Compliance to U.S. FDA UDI-regulation with GS1 standards

A roadmap for suppliers in the healthcare sector

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Disclaimer

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1 Introduction

This document is a roadmap intended for medical device manufacturers who have decided to use GS1 standards to comply with the *U.S. FDA UDI regulation*. As an accredited party we can help you with GS1 barcodes and GS1 Data Source Healthcare to efficiently and effectively meet UDI requirements.

It is assumed that the reader is already familiar with the UDI regulation and its requirements. We advise you to use the following documentation in support of this document:

- *Online training (only available in Dutch)*
- *Tips for data entering (only available in Dutch)*
- *Video how to enter data in GS1 Data Source (available in English)*
- *Attribute overview*

U.S. FDA UDI regulation

The U.S. Food and Drug Administration (FDA) has developed the UDI regulation. This regulation requires suppliers of medical devices to add a Unique Device Identifier (UDI) to products and share product information via the FDA-database (GUDID). Only medical devices with a UDI may be supplied to the U.S. market.

The aim of the legislation is to increase patient safety and healthcare business processes. Through unique identification and registration products can be traced more easily. After this regulation for the U.S. market, legislation for the European market has followed in the Medical Device Regulation (*MDR*) and In Vitro Diagnostic Regulation (*IVDR*).

Contact and support

For questions about this document and how GS1 standards can help you comply with the UDI regulation please send an email to *healthcare@gs1.nl* or call 020 511 38 88. For more information, also visit our *website.*

2 Step 1: Initiate your UDI system

The UDI is a unique numeric or alphanumeric code that includes a device identifier (DI), and production identifier (PI). The DI is specific to a device model and the PI includes the current production information for that specific device, such as the lot/batch number, the serial number, production date, expiration date or a combination. You apply a Unique Device Identifier (UDI) to the base package and higher levels of packaging.

2.1 Assign unique device identifiers

UDIs must be applied to all **medical devices** supplied to the U.S. market, except where the rule provides for an exception. According to the regulation:

- You assign a UDI to each version or model of a device. This is possible with GS1 barcodes. To build a UDI, your organisation must become a member of GS1 and obtain a *GS1 company prefix*, by ordering a GS1 code package. This will form the basis of your ID keys.
- The UDI should be both in human readable interpretation (HRI) format (text) and in non-HRI AutoID format (symbol or machine readable). You need to apply the UDI on the device label and package.

UDI Unique Device Identification	**GS1 standards** Product Identification
UDID Data elements linked to the Device Identifier	**GDSN** Attributes mapped to each UDID data element
DI Device Identifier (DI)	**GTIN** Global Trade Item Number
Production data is not stored in UDI or GDSN databases **PI** Production Identifier (PI) (if applicable) Production Identifier data will vary by medical device type and manufacturer current practice.	**AI** Application Identifiers (AI) • Expiration date AI(17) e.g. 141120 • Batch – lot AI(10) e.g. 1234AB • Serial number AI(21) e.g. 12345XYZ
DI + PI = UDI	**GTIN -or- GTIN + AI(s) = UDI**

Figure 2.1: GS1 standards for the assignment of UDIs

2.2 Barcode symbols

The UDI must appear on the label in a human readable format (text), as well as in a symbol that can be read by automatic identification and data capture (AIDC) technology, such as a linear GS1-128 or 2D GS1 DataMatrix barcode.

(01) 0 5410013 11100 9
(17) 160527
(10) ABC123
(21) 12345678

Figure 2.2 GS1 DataMatrix and GS1-128

Often the GS1 DataMatrix is used on small primary and secondary packages. The GS1-128 is often used on logistical units or packages that have enough space on the label. For more information please visit our *website.*

3 Step 2: Decide on how to share data

As part of the UDI system, the FDA created the Global Unique Device Identification Database (GUDID) which includes a set of data attributes, for each device marked with a UDI. Suppliers are responsible for submitting and maintaining their own data in the FDA's GUDID.

Important: identify your GUDID data and classes and start collecting data as soon as possible.

Data provided is master data and is used by the FDA to collect information on the medical devices. The completeness and accuracy of product data is the responsibility of the Brand Owner. As a Brand Owner you need an internal process to manage the data required by the regulator. This includes:

- Data quality checks and procedures.
- Data management process and policies.
- Enterprise-wide data governance policies.
- Roles and responsibilities which outline who has the authority to create, modify and approve the data.

The GUDID has a public interface which can be used by anyone to search information about medical devices. Some information submitted however will be private and only used by the FDA.

3.1 GS1 Data Source

The information requested by the FDA can be submitted via GS1 Data Source. GS1 Data Source is a solution for the uniform, reliable exchange of trade item data and is connected to the Global Data Synchronization Network (GDSN). This certified data pool interfaces with the FDA Global Unique Device Identification (GUDID). After entering data into the web interface you are able to publish the data to the FDA GUDID.

Manufacturers are also able to leverage the data pool to publish their product information to all trading partners using the GDSN, based on the principle 'publish once to all'. The solution can be fed manually – including Excel upload – or automatically through a middleware solution implemented by the manufacturer himself.

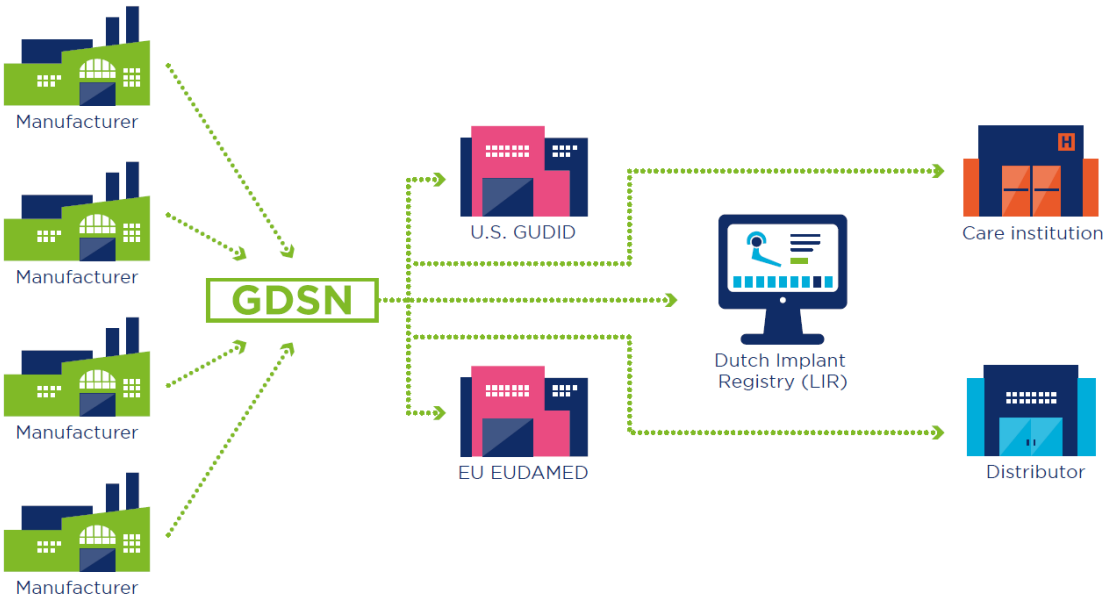

Figure 3.1: Global Data Synchronization Network

3.1.1 Assign GLN

To be able to use GS1 Data Source you need a GS1 Global Location Number (GLN). A GLN identifies the company location. You can *order* a GLN at our website or use one from another GS1 member organization. It is also possible to create a GLN if you already have a GS1 code package.

4 Step 3: Prepare for FDA requirements

Before you start entering your data into the web interface and send it to the GUDID, you need to prepare for some procedures required by the FDA. Read the sections below and follow the steps explained carefully. We advise you to use *this guidance* developed by the FDA.

1. **Request a DUNS number**

Request a DUNS number from *Dun & Bradstreet*. DUNS is an international business identification system used by businesses, banks and governments in the U.S.

2. **Identify individuals**

Identify the individuals for GUDID account management roles and submissions.

3. **Set up a FDA GUDID account**

By using GS1 Data Source Healthcare to publish data to the FDA GUDID you are using Atrify as third party submitter. Register Atrify as your third party submitter by establishing a *GUDID account* (Global Unique Device Identification Database account) and indicate that Atrify is the GDSN partner. Also request a HL7 SPL account, not a GUDID Web Interface account and provide the following 'Third party' information:

Atrify as your GDSN data pool

DUNS: 333121965

Address: Maarweg 165, 50825 Köln, Germany

5 Learn how to use the attribute list

On our website an attribute list is available: 'core-echo-datamodel'. *This data model* published on our website needs to be filtered, in order for you to find out which FDA attributes are mandatory.

5.1 Filter

Open the Excel file, go to tab 'US FDA' and go to column 'Mandatory FDA'. Filter all values with 'Yes' and 'Yes, if'. Now you can see every attribute that is 'mandatory' and 'mandatory if'. Notice that some attributes cannot be changed after the Grace period (column 'FDA Edit Rules After Grace Period'). In the test environment the Grace period is 1 day. In the Live environment it is 30 days. Also watch carefully which values are permitted by the FDA (column 'FDA Entry List of Values (LOV)').

Mandatory FDA	FDA Edit Rules After Grace Period	FDA Entry List of Values (LOV)	FDA New DI Trigger?	FDA Public/Private Status
YES	Add, Delete, Edit	Yes/No	YES	Public
YES	None (NO edit, add, or delete are allowed)	*N/A*	YES	Public
YES, if device is	Add, Delete, Edit		NO	Public

Figure 5.1: filtering the Excel file 'GZHZ_GS1DAS_EchoDataModel'

6 Step 4: Collect data

Start collecting data at an early stage. When doing this, it is important to:

1. Identify your GUDID data and product classes.
2. Collect, verify and validate GUDID data according to the attribute overview.
3. Determine any gaps in the relevant data.
4. Capture data from your labels (if necessary).

The GUDID has a set of attributes for population of information about a medical device. These attributes are of various types and either 'Required' or 'Not required'. The specifics of each attribute vary based upon the information requested by the attribute's definition and the type of device being described.

7 Step 5: Complete GUDID testing

Once the GUDID account is established, complete GUDID testing prior to production submission. According to the FDA, the purpose of GUDID testing is to catch issues early on, so once you transition to production submissions, there are no major problems due to improper formatting, incorrect values or validation failures in the submission. The FDA encourages you to do testing that closely mimics real world scenarios applicable to your devices as there are many business rules that may affect the success of the submission.

Make sure your testing includes all changes to DI records during the lifecycle of your device before requesting access to the production environment.

7.1 Start testing

GS1 will provide login data in the test environment of GS1 Data Source Healthcare. For more information about the use of the web interface please read the web interface user manual provided by GS1 Netherlands.

Link to test environment: *https://uat-datasource.gs1.nl/*

Important: testing may take up to a couple of weeks depending on the workload of the FDA at that moment.

7.1.1 Testing process

Take the following steps:

1. Prepare test scenario cases thoroughly (paragraph 9.2.1).
2. Enter data and publish scenario 1, 2 and 3 to the FDA. Make sure to do this at the beginning of the week. The FDA wants you to add or change attributes within one or two days.
3. The FDA performs five steps of validations on items published to the FDA GUDID test environment:
    1. Is the file in valid XML format?
    2. Is the file a duplicate or a previous file sent?
    3. Are the values provided for attributes that have a finite valid value list correct?
    4. Are all required attributes present in the file? Also, is the labeler DUNS Number accurate? Additionally, is the Primary DI Number submitted a duplicate of one already sent?
    5. Are the data attributes valid per the FDA UDI attribute requirements?

    These steps correspond with the CIC Review messages you may receive after publishing to the FDA.
4. Wait for CIC messages that contain a CoreID for each publication and possibly a corrective action. If an item fails at any of the five steps, a GDSN CIC (Catalog Item Confirmation) response of REVIEW will be returned to the GS1 Data Source web interface. For REVIEW messages the error message can be viewed in the REVIEW CIC response (which can be found in the upper menu under 'Messages', see 9.1).

    Adjust these items and send them it to the FDA again. Keep in mind that you wait at least 4 hours after receiving the CIC REVIEW from the FDA, before sending your modified item to the FDA.

    You completed the process when you receive ACCEPTED CIC's for all items to be synchronized with the FDA.
5. When you receive an ACCEPTED CIC, collect the CoreID, for each test case. For your convenience set up a separate Excel sheet for documentation or use the template *UDI test scenario template* provided by GS1.
6. After receiving an ACCEPTED CIC for scenario 1, 2 and 3 you need to perform scenario 1a and 2a within one day after the FDA GUDID Publish Date. Scenario 3a needs to be performed from one day after the grace period (which is one day in the test environment). If you publish scenario 1, 2 and 3 on Monday, publish 1a and 2a on Tuesday and 3a on Wednesday.
7. For each test scenario collect the Core ID and Primary DI Number (GTIN). For scenario 1a, 2a and 3a collect GUDID Data Elements changed, value before change and value after change.
8. After finishing the test scenario's, send collected CoreIDs with all collected information to *gudidsupport@fda.hhs.gov*, or via the *FDA UDI Helpdesk* and ask for approval to publish data in the

production system. The FDA UDI staff reviews your information and indicates next steps for data publication.

Important:

- Unless stated otherwise in the test scenario scheme, you make changes in the test environment within the **one day** grace period. This means that when the FDA requests to correct any published items, you will need to do so within one day after receiving the CIC message.
- Follow the test scenarios exactly as stated by the FDA. If you didn't receive a CIC message from the FDA within the grace period then you still need to perform the next step.
- All CIC's should be returned within 4 to 48 hours by the FDA after the receipt of the published information.
- It is possible to undertake the test scenarios simultaneously.

Make sure to take the following into account:

- There are **no validations** (red marks/errors) in the web interface on the attributes listed below, but some are mandatory or should be taken into account. For more information about these attributes refer to the data model:
  - *Trade Item Date On Packaging Type Code* is **mandatory.**
  - *Product code* (unless device is a kit or IVD with a BL premarket submission number) is **mandatory.**
  - *FDA Medical Device Listing* (unless device is an HCT/P, kit or IVD with a BLN premarket submission number) **is mandatory.**
  - *Initial Manufacturer Sterilisation*: if information is not provided, the FDA will interpret it as False.
  - *Initial Sterilisation Prior to Use Code*: if information is not provided, the FDA will interpret it as False.
  - *Does Trade Item Contain Latex*: choose 'True' or 'False'.

8 Find the correct attributes

If you can't find the required attributes in the GS1 Data Source web interface, there's a search engine you may want to use. Always search the name that is used in GS1 Data Source instead of the FDA name.

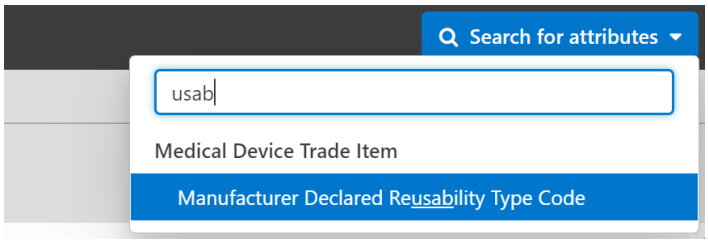

Figure 8.1: using the search engine in GS1 Data Source

Basically you can follow these steps for adding the required attributes:

1. Fill in all attributes with errors in the checklist in red (mandatory basic attributes)
2. Search for all attributes that are 'Mandatory for FDA' (use the filtered 'GZHZ_GS1DAS_DataModel') and fill in these attributes (if applicable).
3. Tip: always fill in the 'Trade Item Description' and 'Description Short', because it will help you in the overview screen to recognize your products easier.

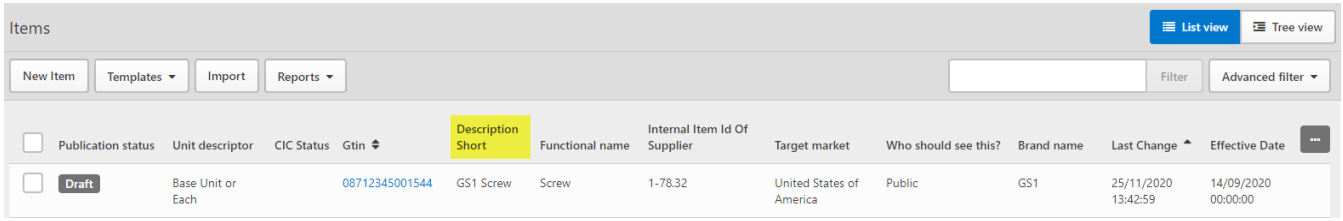

Figure 8.2: recognize your products easier by filling the attribute 'Description Short'

9 Validations and CIC messages

When you publish or modify and release your data, the FDA validates your data and sends back a CIC (Catalog Item Confirmation). You can find CIC messages in the upper menu under 'Messages'.

9.1 What CIC messages look like

There are 3 kinds of CIC messages: Synchronized, Review and Reject.

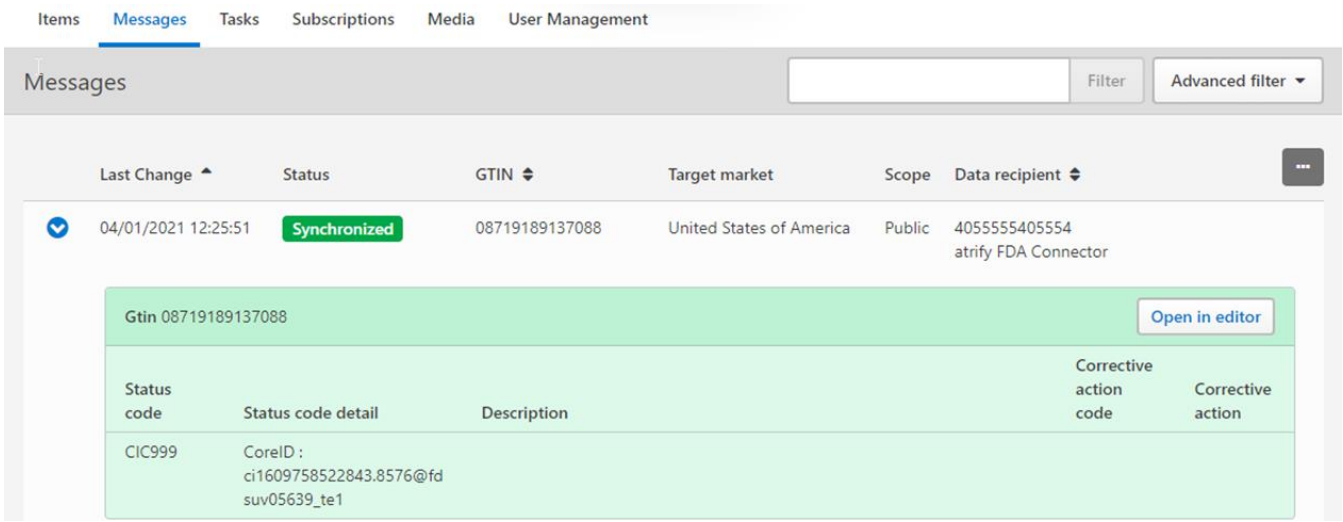

Figure 9.1: example of a Synchronized CIC

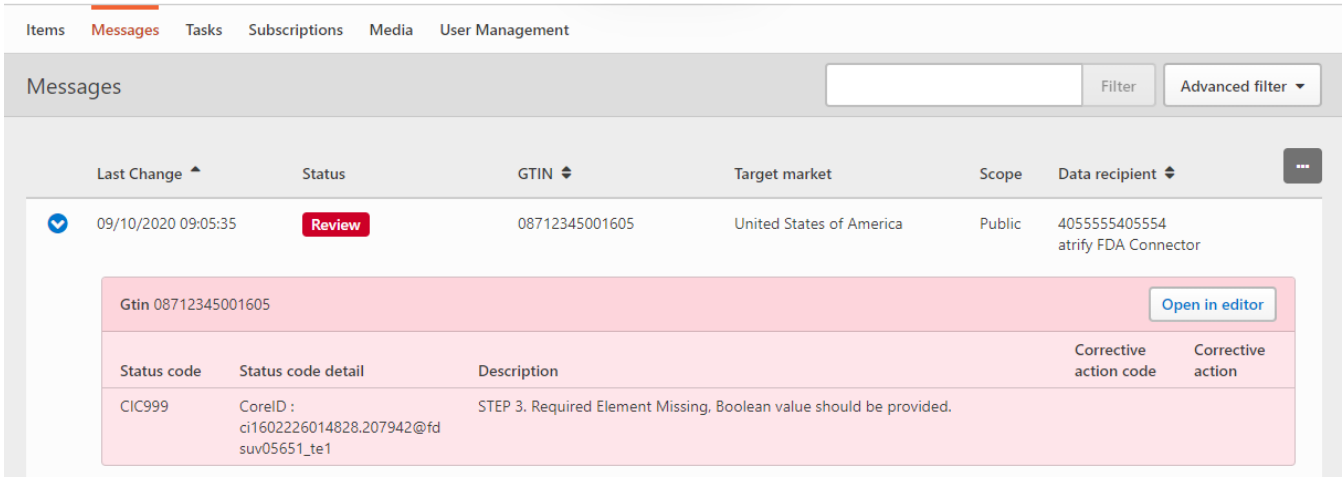

Figure 9.2: example of a CIC Review (action needed)

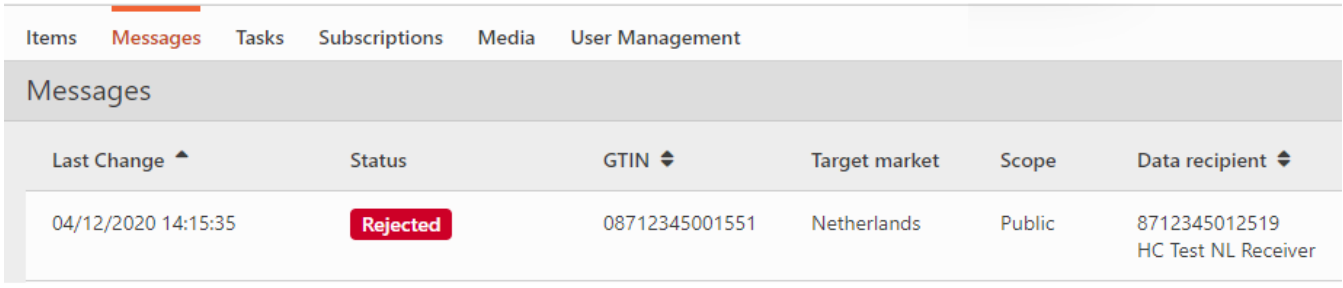

Figure 9.3: example of a CIC Reject (action needed)

9.2 CIC Review messages

Below you'll find the errors that can occur within the different steps, their explanations and the required actions needed to solve the issue.

Step	Review message (CIC)	Explanation	Action
2	Unable to parse XML	1. Can occur if the supplier sent the item twice with the same information 2. Can occur when the value 'NA' (Not Applicable) is given, while the FDA only accepts the values True/False	1. Do not republish after a GTIN is already published, just releasing the changes is enough 2. Look for valid values in the Excel file 'GHZ_GS1DAS_DataModel' or 'Data Model FDA GUDID UCM396592'
3	FDA Preferred Term must be 4 characters	An incorrect amount of characters has been given for attribute 'FDA Preferred Term Code'	Login to your FDA- account and look it up (a correct example is 'RFGW') or fill attribute 'GMDN Preferred Term Code' and leave this attribute empty
3	Not a valid Listing Number	Can occur when the 'FDA Medical Device Listing number' is incorrect or when it is relatively new (and therefore not updated by the FDA)	Change the value into a valid FDA Medical Device Listing number*
3	Not a valid unit of measure	Can occur when an UOM (Unit Of Measure) is given that the FDA doesn't accept	Look for valid values in the Excel file 'GHZ_GS1DAS_DataModel' or 'Data Model FDA GUDID UCM396592'
3	Not a valid unit of measure for storage and handling	Can occur when an UOM (Unit Of Measure) is given on Storage and Handling information that the FDA doesn't accept	Look for valid values in the Excel file 'GHZ_GS1DAS_DataModel' or 'Data Model FDA GUDID UCM396592'
3	Required Element Missing. Boolean value should be provided.	Can occur when a FDA Boolean attribute is entered with the value UNSPECIFIED or NOT_APPLICABLE. For example: 'Does Trade Item Contain Latex' or 'Does Trade Item Contain Human Tissue'	Change the value to TRUE or FALSE
4	The document number: Exempt with supplement number:000 does not exist in the database	The value for FDA Premarket Submission Number must be a valid value	Replace the value for a valid number or set the 'Exempt From FDA Pre Market Authorization' on 'True'
5	At least one valid FDA listing number is required because kit not selected, tissue not selected, and Licensed IVD not provided	A value for attribute 'FDA Medical Device Listing' is missing	If the item is not a Kit or Grouped Product, doesn´t contain human tissue and/or doesn´t have a Licensed IVD, an FDA Medical Device Listing Number is needed. Add a valid FDA Medical Device Listing number*
5	At least one valid Product Code is required because kit is not selected and Licensed IVD not provided	A value for attribute 'Product Code' is missing	Login to your FDA- account and look it up (a correct example is 'CEW')

Step	Review message (CIC)	Explanation	Action
5	At least one valid FDA listing number is required	A value for attribute 'FDA Medical Device Listing' is missing	An FDA Medical Device Listing Number is needed. Add a valid FDA Medical Device Listing number*
5	DI record contains only inactive FDA Listing Number(s).	A value for attribute 'FDA Medical Device Listing' is incorrect	An FDA Medical Device Listing Number is needed. Add a valid FDA Medical Device Listing number*
5	The premarket number K000473 does not exist	Can occur when the 'FDA Premarket Submission Number' is incorrect	Add a valid 'FDA Premarket Submission Number' or ask the FDA for a valid example
5	The GMDN Code 12345 does not exist; contact the GMDN Agency (www.gmdnagency.com) to obtain a valid GMDN PT Code.	Can occur when the 'GMDN Preferred Term Code' is incorrect	Login to your GMDN- account and look it up or fill attribute 'FDA Preferred Term Code' and leave this attribute empty
5	The discontinued date must be same or later than publish date	The value for 'Discontinued Date Time' lies in the past	Change the 'Discontinued Date Time' into the same date as the 'Last Ship Date Time' but later than de 'FDA GUDID Publish Date' on both levels
5	The device with primary device identifier 08712345678906 is currently published and cannot be unpublished via SPL	Can occur when the 'Last ship Date Time' and/ or the 'Discontinued Date Time' are in the past	New GTIN required
5	The device information cannot be updated because the grace period has expired and fields that trigger a new Device Identifier has changed	Can occur when attributes are filled that may not be changed after the Grace period	New GTIN required
5	The Unit of Use DI cannot be provided when the device count is equal to one	Attribute *FDA Unit Of Use GTIN* has been filled while attribute *UDID Device Count* is filled with 1	Empty attribute *FDA Unit Of Use GTIN*

Table 9.2: CIC Review messages explained

*
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053199.htm

Please be aware that this list is not exhaustive. Please let us know if you find any other errors, so that we can include them in this list.

9.2.1 Test cases

	Test description	Changes/updates	Success criteria	Comments GS1
1.	Create a new DI record with today's publish date.		DI record is uploaded to GUDID as a **'Published'** DI record	A new DI record is a new GTIN. A record with today's publish date is a **'Published'** DI record.
1a.	Update the newly created record **during** grace period. **Please note:** Grace Period in the preproduction (test) GUDID environment starts the day after a DI record is published and is set to 1 day	Change any of the following data elements: Brand Name, Version or Model Number, For Single Use, Latex information, or MRI Safety Information.	DI record is updated correctly.	
2.	Create a **new** DI record with a future publish Date. Must include a Premarket Submission Number.		DI Record is uploaded to GUDID as an **Unpublished** DI record.	An **Unpublished** DI record means that the record has a future publish date. Make sure to at least put the date a couple weeks in the future.
2a.	Update the newly created record.	Change DI Record FDA GUDID Publish Data to today's date. Add a second FDA Premarket Submission Number.	DI record is updated correctly. DI record status shows as **Published**, and new Premarket Submission Number is added correctly.	The Premarket Submission Number is associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA, and NDA.
3.	Create a **new** DI record with today's publish date. The DI record must include a package hierarchy.		DI record is uploaded to GUDID as a **Published** DI record and the package hierarchy is reflected correctly.	Please register not only a base item but also a package and make sure these items are linked. Every hierarchy must contain at least one orderable unit.
3a.	Update the newly created record **after** grace period. **Note**: Grace Period in the preproduction (test) GUDID environment starts the day after a DI record is published and is set to 1 day.	Add/Change the following data elements: Commercial Distribution End Date, Storage and Handling information, Clinically Relevant Size information.	DI record is updated correctly.	Commercial Distribution End Date is shown as Last Ship Date Time in the web interface. Storage and Handling information and Clinically Relevant Size Information can be found under chapter Health Industry Information – Additional FDA Information.

Table 9.3: test cases FDA

10 Timeline and actions

10.1 Timeline

The FDA test scenarios can be done within 3 days. If you start with scenario 1 and 2, please be aware that the Grace period (in test) is 1 day so if you want to succeed, you need to follow up within 1 day (after the FDA GUDID Publish Date). You may not start on a Friday, because it will require action on Saturday.

Example:

Monday: start scenario 1, 2 and 3 and wait for a successful CIC. If you receive a CIC SYNCHRONIZED, please write down the CoreID of the CIC message in your Excel file. If you receive a CIC REVIEW, please resolve the error(s) and release the information again until you receive a CIC SYNCHRONIZED

Tuesday: if scenario 1 and 2 were successful, follow up with scenario 1a and 2a and release your updates. Please write down all changes you have made to the products. If you receive a REVIEW, please correct the error(s) and release the information again until you receive a CIC SYNCHRONIZED.

Wednesday: follow up with scenario 3a and release your updates. Please write down all changes you have made to the products. If you receive a REVIEW, please resolve the error(s) and release the information again until you receive a CIC SYNCHRONIZED.

10.2 Registering your actions

One important thing is registering every step you perform during the testing period. You can use the Excel file 'gzhz_udi_fdatestscenarios' to do this. The document can be found on our *web page* under 'UDI FDA testscenario's'.

GS1 Nederland

UDI- regulation - Test scenarios

Please note: for each test scenario collect the Core ID and Primary DI Number (GTIN).
For scenario 1a, 2a and 3a collect the data elements changed, value before change and value after change. Please inform the FDA about the collected information via the FDA Help Desk after the test scenarios and request data publication in live environment.
This document is only available for your own administration and will not be accepted by the FDA.

Scenario	FDA test description	Changes/updates	Success criteria	Comments GS1	GTIN	Examples of attributes changed	Date/time sent to FDA Dutch timezone	Core ID
Scenario 1	Create a **new** DI record with today's publish date.		DI record is uploaded to GUDID as a **Published** DI record	A new DI record is a new GTIN. A record with today's publish date is a **'Published'** DI record.	08712345678901	N/A	29-11-2016 15:03	CoreID : oi/480430804210.f521385@fdsuv05636_te2
Scenario 1a	Update the newly created record **during** grace period. (**Note**: Grace Period in the preproduction (test) GUDID environment starts the day after a DI record is published and is set to 1 day)	Change any of the following data elements: Brand Name, Version or Model Number, For Single Use, Latex Information, or MRI Safety information.	DI record is updated correctly.			Changed the Brand Name into ... Changed Manufacturer Declared Reusability Type Code into .. Does Trade Item Contain Latex into 'false' (only use false or true)	30-11-2016 10:03	CoreID : oi/480499236022.694192@fdsuv05638_te1
Scenario 2	Create a **new** DI record with a future publish Date. Must include a Premarket Submission Number.		DI record is uploaded to GUDID as an **Unpublished** DI record	An **Unpublished** DI record means that the record has a future publish date. Make sure to at least put the date a couple weeks in the future.	08712345678902	N/A	29-11-2016 15:03	CoreID : oi/480430800350.725090@fdsuv05637_te1
Scenario 2a	Update the newly created record.	Change DI Record Publish Date to today's date. Add another FDA Premarket Submission Number.	DI record is updated correctly - DI record status shows as **Published**, and new Premarket Submission Number is added correctly.	The Premarket Submission Number is associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA, and NDA.		Changed the DI Publish Date into ... **Added** Premarket Submission Number ...	30-11-2016 10:03	CoreID : oi/480500239973.1648977@fdsuv05636_te2
Scenario 3	Create a **new** DI record with today's publish date. The DI record must include a package hierarchy.		DI record is uploaded to GUDID as a **Published** DI record and the package hierarchy is reflected correctly.	Please register not only a base item but also a package and make sure these items are linked.	Base item: 08712345678903 Package: 08712345678904	N/A	29-11-2016 15:20	CoreID : oi/480431805787.f522325@fdsuv05636_te2
Scenario 3a	Update the newly created record **after** the grace period. (**Note**: Grace Period in the preprod (test) GUDID environment starts the day after a DI record is published and is set to 1 day)	Add/Change the following data elements: Commercial Distribution End Date, Storage and Handling information, Clinically Relevant Size information.	DI record is updated correctly.	Commercial Distribution End Date is shown as Last Ship Date Time in the web interface. Storage and Handling information and Clinically Relevant Size Information can be found under chapter Health Industry Information – Additional FDA Information.	Base Item: 08712345678905	Last Ship Date Time set to ... Discontinued Date Time set to ... Transportation Environment Atmospheric Press Max into ... Transportation Environment Atmospheric Press Max UoM into ... Storage Environment Atmospheric Pressure Maximum into ... Storage Environment Atmospheric Pressure Maximum UoM into ... Clinical Size Type into ... Clinical Size Value into ... Clinical Size Value UOM into ...	1-12-2016 00:00	CoreID : oi/480499239843.243692@fdsuv05638_te1

Figure 10.1: the Exel file 'gzhz_udi_fdatestscenarios'

Empty the information for column 'GTIN', 'Examples of attributes changed', 'Date/time sent to FDA Dutch timezone' and 'Core ID'. Register your actions in the columns when performing your testing period.

When the FDA test is finished and you have collected all 6 CIC CoreIDs, you need the information that's in your 'gzhz_udi_fdatestscenarios' file to apply for a live account.

10.3 Applying for a live account at FDA

Go to the *FDA website* and fill in the FDA UDI Help Desk form. It's not possible to upload your Excel file, so you need to copy-past your GTINS, the CoreID's with their date/time and the changes you've made into the 'Question' field.

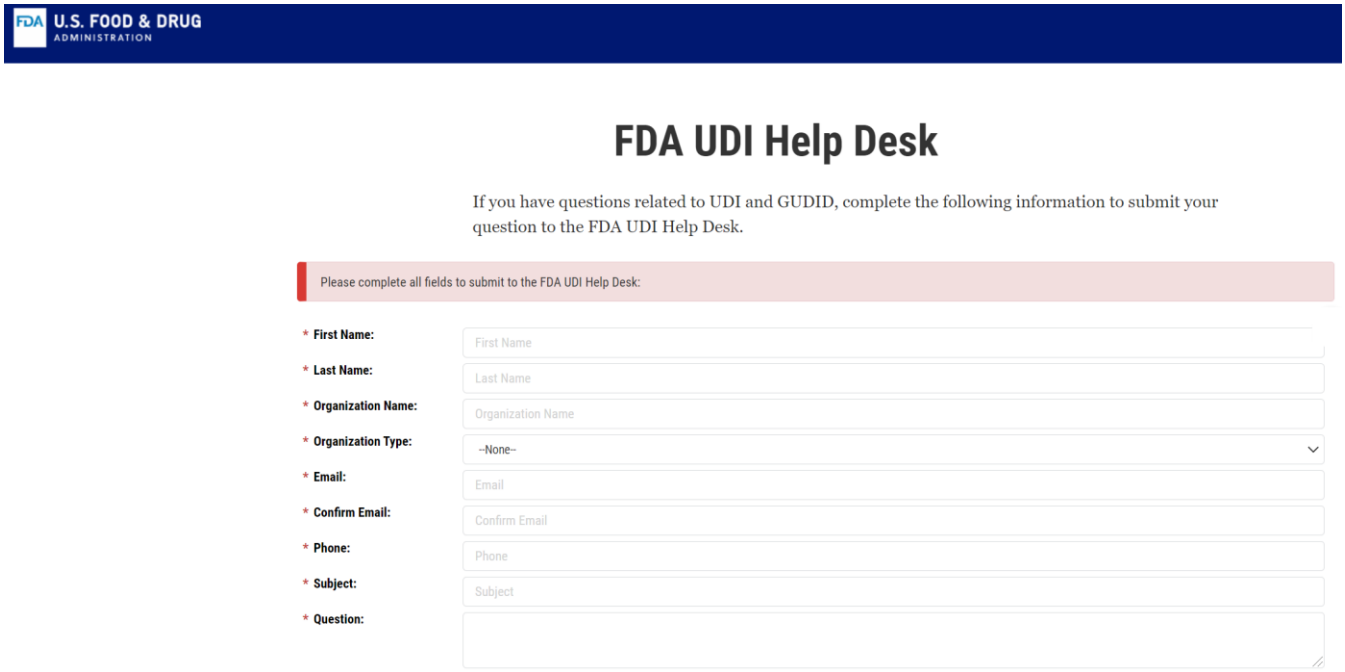

Figure 10.2: the FDA UDI Help Desk form

11 Step 6: Live publication

After successful testing and approval from the FDA you are ready to go on with the GUDID production system. Request registration in the live environment via *healthcare@gs1.nl*. GS1 Netherlands provides you the link for the live environment and log in information.

The *GS1 website* including webinars informs you on how to create items and publish information.

11.1 Data attributes

You are allowed to publish additional packaging configurations for a particular product item hierarchy at any time. You are only allowed to modifying or delete a published item hierarchy to the FDA within 7 days of the date that you populated in the attribute 'FDA GUDID Publish Date'.

Note: There are certain attributes that may not be added, deleted or edited 7 days after the date indicated in the attribute 'FDA GUDID Publish Date'.

- If the date you entered in the field 'FDA GUDID Publish Date' is at least 30 days in the past and the item is published to the FDA GLN, **none** of the UDI attributes listed below can be added, deleted or edited:
  - Issuing Agency
  - Primary DI Number
  - Device Count
  - Brand Name
  - Version or Model Number
  - DI Record Publish Date
  - Secondary DI Issuing Agency
  - Device required to be labelled as containing natural rubber latex or dry natural rubber
  - Kit
  - Combination Product
  - Device Exempt from Pre-market Submission
  - For Single Use
  - Device Packaged as Sterile
  - Requires Sterilization Prior to Use
  - Secondary DI Number
- If the date you entered is at least 30 days in the past and the item is published to the FDA GLN, **none** of the UDI attributes listed below can be deleted or edited. If they do not exist, they can be added:
  - Package DI Number
  - Contains DI Package
  - Quantity per Package
  - Package Type
  - Package Discontinue Date
  - FDA Premarket Submission Number
  - Supplement Number
  - FDA Listing Number
  - Size Type
  - Size Value
  - Size Unite of Measure
  - Size Type Text

If these UDI attributes need to be maintained after the FDA Publish Date contact the FDA directly.

11.2 Attribute names

Some attribute names the FDA uses, are not similar to the attribute names in the web interface. For example: 'For single-use' (column 'FDA Attribute name'). You can find the GS1 Data Source name 'Manufacturer Declared Reusability Type Code' right next to it (column 'Attribute name English') in the tab USA FDA in the *data model*.

