish to use the GS1 UDI System must apply for membership and a Company Prefix from GS1. A GS1 Company Prefix is a unique string of digits assigned to a company. Once a medical device labeler has a GS1 Company Prefix, it will be able to identify its products and locations with globally-unique GS1 identification numbers. When used in a GTIN, the GS1 Company Prefix will identify the medical device labeler throughout the product's life cycle in the supply chain.

GS1 Member Organizations, such as GS1 US, provide relevant information on GS1 membership and the formalities for applying for a GS1 Company Prefix on their website. This information includes an application form, guidelines, and other instructions. GS1 US will serve as the first point of contact for the FDA and UDI labelers located in the United States. Therefore, we include hereafter the application process used at GS1 US.

APPLICATION PROCESS

The GS1 US website describes the steps for becoming a GS1 member to identify products with GS1 Identification Numbers as follows:

1. Estimate your bar code needs and fees.
How much do you need to identify? It's based on how many products you have as well as the number of variations for each—sizes, colors, packages, etc. Your licensing fees are based on your bar code needs as well as your estimated annual sales revenue.

2. Fill out our online application.
You will need to provide your estimated annual sales revenue, the approximate number of product variations you need bar codes for, and your company contact information.

3. Submit your payment online or by mail.
Your initial registration fee licenses the GS1 Company Prefix to you for one year. After that, you'll pay a small annual renewal fee to continue using the prefix for your bar codes.

4. Build your bar codes.
Once we receive your payment, we'll send your GS1 Company Prefix to you by email within one business day. You can now start to build your own bar codes with our easy-to-use online tool called Data Driver.

To support applicants, GS1 US provides a short video on how the GS1 Company Prefix works, as well as online tools such as a Bar Code and Fee estimator (http://www.gs1us.org/estimator).

MATERIALS GS1 SENDS TO APPLICANT

Once the application process is finalized, new members of GS1 US receive a GS1 US Membership Welcome Packet, a GS1 Company Prefix certificate, and a license agreement:

Welcome to GS1 US! The Global Language of Business

Dear …..,

Congratulations on getting your unique and authorized GS1 Company Prefix—the foundation for creating bar codes accepted by trading partners worldwide.
…… is now a member of GS1 US Partner Connections, a program designed to help you create bar codes easily.

Key Membership Information

Company Name: ……..
Account Number: 12345678

Username: …….
Password: ……..

Your GS1 Company Prefix certificate and license agreement are attached.
Your Prefix allows you to create 1,000 U.P.C. bar codes and 1,000 locations.
To continue use of the Prefix, renew your annual license on or before 06/30/2014.

U.P.C. Company Prefix: 87654321
Use this number to create U.P.C. bar codes.

myGS1 US Member Center
members.gs1us.org<http://members.gs1us.org?utm_source=GS1%2BUS%2BDayton&utm_medium=Email&utm_campaign=Partner%2BConnections%2BWelcome%2BEmail%2B2012>

Member Service
Call Toll-Free: +1 866.648.0507
Monday - Friday, 8 AM - 8 PM ET
Fax: +1 937.435.7317
Email: pcinfo@gs1us.org

Click here to download an explanation of key membership information
http://www.gs1us.org/keymembershipinfo?utm_source=GS1%2BUS%2BDayton&utm_medium=Email&utm_campaign=Partner%2BConnections%2BWelcome%2BEmail%2B2012

Create Bar Codes Now: http://www.gs1us.org/resources/tools-and-services/data-driver?utm_source=GS1%2BUS%2BDayton&utm_medium=Email&utm_content=Data%2BDriver%2B-%2BBanner&utm_campaign=Partner%2BConnections%2BWelcome%2BEmail%2B2012

Our easy-to-use online tool:

http://www.gs1us.org/resources/tools-and-services/data-driver?utm_source=GS1%2BUS%2BDayton&utm_medium=Email&utm_content=Data%2BDriver%2B-%2Bonline%2Btool&utm_campaign=Partner%2BConnections%2BWelcome%2BEmail%2B2012 makes it simple for you to create, manage, and print your bar codes. Just sign in with your username and password (see box at right). No technical knowledge is required!

Please retain your key membership information for future reference and feel free to contact us for further assistance. We are here to help!

Best regards,

LINKS

- "Get started" GS1 US webpage: http://www.gs1us.org/get-started
- GS1 US Member Application Form: https://www.gs1us.org/application_for_barcodes_authorized_by_gs1_us#Contact Information

POLICIES AND PROCEDURES FOR DEFICIENCIES IN USE OF UDI

GS1, via its local Member Organization such as GS1 US, provides a bar code verification service to assist in ensuring conformance to GS1 Standards and better reading rates, supporting the drive for accuracy and efficiency of bar code scanning. This increases confidence, helps to establish credibility and inspires assurance that products in conformance to GS1 Standards will perform as intended. The GS1 BarCode Verification Process Implementation Guide provides a harmonized framework to GS1 Member Organizations to ensure that GS1 BarCodes are being verified though a systematic and consistent way worldwide.

Awareness and understanding of overall bar code symbol quality, and the complete process to determine and understand it, can have many benefits to the users of bar code-driven AIDC systems. GS1 Member Organizations, including GS1 US, may be asked to carry out verification for one or more of the following purposes:

- **To test the individual GS1 BarCodes on a product for compliance – testing the bar code symbols and their data content.** This can be done during the bar code symbol creation process and is usually requested at least at the packaging design stage of a product's life cycle.
- **To test whether a completed product ready for market is identified with GS1 Identification Key(s) and GS1 BarCode(s) that comply with GS1 Standards.** This will typically be requested when the product is manufactured and ready for dispatch. The requesting parties may need the report to satisfy a customer (or FDA) that the product will flow smoothly through the customer's distribution channels.

GS1 US Bar Code Verification Service tests if your bar codes comply with GS1 Standards, and checks each bar code symbol on a variety of scanners. GS1 US tests the bar code for compliance to the GS1 Standards through a verification process and the GS1 General Specifications. This method assesses size, color, print quality, and quiet zones. GS1 US also assesses encoded data format, bar code height, location/placement of the bar code, and the correct calculation of the check digit. The GS1 US Bar Code Verification Service comprises of the following high level steps:

1. Record of receipt of the sample(s)
2. Record of data associated to a bar code (in a database)
3. Verify the bar code symbol print quality
4. Perform the additional tests on the bar code, such as compliance of the format of the encoded data
5. Create and send Bar Code Verification Report
6. Ensure availability of the Bar Code Verification Report

LINKS

- *GS1 BarCode Verification Process- Implementation Guide*: http://www.gs1.org/docs/barcodes/GS1_Bar_Code_Verification.pdf
- GS1 US BarCode Verification Services: http://www.gs1us.org/resources/services/barcode-verification-services
- GS1 US Product Measurement Services: to help members to ensure that dimensional data in the Global Data Synchronization Network® (GDSN®) is accurate, as well as standards compliant. http://www.gs1us.org/resources/services/product-measurement-services

POLICIES FOR REVOKING A LABELER'S USE OF THE GS1 UDI SYSTEM

The Terms and Conditions of GS1 Member Organizations generally include clauses stating that the member's right to use the GS1 System may be revoked in cases of misuse of the system and if the member does not meet its fees obligations to the GS1 Member Organization. GS1 US will serve as the first point of contact for the FDA and UDI labelers located in the United States. Therefore, we include hereafter the policies and procedures that GS1 US has adopted for suspending or revoking a labeler's use of the GS1 UDI System.

GS1 US POLICIES & PROCEDURES

Upon joining GS1 US, companies are assigned a GS1 Company Prefix. The GS1 Company Prefix is part of the data structure for all GS1 Identifiers (e.g., GTIN, GLN, etc.) and provides the foundation for generating all of the GS1 Identification Numbers. GS1 Company Prefixes are licensed to companies as part of their GS1 US membership, and those licenses are renewed annually in conjunction with the payment of membership fees.

The GS1 US renewal process is as follows:

- One hundred and twenty (120) days prior to the license renewal date, GS1 US notifies members of their upcoming renewal.
- Ninety (90) days prior to the renewal date, GS1 US sends companies their invoice and renewal license.
- Thereafter, GS1 US follows-up with the member every thirty (30) days or until the renewal invoice is paid (whichever is first).
- If the invoice remains unpaid sixty (60) days after the invoice is due, the member is notified that their GS1 Company Prefix is no longer licensed, and their access to GS1 US tools is blocked.

In total, GS1 US works with a member for six months for the period leading up to the renewal date and thereafter. Keeping licensees active and in good-standing are high priorities for the GS1 US team, and we work diligently with licensees on an on-going basis to achieve that goal.

GS1 US ALIGNMENT WITH FDA

GS1 US will work with the FDA and meet as needed to support alignment of GS1 Company Prefixes and authorized licenses in FDA databases.

GS1 US GOVERNANCE

The GS1 US Board of Governors is a representation of key industry leaders who are committed to the voluntary adoption and usage of GS1 Standards for the benefit of their stakeholders. The Board of Governors makes it possible for industry to improve patient safety and supply chain efficiency in a collaborative manner.

DESCRIPTION OF GS1 ELECTRONIC DATA MANAGEMENT SYSTEM

The GS1 data management system is the Global Data Synchronization Network (GDSN). The GDSN is an internet-based, interconnected network of interoperable data pools and a global registry that enables companies around the globe to exchange standardized and synchronized supply chain data with their trading partners. It assures that data exchanged between trading partners is accurate and compliant with universally supported standards.

GS1 GLOBAL DATA SYNCHRONIZATION NETWORK (GDSN)

The GDSN is built around the GS1 Global Registry, GDSN-Certified Data Pools, the GS1 Data Quality Framework, and GS1 Global Product Classification (GPC) -- which when combined, provide a powerful environment for secure and continuous synchronization of accurate data. Trade items are identified in the GDSN using GS1 Global Trade Item Numbers (GTIN). Partners and locations are identified by GS1 Global Location Numbers (GLNs). A combination of GTIN, GLN and Target Markets (the geographical area where the catalogue item is intended to be sold) allows information to be shared in the network.

The GDSN provides a single point of truth for product information. Any changes made to one company's database can be automatically and immediately provided to all of the other companies who subscribe to the data through GDSN. When a supplier and a customer know they are looking at the same accurate and up-to-date data, doing business together is smoother, quicker and less expensive.

PROCESS OVERVIEW FOR UDI PRODUCT DATA REGISTRATION

Step 1: The medical device manufacturer registers their UDI product data with a GDSN-Certified Data Pool and instructs the data pool to submit the product data on their behalf to the FDA GUDID. (Note: The Labeler will need to designate the Data Pool as a "third-party submitter" authorized to submit data to the GUDID on the labeler's behalf.)

Step 2: The GDSN Data Pool registers a small subset of the data in the GS1 Global Registry. This includes the name and GLN of the device manufacturer, the GTIN, Target Market and GPC code (which identifies the GTIN and a Medical Device). By registering the product data in the GS1 Global Registry, the manufacturer is ensuring that their trading partners (e.g., hospitals, distributors, wholesalers, and Group Purchasing Organizations) who are also using the GDSN can subscribe to the larger set of medical device product data beyond what will be stored in the GUDID.

Step 3: The Data Pool converts the GDSN message to the FDA required HL7 Structured Product Labeling (SPL) format, and registers the data with the FDA GUDID.

Step 4: The Data Pool confirms the registration of the product data with the manufacturer.

LINKS

- *GDSN Roadmap* (this document provides an overview of the GDSN, including Scope, Vision, Mission, Principles and Governance):
  http://www.gs1.org/docs/gdsn/gdsn_roadmap.pdf

- *GDSN Operations Manual* (this document provides a detailed explanation of the GDSN including how to use the network):
  http://www.gs1.org/docs/gsmp/gdsn/GDSN_2_8_Operations_Manual_i1.pdf
- *GDSN Implementation Guide* (this document provides guidance on how to implement the GDSN):
  http://www.gs1.org/docs/gsmp/gdsn/GDSN_Trade_Item_Implementation_Guide.pdf

FEE SCHEDULES

For anti-trust reasons, each GS1 Member Organization is free to establish its own fee rates and this cannot be decided centrally by GS1 Global Office. Nonetheless, each GS1 Member Organization is expected to operate on a not-for-profit basis and have a Management Board governed by the local companies that use GS1 Standards. This helps to ensure that GS1 Member Organization fees remain reasonable and affordable for the companies.

In general, GS1 Member Organizations structure their fees according to (a) number of GTINs allocated, (b) size of company (based on annual sales turnover), or a combination of (a) and (b). Some GS1 Member Organizations charge additional fees in the case of additional (premium) services beyond the basic service offering. Most GS1 Member Organizations publish their fees on their websites.

Because GS1 US will serve as the first point of contact for the FDA and UDI labelers located in the United States, we have listed GS1 US' fee structure below.

Number of Items Needing a Bar Code/GTIN	Initial Fees	Renewal Fees
1 10	$250	$50
1 100	$750	$150
1 1000	$2,500	$500
1 10,000	$6,500	$1,300
1 100,000	$10,500	$2,100

LINKS

- GS1 Member Organization contacts:
  http://www.gs1.org/contact

INFORMATION ABOUT ANY RELATIONSHIP WITH A LABELER OR GOVERNMENTAL ENTITY

GS1 US will serve as the first point of contact for the US FDA and for UDI labelers located in the US. Therefore, this section provides information from GS1 US Code of Ethics preventing potential conflicts of interest between GS1 US and a labeler or governmental entity.

While business practices may change over time, our commitment to the highest standards of integrity remains constant. We believe that conducting business ethically is critical to our success. It means more than just obeying the law; it means that the highest standards of integrity underlie everything we do at GS1 US. To promote those standards, there is a formal Code of Ethics / Conflict of Interest Policy that governs GS1 US and its subsidiaries. The full policy is provided in Appendix C of this document. Key points include:

- Any activities that may provide for personal gain or personal interest, including matters of personal interest to an employee's immediate family (spouse, parents, children), are prohibited.
- Employees must not influence either directly or indirectly, GS1 US dealings with any supplier with whom the employee has a significant personal or financial relationship. If an employee has a significant personal or financial interest in a GS1 US supplier or other business partner, including GS1 US members or subscribers, the employee is required to disclose it to a member of the GS1 US Ethics Committee.
- Employees must not work for or represent a supplier in its dealings with GS1 US. Generally, employment or representation outside of an employee's full time position with GS1 US is considered a conflict and is prohibited.
- Service on outside Boards of Directors may present a conflict or a possible liability situation to GS1 US. All outside Board service must be declared (note: this does not include Homeowners Associations, Church Boards, Charitable Organizations, etc.) and approved by the GS1 US Ethics Committee.
- Annually each employee is asked to sign a "Notification of Compliance" which reasserts that the employee is in compliance with the Code of Ethics / Conflict of Interest Policy. Additionally, it gives the employee the opportunity to declare any possible discrepancies or conflicts for review by the GS1 US Ethics Committee.
- Employees that become aware of possible conflicts of interest of their own, or others in the Company, must report the conflicts to a member of the GS1 US Ethics Committee as soon as the possible conflict arises. Conflicts may also be reported anonymously through the GS1 US Employee Suggestion email box.

The GS1 US Ethics Committee oversees adherence to the Code of Ethics / Conflict of Interest Policy. The GS1 US Ethics Committee is comprised of the Chief Financial Officer, Chief Human Resources Officer and GS1 US General Counsel.

APPENDIX A: BELGIAN OFFICIAL JOURNAL OF ACTS AND DECREES 'MONITEUR BELGE' OF 13 JULY 2012

MOD 2.2

Volet B

Copie à publier aux annexes du Moniteur belge après dépôt de l'acte

Réservé au Moniteur belge

12124273

4 JUIL 2012

Greffe

Bijlagen bij het Belgisch Staatsblad - 13/07/2012 - Annexes du Moniteur belge

N° d'entreprise : 419.640.508

Dénomination
(en entier) : GS1
(en abrégé) :

Forme juridique : Association Internationale Sans But Lucratif

Siège : Avenue Louise, 326 - Bte 10, 1050 Bruxelles

Objet de l'acte : **Modifications de statuts**
Démissions-Réélections-Nominations d'Administrateurs et Commissaire

Suite à l'assemblée générale du 23 mai 2012:

L'assemblée générale a décidé d'apporter les modifications suivantes aux statuts de l'association :

A l'article 10, alinéa 1, la première phrase : « Le Comité de Direction ne peut compter moins de quinze membres ni plus de trente membres.. » est remplacée par la disposition suivante : « Le Comité de Direction ne peut compter moins de quinze membres ni plus de quarante membres ».

A l'article 10, alinéa 5, la deuxième phrase : « Le Directeur Général n'est pas compris dans le nombre maximum de 35 membres. » est remplacée par la disposition suivante : «Le Directeur Général n'est pas compris dans le nombre maximum de 40 membres. »

Démissions d'administrateurs:

Bouchut Pierre, 25 rue de Longchamp -92200 Neuilly sur Seine, France
Edwards Bruce, 6416 Lake Trail Drive Westerville, OH 43082 - Etats Unis
Wilson Jerry S., 1219 Bluffhaven Way, Atlanta, GA, 30319, Etats Unis

Réélection d'administrateurs

Spagnoletti Joseph, 6 Rainbow Drive,Sewell, NJ 08080, Etats Unis
Giraldo Carlos Mario, Av. El Dorado 70 - 16, Bogota D.C, Colombie
Palazzolo Maria, 3 Woodhall Wynd, Donvale, Victoria 3111, Australie
Pretzel Jörg, Meisenweg 18, 50171 Kerpen, Allemagne
Georget Pierre, 114, Rue de Grenelle,75007 Paris France
Smith Arthur N., 1897 Will Scarlett Drive, Mississauga,L5K 1J5, Ontario, Canada
Ueno Hiromu, 2-13-22-503 Kamiosaki -Shinagawa - Ku, Tokyo 1410021, Japon

Nominations d'administrateurs:

Myers Daniel, 145 Moffett Road, Lake Bluff, IL 60044, Etats Unis, né le 14 Mars 1955 aux Etats Unis
Gilbert John, 2711 Hawthorn Road, Upper Arlington, OH 4322, Etats Unis, né le 6 Septembre 1965 aux Etats Unis

Désormais le conseil d'administration se compose comme suit:

Lopez José, président;
Smucker Timothy, vice président;
Wang Zong-nan, vice président;

Mentionner sur la dernière page du Volet B : Au recto : Nom et qualité du notaire instrumentant ou de la personne ou des personnes ayant pouvoir de représenter l'association, la fondation ou l'organisme à l'égard des tiers
Au verso : Nom et signature

MOD 2.2

'Réservé au Moniteur belge

Volet B - Suite

Lopera Miguel, directeur général;
Ford Rollin, administrateur;
Ching David, administrateur;
Lugan Meinrad, administrateur;
Calleja Urry David, administrateur;
Palaczolo Maria, administrateur;
Pretzel Jörg, administrateur;
King Sonny, administrateur;
McMullen Rodney, administrateur;
Sigismondi Pier-Luigi, administrateur;
Rogers Dave, administrateur;
Shetty Ajit, administrateur;
Lambotte Philippe, administrateur;
Ueno Hiromu, administrateur;
Spagnoletti Joseph C., administrateur;
Giraldo Carlos Mario, administrateur;
Georget Pierre, administrateur;
Smith Arthur N., administrateur;
Carpenter Bob, administrateur;
Geissler Werner, administrateur;
McNamara Mike, administrateur;
Gilbert John, administrateur
Myers Daniel, administrateur
Dougherty Kevin M., administrateur;
Peralta Miguel-Angel, administrateur;
Eeckhout Michel, administrateur;
Phi Joseph, administrateur;
Macho Silvester, administrateur;
Agata Atsunobu, administrateur;
Biyani Rakesh, administrateur.

Réélection - Commissaire

L'assemblée générale des membres du 23 mai 2012 a renouvelé le mandat du commissaire, la société BDO Reviseurs d'Entreprises, pour une durée de trois ans. La société BDO Reviseurs d'Entreprises sera représentée par Monsieur Dominique Mils, reviseur d'entreprises, dans l'exercice de son mandat pour les exercices comptables clôturés aux 30 juin 2012, 2013 et 2014.

Certifié exact.
Monica Walsh
Directeur Corporate Services

Bijlagen bij het Belgisch Staatsblad - 13/07/2012 - Annexes du Moniteur belge

Mentionner sur la dernière page du Volet B : Au recto : Nom et qualité du notaire instrumentant ou de la personne ou des personnes ayant pouvoir de représenter l'association, la fondation ou l'organisme à l'égard des tiers
Au verso : Nom et signature

APPENDIX B: IRS LETTER GRANTING EXEMPTION

POOK

Department of the Treasury

District Director
Internal Revenue Service

Date: August 5, 1976

In reply refer to: Case 601802
EO:T:201:N.J.Schreiber

Telephone: 301-962-4769

Uniform Product Code Council, Inc.
1775 K Street, N.W.
c/o Stephen A. Brown
Washington, D.C. 20006

Internal Revenue Code: Section 501(c) (6)
Form 990 Required: ☒ Yes ☐ No
Accounting Period Ending: May 31

Dear Applicant:

Based on information supplied, and assuming your operations will be as stated in your application for recognition of exemption, we have determined you are exempt from Federal income tax under the provisions of the Internal Revenue Code section indicated above.

Unless specifically excepted, you are liable for taxes under the Federal Insurance Contributions Act (social security taxes) on remuneration of $50 or more to each of your employees during a calendar quarter. And, unless excepted, you are also liable for tax under the Federal Unemployment Tax Act on remuneration of $50 or more to each of your employees during a calendar quarter if, during the current or preceding calendar year, you have one or more employees at any time in each of 20 calendar weeks or pay wages of $1,500 or more in any calendar quarter. If you have any questions about excise, employment, or other Federal taxes, please address them to this office.

If your purposes, character, or method of operation is changed, you must let us know so we can consider the effect of the change on your exempt-status. Also, you must inform us of all changes in your name or address.

The block checked at the top of this letter shows whether you must file Form 990, Return of Organization Exempt From Income Tax. If the Yes box is checked, you are only required to file Form 990 if your gross receipts each year are normally more than $5,000. If a return is required, it must be filed by the 15th day of the fifth month after the end of your annual accounting period. The law imposes a penalty of $10 a day, up to a maximum of $5,000, for failure to file the return on time.

Form L-179 (Rev. 4-73)

You are not required to file Federal income tax returns unless you are subject to the tax on unrelated business income under section 511 of the Code. If you are subject to this tax, you must file an income tax return on Form 990-T. In this letter we are not determining whether any of your present or proposed activities are unrelated trade or business as defined in section 513 of the Code.

You need an employer identification number even if you have no employees. If an employer identification number was not entered on your application, a number will be assigned to you and you will be advised of it. Please use that number on all returns you file and in all correspondence with the Internal Revenue Service.

Please keep this determination letter in your permanent records.

Our determination letter dated January 2, 1976 is hereby superseded.

Sincerely yours,

Gerald G. Portney
District Director

cc: Stephen A. Brown
1775 K Street, N.W.
Washington, D.C. 20006

Form L-179 (Rev. 4-73)

APPENDIX C: GS1 US CODE OF ETHICS / CONFLICT OF INTEREST POLICY

GS1 US and Subsidiaries
Code of Ethics / Conflict of Interest

Revised Date: December 2009
Effective Date: January 2003
Approved by: Chief Executive Officer

I. Policy

While business practices may change over time, our commitment to the highest standards of integrity remains constant. We believe that conducting business ethically is critical to our success. It means more than just obeying the law; it means that the highest standards of integrity underlie everything we do at GS1 US. This is a legacy of which we can all be proud and which we, as individuals, help maintain.

Of course, we cannot anticipate and address every situation. In many cases, common sense and good judgment will be your best guide. In other cases, you also may want to discuss the matter with your supervisor. Remember, whatever you do: When you act on the Company's behalf, the reputation for honesty and integrity is in your hands.

Under this policy, the use of "Company and/or GS1 US" represents all divisions or subsidiaries of the GS1 US and applies to all employees.

II. Acting for Personal Gain/Conflict of Interest

You must not let personal interest interfere with business dealings. A conflict of interest may exist when an employee is involved in an activity or has a personal interest that could interfere with the employee's objectivity in performing company duties and responsibilities. Therefore, any activities that may provide for personal gain or personal interest, including matters of personal interest to the employee's immediate family (spouse, parents, children), is prohibited. For instance, you must not hold an interest of more than one percent of the net worth or market value of a business that provides goods or services to GS1 US. (Note: common stocks held in your 401(k) or in other mutual fund holdings are at the discretion of the investment manager and are not to be considered in this context.) .

Additionally:

- Do not influence either directly or indirectly, GS1 US dealings with any supplier with whom you have a significant personal or financial relationship. If you have a significant personal or financial interest in a GS1 US supplier or other business partner, including GS1 US members or subscribers, you are required to disclose it to a member of the GS1 US Ethics Committee. The GS1 US Ethics Committee is comprised of the Chief Financial Officer, Chief Human Resources Officer and GS1 US General Counsel. In deciding whether a personal or financial relationship is significant and should be reported, err on the side of caution and report it (see "Prudent Observer" test elsewhere in this policy). If the GS1 US Ethics Committee believes that a conflict exists, a member of the committee will discuss the matter with you.

- Do not work for or represent a supplier in its dealings with GS1 US. Generally, employment or representation outside of your full time position with GS1 US is considered a conflict and is prohibited. If you believe that you may be in conflict, you must declare the potential conflict to a member of the GS1 US Ethics Committee for consideration, as soon as the possible conflict arises and annually as prescribed herein. Service on outside Boards of Directors may present a conflict or a possible liability situation to GS1 US. All outside Board service must be declared (note: this does not include Homeowners Associations, Church Boards, Charitable Organizations, etc.) and approved by the GS1 US Ethics Committee.

- Do not use GS1 US name, information, property, time, or other resources to perform outside activities such as a second job, or as a volunteer for community activities not specifically sponsored or approved by the Company. These activities must always be kept separate from your employment with GS1 US. Additionally, personal use of GS1 US time, supplies and other resources is prohibited. (Note: certain exclusions exist such as moderate, prudent and infrequent use of telephone and Internet services at work on the associate's own time.)

III. Business Courtesies

A. Courtesies

Business courtesies can consist of presents, gifts, hospitality, or other favors from persons or firms that do business, or wish to do business, with GS1 US. Since the acceptance of such courtesies may subject the associate to a conflict of interest, acceptance of business courtesies is generally prohibited. However, gifts of modest value (less than $50) may be accepted if it alleviates a potentially embarrassing circumstance. Also, fruit and candy assortments received at Holiday time may be difficult or impossible to return. From time to time hospitality, in the form of meals or entertainment, may be acceptable. Generally, if the hospitality is reasonable and prudent and offered in a business context that promotes successful working relationships for GS1 US, it is probably authorized. In these circumstances GS1 US should probably reciprocate at the next prudent opportunity with the appropriate pre-approvals.

In parts of the world where gift-giving is a common practice and not accepting a gift could reflect badly on GS1 US, it may be appropriate to accept an expensive gift as-long-as doing so would not violate any laws or in any way discredit GS1 US, and the gift is unsolicited and not given to influence your judgment. All gifts of this nature become the property of GS1 US and must be declared. The GS1 US Ethics Committee will decide if you should be allowed to keep the gift/courtesy.

IV. "Prudent Observer" Test

Whenever an employee of GS1 US is presented with a possible conflict, the employee should apply the mandates of this policy. If the potential conflict is unclear, apply the "Prudent Observer" Test. The questions are: "Would a prudent outside observer believe that the employee is or could be compromised by the courtesy involved?" "Could the situation embarrass or reflect poorly on GS1 US?" If the answer is "yes, or maybe", the situation should be avoided. If you are still unsure, you should discuss with your supervisor or the appropriate member of the GS1 US Senior Leadership Team. Commonly asked questions are available in Exhibit A.

V. Protection Against Retaliation

Employees have a right and a responsibility to report any circumstance in which they have knowledge or good faith reason to believe that the law or Company policies or internal controls have been compromised. Employees who believe they have knowledge that the law, or a Company policy or internal control procedure has been violated should discuss their concern with a member of the GS1 US Ethics Committee. The Company ensures that any employee who acts in good faith in making a report pursuant to this policy will be protected against retaliation or other penalty resulting from their decision to come forward.

VI. Doctrine of Self Disclosure

A. Annual Self Disclosure

Annually each employee will be asked to sign the "Notification of Compliance" (See Exhibit B), which reasserts that the employee is in compliance with this policy. Additionally, it gives the employee the opportunity to declare any possible discrepancies or conflicts for review by the GS1 US Ethics Committee.

B. On-going Self Disclosure

Employees that become aware of possible conflicts of interest of their own, or others in the Company, must report the conflicts to a member of the GS1 US Ethics Committee as soon as the possible conflict arises. Conflicts may also be reported anonymously through the GS1 US Employee Suggestion email box.

From: Fields, Erin
Sent: Thursday, October 31, 2013 1:01 PM
To: 'Geraldine.Lissalde.Bonnet@gs1.org'
Subject: RE: CORRIGENDUM: GS1 application UDI Accredited Issuing Agencies

Dear Ms. Lissalde-Bonnet,

Thank you for your interest in becoming an FDA-accredited issuing agency. We have reviewed your application and are requesting additional information to be submitted to FDA to clarify the application for accreditation. Please provide us with the following information:

1. Verify that GS1 is a private organization.
2. Confirm that GS1 will maintain a list of labelers that use its system for the assignment of UDIs and be able to and provide FDA a copy of such list in electronic form by December 31 of each year.
3. Provide a more detailed description of the guidelines that govern assignment of a unique device identifier (UDI) to a device. Please include, data type and length for the DI and each PI. Also, how are the GS1 company prefixes assigned?
4. Describe procedures for monitoring a labeler's correction of deficiencies in its use of UDIs.
5. Provide policies and procedures for suspending or revoking a labeler's use of the applicant's UDI system, including any appeals process. If not appeals process is available, please state that fact.
6. State whether GS1 offers fee waivers or reductions.

Please directly reply to this e-mail with the requested information. Thank you and we look forward to receiving the additional information.

Regards,

Erin Fields
Office of Surveillance and Biometrics
Center for Devices and Radiological Health

Erin.Fields@fda.hhs.gov
301-796-1513

For more information on UDI and the UDI help desk, see www.fda.gov/udi

From: Geraldine Lissalde Bonnet [mailto:Geraldine.Lissalde.Bonnet@gs1.org]
Sent: Thursday, October 24, 2013 3:49 PM
To: Unique Device Indentification
Cc: Ulrike Kreysa
Subject: CORRIGENDUM: GS1 application UDI Accredited Issuing Agencies

GS1 hereby submits an amended version of its application for accreditation as an Issuing Agency for the assignment of UDIs in the context of the U.S. FDA Unique Device Identification System.

Please take into consideration this updated version of the application when assessing how GS1 meets the accreditation criteria established by the FDA.

GS1 is pleased to have the opportunity to apply for accreditation.

Yours sincerely,

Géraldine Lissalde-Bonnet

on behalf of Ulrike Kreysa
Vice-President Healthcare, GS1 Global Office

The global language of business®

Blue Tower, Avenue Louise 326, Bte 10
B-1050 Brussels
T +32 2 788 78 37
M +32 473 633367
F +32 2 788 78 99
ulrike.kreysa@gs1.org
http://www.gs1.org

From: Geraldine Lissalde Bonnet
Sent: Wednesday, October 23, 2013 5:43 PM
To: 'udi@fda.hhs.gov'
Cc: Ulrike Kreysa (ulrike.kreysa@gs1.org)
Subject: GS1 application UDI Accredited Issuing Agencies

GS1 hereby submits its application for accreditation as an Issuing Agency for the assignment of UDIs in the context of the U.S. FDA Unique Device Identification System.

The information contained within this application demonstrates how GS1 meets the accreditation criteria established by the FDA.

GS1 is pleased to have the opportunity to apply for accreditation.

Yours sincerely,

Géraldine Lissalde-Bonnet

on behalf of Ulrike Kreysa
Vice-President Healthcare, GS1 Global Office

The global language of business®

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ulrike.kreysa@gs1.org
http://www.gs1.org

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GS1 AISBL

to the

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

for

Supplemental Information to Support the GS1 Application for Accreditation as an Issuing Agency for Unique Device Identifiers (UDIs)

Thank you for your request for additional information to support the GS1 application for accreditation as an Issuing Agency for the assignment of UDIs in the context of the U.S. FDA Unique Device Identification System. GS1 is pleased to have this opportunity to provide further information about our organization and our standards to the FDA.

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LIST OF ADDITIONAL INFORMATION REQUESTED BY FDA

On October 31, 2013, the FDA requested additional information to support the GS1 UDI Issuing Agency application. Specifically, the FDA requested that GS1:

1. Verify that GS1 is a private organization.

2. Confirm that GS1 will maintain a list of labelers that use its system for the assignment of UDIs and be able to and provide FDA a copy of such list in electronic form by December 31 of each year.

3. Provide a more detailed description of the guidelines that govern assignment of a unique device identifier (UDI) to a device. Please include, data type and length for the DI and each PI. Also, how are the GS1 company prefixes assigned?

4. Describe procedures for monitoring a labeler's correction of deficiencies in its use of UDIs.

5. Provide policies and procedures for suspending or revoking a labeler's use of the applicant's UDI system, including any appeals process. If not appeals process is available, please state that fact.

6. State whether GS1 offers fee waivers or reductions.

The requested information is provided (in the order shown above) throughout the remainder of this document.

PRIVATE ORGANIZATION

GS1 is a private organization owned by its membership. GS1 is organized as a Belgian *Association Internationale Sans But Lucratif* (AISBL), which is an international not-for-profit organization under Belgian law. Appendix A of our application to the FDA provided a copy of the official decree from the Belgian government granting AISBL status to GS1. This document provides proof of being a private organization under Belgian law. Nonetheless, we understand that terminology and business registration processes vary between the United States and Belgium, and we seek to provide certainty to the FDA in this important area. Therefore, we provide additional information about GS1 below in the hope that it "builds a bridge" between the definition of our business structure under Belgian law and the U.S. FDA requirements:

As an AISBL, GS1 is a private, non-governmental organization (NGO) that has the legal form of a non-stock, not-for-profit membership association owned by its members. The members of GS1 are 111 Member Organizations from around the world. We believe the equivalent under US law would be a non-stock, not-for-profit membership corporation. See, for example, information about a non-stock, not-for-profit corporation under Delaware law at the following website: http://www.advantage-de.com/information-center/type-de-bus-entities/non-stock-corp/

GS1 membership is restricted to national or pluri-national organizations known as "GS1 Member Organizations." GS1 Member Organizations support their local members, and are required to operate on a not-for-profit basis. The US Member Organization, GS1 US, is organized as a Section 501(c)(6) organization. GS1 has a federated governance structure through its Member Organizations around the globe. This allows for local involvement and, where required, local regulatory oversight. The highest level of governance in GS1 is the GS1 Management Board, which is composed of representatives of all 25 global industries that GS1 now serves.

All services provided by GS1 are operated on a cost-recovery basis. GS1 Company Prefixes, which give users the capacity to create GS1 identification numbers, are issued by GS1 Member Organizations. Each GS1 Member Organization is free to set its own fees for GS1 Company Prefixes within the GS1 not-for-profit, cost recovery model. Every GS1 Member Organization is required to operate on a not-for-profit basis, and that status imposes legal limitations on revenue relative to costs and therefore serves to keep fees matched to the actual costs of providing services. The fees that each GS1 Member Organization charges are also subject to review and approval by its governing boards.

MAINTAIN & SUBMIT LIST OF GS1 UDI LABELERS

GS1 will maintain a list of labelers that use the GS1 System for the assignment of U.S. FDA UDIs, and will provide an electronic copy of this list (in a mutually agreed upon format) to the FDA by December 31 of each year (commencing December 31, 2014).

DESCRIPTION OF THE GUIDELINES GOVERNING ASSIGNMENT OF UDIS

GS1 Member Organizations (e.g., GS1 US) assign GS1 Company Prefixes to their own members. A GS1 Company Prefix is a globally unique number used exclusively within GS1 identification standards. A GS1 Company Prefix assigned to a member of any GS1 Member Organization entitles that member to create any of the GS1 Identification Keys (e.g., GTIN, GLN, etc.).

Assignment of GS1 Company Prefixes

GS1 Company Prefixes are assigned in varying lengths (depending on the company's needs) and in random order. A GS1 Company Prefix consists of two segments: a GS1 Prefix and a Company Number.

- A GS1 Prefix is a number with two or more digits, administered by the GS1 Global Office. The GS1 Global Office assigns GS1 Prefixes to GS1 Member Organizations (MOs) and/or for Restricted Circulation Numbers. The main purpose of the GS1 Prefix is to enable decentralization of the administration of identification numbers (i.e., each GS1 MO allocates GS1 Company Prefixes under their own GS1 Prefix).
- Company Numbers are assigned by GS1 MOs. Each GS1 MO assigns Company Numbers to its own members.

GS1 Company Prefixes may not be sold, leased, or given, in whole or in part, for use by any other company. (The GS1 General Specifications include additional guidelines that apply when a company changes legal status as a result of an acquisition, merger, partial purchase, split, or "spin-off.") GS1 Company Prefixes are stored in the assigning-MO's Customer Relationship Management (CRM) system for perpetual recording. All GS1 MO CRMs are interlinked.

The GS1 Company Prefix is part of the GS1 data structures and provides the foundation for generating all of the GS1 Identification Keys. With a GS1 Company Prefix and the GS1 Standards and allocation rules, user companies can create any of the GS1 Identification Keys.

UDIs Using the GS1 System

Using the GS1 System, the UDI device identifier (DI) is represented by a GTIN, and UDI production identifiers (PI) are represented by GS1 Application Identifiers (AIs).

Table 1: Additional Details about GS1 Standards for UDI

UDI SEGMENT	GS1 STANDARD	DATA TYPE	LENGTH IN SOFTWARE	LENGTH IN BARCODE
DI	GS1 GTIN	Text	Fixed - 14 digits	*(see table 2 below)*
PI: Batch/lot number	AI (10)	Alphanumeric	Variable - 20 digits	22 digits
PI: Production date	AI (11)	Numeric	Fixed – 6 digits	8 digits
PI: Expiration date	AI (17)	Numeric	Fixed – 6 digits	8 digits
PI: Serial number	AI (21)	Alphanumeric	Variable - 20 digits	22 digits

Information about assigning and using these standards is provided below. For more information, consult the *GS1 General Specifications*, which can be found at: http://www.gs1.org/genspecs

Assigning GTINS

GS1 member companies assign their own GS1 Identification Keys based GS1 Standards and allocation rules. The principles of GS1 Identification Key allocation ensure non-significant, secure and globally unique numbers that can be used by all trading partners, independent of industry sector or location. Each company's GS1 Company Prefix

serves as the foundation for any GS1 Identification Key that company assigns. GS1 member companies can assign GS1 Identification Keys manually, or use a number-generator software from one of their vendors or their GS1 MO (if provided). For example, GS1 US offers an online tool called DataDriver which GS1 US member companies can use to allocate GS1 Global Trade Item Numbers (GTINs) and print GS1 BarCodes.

Each labeler will assign their own GTINs. GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length (known as GTIN-8, GTIN-12, GTIN-13, and GTIN-14 respectively). GS1 BarCode standards prescribe how GTINs are to be encoded in each GS1 BarCode. However, regardless of how they are assigned and encoded, GTINs are always represented in software applications as 14 digits by right justifying and zero-filling to the left as appropriate (i.e. GTIN-14, **or** GTIN-8, GTIN-12 or GTIN-13 *in 14-digit format using leading zeros*.) In order to preserve any leading zeros that may be present, the GTIN field should be represented in databases and software applications as a text field, not as a *numeric* field. (For more information, consult the *GTIN Allocation Rules for the Healthcare Sector*, which can be found at:
http://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

Table 2: GTIN Length When Assigning, Encoding, and Storing

ASSIGNING GTINs	ENCODING GTINs	STORING GTINs
8 digits (GTIN-8) *or* **12 digits (GTIN-12)** *or* **13 digits (GTIN-13)** *or* **14 digits (GTIN-14)**	**UPC barcode**: 12 digits (GTIN-12 only) **GS1-13 barcode**: 13 digits (GTIN-13 only) **All other GS1 BarCodes**: 14-digits (i.e. GTIN-14 or GTIN-8, GTIN-12 or GTIN-13 in 14-digit format using leading zeros)	14-digit format (i.e. GTIN-14 or GTIN-8, GTIN-12 or GTIN-13 in 14-digit format using leading zeros)

Batch/Lot Number - AI(10)

A Batch/Lot Number is typically assigned at the point of manufacturer using a production lot number, a shift number, a machine number, a time or an internal production code. Batch/Lot Number is represented by Application Identifier (10).

- The two-digit AI (10) is used to indicate Batch/Lot Number.
- A variable-length field of up to 20 alphanumeric characters of Batch/Lot Number data follows the AI.
- The data syntax for the Batch/Lot Number component is n2 + a 20.
- **EXAMPLE: (10)987654321GFEDCBA**

Manufacturing/Production Date - AI (11)

Manufacturing Date can also be referred to as production date. It indicates the production or assembly date determined by the manufacturer. Manufacturing Date is represented by Application Identifier (11).

- The two-digit AI **(11)** is used to indicate Manufacturing Date.
- A fixed-length field of 6 numeric characters representing Manufacturing Date follows the AI.
  - YY = the tens and units of the year (e.g., 2003 = 03).
  - MM = the number of the month (e.g., January = 01).
  - DD = the number of the day of the relevant month (e.g., second day = 02).
- The data syntax for the Manufacturing Date component is n2 + n6.

- **EXAMPLE: (11)130726**

Expiration Date - AI (17)

Expiration Date is often referred to as expiry date or maximum durability date. It indicates the limit of consumption or use of a product. Expiration Date is represented by Application Identifier (17).

- The two-digit AI (17) is used to indicate Expiration Date.
- A fixed-length field of 6 numeric characters representing the Expiration Date as YYMMDD follows the AI.
  - YY = the tens and units of the year (e.g., 2003 = 03).
  - MM = the number of the month (e.g., January = 01).
  - DD = the number of the day of the relevant month (e.g., second day = 02).
- The data syntax for the Expiration Date component is n2 + n6.
- **EXAMPLE: (17)101231**

Serial Number - AI (21)

Serial Number is represented by Application Identifier (21). The data is alphanumeric and the length is variable up to 20 alphanumeric characters.

- The two-digit AI (21) is used to indicate the Serial Number.
- A variable-length field of up to 20 alphanumeric characters of Serial Number data follows the AI.
- The data syntax for the Serial Number component is n2 + a 20.
- **EXAMPLE: (21)ABCDEFG123456789**

PROCEDURES FOR MONITORING DEFICIENCIES IN THE USE OF UDIs

GS1 will support members who are using the GS1 System to comply with the U.S. FDA UDI Rule with education and training, as well as barcode verification services. In the event that a labeler is not using the GS1 System correctly, we will engage to guide and assist them with correcting the errors. In addition, deficiencies in the use of GS1 Standards are often recognized and monitored by trading partners in the course of conducting business with one another. Ultimately, the use of the GS1 System is voluntary.

POLICIES & PROCEDURES FOR SUSPENSION AND/OR REVOKATION

A GS1 Member Organizations can suspend/revoke a member's use of the GS1 System for non-payment of their annual membership renewal fees. For re-instatement, a company simply needs to pay their past due fees. There is no appeals process. For example, GS1 US membership is renewed annually with the payment of a renewal fee. (Please refer to the detailed information about how GS1 US manages this process with members through continued communications for six months prior to their renewal deadline.) If a member's renewal invoice remains unpaid sixty (60) days after the invoice is due, the member's use of the GS1 System will be suspended. At that time, the member is notified that their GS1 Company Prefix is no longer licensed, and their access to GS1 US tools is blocked. Once the member pays their past due fees, the member is reinstated.

NOTE: GS1's application included the following sentence regarding revocation and/or suspension: "The Terms and Conditions of GS1 Member Organizations generally include clauses stating that the member's right to use the GS1 System may be revoked *in cases of misuse of the system* and if the member does not meet its fees obligations to the GS1 Member Organization." (emphasis added) We believe the emphasized language was in error. Although each

Member Organization manages the terms and conditions with its members, we are not aware of any Member Organization that has a "misuse of the system" policy. In terms of GS1 US, the member's right to use the system is only revoked for non-payment of fees, as described in the "Termination" section of the GS1 US Company Prefix Licensing Agreement which is provided below.

TERMINATION:

This license shall terminate immediately if Licensee does not comply directly or indirectly with any term of this License Agreement. GS1 US may terminate this license at any time. This license shall automatically terminate after one year from the date of issuance by GS1 US unless Licensee renews said license by timely payment of the then-current, annual renewal fee to GS1 US. Licensee shall be responsible for and pay GS1 US for all costs, expense or fees (including attorney fees) relating to the collection of renewal payments. This license shall terminate should Licensee cease doing business and no refunds shall be applied.

Upon termination, this license shall cease and use of the Prefixes by Licensee must cease. Use of the Prefixes after termination is not authorized by GS1 US and shall be considered by GS1 US to be an infringement of GS1 US's intellectual property rights, in addition to any rights that may accrue to GS1 US by such use. Please be aware that, upon termination of the license, GS1 US may reissue the Prefixes to other parties.

FEE WAIVERS OR REDUCTIONS

Neither GS1 nor GS1 US offer fee waivers or reductions. Instead, each GS1 Member Organization operates on a cost-recovery, not-for-profit basis and has a Management Board governed by the local companies that use GS1 Standards in order to ensure that membership fees remain reasonable and affordable for the companies. For example, the GS1 US pricing policy (which was provided with the GS1 application) recently underwent a thorough review after which the basis of the pricing model was changed from *size of company* (based on annual sales turnover) to *volume* (based on number of items needing a barcode/GTIN) -- which resulted in a fee reduction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Date: November 13, 2013

From: Erin Fields, MS
Program Analyst
Office or Surveillance and Biometrics
Center for Devices and Radiological Health

Subject: Application for GS1 as an FDA-accredited issuing agency

To: Nancy Stade, JD
Deputy Center Director for Policy
Office of the Center Director
Center for Devices and Radiological Health

Through: Thomas Gross, MD
Director
Office or Surveillance and Biometrics
Center for Devices and Radiological Health

I recommend the accreditation of GS1 as an issuing agency for the purpose of issuing Unique Device Identifiers because GS1 meets the eligibility and accreditation criteria under 21 CFR 830.100. GS1 has submitted an application for accreditation as an issuing agency for Unique Device Identifiers as well as supplemental information to support its application. The application and supplemental information contain the information required under 21 CFR 830.110(a).

The initial term of accreditation for GS1 will be 3 years. FDA may suspend or revoke the accreditation of GS1 in accordance with 21 CFR 830.130 if the issuing agency fails to fulfill the responsibilities of an FDA-accredited issuing agency, outlined in 21 CFR 830.120, or meets any other criteria under 21 CFR 830.130.

Draft: EFields 11/13/13
Reviewed: AHawthorn 11/13/13
Concurred TGross 11/15/13 (via email)