

1 SAP Global UDI Add-On – Version 2025/01

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2 Change history

Version	Date	User	Description
2025-08	25.08.2025	AY	Timestamp field change, Technical issues with old field type
2025-08	25.08.2025	AY	“Last released version” filter added in “Submission Status” app
2025-08	25.08.2025	AY	Search help added for some fields
2025-08	25.08.2025	AY	“Authority version” can now be changed in “UDI Submission reset”
2025-08	25.08.2025	AY	Error description field in Submission status has been extended

3 Support und contact information

A support request is usually made by e-mail. In urgent cases you can call us.

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4 Introduction

Our manual begins with a quick introduction where we explain how our solution is built and how you can pre-organize it to tailor it to your specific requirements using the settings provided.

4.1 SAP Global UDI Add-On

As a manufacturer of medical devices, ensuring the safety and efficacy of your products while simultaneously meeting global regulatory standards is imperative. Our SAP Global UDI Add-On can assist you in overcoming these challenges while optimizing your business processes.

The SAP Global UDI Add-On facilitates the maintenance of UDI attributes within SAP. These attributes, along with their characteristics, have been defined by various regulatory and health authorities worldwide such as the FDA, EUDAMED, SFDA, etc.

In accordance with these regulatory requirements, information about all medical devices placed on the market must be submitted to the appropriate database. The SAP Global UDI Add-On enables companies to administer UDI master data in SAP.

The functionality of the SAP Global UDI Add-On is divided into three sections:

- 1) **UDI Determination**
In this section, you can designate your data as UDI-relevant and create different versions, each containing the desired information about the data.
- 2) **Data maintenance and Validation**
This category encompasses all applications where you can maintain and evaluate the UDI attributes.
- 3) **UDI Data Release & UDI Data Submission**
In this area, you can prepare the release of your UDI data and submit it to the selected authority of your choice. These processes can be visualized with the help of a detailed workflow and audit trail, allowing you to track the status of your submission.

Our solution is using SAP Fiori UI and CDS technology and is compatible with SAP Netweaver 7.50 and higher. Additionally, it is fully prepared for S/4 HANA (1809 or higher). Moreover, our solution is optimized for On-Premise installation, eliminating the necessity for cloud integration.

4.2 Fiori Menu

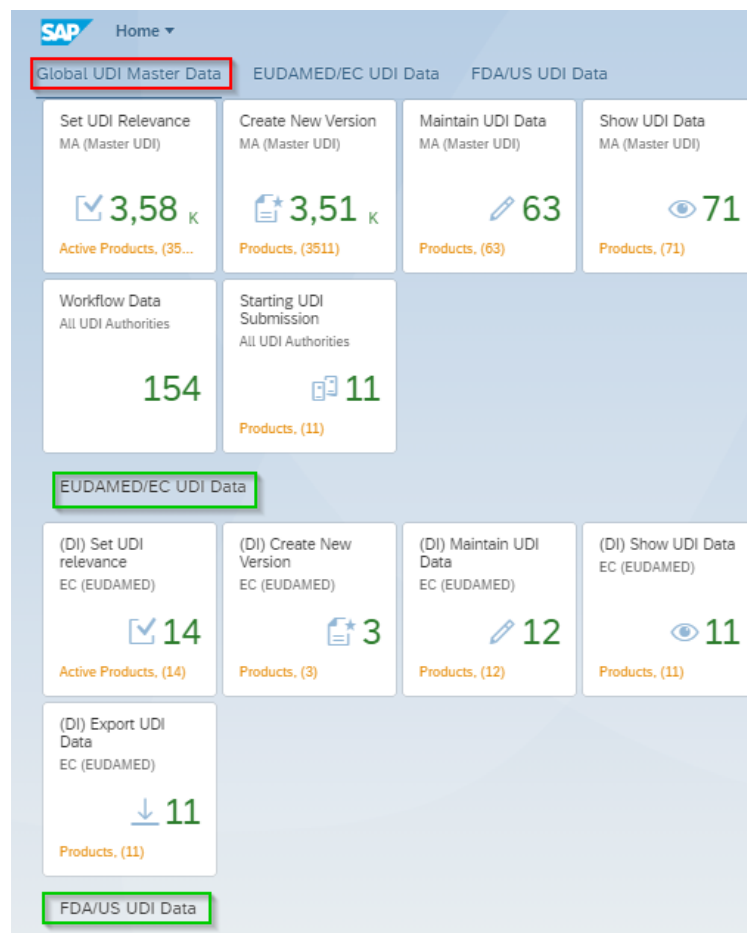
We designed our menu to offer an intuitive and user-friendly experience, guiding you through a structured workflow for collecting, preparing, and submitting your data to the relevant authorities.

Global UDI Master Data

In this section, you can centrally manage all UDI common data not specific to any regulatory authority. This data serves as a foundation for other UDI plugins, reducing redundant data entry. We encourage you to input as much data as possible here to streamline maintenance across other plugins.

UDI Plugins for different authorities

We've developed multiple Fiori groups tailored to help you manage your products in accordance with the requirements of various regulatory authorities. Whether it's EUDAMED, FDA, SFDA, or others, each authority has its dedicated Fiori group. Depending on the UDI plugins you've installed, you'll find corresponding Fiori groups displayed on your Fiori Dashboard. This setup ensures easy access and navigation through functionalities relevant to your regulatory compliance needs.



Fiori Menu in the SAP Global UDI Add-On

4.3 Settings

In this section, we'll explore the various settings you can adjust before beginning your data management.

4.3.1 Basic application settings and Code List

The basic settings for the UDI Add-On can be accessed through the SAP GUI transaction code "SPRO." Within the "Global UDI Solution" section, you'll find configuration options to customize the general functionality of the UDI Fiori application.

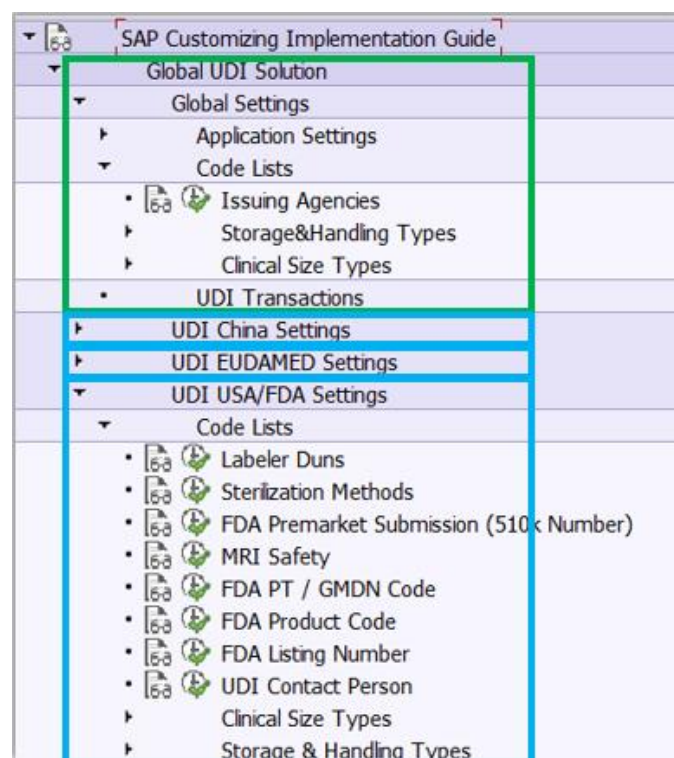
Transaction Code:
SPRO

Global Settings:

The basic settings for the UDI Add-On can be accessed through the SAP GUI transaction code "SPRO." Within the "Global UDI Solution" section, you'll find configuration options to customize the general functionality of the UDI Fiori application.

Plugin Settings:

The configuration within the UDI Authority settings is specific to the designated authority, allowing for tailored adjustments according to regulatory requirements.



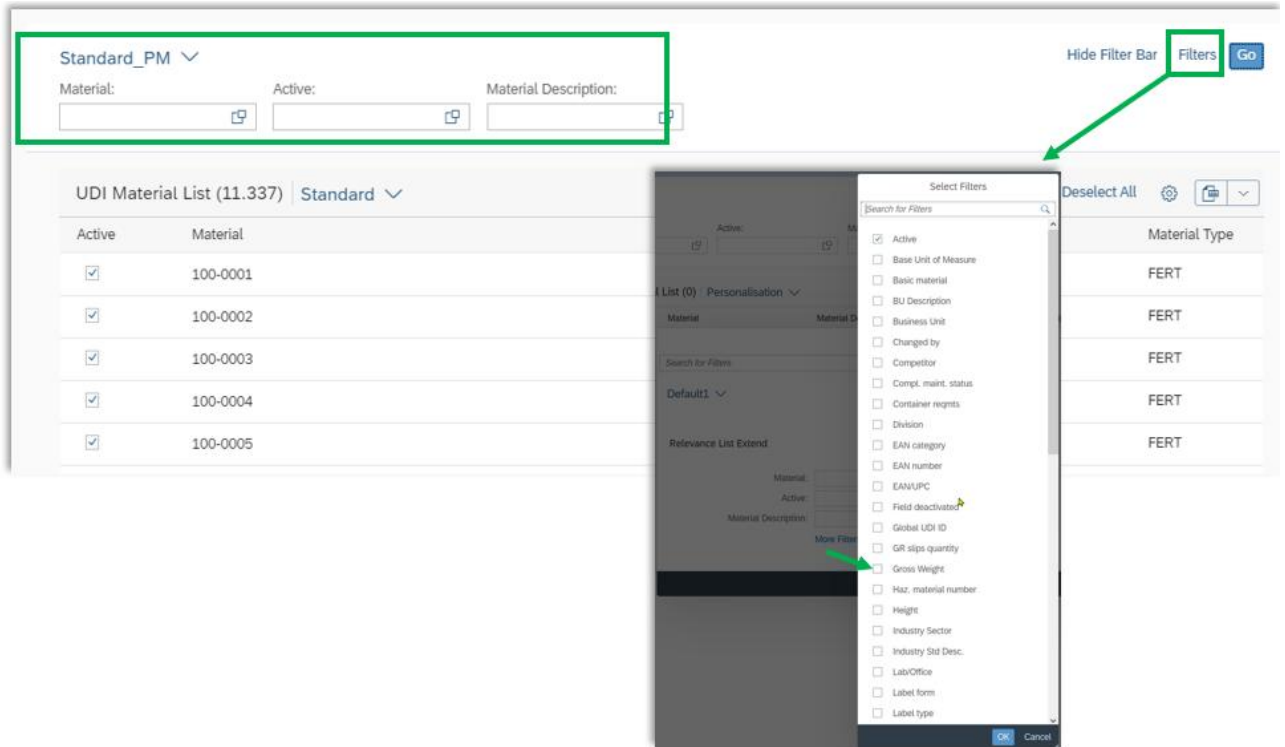
Basic application and code list in the SAP Global UDI Add-On

Info

The authority node e.g. "USA/FDA" or "EUDAMED" is only visible when the related UDI Plugin has been installed in your system

4.3.2 Filter Settings

Within our comprehensive solution, you can utilize the SAP Fiori filter functionality at any time to display specific data. Simply click on the "Filter" link to reveal all available fields.



Customize the display according to your preferences with the Fiori Filter in the SAP Global UDI Add-On

Info

You can save your standard filter selection user based or even as a global default filter.

4.3.3 Column Settings

SAP's default Fiori functionality empowers you to customize the list according to your preferences. There are four primary categories of settings available:

1. Columns

Here, you can select the fields you wish to display in the list and arrange them in your preferred order.

2. Sort

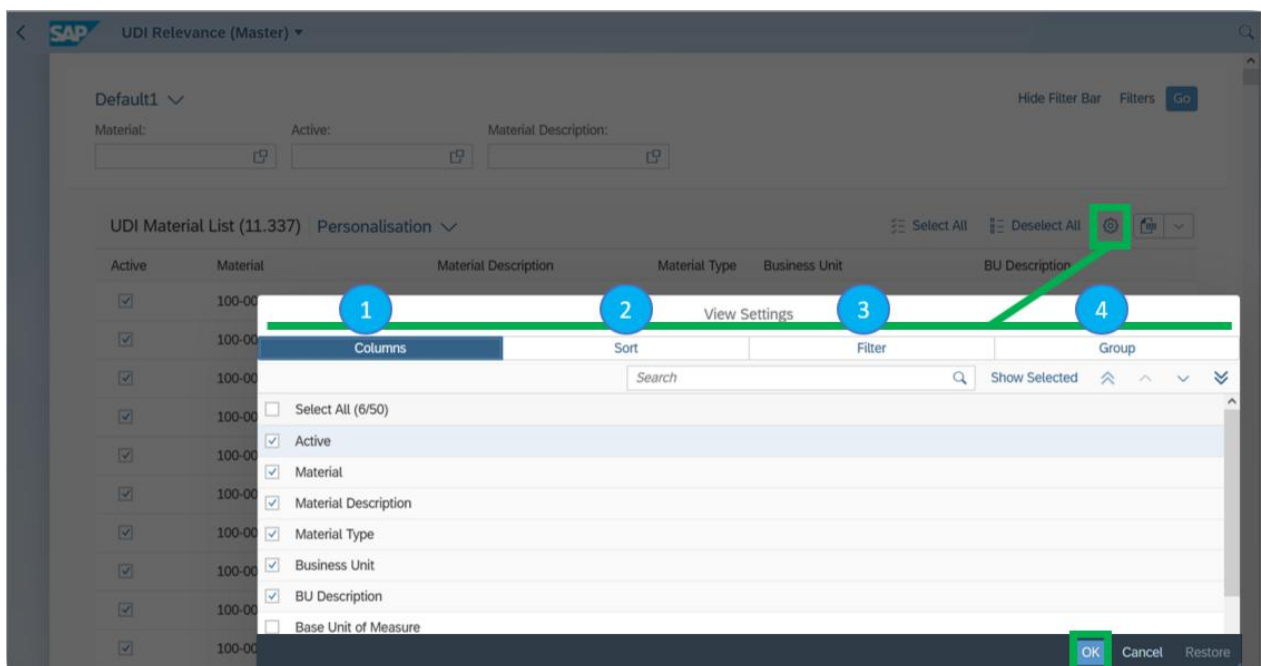
This section allows you to modify the sorting order based on one or more fields, providing flexible data organization.

3. Filter

Here, you can apply predefined filter criteria. Only data meeting these criteria will be displayed in the list, streamlining your view.

4. Group

In this section, you can designate one or more fields for grouping the data. This feature organizes the data based on the selected fields, facilitating a structured overview.




Customize the columns according to your preferences in the SAP Global UDI Add-On

4.3.4 Autorisation & permission settings

In the GUDI application, you can finely configure permissions and controls for individuals within your organization. This functionality enables you to determine which features or modules are accessible to each user through their menu interface. This approach to permission management allows you to precisely define the actions a user can take based on their role and responsibilities within the organization. Each user can be assigned specific permissions that govern their access to certain features or actions within the application. For instance, a system administrator may have broad permissions, allowing them to modify global settings, create and manage user accounts, and access all available features. Conversely, a standard user may be limited to specific functions, such as viewing or maintaining data within the FDA Plugin or Master Data.

For example:



Authority	Display	Change	Release Step 1	Release Step 2	Data Submission
SAP Role 1 (with Release Step 1)	MASTER	Yes	No	No	No
	FDA	No	No	No	No
	EC	Yes	Yes	Yes	No
	NMPA	No	No	No	No
Authority	Display	Change	Release Step 1	Release Step 2	Data Submission
SAP Role 2 (with Release Step 2)	MASTER	Yes	No	No	No
	FDA	No	No	No	No
	EC	Yes	Yes	No	Yes
	NMPA	No	No	No	No

Example of permission and role settings in the SAP Global UDI Add-On

4.4 Business Unit

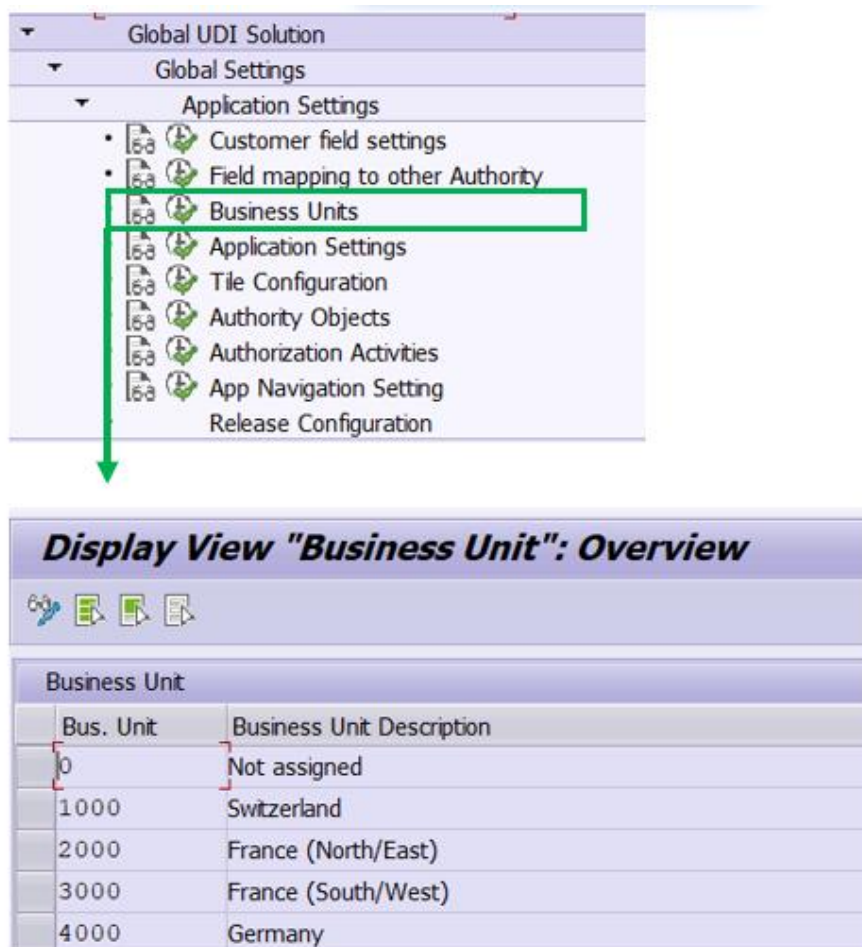
To ensure efficient organization and streamlined access control, you can assign all your materials to various Business Units within the software. So you can separate the data for users with different access control.

4.4.1 Configuration of the Business Unit

Before you can apply Business Units to your materials, you must define the required Business Units within the SAP GUI using Transaction Code SPRO and input all relevant units.

Transaction Code:
SPRO

Additionally, remember to provide descriptions in other necessary languages. To maintain descriptions in different languages, simply log in to SAP in the required language and enter the corresponding description.



The image shows two screenshots from the SAP GUI. The top screenshot is a navigation tree for 'Global UDI Solution' with 'Global Settings' expanded to 'Application Settings'. The 'Business Units' option is highlighted with a green box, and a green arrow points down to the second screenshot. The second screenshot is the 'Display View "Business Unit": Overview' screen, which contains a table with the following data:

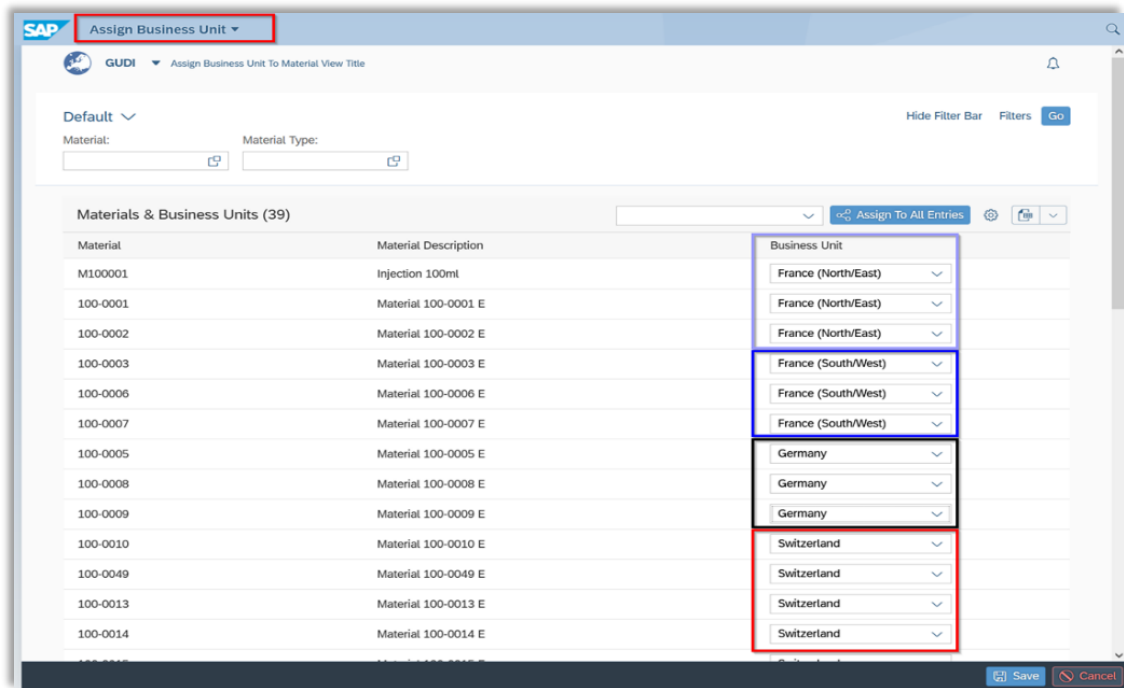
Bus. Unit	Business Unit Description
0	Not assigned
1000	Switzerland
2000	France (North/East)
3000	France (South/West)
4000	Germany

Configuration of a Business Unit in the SAP Global UDI Add-On

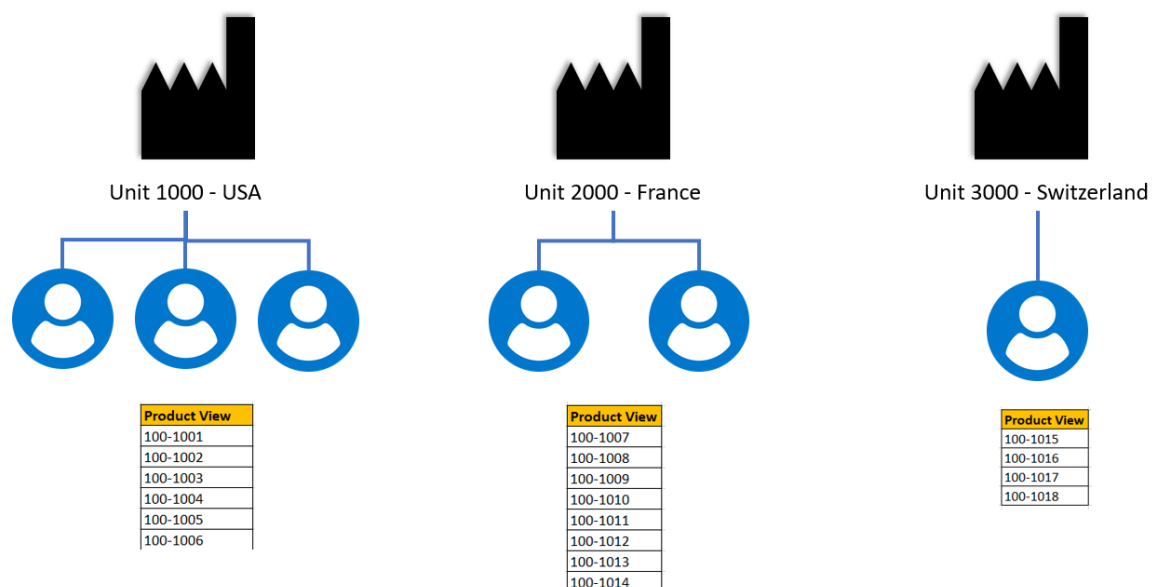
4.4.2 Assigning “Business Units” to materials

The business unit acts as an authorization field, giving users permissions tailored to specific business units. Users granted authorization for particular business units will only have visibility and access to those units, regardless of the filter criteria.

In every Fiori selection list, the business unit is included as both a field and filter criteria. This facilitates the display and maintenance of specific product groups, improving usability and efficiency.



Assigning a Business Unit in the SAP Global UDI Add-On



Assignment of product data to business units

4.5 Monitoring of any data changes – Audit Trail

We've developed features that let you know where you stand and keep track of what has been done and what remains to be done in the overall process.



4.5.1 Audit Trail

In regulated industries such as medical device manufacturing, having an audit trail is crucial for successful validation by auditors. The "Show Audit Trail" application tile is the primary tool within the Global UDI plugin, displaying all recorded data changes. Within this application, you can view all recorded changes in list form. Customize the fields in the settings to display the information relevant to your needs. Clicking on a specific row provides detailed information on a separate screen, allowing for thorough examination of each recorded change.

Change Number	Data area	UTC Time Stamp	Authority	Date	Time	Object Guid	Material	UDI Version	Key field name(s)	Key field value(s)
S254004B97961EED80A3E1EB92009EBF	DATA	20220711134053	MASTER	11.07.2022	15:40:53	S254004B97961EED80A3E1EB92009EBF	M100001	1		
Change indicator: 1 Change type: Insert User Name: DEMII Full Name: Ismail Demiralp Table Name: AUDWLINK Field Name: MATNR Old value: New value: M100001 Business Unit: 0 Business Unit Description: Not assigned										
S254004B97961EED80A3E1EB92009EBF	DATA	20220711134053	MASTER	11.07.2022	15:40:53	S254004B97961EED80A3E1EB92009EBF	M100001	1	AUTHVERSION	MASTERIL
Change indicator: 1 Change type: Insert User Name: DEMII Full Name: Ismail Demiralp Table Name: AUDWVERSION Field Name: AUTH Old value: New value: MASTER Business Unit: 0 Business Unit Description: Not assigned										


Changes made to data are recorded in the audit trail in the SAP Global UDI Add-On

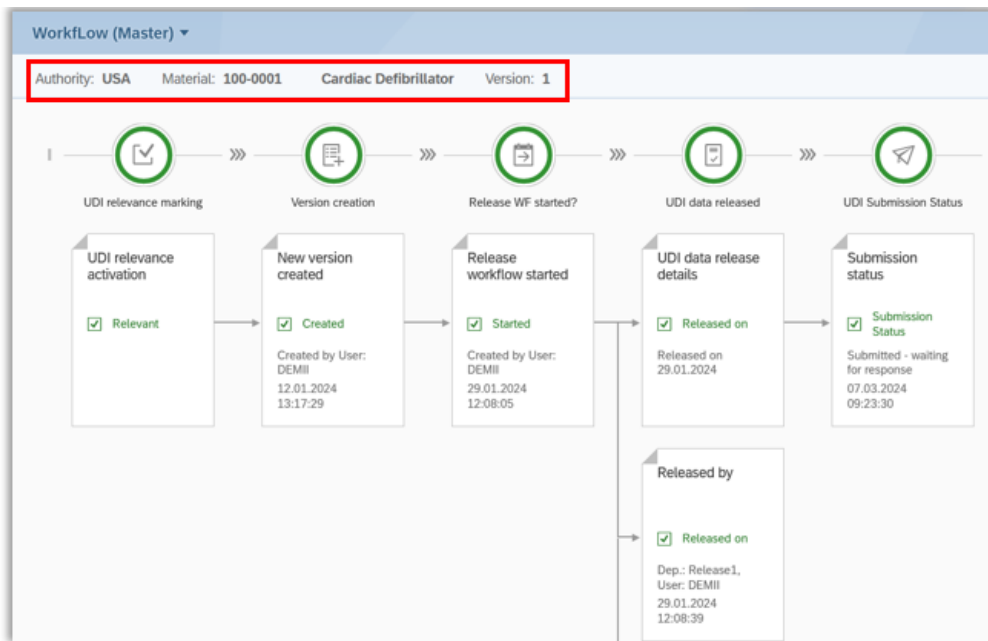
4.5.2 UDI workflow

The workflow application is an essential tool for viewing key information regarding UDI records. Designed solely for viewing purposes, it provides comprehensive details from the moment a record is designated as UDI relevant through to its release and data submission.

There are five status categories for a UDI record:

1. UDI relevant
2. Version created
3. Release workflow started
4. Release status for all departments
5. UDI submission status

 In various material lists, you may come across a specific icon. Clicking on this icon will quickly navigate the application to the corresponding overview for your convenience.



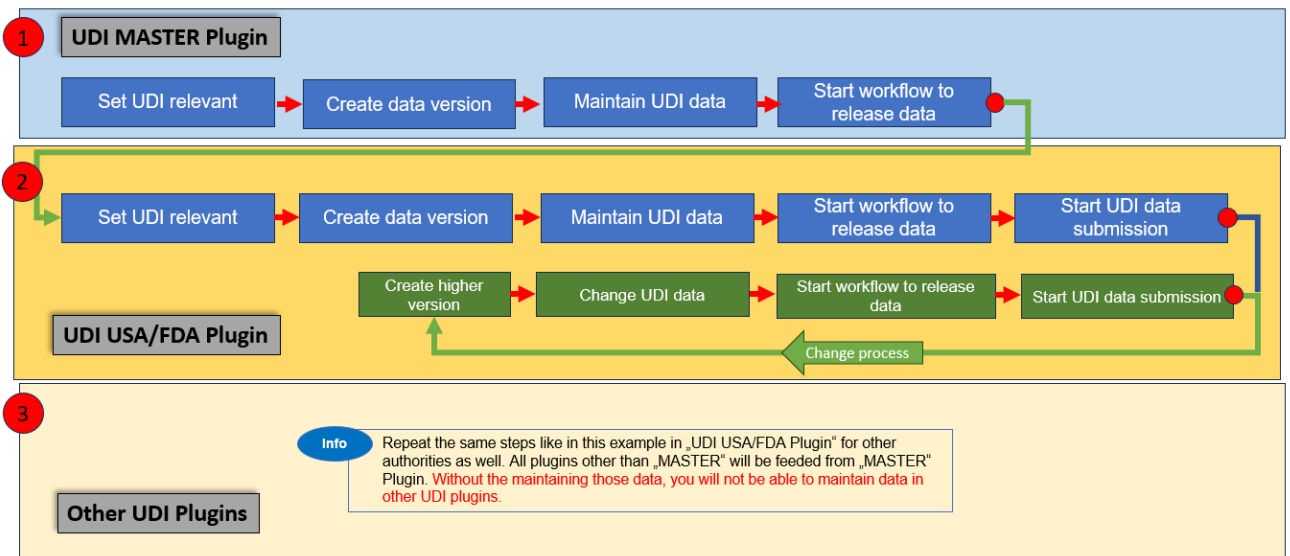
Workflow showing the entire UDI process in the SAP Global UDI Add-On

4.5.3 UDI data management process

This roadmap outlines the steps needed to manage your data efficiently and successfully. Initially, you'll start in the UDI Master Plugin to maintain common data within this menu. After initiating the release workflow, you'll choose the Authority (and consequently, the plugin) to which you wish to submit the UDI data later.

In the selected plugin (for example, FDA in this roadmap), you'll then maintain the specific data of the authority. The common data will be automatically uploaded from the master data to the plugin. This step must be completed for all plugins to which you intend to transfer your data.

After completing these steps, the only task left is to transfer and submit your data to the authorities through the UDI Data submissions process.



Roadmap of UDI Data Management

5 Set UDI Relevance

5.1 Change the material as status to „UDI relevant”

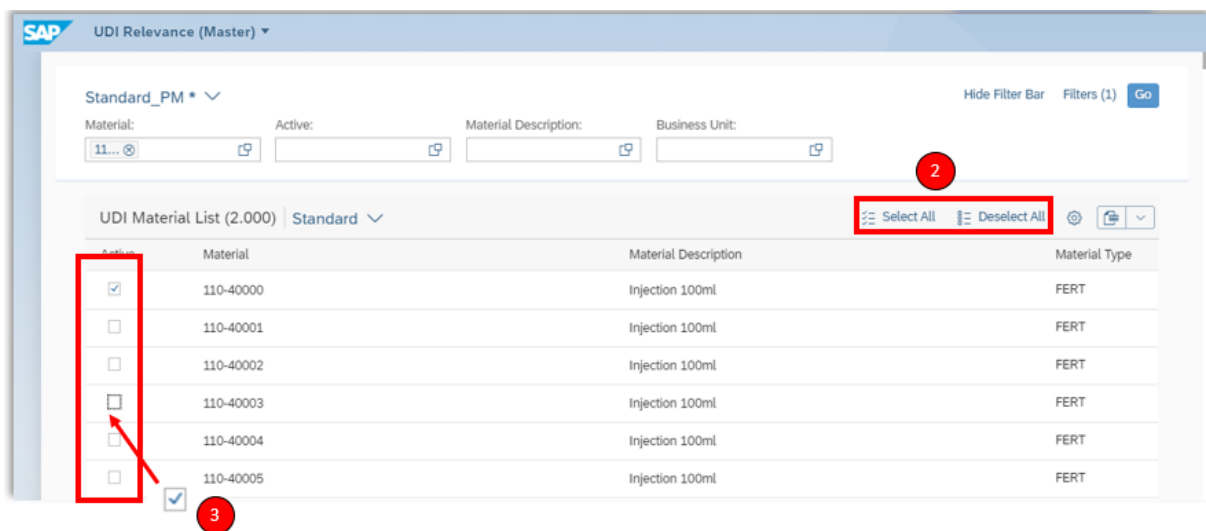


To begin the UDI data management process, the first step is to activate the material as UDI relevant. This step is crucial to ensure the subsequent provision of the necessary UDI information.

Here's how you can proceed:

- 1. Access the "Set UDI Relevance" Application: Begin by accessing the "Set UDI Relevance" application from your Fiori dashboard.**
- 2. View Existing Materials: The application will display all existing materials in your SAP database. If necessary, utilize the filter option to narrow down the list.**
- 3. Activate Materials: Check the "Active" column for each material that needs to be activated or use the button to select multiple materials simultaneously. Once selected, click on the "Save" button to confirm the activation.**

Following these steps ensures that your materials are appropriately marked as UDI relevant, laying the foundation for seamless UDI data management. For efficiency, you may choose to activate all materials at once using the "Select All" option, thus expediting the process.



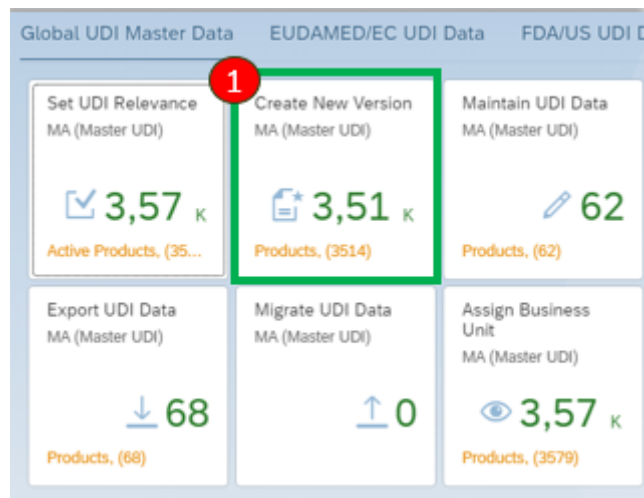
Steps to define UDI as "relevant" in SAP Global Add-On

5.2 Creation of a UDI version

Once you've updated the UDI relevance status, the counter on the Fiori tile "Set UDI Relevance" will automatically reflect the count of all products that have been activated.

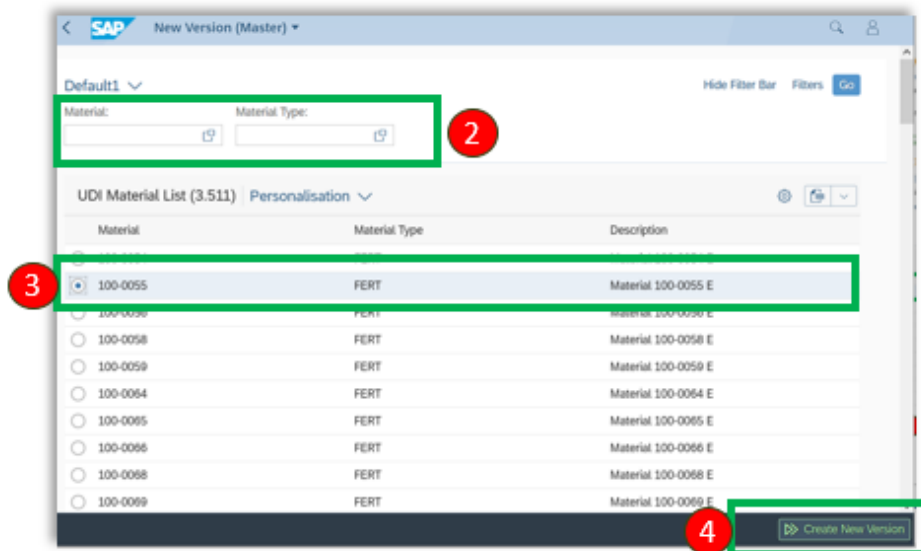
Here's a step-by-step guide for creating a new version for your product:

- 1) Open the "Create a New Version" app & select your desired product.



"Create New Version" Tile in the Fiori Menu

- 2) Input your filter criteria and initiate the selection process.
- 3) Choose the product for which you intend to create a new version.
- 4) Click on the "Create new version" button to proceed.



Steps to create a new version in the SAP Global UDI Add-On

5) Enter the "Valid from" date as a date in the future. The date you enter reflects your local date and time, which is then saved in UTC time format. Other users will view the "valid from" date and time in their local date and time.

6) If you wish to duplicate existing UDI data, input the material number in the "Template Material" field. Otherwise, leave it blank.

Info

You can only enter a template material for the **version 1**. Higher versions are always based on the UDI data of the prior version of the same material.

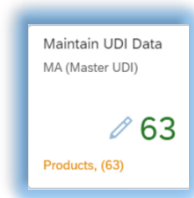
7) Provide details about the previous version of the product.

8) Click the "Create New Version" button to proceed.

The screenshot shows the SAP 'New Version (Master)' form for UDI. The form is divided into two main sections: 'New Version Information' and 'Previous Version Information'. The 'New Version Information' section includes fields for 'Version' (set to 1), 'Valid From' (01.04.2024, 15:00), and 'Template Material'. The 'Previous Version Information' section includes fields for 'Version' (set to 0), 'Released On', 'Valid From', 'Released' (checkbox), and 'Released By'. A 'Create New UDI Version' button is highlighted at the bottom right. Red circles with numbers 5, 6, 7, and 8 are overlaid on the form to indicate the steps described in the text.

Information required to create a new version in the SAP Global UDI Add-On

6.1 Manual data maintenance in Fiori



In this application, you can input all your UDI data conveniently. The user interface (UI) is organized into several data areas, each serving a specific purpose. The available data sections include:

- 1) Material Number and Material Description
- 2) Any validation errors will be displayed. Upon clicking the "Save" or "Validate" buttons, error messages will be updated accordingly.
- 3) New Version Information:
 - You can modify the "Valid from" date if the data has not been released.
 - The "Valid from" date cannot be set in the past; if it is, it will automatically default to the release date.
- 4) Previous Version Information
- 5) UDI data is categorized into different sections. Clicking on the header line will scroll the UI to the selected section. Alternatively, you can utilize the scrollbar to navigate to the desired section.
- 6) You can initiate a validation check at any time to ensure data accuracy. Any errors detected will be displayed in section (2). The "Save" button always triggers validation and saves the UDI data. Lastly, the "Cancel" button allows you to return to the material list without saving any changes.

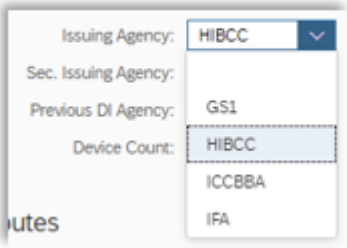
The screenshot shows the 'Maintain UDI Data' Fiori application interface. The top header displays 'GUDI' and 'UDI Maintenance Data'. Below the header, there are input fields for 'Material: 100-0055' and 'Material Description: Material 100-0055 E'. The interface is divided into two main sections: 'New Version information' and 'Previous Version Information'. The 'New Version information' section includes fields for 'Version: 1' and '*Valid From: 01.04.2024, 15:00'. The 'Previous Version Information' section includes fields for 'Version: 0', 'Released On:', and 'Valid From:'. A 'Released:' checkbox and a 'Released By:' field with a 'Show Details' button are also present. Below these sections is a navigation bar with tabs: 'Device', 'Additional Identifiers', 'Attributes', 'Direct Marking', 'Production Information', 'Clinical Sizes', 'Storage & Handling', and 'Packaging Hierarchy'. The 'Device' tab is selected. Below the navigation bar are search fields for 'Device Search Key:', 'Brand Or Trade Name:', 'Device Model Or Version:', 'Device Name Or Catalog No:', 'Issuing Agency:', and 'Primary DI Number:'. At the bottom right, there are three buttons: 'Validate', 'Save', and 'Cancel'.

Data sections in the "UDI Maintenance Data" Menu

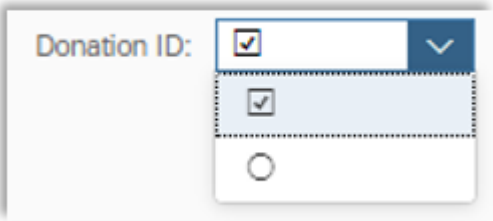
In the data maintenance screen, you can enter your UDI data. The data fields can have different input field types:

- **Text field**
- **Dropdown field**
- **Dropdown boolean field (initial, true, false)**
- **Table**

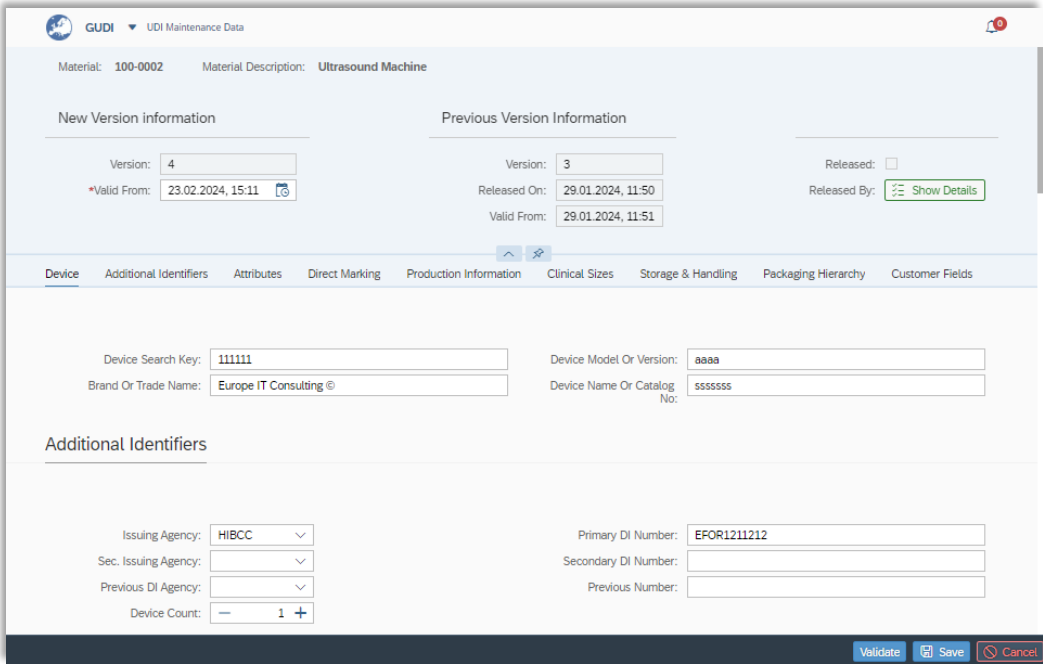
Example for Dropdown field



Example for Dropdown boolean field



Example of data field in the SAP Global UDI Add-On



Example of what the different sections look like once the user has entered the UDI information.

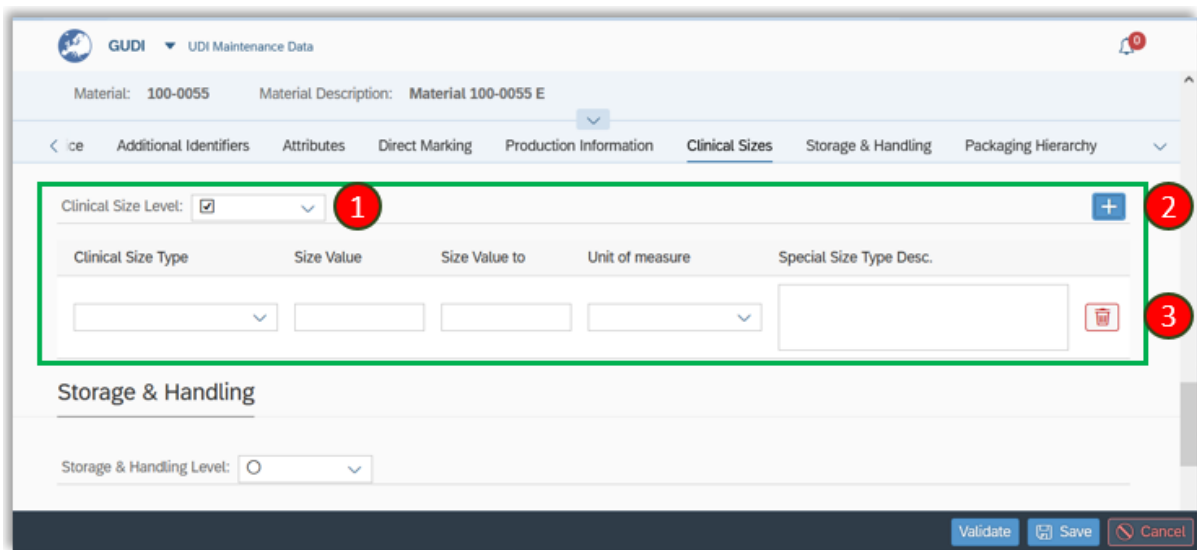
6.1.1 UDI data tables

In certain instances, UDI data must be entered in a table format.

(1) Typically, each table contains a checkbox above it. To utilize the data within the table, you must first activate this checkbox.

(2) To add a new row, simply click on the "+" button.

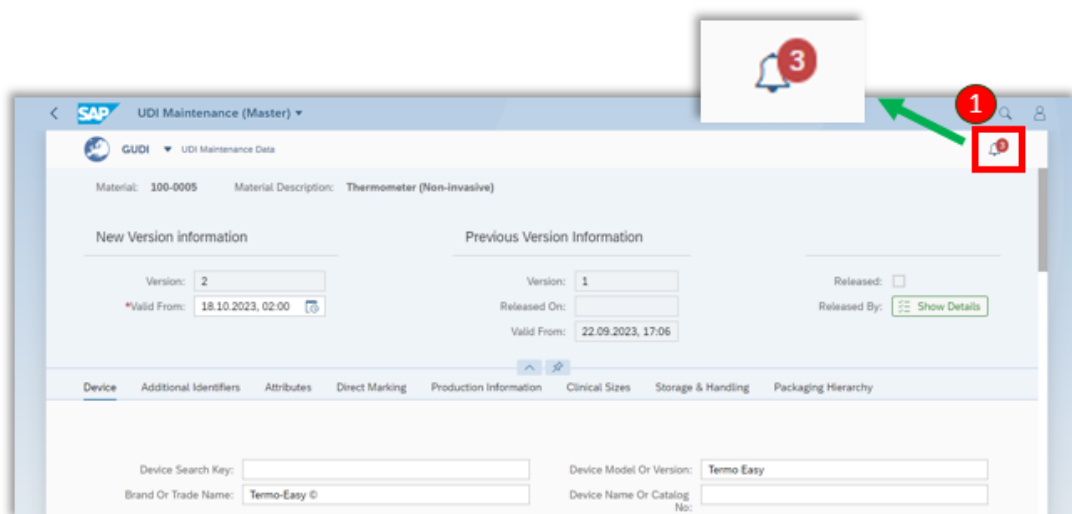
(3) To remove a row, click on the trash button.



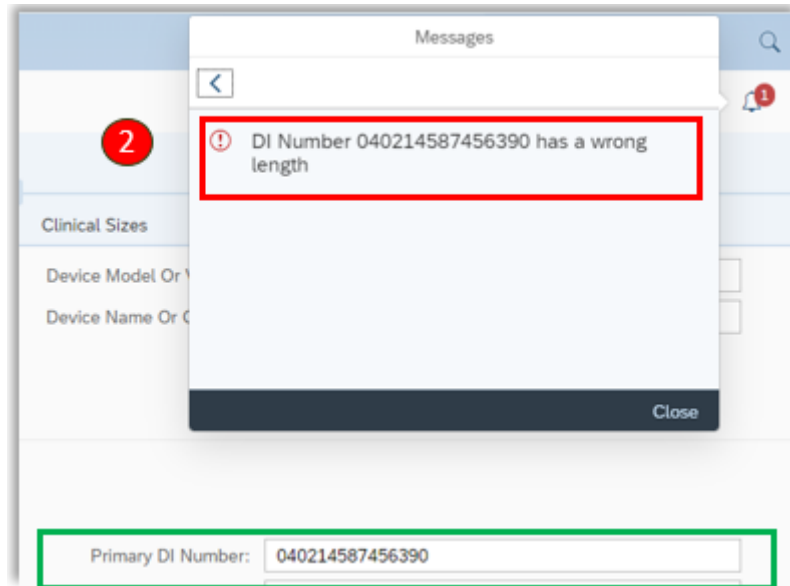
6.1.2 Error messages

To maintain the accuracy of the information you provide; our software includes a data validation check feature.

- You can view the validation results by clicking on the “Bell” icon. (1)

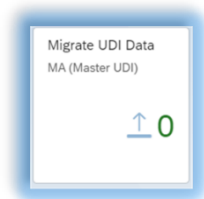


- The red number displayed on the bell icon indicates the number of failed validation checks.
- Clicking on the bell icon will display all validation messages. (2)

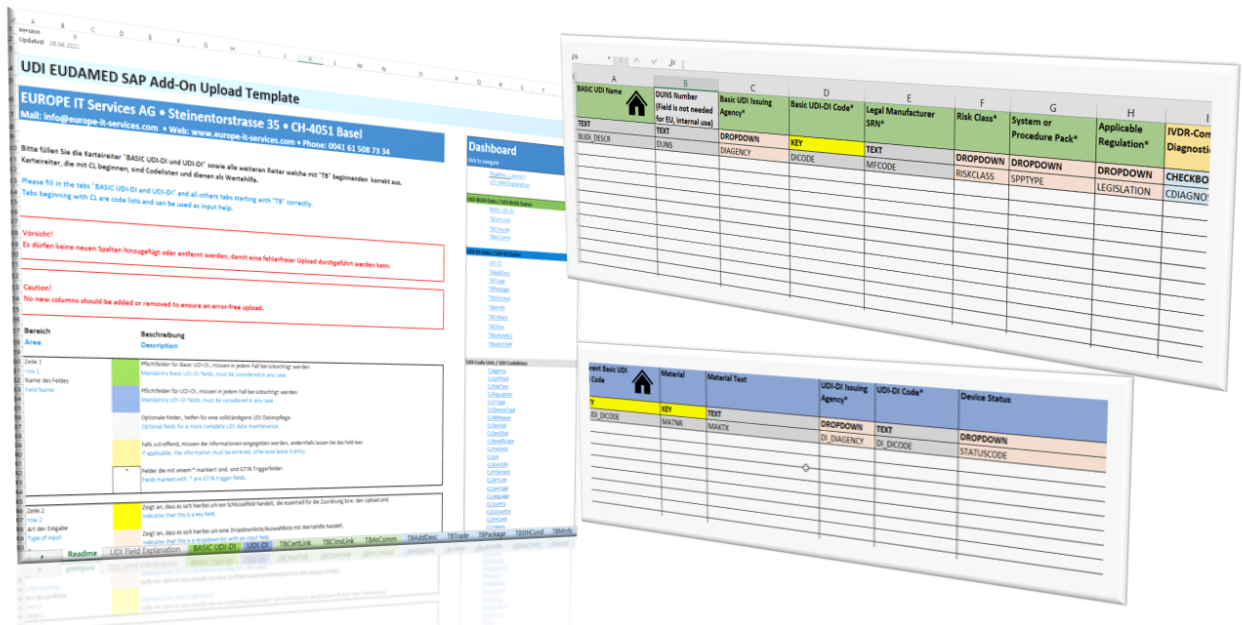


In the following example, the entered GS1 number has an incorrect length

6.2 Mass upload of UDI data using excel template.



Each UDI Plugin comes with its own Excel spreadsheet template, facilitating quick uploads of UDI data. To utilize this feature, it is necessary to have authority in the "Master" plugin for the "Migrate UDI Data" application.



Here are some important instructions for using the Excel spreadsheets provided:

1. Excel Version Indicator:

Located in the upper left corner of the first sheet, you'll find the version of the Excel spreadsheet. Ensure you're using the most recent version, which will be available with every UDI plugin installation or upgrade.

2. Material Number Field:

The material number field serves as the matching code between the data entered in Excel and the SAP system. It's crucial to enter the exact same number to maintain consistency and accuracy.

3. Data Entry Sheets (TB):

Sheets with names starting with "TB" are designated for entering your data. Please input your information only in these sheets to ensure proper organization and functionality.

4. Lookup Tables (CL):

Sheets with names starting with "CL" serve as lookup tables for dropdown fields. These sheets are solely for reference purposes and should not be modified for data entry.

3. Upload Excel File: Once you've filled out the spreadsheet, select the file (3) and initiate the upload process (4).

Upload UDI data from excel spreadsheet

Authorization selection

UDI Authority **1**

- USA | FDA - Federal Drug Administration
- EU_BU | EC - BASIC UDI-DI
- EU_DI | EC - UDI-DI
- MASTER | UDI Master data
- CHINA | NMPA - National Medical Products Admin.

Excel template file download

Upload Excel File

Excel template file download

2 Download Excel for selected authority Please don't remove columns in excel file

Upload UDI data from excel spreadsheet

Authorization selection

UDI Authority **4** MASTER | UDI Master data

Excel template file download

Upload Excel File **3** C:\Temp\Master_Data_Upload.xlsx

Excel template file download

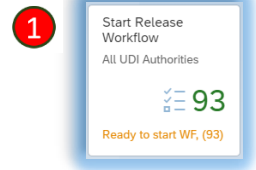
Download Excel for selected authority Please don't remove columns in excel file

The following steps enable you to upload data maintained in Excel to the SAP Global UDI Add-On.

Info

- You can upload UDI data for all your products which have no data yet or overwrite existing data. It is not possible to overwrite udi data for those which are in the middle of a release workflow.
- When you have released data, a new version will be created automatically with the uploaded data.
- For products which are still in maintenance status, the data will be updated in the recent version.

7 UDI data release



7.1 Start release Workflow

Once you have ensured the accuracy of your data and resolved any validation errors, you can initiate the release workflow. This feature is accessible within the "Master" plugin and displays all UDI authority data to which you have authorization.

- To begin, navigate to the "Start Release Workflow" application by selecting the corresponding tile (1).
- Initiate the selection process by clicking the "GO" button. If you prefer to view data for a specific authority, utilize the filter options accordingly.
- Please note that only UDI data without validation errors can be selected (2). Should you need to review the data again, simply click on the respective row to access the maintenance view (3).
- Once you have identified the UDI records for release, mark them by checking the "Workflow Started" checkbox (4), then proceed by clicking the "Start Release Workflow" button (5).

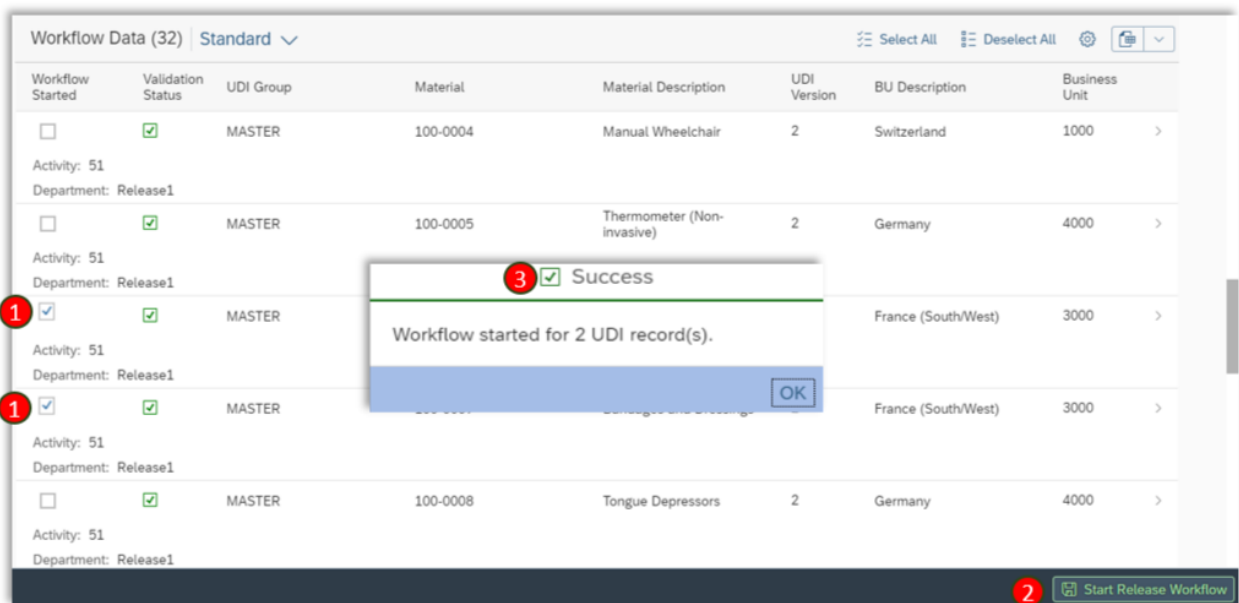
A screenshot of a software interface showing a table of workflow data. The table has columns for 'Workflow Started', 'Validation Status', 'UDI Group', 'Material', 'Material Description', 'UDI Version', 'BU Description', and 'Business Unit'. There are five rows of data. Red circles with numbers 1 through 5 are overlaid on the image to indicate key steps: 1 points to the 'Start Release Workflow' tile; 2 points to a green checkmark in the 'Validation Status' column; 3 points to a chevron icon in the 'Business Unit' column; 4 points to a checkbox in the 'Workflow Started' column; 5 points to a 'Start Release Workflow' button at the bottom right of the table.

Workflow Started	Validation Status	UDI Group	Material	Material Description	UDI Version	BU Description	Business Unit
<input type="checkbox"/>	<input checked="" type="checkbox"/>	MASTER	100-0004	Manual Wheelchair	2	Switzerland	1000
<input type="checkbox"/>	<input checked="" type="checkbox"/>	MASTER	100-0005	Thermometer (Non-Invasive)	2	Germany	4000
<input type="checkbox"/>	<input checked="" type="checkbox"/>	MASTER	100-0006	Blood Pressure Cuff	2	France (South/West)	3000
<input type="checkbox"/>	<input checked="" type="checkbox"/>	MASTER	100-0007	Bandages and Dressings	2	France (South/West)	3000
<input type="checkbox"/>	<input checked="" type="checkbox"/>	MASTER	100-0008	Tongue Depressors	2	Germany	4000

The following steps enable you to start the release Workflow in the SAP Global UDI Add-On.

To release the data, follow these simple steps:

1. Check the box labelled "Workflow started".
2. Click on the "Start Release Workflow" button.
3. Wait for the success notification to appear.



The following steps enable you to start the release Workflow in the SAP Global UDI Add-On.

7.2 Release UDI Data



Once you have initiated the release workflow, the UDI data becomes locked, preventing any further modifications until the data are released or the release workflow is rejected.

The number of departments responsible for the release process may vary depending on the configuration of your SAP system. However, it is essential to have at least one department with at least one user assigned to facilitate the release process.

Within the global settings for the release department, you have the flexibility to configure the release strategy according to your specific needs. For each UDI plugin, you can designate up to 9 departments. Typically, it is recommended to allocate 1 to 3 departments to expedite the release process.

The following settings can be configured:

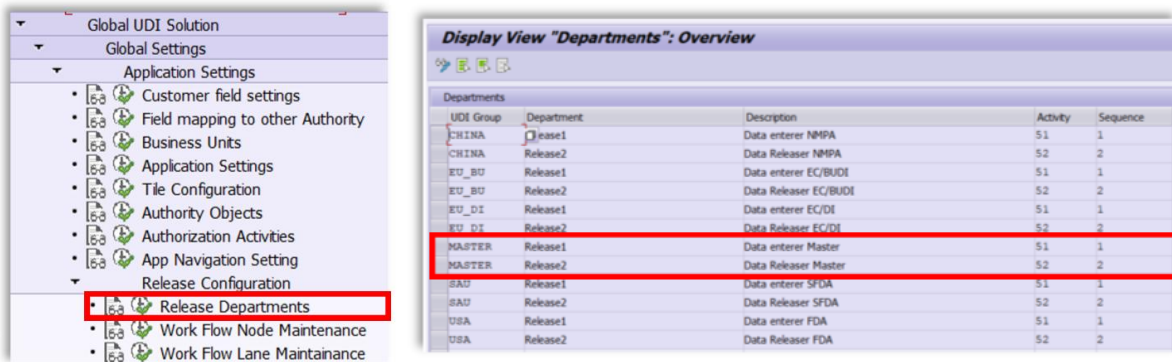
UDI Group: Name of the authority in the plugin (may differ from the original authority).

Department: Name of the department.

Description: Description of the department.

Activity: SAP authorization activity code, with possible values ranging from 51 to 59.

Sequence: The sequence in the release workflow.



Configure the release strategy according to your specific needs in the SAP Global UDI Add-on

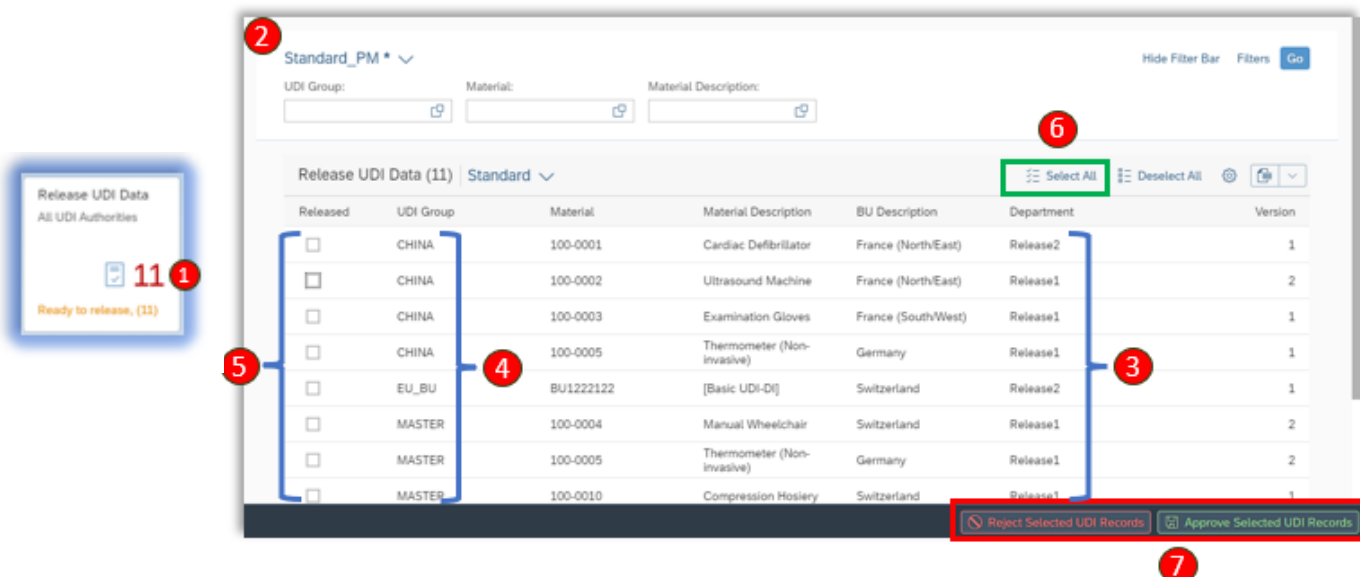
In this application, you will find a counter displayed on the tile, indicating the number of release workflows awaiting your approval (1).

Please note that this counter is personalized based on your user rights, and other users may see a different number. The release application serves as a central hub, providing a comprehensive view of all authorities for which you are authorized. The data are pre-filtered according to the business units to which they are assigned.

In the example depicted in the image on the right (2), the user has authorization for two departments: "Release1" and "Release2" (3), as well as access to multiple UDI authorities such as CHINA, EU, and MASTER (4).

To release UDI records, simply check the "Released" column (5) or utilize the "Select All" (6) button for bulk actions.

Finally, approve or reject the selected UDI records by clicking on the corresponding button (7). The list will be promptly updated, and the entries will be removed. Other users will then see their updated list with the pending release steps.



The following steps enable you to release selected UDI Records in the SAP Global UDI Add-On.

8 Specific Authority

8.1 Plugin Menu

Once you have completed data maintenance in the Master section, you can proceed to access the specific plugin for the selected authority (e.g., FDA).

For each plugin you have to set the material as relevant again for the specific authority. Only materials which has been set as relevant in Master plugin can be set as relevant in any other plugin.

After completing the release step in the Master section, the data will become available in all relevant plugins.

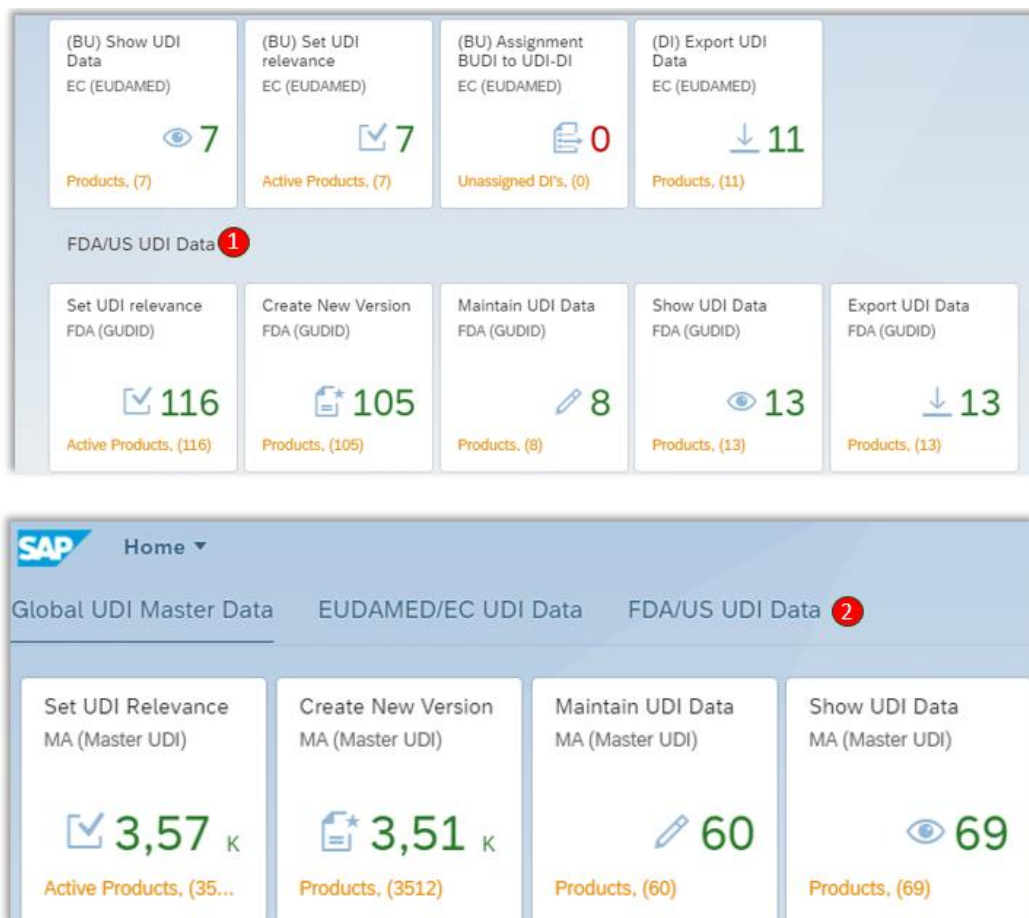
You have two options to access the authority-specific plugin:

Scrolling in the Main Menu (1):

Navigate through the main menu until you locate the desired authority.

Direct Selection from the Top Menu (2):

Click on the authority's name located at the top of the menu to directly access the plugin for that authority.



Plugin Menu in the SAP Global UDI Add-On

When you are within the appropriate plugin, you can initiate the same process as in the Master plugin.

Follow these steps:

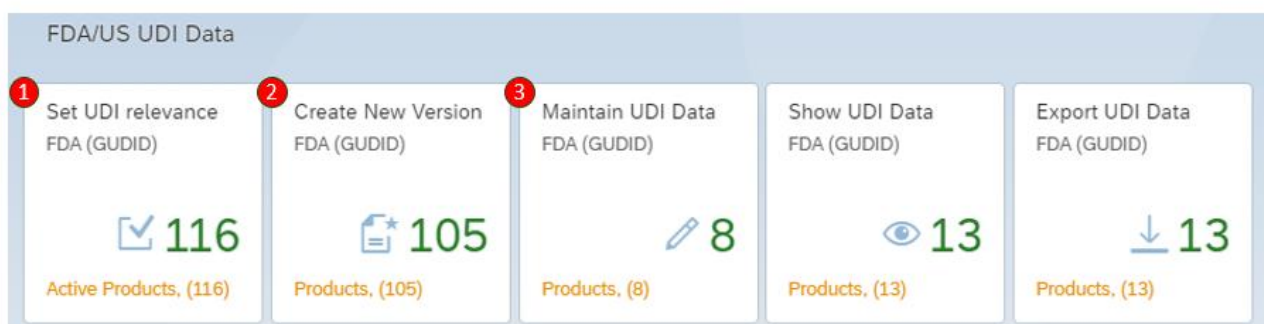
1. **Scroll to the right authority group.**
2. **Set the material as “UDI Relevant” (Page 15)**
3. **Create new version (Slide 16)**
4. **Maintain your UDI data (Slide 18)**
5. **Release workflow and data submission should started using the applications in the “Master” plugin.**

The common data will be retrieved from the Master data. In the customizing you can decide which data section will be used in other authority. Those data only changeable on in the Master maintenance screen.

The only variation is that authorisation-related information such as FDA (Food and Drug Administration) data is maintained in the respective plugin instead of general data as in the master menu.

This means that the data in each plugin is updated and managed specifically for the regulatory requirements of the respective instance.

The plugins always use the data from the last released version in the master data. This means that the data released in the master data is automatically copied for all other plugins. This is used to ensure consistent and up-to-date data utilisation.



Maintain your data in the plugin for the selected authority (here: FDA / US)

It is important to note that this process must be repeated for each plugin/authority for which data is to be submitted. Each plugin may have different requirements and specifications, so it is necessary to carry out the process for each individual plugin;

8.2 Release the new UDI Data

After you have entered all the necessary information required by the authority, **return to the Master menu (1)**.

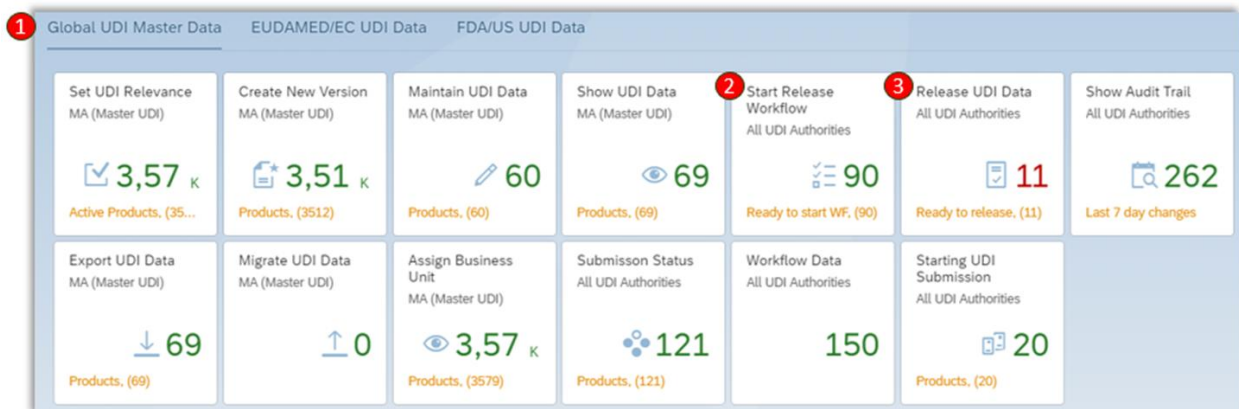
As new information has been added to the material, it is imperative to commence a new release process. This process can proceed in the same manner as before.

(2) "Start Release Workflow" (Page 25)

To begin the release workflow, the system locks the UDI data, preventing any alterations until the release process is complete. This security measure ensures data integrity throughout the release procedure. Simultaneously, a new entry is generated in the "Release UDI Data" section, marking the initiation of the release process. This entry serves as a dedicated space for managing and finalizing the release of UDI data, providing a structured workflow for efficient completion.

(3) "Release UDI Data" (Page 26)

After initiating the release workflow, a new entry appears for the authorized personnel, allowing them to review and finalize the UDI data. At this stage, they have the option to release the data if it meets the necessary criteria or reject it if there are any issues or inaccuracies. Once the data is fully released, it will be removed from the workflow, indicating completion. However, if the data is rejected, it can be accessed again for further maintenance or corrections before resubmission.




Release the new data by repeating the release procedure in the Master menu.

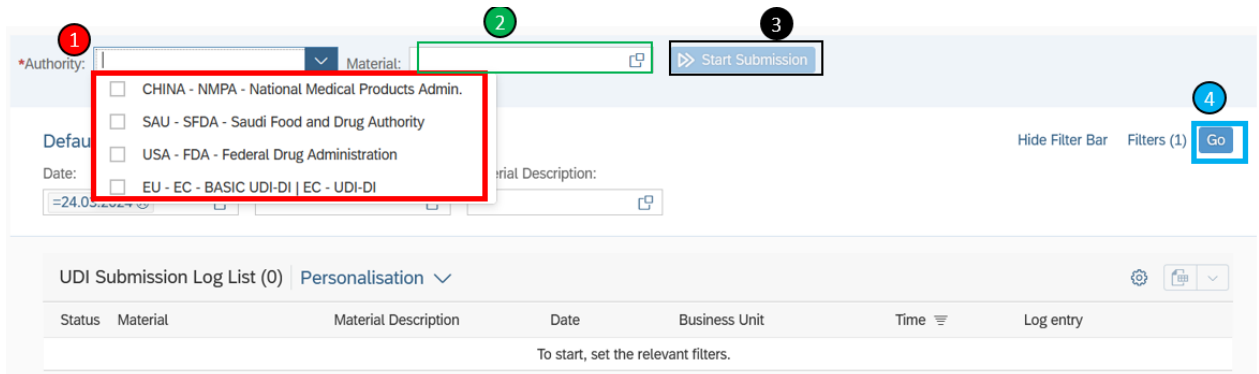
9 UDI Data submission

9.1 Data submission



You are now ready to begin the data transfer process to your desired authority. Follow these steps:

- (1) Navigate to the "Authority" section and select the appropriate authority to which you intend to submit the data.
- (2) In the "Material" section, select the specific material you wish to submit by clicking on the corresponding icon. 
- (3) Once you have made your selections, click on the "Start Submission" button to initiate the data transfer.
- (4) By clicking on "Go" button the log entry about the recent status of the submission will be listed below



Starting UDI submission in the SAP Global UDI Add-On

Start by clicking on the symbol, which will open a new page for you.

Here, you'll be able to select all the materials you wish to submit. Feel free to choose multiple items at once - just click on each one to include it in your selection. Don't forget to click "OK" to save your choices.

With your materials selected and saved, it's time to initiate the submission process. Simply click on "Start Submission" to proceed.

Material

SELECT FROM LIST DEFINE CONDITIONS

Go

Items

<input type="checkbox"/>	Material	Material Description
<input type="checkbox"/>	100-0001	CARDIAC DEFIBRILLATOR
<input type="checkbox"/>	100-0002	ULTRASOUND MACHINE
<input type="checkbox"/>	100-0003	EXAMINATION GLOVES
<input type="checkbox"/>	100-0004	MANUAL WHEELCHAIR
<input type="checkbox"/>	100-0005	THERMOMETER (NON-INVASIVE)
<input type="checkbox"/>	100-0006	BLOOD PRESSURE CUFF
<input type="checkbox"/>	100-0007	BANDAGES AND DRESSINGS
<input type="checkbox"/>	100-0008	TONGUE DEPRESSORS

∨ No items selected

OK Cancel

*Authority: Material: Start Submission

The following steps enable you to start the submission.

9.2 Submission status



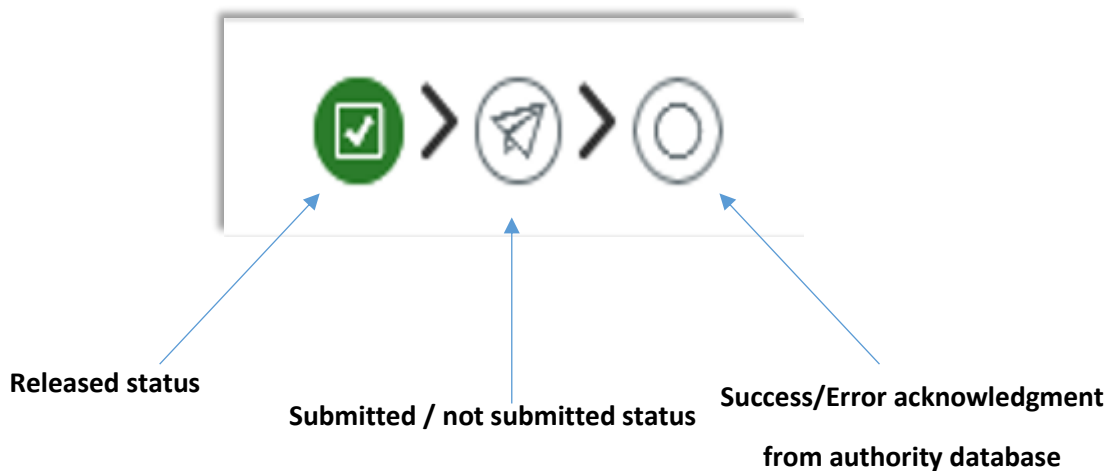
In this dedicated section, you'll find the Submission status feature, offering you a streamlined view of the data you've already submitted. This convenient overview allows you to track the progress of your submissions immediately, ensuring you stay informed every step of the way.

Status	Material	Material Description	Material Type	Released	UDI Version
🟢 > 🟡 > 🟠	100-0001	Material 100-0001 E	FERT	No	1
🟡 > 🟠 > 🟢	100-0001	Material 100-0001 E	FERT	No	6
🟢 > 🟡 > 🟠	100-0002	Material 100-0002 E	FERT	Yes	1
🟡 > 🟠 > 🟢	100-0002	Material 100-0002 E	FERT	No	3
🟡 > 🟠 > 🟢	100-0003	Material 100-0003 E	FERT	No	3
🟡 > 🟠 > 🟢	100-0004	Material 100-0004 E	FERT	No	1
🟡 > 🟠 > 🟢	100-0004	Material 100-0004 E	FERT	No	1
🟡 > 🟠 > 🟢	100-0005	Material 100-0005 E	FERT	No	2
🟡 > 🟠 > 🟢	100-0006	Material 100-0006 E	FERT	No	2

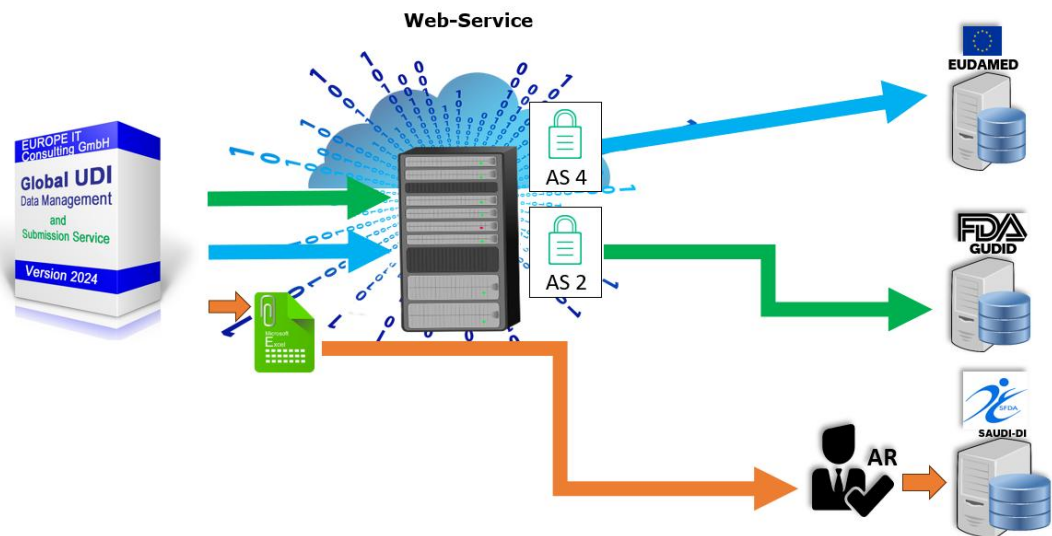
On the left side of the screen, you can see the three different stages of the submission represented by three different icons.

Color coding:

- Blue:** Ready
- Green:** Success
- Yellow:** Warning or waiting
- Red:** Error



These icons allow you to see whether the data transfer has been completed or if there are remaining steps to validate.



UDI Data Submission Gateway / Outgoing connection – no open Port or VPN needed.

As a technology company, Europe IT Consulting offers a service to transform UDI data into the HL7 SPL format and submit it to the authorities.

→ This allows you to interact with the authorities securely, with less pain and cost.

With our SAP Global UDI Add-On, you can directly export and upload the data from your ERP system to our cloud server.

You will receive confirmation of successful upload to our cloud server directly through a RESTful Webservice.

The SAP Global UDI Add-On then automatically checks the status of the data transfer and the status on the regulatory authority's database in the background, keeping you always up to date.