Teleflex®

Data Synchronization Implementation Guide

Teleflex - Data Recipient

Prepared by Teleflex Incorporated
Version 2.0

Revision History

Date	Version	Author/s	Description
5 JAN 2018	1.0	Carey Barlett	Initial release
9 DEC 2020	2.0	Bridget Curran (1WorldSync)	Section 3: Updated links for 1WorldSync Contact Us and 1WorldSync Teleflex Data Recipient Landing Page. Section 4.1 Updated links for 1WorldSync website and for 1WorldSync Teleflex Data Recipient Landing Page.

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1. Introduction

Teleflex Inc., a global provider of medical devices, has undertaken the project to begin collecting product data from their data source providers in order to attain GS1 compliance, as well as, gain efficiencies within their company. This document provides the process and methods to be used in achieving this goal.

1.1 GDSN Overview

Data Synchronization is the electronic transfer of standardized product and location information between trading partners and the continuous synchronization of that data over time. The Global Data Synchronization Network (GDSN) is an automated, standards based global environment that enables secure and continuous data synchronization, allowing all partners to have consistent item data in their systems at the same time.

The GDSN connects suppliers and retailers, operators, providers, distributors, and other recipients to the GS1 Global Registry via selected data pool providers. The purpose of this document is to provide clarity on Teleflex specific processes on how to get started using the GDSN with Teleflex.

2. Teleflex Global Data Synchronization Information

2.1 Teleflex's GLN – Publish to

- Production: **0801902000002**
- Teleflex's Global Data Synchronization Network (GDSN) Data Pool is **1WorldSync**.

3. Steps to Begin Syncing your Data with Teleflex

1. Sign up with a GDSN-certified data pool (e.g. 1WorldSync), if you are currently not a customer. Learn about the implementation options offered by 1WorldSync and choose the option that works best for your company.
2. Obtain Education/Training from your data pool or solution provider.
3. Complete the Teleflex Trading Partner Form located at: 1WorldSync Teleflex Data Recipient Landing Page or work directly with your Teleflex contact.
4. Teleflex will request, via data pool, a Catalog Item Subscription (CIS) to your Information Provider GLN.
5. Teleflex will send you a list of required SKUs/Product Codes that they wish to receive from you. Review the requirements to ensure you can meet Teleflex's requirements. Contact Teleflex if you have any questions, or desire further assistance.
6. Load existing and/or new items into your data pool's Production environment and publish items to Teleflex's GLN.
7. Before publishing, please ensure:
   a. All records include all of the required attributes and as many of the desired attributes as possible.
   b. All relevant packaging levels for all items (e.g., Each, Inner Pack, Case) are loaded and linked.
   c. Data accuracy (GTIN, manufacturer part number, product description, pack quantities, measurements, weights, etc.) prior to publishing. Several of these attributes will not be allowed to be modified after initial publication so it is important they are initially accurate.

8. An automatic "RECEIVED" CIC message will be sent to you for all published GTINs received by Teleflex indicating that we have received the data but no definitive business decision has been made to integrate it into our enterprise system.
9. At this point, Teleflex will review the received records and will send one of the following CIC messages:
   a. A "REVIEW" CIC indicates that Teleflex has received discrepant data, which we cannot synchronize. This means that the data needs to be reviewed and corrected by you before synchronization can occur. Please reference the reason and/or correction action that is included in the CIC.
   b. A "SYNCHRONIZED" CIC comes after the initial RECEIVED message was sent indicating that Teleflex has incorporated the Catalog Item and data into their enterprise/back-end system.
   c. Note: Teleflex is using the CIC status details. If you receive a "REVIEW" or "REJECT" CIC response, the CIC status detail message will provide clarification on why Teleflex sent this response.
10. Once a CIC **Synchronized** message has been received, you can accept that the publication process is complete.

3.1.1 Item Maintenance

1. If any product data changes during the course of the product lifecycle, be sure to update the data in your respective GDSN solution. This action is known as an Item Modify. If a record has been previously published, item modifications will automatically be sent to Teleflex.
2. Ongoing item maintenance will be pushed through your GDSN Certified Data Pool to Teleflex. The data will be systematically pushed/published to Teleflex within 1 hour of submission.

4. Teleflex Requirements

4.1 Teleflex's Hierarchy Requirements

Examples of Acceptable GTIN Hierarchies:

5 LEVEL					**PL**
4 LEVEL				**PL**	**CA**
3 LEVEL			**CA**	**CA**	**PK2**
2 LEVEL		**CA**	**PK**	**PK**	**PK**
1 LEVEL	**EA**	**EA**	**EA**	**EA**	**EA**

Key	Description
Each (EA):	The base level of a device – normally the first level of packaging, for a sterile device it is the sterile barrier.
Inner Pack (PK):	This is also known as an inner pack/warehouse pack. May be a logistical unit between a case and each that contains a single instance of a GTIN. Is typically bar-coded. All components of the pack have their own separate bar codes physically attached. The SBS type box (no significant mechanical strength), unusually the Shelf Keeping Unit in the hospital, the airborne protection level – retaining external sterile barrier cleanliness.
Inner Pack 2 (PK2)	A second inner box level, rarely introduced, aiding improved packaging for integrity purposes.
Case (CA):	Generally, the standard shipping unit level The qualified transport level – ISO-11607 (normally a single or double wall corrugate case of significant mechanical strength).
Pallet (PL):	A pallet level containing the same Device of an absolute fixed measure quantity – no variability allowed for content or count.

Healthcare Related Hierarchy Terminology

These Device Identifiers are important to the US FDA GUDID implementation. Though these DIs are not part of the hierarchy in the traditional sense, it is important to call out their definitions and applicability.

Key	Description
Unit of Use (UU) Device Identifier	The level for virtual GTIN allocation relating to a single medical device when contained as a grouping of more than one at the each level. Used in patient eRecords for indication of the number of individual devices used.
Direct Mark (DM) Device Identifier	An identifier that is marked directly on the medical device, which may or may not be different from the Primary DI Number. Direct Mark DI is only applicable to devices subject to Direct Marking requirements under 21 CFR 801.45.

5. Appendix

5.1 Resources

All partners in the healthcare supply chain need to be aware of this industry-wide initiative and understand the benefits of using one common global data standard. The Healthcare Supplier Tool Kit supports these industry sunrise goals and provides what you need to know to get started with GS1 standards today.

Access the GLN, GTIN and GDSN Healthcare Supplier Tool Kits at: www.gs1us.org/hcsuptoolkit

Additional Resources:

1. Training through your GS1 Certified Data Pool Provider
2. GS1 Packaging Measurement Standards
3. GTIN Healthcare Allocation Rules
4. 1WorldSync Website
5. 1WorldSync Teleflex Data Recipient Landing Page

5.2 Definitions, Acronyms, and Abbreviations

Term	Definition
1WorldSync	1WorldSync- Teleflex GDSN data pool provider and project partner
DATA POOL	A GDSN-authorized organization facilitating Product information communication between supply-chain and regulatory agencies; 1WorldSync is a large data pool
GDSN	Global Data Synchronization Network. The network of data pools that GS1 has established for synchronization of product data across geographies
GS1	Global Standards organization that provides the tools and standards for identification and publication of product data across all industries and geographies
GUDID	Global Unique Device Identifier Database – FDA data store for Public access to Medical Device information

LABELER	This term would mean any person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label.
UDI	Unique Device Identifier- the unique identification used for a Medical Device