

UDI Add-On for FDA manual - Version 2021/06

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1 Change history

| Version | Date | Description |
|---------|------------|---|
| 1.4 | 05.01.2019 | UDI record creation with templates has been added |
| 1.4 | 05.01.2019 | UDI Online functionality has been added |
| 1.5 | 20.04.2020 | Namespace changed to /UDI/ |
| 1.6 | 02.04.2020 | Revision |
| 1.7 | 26.05.2020 | Adjustment release |
| 1.8 | 13.07.2020 | Description Area menu added |

2 Support und contact information

A support request is usually made by e-mail.

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3 Introduction

The UDI SAP Add-On enables the maintenance of UDI fields in SAP, the characteristics of which have been defined by the American health authority FDA.

According to the regulatory requirements of the FDA, all medical products imported into the USA must be recorded in the GUDID (Global UDI Database) in the future.

The UDI SAP Add-On offers companies the management of UDI master data in SAP and also enables digital data transfer to the GUDID using a Webservice.

The UDI Add-On is divided into three areas.

1) **Code lists**

Within these SAP transactions, default values are defined, which later serve as selection aids in the UDI master data maintenance. For this purpose, value ranges are defined for units as well as approval data acquired by the respective company (e.g. 510k approval, listing numbers, product codes, etc.).

The captured values in the code lists support the user for faster data entry. In addition, the captured values are checked against them during data export and data transfer.

2) **UDI application settings**

In this area, basic settings of the application are made. These concern the UDI maintenance transaction, the authorizations and the layout of the UDI status log.

3) **UDI transactions**

This category includes all applications where you can maintain, evaluate, release and export the UDI attributes.

4 Structure of the transactions

All available transactions are listed in the transaction SPRO -> SAP Reference IMG under the entry "UDI Add-On (US - FDA) - Europe IT Consulting GmbH".

To facilitate your daily work, you can store the transactions you need most in the favorites area of the SAP user menu.

In addition, it is possible to call up an area menu that displays an overview of all transactions. This can be activated by the transaction **/n/UDI/US**, which must also be entered in the SAP user menu.

| UDI Add-On (FDA) - Europe IT Consulting GmbH | |
|--|----------------------|
| Code listen | |
| • DUNS number of the company | Z_MM_CL_DUNS |
| • UDI contact person | Z_MM_CL_CONTACT |
| • UDI Issuing Agency | Z_MM_CL_AGENCY |
| • UDI sterilization methods | Z_MM_CL_SMETHOD |
| • GMDN Code | Z_MM_CL_GMDN |
| • UDI FDA Product Code | Z_MM_CL_PRODUCT |
| • FDA Listing Number | Z_MM_CL_LISTING |
| • FDA Premarket Submission Number (510k) | Z_MM_UDI_PREMARKE |
| • UDI MRI Safety | Z_MM_CL_MRI |
| UDI Clinical Size Types | |
| • UDI Clinical Size Types | Z_MM_CL_CLINICAL |
| • UDI Clinical Size Unit of Measurement | Z_MM_CL_CLINICALX |
| UDI Storage & Handling Types | |
| • UDI Storage & Handling Types | Z_MM_CL_SH |
| • UDI Storage & Handling Unit of Measurement | Z_MM_CL_SHX |
| UDI Applikationseinstellungen | |
| • UDI maintenance transaction field settings | Z_MM_UDI_FLD_CTRL |
| • UDI printout settings | Z_MM_UDI_PRT_SETT |
| • UDI authority settings | Z_MM_UDI_AUTH |
| • UDI Online Funktionen konfigurieren | Z_MM_UDI_ONL |
| UDI Transaktionen | |
| • UDI data creation with template | Z_MM_UDI_AMV |
| • UDI master data maintenance | Z_MM_UDI_DATA |
| • UDI master data list view | Z_MM_UDI_VIEW02 |
| • UDI mass maintenance | Z_MM_UDI_MASS |
| • UDI Reminder | Z_MM_UDI_REMINDER |
| • UDI master data file export | Z_MM_UDI_EXPORT |
| • UDI Audit trail | Z_MM_UDI_AUDIT |
| • UDI data migration / excel upload | Z_MM_UDI_UPLOAD |
| • UDI Daten Upload per Webservice | Z_MM_UDI_TRANSFER |
| • UDI Status Update Report | Z_MM_UDI_STATUS_UPD |
| • UDI Online status check program | Z_MM_UDI_STATUS_TEST |

5 Code lists

The code lists support you in your daily work. All available entries in the code lists will be displayed in the maintenance transactions as dropdown list. Additionally, these values also have an influence on data export and data upload.

| UDI Add-On (FDA) - Europe IT Consulting GmbH | |
|--|----------------------|
| Codelisten | |
| • DUNS number of the company | Z_MM_CL_DUNS |
| • UDI contact person | Z_MM_CL_CONTACT |
| • UDI Issuing Agency | Z_MM_CL_AGENCY |
| • UDI sterilization methods | Z_MM_CL_SMETHOD |
| • GMDN Code | Z_MM_CL_GMDN |
| • UDI FDA Product Code | Z_MM_CL_PRODUCT |
| • FDA Listing Number | Z_MM_CL_LISTING |
| • FDA Premarket Submission Number (510k) | Z_MM_UDI_PREMARKE |
| • UDI MRI Safety | Z_MM_CL_MRI |
| UDI Clinical Size Types | |
| • UDI Clinical Size Types | Z_MM_CL_CLINICAL |
| • UDI Clinical Size Unit of Measurement | Z_MM_CL_CLINICALX |
| UDI Storage & Handling Types | |
| • UDI Storage & Handling Types | Z_MM_CL_SH |
| • UDI Storage & Handling Unit of Measurement | Z_MM_CL_SHX |
| UDI Applikationseinstellungen | |
| • UDI maintenance transaction field settings | Z_MM_UDI_FLD_CTRL |
| • UDI printout settings | Z_MM_UDI_PRT_SETT |
| • UDI authority settings | Z_MM_UDI_AUTH |
| • UDI Online Funktionen konfigurieren | Z_MM_UDI_ONL |
| UDI Transaktionen | |
| • UDI data creation with template | Z_MM_UDI_AMV |
| • UDI master data maintenance | Z_MM_UDI_DATA |
| • UDI master data list view | Z_MM_UDI_VIEW02 |
| • UDI mass maintenance | Z_MM_UDI_MASS |
| • UDI Reminder | Z_MM_UDI_REMINDER |
| • UDI master data file export | Z_MM_UDI_EXPORT |
| • UDI Audit trail | Z_MM_UDI_AUDIT |
| • UDI data migration / excel upload | Z_MM_UDI_UPLOAD |
| • UDI Daten Upload per Webservice | Z_MM_UDI_TRANSFER |
| • UDI Status Update Report | Z_MM_UDI_STATUS_UPD |
| • UDI Online status check program | Z_MM_UDI_STATUS_TEST |

5.1 DUNS number of the company

The DUNS number is a globally unique number assigned to your company by Dun&Bradstreet. This number is mandatory if you want to capture your UDI data and upload it to GUDID.

| Display View "Labeler DUNS number": Overview | |
|---|---------------------------|
| Labeler DUNS number | |
| DUNS no. | Description |
| 486212074 | Europe IT Consulting GmbH |

If you do not yet have a DUNS number or do not know it, you can apply for or search for a DUNS number on the <https://www.upik.de/> website.

Please enter here all DUNS numbers of your company for which you want to collect medical device data. If you distribute your products through a partner company, but you are responsible for the data, the DUNS number of the partner company should also be entered and later linked to the product during data entry.

The description text of the DUNS number is only for a better distinction during the input. The address information and company name will be synchronized via the **Dun&Bradstreet** database after the upload to the GUDID.

5.2 UDI contact person

In this transaction you enter the contact information phone and email address for the respective product. Currently, only one phone number and one e-mail address can be assigned per item. Alternatively, you can leave the two optional fields blank, as they are not mandatory for the GUDID.

Enter the phone number either in the American format or in the international format.

Ex: +41(800)123-4567 or +41(800)12345678

This information will also be visible on the GUDID later.

5.3 Issuing Agency

The Issuing Agency code list is used to enter the organizations that will be used for the globally unique numbering of your products.

You should only enter the organization that is used by your company or by that of your partner company.

Recognized Issuing Agencies are:

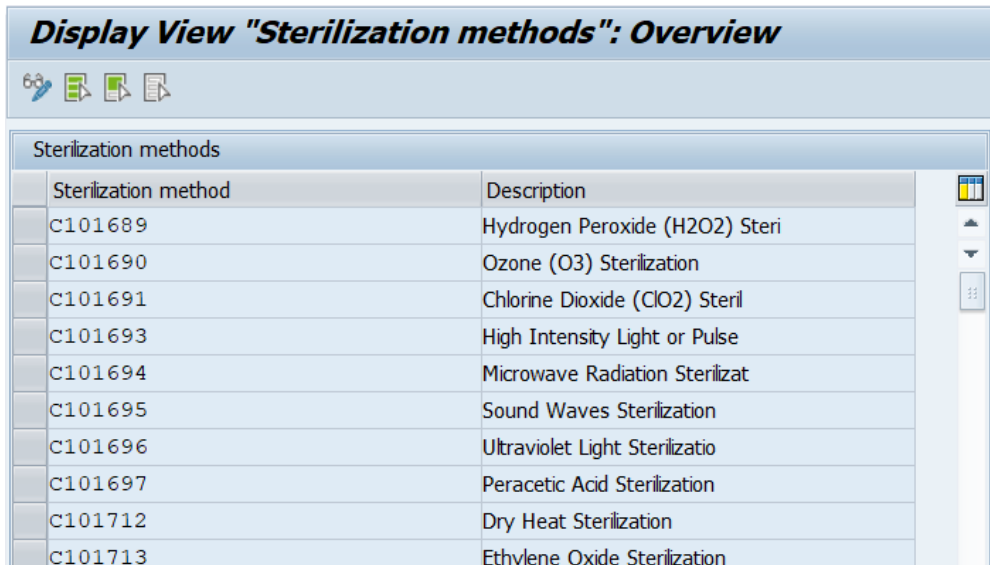
- GS1
- HIBCC
- ICCBBA
- NDC (only allowed as "Secondary Issuing Agency")

| Display View "Issuing Agency": Overview | |
|--|---|
| Issuing Agency | |
| Iss.Agency | Description |
| GS1 | Global Standards 1 |
| HIBCC | Health Industry Bar Code |
| ICCBBA | International Council for Commonality in Blood Banking Automation, Inc. |
| NDC | National Drug Code Directory |

5.4 UDI sterilization method

There are sterilization methods predefined by the FDA. These should be listed here. The code for the sterilization methods later plays an important role in an XML export, so that the generation of a valid HL7 XML data set is possible.

Display View "Sterilization methods": Overview



The screenshot shows a software interface titled "Display View 'Sterilization methods': Overview". It features a toolbar with icons for search, refresh, and print. Below the toolbar is a table with two columns: "Sterilization method" and "Description". The table lists ten different sterilization methods with their corresponding codes. On the right side of the table, there are navigation controls including a scroll bar and a refresh icon.

| Sterilization method | Description |
|----------------------|--------------------------------|
| C101689 | Hydrogen Peroxide (H2O2) Steri |
| C101690 | Ozone (O3) Sterilization |
| C101691 | Chlorine Dioxide (ClO2) Steril |
| C101693 | High Intensity Light or Pulse |
| C101694 | Microwave Radiation Sterilizat |
| C101695 | Sound Waves Sterilization |
| C101696 | Ultraviolet Light Sterilizatio |
| C101697 | Peracetic Acid Sterilization |
| C101712 | Dry Heat Sterilization |
| C101713 | Ethylene Oxide Sterilization |

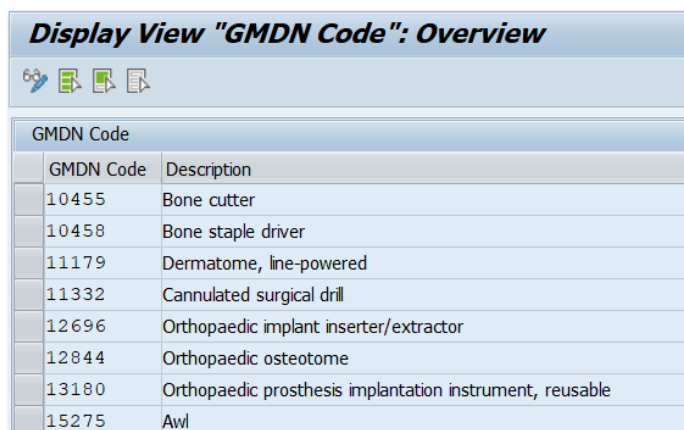
5.5 GMDN Codes

The GMDN organization defines the GMDN codes and their meaning. Currently, there are about 260 (as of 2018) GMDN codes. Your company will only need a few of these GMDN codes. You should only enter the codes that you really need. Additional GMDN codes can be added later.

From time to time, some codes are declared invalid by the GMDN Agency and replaced with new codes.

For more information, please visit the website <https://www.gmdnagency.org>

Display View "GMDN Code": Overview



The screenshot shows a software interface titled "Display View 'GMDN Code': Overview". It features a toolbar with icons for search, refresh, and print. Below the toolbar is a table with two columns: "GMDN Code" and "Description". The table lists eight different GMDN codes with their corresponding descriptions. On the right side of the table, there are navigation controls including a scroll bar and a refresh icon.

| GMDN Code | Description |
|-----------|--|
| 10455 | Bone cutter |
| 10458 | Bone staple driver |
| 11179 | Dermatome, line-powered |
| 11332 | Cannulated surgical drill |
| 12696 | Orthopaedic implant inserter/extractor |
| 12844 | Orthopaedic osteotome |
| 13180 | Orthopaedic prosthesis implantation instrument, reusable |
| 15275 | Awl |

5.6 UDI FDA product code

The FDA Product Codes is used to classify your products. Enter the product codes you need for your products here.

| Display View "FDA Product Code": Overview | |
|--|-------------------------------------|
| | |
| FDA Product Code | |
| Prod.Code | Description |
| EXW | Extra Product code |
| FSM | Tray, Surgical, Instrument |
| FTY | Tape, Measuring, Rulers And Calpers |
| FZO | Chisel, Surgical, Manual |
| FZT | Cutter, Surgical |
| FZX | Guide, Surgical, Instrument |
| FZY | Hammer, Surgical |

5.7 FDA listing numbers

For a registered medical device, a registration number, owner/operator number, and listing number(s) must be provided to facilitate shipment of the device to the United States. However, the listing number(s) for medical devices are not publicly available.

| Display View "FDA Listing Number": Overview | |
|--|-------------------------|
| | |
| FDA Listing Number | |
| List.no. | Description |
| A866814 | FDA Listing No. Example |
| A896206 | Test2 |
| D201354 | Test1 |

5.8 FDA premarket submission number (510k)

The Abbreviated 510(k) is a process built on compliance and adherence to standards, "Special Controls" and FDA "Guidance Documents".

Change View "FDA Premarket Submission (510k Number)": Overview

New Entries

| FDA Premarket Submission (510k Number) | |
|--|-------------|
| Prem.No. | Description |
| K123347 | Test |
| K140962 | Test |
| K151407 | Test |
| K151708 | Test |
| K152256 | Test |
| K152312 | Test |
| K914476 | Test |
| K982664 | Test |

5.9 UDI MRT safety

The MRI Safety values are specified by the FDA. Currently, only 4 values exist. These also serve as a selection list for data acquisition.

In conjunction with the C codes, the prerequisite for generating an HL7 XML file is given.

Display View "MRI Safety": Overview

| MRI Safety | | |
|-------------|---------|-----------------------------------|
| MRI Safety* | C-Code | Description |
| CONDITIONAL | C106046 | MR Conditional |
| SAFE | C106045 | MR Safe |
| UNSAFE | C106047 | MR Unsafe |
| UNSPEC | C113844 | Labeling does not contain MRI Saf |

5.10 Clinical Size Type and Clinical Size Type Unit of measure

The clinical sizes describe the shape of the medical device. If clinical sizes are printed on the label of the product, they should also be included in the data collection.

Display View "Clinical Size Types": Overview

| Clinical Size Types | | |
|---------------------|---------|------------------------|
| Clinical Size | C-Code | Description |
| ANGLE | C67505 | Angle |
| AREA | C25244 | Area/Surface Area |
| ATHER_CUTT_DIAM | C150233 | Atherectomy Cutter L |
| ATHER_CUTT_LEN | C150230 | Atherectomy Cutter L |
| ATHER_ROTAT_DIA | C150244 | The diameter of the r |
| ATHER_ROTAT_LEN | C150243 | The length of the rot |
| ATH_DEV_T_LEN | C150200 | Atherectomy Device |
| BALLOON_CATH_T_LEN | C150163 | Balloon Catheter Tip L |
| BALLOON_DIA | C150145 | Balloon Diameter |
| BALLOON_LEN | C150146 | Balloon Length |
| BALLOON_NOMINAL | C150147 | Balloon Nominal (Infla |
| BALLOON_PROX_DIA | C150161 | Balloon Proximal Oute |
| BALLOON_RAT_PRES | C150164 | Balloon Rated Burst P |
| CATH_GAUGE | C101680 | Catheter Gauge |

Since the entry of the clinical sizes is a table with the type of size, unit and value, this table serves as a match code. This ensures that the size type is entered with the unit that is valid for it.

Display View "Clinical Size Types": Overview


| Clinical Size Types | | |
|---------------------|-----------------------------|-------------------|
| Clinical Size | Clinical Unit of measure... | Description |
| ANGLE | deg | Degree |
| AREA | [sft_] | Square foot |
| AREA | [sin_] | Square inch |
| AREA | cm2 | Square centimeter |
| AREA | m2 | Square meter |
| AREA | mm2 | Square millimeter |
| ATHER_CUTT_DIAM | [ft_] | Feet |
| ATHER_CUTT_DIAM | [in_] | Inch |
| ATHER_CUTT_DIAM | [yd_] | Yard |
| ATHER_CUTT_DIAM | cm | Centimeter |
| ATHER_CUTT_DIAM | dm | Decimeter |
| ATHER_CUTT_DIAM | fm | Femtometer |
| ATHER_CUTT_DIAM | km | Kilometer |
| ATHER_CUTT_DIAM | m | Meter |
| ATHER_CUTT_DIAM | mm | Millimeter |

5.11 Storage & handling conditions and storage & handling unit of measure

The storage and handling table describes how a product should be stored and what must be observed during transport.

As far as the storage and handling are printed on the label of the product, these should also be indicated during data collection.


Display View "Storage & Handling Size Types": Overview



| Storage & Handling Size Types | | | |
|-------------------------------|------------------|---------|---|
| | Storage handling | C-Code | Description |
| | SPC_STOR_COND | C101704 | Special Storage Conditions |
| | STR_ENV_ATM_PRS | C101705 | Storage Environment Atmospheric Pressure |
| | STR_HDL_HUM | C101706 | Storage Environment Humidity |
| | STR_HDL_TMP | C101707 | Storage Environment Temperature |
| | TRN_ENV_ATMS_PRS | C101681 | Handling Environment Atmospheric Pressure |
| | TRN_HUM | C101682 | Handling Environment Humidity |
| | TRN_TMP | C101683 | Handling Environment Temperature |

Since the Storage&Handling entry is a table with storage type, unit and value, this table serves as a match code. This ensures that the correct unit is recorded per Storage&Handling Type.

Display View "Storage & Handling Size Types": Overview



| Storage & Handling Size Types | | | |
|-------------------------------|------------------|----------------------|--------------------------------|
| | Storage handling | Storage handling UoM | Description |
| | SPC_STOR_COND | | Only text description possible |
| | STR_ENV_ATM_PRS | in[Hg] | Inches of Mercury |
| | STR_ENV_ATM_PRS | kPa | KiloPascal |
| | STR_ENV_ATM_PRS | mbar | millibar |
| | STR_ENV_ATM_PRS | mm[Hg] | Millimeter of Mercury |
| | STR_HDL_HUM | Percent | Percent (%) Relative Humidity |
| | STR_HDL_TMP | Cel | Degrees Celsius |
| | STR_HDL_TMP | K | Degrees Kelvin |
| | STR_HDL_TMP | [degf] | Degrees Fahrenheit |
| | TRN_ENV_ATMS_P.. | in[Hg] | Inches of Mercury |
| | TRN_ENV_ATMS_P.. | kPa | KiloPascal |
| | TRN_ENV_ATMS_P.. | mbar | millibar |
| | TRN_ENV_ATMS_P.. | mm[Hg] | Millimeter of Mercury |
| | TRN_HUM | Percent | Percent (%) Relative Humidity |
| | TRN_TMP | Cel | Degrees Celsius |
| | TRN_TMP | K | Degrees Kelvin |
| | TRN_TMP | [degf] | Degrees Fahrenheit |

6 UDI application settings

The UDI application settings are basic settings for the appearance and behavior of the maintenance transaction. The layout settings of the state log and the permissions for the applications can also be customized here.

| UDI Add-On (FDA) - Europe IT Consulting GmbH | |
|--|----------------------|
| Codelisten | |
| • DUNS number of the company | Z_MM_CL_DUNS |
| • UDI contact person | Z_MM_CL_CONTACT |
| • UDI Issuing Agency | Z_MM_CL_AGENCY |
| • UDI sterilization methods | Z_MM_CL_SMETHOD |
| • GMDN Code | Z_MM_CL_GMDN |
| • UDI FDA Product Code | Z_MM_CL_PRODUCT |
| • FDA Listing Number | Z_MM_CL_LISTING |
| • FDA Premarket Submission Number (510k) | Z_MM_UDI_PREMARKE |
| • UDI MRI Safety | Z_MM_CL_MRI |
| UDI Clinical Size Types | |
| • UDI Clinical Size Types | Z_MM_CL_CLINICAL |
| • UDI Clinical Size Unit of Measurement | Z_MM_CL_CLINICALX |
| UDI Storage & Handling Types | |
| • UDI Storage & Handling Types | Z_MM_CL_SH |
| • UDI Storage & Handling Unit of Measurement | Z_MM_CL_SHX |
| UDI Applikationseinstellungen | |
| • UDI maintenance transaction field settings | Z_MM_UDI_FLD_CTRL |
| • UDI printout settings | Z_MM_UDI_PRT_SETT |
| • UDI authority settings | Z_MM_UDI_AUTH |
| • UDI Online Funktionen konfigurieren | Z_MM_UDI_ONL |
| UDI Transaktionen | |
| • UDI data creation with template | Z_MM_UDI_AMV |
| • UDI master data maintenance | Z_MM_UDI_DATA |
| • UDI master data list view | Z_MM_UDI_VIEW02 |
| • UDI mass maintenance | Z_MM_UDI_MASS |
| • UDI Reminder | Z_MM_UDI_REMINDER |
| • UDI master data file export | Z_MM_UDI_EXPORT |
| • UDI Audit trail | Z_MM_UDI_AUDIT |
| • UDI data migration / excel upload | Z_MM_UDI_UPLOAD |
| • UDI Daten Upload per Webservice | Z_MM_UDI_TRANSFER |
| • UDI Status Update Report | Z_MM_UDI_STATUS_UPD |
| • UDI Online status check program | Z_MM_UDI_STATUS_TEST |

6.1 UDI maintenance transactions field control

The settings in the field control table must always include the authority for which the settings are to apply.

This is already a reaction to the requirements of future requirements of other authorities, so that a distinction can be made between the authorities during data entry as well as during data evaluation.

The field name refers to the technical database structure "/UDI/US_UDI_DATA_S". All fields in it can be specifically changed when displayed in the application. The following properties can be influenced:

6.1.1 Trigger field

If a field is marked as a trigger field, an accidental modification of the data will be prevented later when using the lock function "Lock trigger fields".

6.1.2 Mandatory

If a field is marked as mandatory, the name of the field is displayed in blue in the application. These fields should be filled before you make the data transfer to the GUDID. This setting is based on the default of the corresponding organization.

6.1.3 Editable

If a field is marked as not ready for input, this field cannot be changed by the user.

This prevents the user from entering incorrect data in the first place.

In addition, this property in combination with the "Default value" makes an even more restrictive entry with default values possible.

6.1.4 Visible

If a field is marked as not visible, this field is hidden in the input mask. This means that UDI attributes that do not apply to the company's products can be hidden.

6.1.5 Default value

The default value is a value that is already preassigned when a new UDI master data record is created. Thus, certain attributes such as the issuing agency can already be preset with a value.

Attention: This function is not active during data upload. I.e. the data from the Upload-Excel will be taken over one to one.

6.1.6 Download

This setting determines whether or not the corresponding UDI attribute is included in the overview display when downloading a CSV file.

| Display View "UDI field settings": Overview | | | | | | | | |
|---|-------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|----------------|-------------------------------------|-------------------------------------|
| UDI field settings | | | | | | | | |
| Organi. | Field n. | Trig.Feld | Obligatory | Editable | Visible | Default value | Download | GUDID Exp. |
| FDA | ▼ AGENCY | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | GS1 | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| FDA | ▼ BRAND_NAME | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| FDA | ▼ CATALOG_NO | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| FDA | ▼ COMB_PRODUCT | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| FDA | ▼ CUST_CONT_EMAIL | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| FDA | ▼ CUST_CONT_PHONE | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | +1(800)1234567 | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |

6.2 UDI state protocol print settings

The UDI status log is a PDF printout generated from SAP using Adobe Forms technology (requires an Adobe Document Service connected to the SAP system).

This printout can be generated directly from the UDI maintenance transaction.

To achieve a certain flexibility for the data arrangement in the form, a separate customizing table was created for this purpose.

The following settings can be made in this table:

- Fieldname
 - Technical field name for which the settings apply
- PrintHead
 - This setting that the recent field will be printed in the header area
- PrintBody
 - The recent field will be printed in the details area
- SortHead
 - Sort order of the header fields
- SortBody
 - Sort order of the fields in the detail area / General Data

Display View "Configuration of the UDI protocol": Overview



Configuration of the UDI protocol

| Field Name | PrintHead | PrintBody | SortHead | SortBody |
|--------------------|--------------------------|-------------------------------------|----------|----------|
| AGENCY | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 0 |
| BRAND_NAME | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 0 |
| CATALOG_NO | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 0 |
| COMB_PRODUCT | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 0 |
| CUST_CONTACT_EMAIL | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 0 |
| CUST_CONTACT_PHONE | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 0 |
| DEVICE_DESCR | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 0 |
| DEV_COUNT | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 0 |
| DEV_EX_PREMARKET | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 0 |
| DEV_SUBJECT_DM | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 0 |
| DISTR_ENDDATE | <input type="checkbox"/> | <input checked="" type="checkbox"/> | 0 | 0 |

Print Preview

Print and Archive Archive



UDI master data

Organization FDA
Material 100-200
Material Description Actuation
GTIN Trigger locked No
Last Transmission Date 2019-09-20
Release RA No


General Data

| | |
|--|-----|
| Human Cell, Tissue or Cellular or Tissue-Based | No |
| Kit* | Yes |
| Combination product* | Yes |
| Device Exempt from Premarket Submission | Yes |
| For Single Use* | No |
| Lot or batch number printed | Yes |
| Manufacturing date printed | Yes |
| Serial number printed | Yes |
| Expiration date printed | No |
| Donation Identification Number printed | Yes |
| Device requ. to be labeled as containing rubber/latex* | No |
| Prescription Use (Rx) | No |

6.3 UDI authorization activities

The activities of the authorizations are stored in this table. Basically, these settings are delivered with the UDI module. The associated authorization object "/UDI/USUDI" can be entered in the corresponding user roles.

Display View "UDI Authorities": Overview



| UDI Authorities | |
|-----------------|-----------------------------------|
| Activity | Long Text |
| 1 | UDI master data maintenance |
| 2 | GTIN Trigger field lock/unlock |
| 3 | UDI master data (read only) |
| 10 | Print UDI protocol |
| 20 | UDI Reminder Report |
| 30 | UDI data mass change |
| 31 | UDI record creation with template |
| 50 | Data migration / excel upload |
| 80 | UDI master data release |
| 81 | Release Regulatory Affairs |
| 82 | Release Marketing |
| 83 | Release Development |
| 90 | UDI master data file export |
| 91 | UDi Online Status Update |
| 92 | Online Status Testprogram |

6.4 UDI online functions – configuration

This configuration is necessary to communicate with the UDI web server of Europe IT Consulting GmbH.

There are three functions that depend on the configuration:

- UDI status request for data transfer processing
- GUDID status request for the state on the GUDID
- Data transfer to the Europe IT Consulting web server

The configuration for data transfer to our web server is only necessary if you have the service of data transfer to GUDID performed by Europe IT Consulting GmbH.

If you organize the data transfer yourself, you can omit the entry with the parameter name "RFC_UDI_UPLOAD".

| Authority | Parameter name | Parameter value | Description |
|-----------|----------------|-----------------|--|
| FDA | KUNDENID | YourCustomerID | Your customer ID is provided by us (Europe IT Consulting GmbH) |
| FDA | RFC_UDI_STATUS | UDI_STATUS | Entry in the SM59 with the user and password. |
| FDA | RFC_UDI_UPLOAD | UDI_UPLOAD | Entry in the SM59 with the user and password. |
| FDA | STATUS_UPDATE | 2 | Possible values 1 = Always check online 2 = Always from status table (report must be configured for daily status update) 3 = Off Status table, if no entry found, then Online retrieval |

RFC connection settings in transaction SM59.

| RFC Connections | Type | Comment |
|---------------------------------------|------|-----------------|
| ‣ R/2 Connections | 2 | |
| ‣ ABAP Connections | 3 | |
| ‣ HTTP Connections to External Server | G | |
| ‣ UDI_STATUS | G | Connection to / |
| ‣ UDI_UPLOAD | G | |
| ‣ HTTP Connections to ABAP System | H | |
| ‣ Internal Connections | I | |
| ‣ Logical Connections | L | |
| ‣ TCP/IP connections | T | |
| ‣ Connections via ABAP Driver | X | |

For a secure Internet connection, use port 443. Otherwise, use port 80.

RFC Destination UDI_STATUS

Connection Test

RFC Destination: UDI_STATUS

Connection Type: G HTTP Connection to External Serv Description

Description 1:

Description 2:

Description 3:

Administration Technical Settings Logon & Security Special Options

Target System Settings

Target Host: udi.eu-t.ch Service No.: 80

Path Prefix: /di_status.php

HTTP Proxy Options

Global Configuration

Proxy Host:

Proxy Service:

Proxy User:

Proxy PW Status: is initial

Proxy Password:

The login procedure uses the default authentication method.
Depending on whether you use SSL. Select the appropriate option.

RFC Destination UDI_STATUS

Connection Test

RFC Destination

Connection Type HTTP Connection to External Serv Description

Description

Description 1

Description 2

Description 3

Administration Technical Settings **Logon & Security** Special Options

Security Options

Logon Procedure

No Logon

Basic Authentication

Send SAP Logon Ticket

Status of Secure Protocol

SSL Inactive Active

SSL Client Certificate Cert. List

Authorization for Destination

Logon

User

PW Status

Password

For UDI upload via web service, enter the corresponding URL and path prefix.

RFC Destination UDI_UPLOAD

Connection Test

RFC Destination

Connection Type HTTP Connection to External Serv Description

Description

Description 1

Description 2

Description 3

Administration Technical Settings **Logon & Security** Special Options

Target System Settings

Target Host Service No.

Path Prefix

HTTP Proxy Options

Global Configuration

Proxy Host

Proxy Service


Proxy User

Proxy PW Status

6.5 Setting UDI departments for release

So that the release of UDI data can be carried out by several persons or departments, the relevant departments must first be defined by name and assigned an authorization activity. The authorization activities 81-89 are reserved for this purpose.


Display View "UDI Authorities": Overview



| UDI Authorities | |
|-----------------|-----------------------------------|
| Activity | Long Text |
| 1 | UDI master data maintenance |
| 2 | GTIN Trigger field lock/unlock |
| 3 | UDI master data (read only) |
| 4 | Delete UDI master data record |
| 10 | Print UDI protocol |
| 20 | UDI Reminder Report |
| 30 | UDI data mass change |
| 31 | UDI record creation with template |
| 50 | Data migration / excel upload |
| 80 | UDI master data release |
| 81 | Release Regulatory Affairs |
| 82 | Release Marketing |
| 83 | Release Development |
| 90 | UDI master data file export |
| 91 | UDI Online Status Update |
| 93 | UDI XML data export |

When defining the release departments, the departments must also be entered again in the associated transaction with the appropriate authorization object /UDI/USUDI and the activity.

Display View "Departments": Overview



| Departments | | |
|-------------|------------|----------|
| Department | Object | Activity |
| Labeling | /UDI/USUDI | 82 |
| Marketing | /UDI/USUDI | 83 |
| Quality | /UDI/USUDI | 81 |

Up to 9 departments with authorization activities (81-89) can be created and assigned.

Data integrity

Material data

Organization:
 Material:

Release Status

Release

Release UDI Data

| Released | Department | User | Change date | Change time |
|--------------------------|------------|---------|-------------|-------------|
| <input type="checkbox"/> | Labeling | FELBERC | 09.04.2021 | 11:13:49 |
| <input type="checkbox"/> | Marketing | FELBERC | 09.04.2021 | 11:13:49 |
| <input type="checkbox"/> | Quality | FELBERC | 09.04.2021 | 11:13:49 |

7 UDI transactions

The UDI transactions are the actual applications that have been developed for the maintenance and evaluation of the UDI master data.

Within these transactions, the UDI data can be recorded and evaluated.

| | |
|--|--|
| UDI Add-On (FDA) - Europe IT Consulting GmbH | |
| Codelisten | |
| <ul style="list-style-type: none"> • DUNS number of the company • UDI contact person • UDI Issuing Agency • UDI sterilization methods • GMDN Code • UDI FDA Product Code • FDA Listing Number • FDA Premarket Submission Number (510k) • UDI MRI Safety | <ul style="list-style-type: none"> Z_MM_CL_DUNS Z_MM_CL_CONTACT Z_MM_CL_AGENCY Z_MM_CL_SMETHOD Z_MM_CL_GMDN Z_MM_CL_PRODUCT Z_MM_CL_LISTING Z_MM_UDI_PREMARKE Z_MM_CL_MRI |
| UDI Clinical Size Types | |
| <ul style="list-style-type: none"> • UDI Clinical Size Types • UDI Clinical Size Unit of Measurement | <ul style="list-style-type: none"> Z_MM_CL_CLINICAL Z_MM_CL_CLINICALX |
| UDI Storage & Handling Types | |
| <ul style="list-style-type: none"> • UDI Storage & Handling Types • UDI Storage & Handling Unit of Measurement | <ul style="list-style-type: none"> Z_MM_CL_SH Z_MM_CL_SHX |
| UDI Applikationseinstellungen | |
| <ul style="list-style-type: none"> • UDI maintenance transaction field settings • UDI printout settings • UDI authority settings • UDI Online Funktionen konfigurieren | <ul style="list-style-type: none"> Z_MM_UDI_FLD_CTRL Z_MM_UDI_PRT_SETT Z_MM_UDI_AUTH Z_MM_UDI_ONL |
| UDI Transaktionen | |
| <ul style="list-style-type: none"> • UDI data creation with template • UDI master data maintenance • UDI master data list view • UDI mass maintenance • UDI Reminder • UDI master data file export • UDI Audit trail • UDI data migration / excel upload • UDI Daten Upload per Webservice • UDI Status Update Report • UDI Online status check program | <ul style="list-style-type: none"> Z_MM_UDI_AMV Z_MM_UDI_DATA Z_MM_UDI_VIEW02 Z_MM_UDI_MASS Z_MM_UDI_REMINDER Z_MM_UDI_EXPORT Z_MM_UDI_AUDIT Z_MM_UDI_UPLOAD Z_MM_UDI_TRANSFER Z_MM_UDI_STATUS_UPD Z_MM_UDI_STATUS_TEST |

7.1 Setting the UDI relevant labeling in the material master

The UDI data is basically additional master data for each material. For this reason, an additional subscreen area has been added to the material master (transactions MM01/MM02/MM03) in Customizing.

The area at the bottom of the screen called "UDI Information" allows you to mark materials as FDA UDI relevant when creating or editing them. The "FDA UDI relevant" flag is mapped by a MARA append of the "ZZUDI" field.

As soon as the setting is set to "Yes" or "Preparation", the function for jumping to the UDI master data maintenance is activated.

This setting only has to be made once so that the material is later taken into account in all evaluations.

The UDI master data maintenance itself can also be called up with its own transaction. This has the advantage that even people who do not have authorization to change the material master record can still maintain the UDI data.

Meaning of the selection list:

- J (Yes)
 - The material is flagged as UDI relevant and is considered in all other UDI transactions.
- N (No)
 - The material was explicitly marked as not UDI relevant. Thus, it is not considered in the UDI transactions.
- V (Preparation)
 - The material is fundamentally UDI relevant, but it can be distinguished whether this material is taken into account during the data export or not. Use cases would be if this material becomes relevant later for an export to the USA or if you have newly created a material and want to maintain the data in preparation.
- Not defined
 - This status represents the initial status of the material. All materials that existed before the implementation of the UDI module have this status.

Change Material 100-200 (Semi-finished product)

Additional Data Org. Levels Check Screen Data

Basic data 1 Basic data 2 Classification Sales: sales org. 1 Sales: sales org. 2 Sales: Gener...

General data

| | | | | |
|--|----|----------|-----------------|--------------------|
| Base Unit of Measure | PC | piece(s) | Material Group | 001 |
| Old material number | | | Ext. Matl Group | |
| Division | 01 | | Lab/Office | |
| Product allocation | | | Prod.hierarchy | 001000010500000100 |
| X-plant matl status | | | Valid from | |
| <input type="checkbox"/> Assign effect. vals | | | GenItemCatGroup | |

Dimensions/EANs

| | | | |
|-----------------|--------------|--------------|----|
| Gross Weight | 2,500 | Weight unit | RG |
| Net Weight | 2,500 | | |
| Volume | | Volume unit | |
| Size/dimensions | | | |
| EAN/UPC | 712154521231 | EAN Category | UC |

Packaging material data

| | |
|--------------------|--|
| Matl Grp Pack.Mats | |
| Ref. mat. for pckg | |

Basic Data Texts

Languages Maintained: 0 Basic Data Text Language: [dropdown]

UDI Informationen

| | | |
|-----------------|-------------|--------------------|
| UDI relevant | J Yes | FDA UDI Stammdaten |
| EU UDI relevant | not defined | EU UDI Stammdaten |

Dropdown menu for UDI relevant: J Yes, not defined, J Yes, V Not yet, N No

7.2 UDI data set creation with template

This transaction is used to create UDI data sets where an existing UDI data set serves as a template.

First select the template data record. Then enter all materials for which a UDI master record is to be created. You can create several or only one data record.

All UDI data fields are taken from the template except for the following fields:

- Materialnummer
- Primary DI
- Model /Version
- Catalog Number
- GTIN Unit of Use
- Brand name
- Device Description

These fields are determined based on customizing and customer-specific development.

UDI creation with template


Template material

Template material

Organization








Material

UDI records will be created for these materials

Material to 

Selection screen

UDI creation with template

| Message | Material | Locked | Onl.Status | Organi. | Trans.Date | Trans.Time | Descr. | Iss.Agency | Primary DI number* | Dev.Count* | GTIN UOU | Lab. DUNS | Description |
|---------|----------|--------------------------|------------|---------|------------|------------|-----------|------------|--------------------|------------|----------|-----------|---------------------------|
| | 100-210 | <input type="checkbox"/> | | FDA | | 00:00:00 | Actuation | GS1 | 843059116991 | 1 | | 486212074 | Europe IT Consulting GmbH |






Data record creation

7.3 UDI master data maintenance

The maintenance of the data takes place in only one screen area. In order to see the other areas of the UDI master data maintenance, you must use the scroll bar on the right side of the screen.

Most of the designations have been left in their original English-language designation.

UDI data maintenance for material 100-200

Material data

Organization Material Actuation Last data transfer

Release status

Release RA

Overall status

Transfer Status

Upload time Submit time

Data submitted to GUIDID Successfully submitted to GUIDID

Status Text

Device Version

GUIDID Status

Public Status Publish date

Record Status Version date

Commerc.Distr. Status

Commerc.Distr.End Date Device Version

Device Identifier Information

Issuing Agency* Primary DI number* Device Count* GTIN Unit of Use

Labeler DUNS Number Europe IT Consulting GmbH

Brand Name* Version or Model number* Catalog Number



Device Description

EITC - MEDTECH Tube - ©








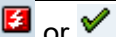
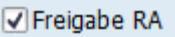
kene Größen mehr

Commercial Distribution

DI Record Publish Date Commercial Distribution End Date

 UDI data were loaded.  ECC (2) 800 SAP01 INS

The following functions are available within this transaction:

| Symbol | Function | Description |
|---|----------------------------|--|
|  | Save | Save data |
|  | Leave transaction | Leaving the transaction. If unsaved changes exist, you will be asked if you want to save before leaving the transaction. |
|  | Print UDI protocol | Print the UDI state protocol. This shows all UDI data in the printout. You have the option to save the log as a PDF file using the standard functions of Adobe Forms. An archiving of the protocol is only possible after a customer-specific adjustment. |
|  | Lock trigger fields | This function locks the UDI trigger fields. Which fields are considered as trigger fields should have been previously made in Customizing for field control. |
|  | Unlock trigger fields | Unlocks the UDI trigger fields. |
|  | Displaying the audit trail | In the UDI Audit Trail you can view all changes to the UDI data. The person who made the changes, the transaction, the time, the old value and the new value are displayed. You also have the possibility to use the SAP standard transaction AUT10 to view the changes. |
|  | Check entries | Checking of inputs according to defined business rules. These checks allow to detect gross errors in data entry. |
|  | UDI Data integrity | Display of the data integrity. The displayed icon signals whether the data is synchronous with the comparison data. Customer-specific fields were defined as comparison data during implementation, which are compared with the UDI master data. |
|  | UDI Release RA | Release indicators for the defined areas. Whenever the UDI data is changed, all release indicators for all departments are reset. How many release indicators exist was previously discussed and adjusted with the customer during implementation. |

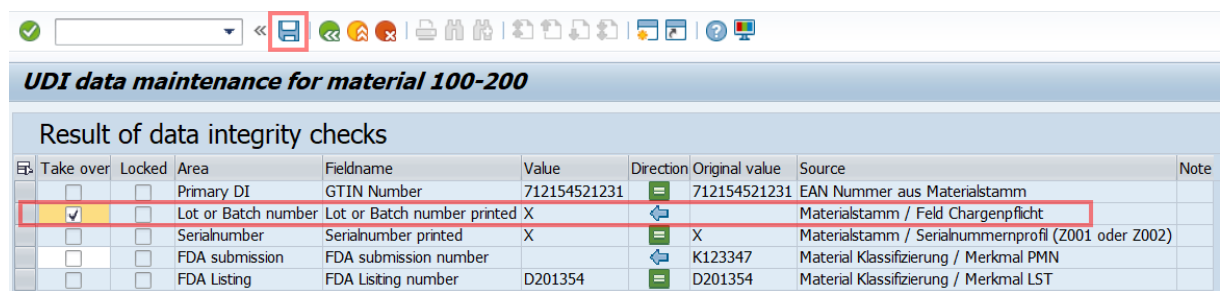
7.3.1 UDI Data integrity check

The data integrity check always checks and displays in the UDI master data entry screen whether differences exist between the UDI data record and the already existing UDI attributes in the SAP system in the standard fields.

For example, you have already created the UDI attribute "FDA Submission Number" in your system and do not want to change the entry and maintenance of this field. By customizing, the values of these fields can be transferred to the UDI module in the corresponding field when creating the data record. In order to avoid unknowingly changing a locked UDI data record, your consent is required when transferring these values to the UDI master data record. Accidental changes to GTIN trigger fields can thus be avoided.

In case of a detected change of such "mirrored" fields, you can, as shown in the figure below, transfer all values into the UDI master record by pressing a button.

Only the source data is transferred to the UDI master record. The original value of the data source remains unaffected by the change, since it was set as the leading field.



UDI data maintenance for material 100-200

Result of data integrity checks


| Take over | Locked | Area | Fieldname | Value | Direction | Original value | Source | Note |
|-------------------------------------|--------------------------|---------------------|-----------------------------|--------------|-----------|----------------|--|------|
| <input type="checkbox"/> | <input type="checkbox"/> | Primary DI | GTIN Number | 712154521231 | → | 712154521231 | EAN Nummer aus Materialstamm | |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Lot or Batch number | Lot or Batch number printed | X | ← | | Materialstamm / Feld Chargenpflicht | |
| <input type="checkbox"/> | <input type="checkbox"/> | Serialnumber | Serialnumber printed | X | → | X | Materialstamm / Serialnummernprofil (Z001 oder Z002) | |
| <input type="checkbox"/> | <input type="checkbox"/> | FDA submission | FDA submission number | | ← | K123347 | Material Klassifizierung / Merkmal PMN | |
| <input type="checkbox"/> | <input type="checkbox"/> | FDA Listing | FDA Listing number | D201354 | → | D201354 | Material Klassifizierung / Merkmal LST | |

To save the selected field contents, click the Save icon. This only transfers the value to the calling mask. The changes are not applied until you click on Save again in the UDI master data maintenance.

7.4 UDI master data overview

The color of the icon in the Messages column indicates whether data validation errors have been detected.

Show UDI data




Organizational criteria

Organization

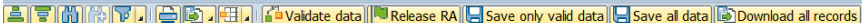







UDI relevant

With integrity check

Material selection

Material to 

UDI Overview in ALV table

| UDI attributes - selected records: 6 | | | | | | | | | | | | | | |
|---|--------------------------|----------|--------------------------|---|-----------|-------------|------------|--------------------|------------|--------------------|-------------|----------|---------------|-------------------------------------|
|  | | | | | | | | | | | | | | |
| Messa... | Rel RA | Material | Locked | Onl.Status | Organi... | Transm.Date | Trans.Time | Description | Iss.Agency | Primary DI number* | Dev.Coun... | GTIN UOU | Lab. DUNS | Description |
|  | <input type="checkbox"/> | 100-200 | <input type="checkbox"/> | | FDA | 20.09.2019 | 09:58:26 | Actuation | GS1 | 712154521231 | | 1 | 486212074 | Europe IT Consulting GmbH |
|  | <input type="checkbox"/> | 100-210 | <input type="checkbox"/> |  | FDA | 16.07.2019 | 20:11:23 | Slug for fly wheel | GS1 | 843059116991 | | 10 | 486212074 | Europe IT Consulting GmbH |
|  | <input type="checkbox"/> | 100-300 | <input type="checkbox"/> | | FDA | 16.07.2019 | 20:11:23 | Hollow shaft | GS1 | 7612546833448 | | 2 | 7612500825421 | 486212074 Europe IT Consulting GmbH |
|  | <input type="checkbox"/> | 100-400 | <input type="checkbox"/> | | FDA | 16.07.2019 | 20:11:23 | Electronic | GS1 | 7612546828999 | | 2 | 486212074 | Europe IT Consulting GmbH |
|  | <input type="checkbox"/> | 100-500 | <input type="checkbox"/> | | FDA | 16.07.2019 | 20:11:23 | Bearing case | GS1 | 4123456789124 | | 2 | 486212074 | Europe IT Consulting GmbH |
|  | <input type="checkbox"/> | 100-80 | <input type="checkbox"/> | | FDA | 16.07.2019 | 20:11:23 | Colour | HIBCC | J017EC40M1TCT4020 | | 1 | 486212074 | Europe IT Consulting GmbH |

Meaning of the colors in the column Messages:

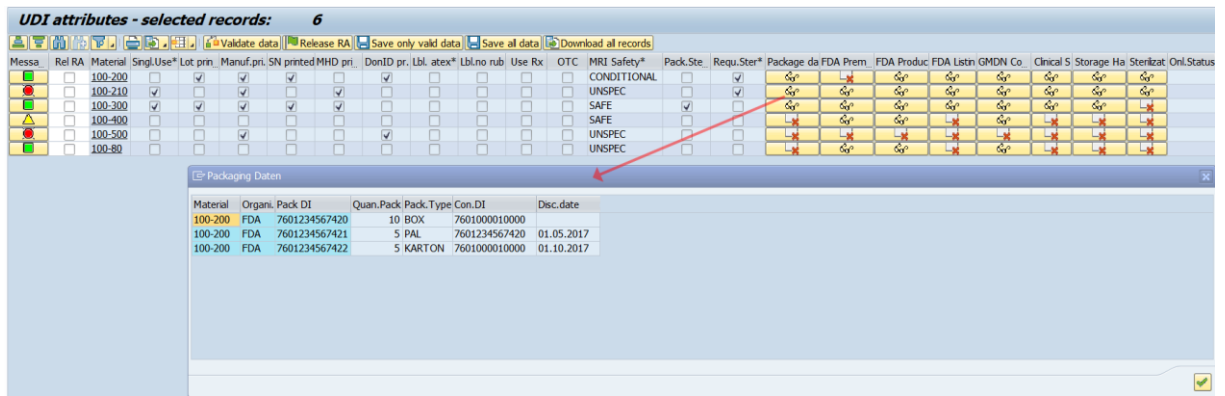
Green: No errors were detected. The data is valid.

Yellow: Errors have been detected. These should be fixed before the data is uploaded to the GUDID.

Red: Serious errors were detected. These must be fixed before you upload them to the GUDID.

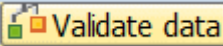
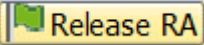
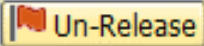
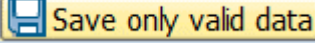
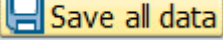
7.4.1 Displaying multi-value data

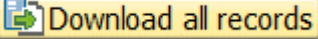
At the end of the ALV table, the details of the tabular data are displayed as buttons. The eyeglasses icon indicates that there exists data for this line. The recorded data is displayed in a pop-up window after clicking the button.



7.4.2 Functions in UDI master data overview

This transaction offers the possibility of mass release of all selected UDI data records. In addition, all displayed data can be checked and downloaded as a CSV export.

| Symbol | Function | Description |
|--|--|--|
|  Validate data | Data check according business rules for UDI data | This function starts the check of the data. When entering the transaction, the check is initially triggered. Warnings and errors are displayed in the first column labeled "Messages". You can see the exact details of the error messages after clicking the button. A popup with all the error messages will appear. |
|  Release RA | Release | This function sets all release flags that are checked in the subsequent popup for the displayed records. |
|  Un-Release | Undo release | This function unchecks all release flags that are checked in the subsequent popup for the records displayed. |
|  Save only valid data | Save only valid records | Only those data records are saved that have no errors according to the Business Rules. |
|  Save all data | Save all records | All data records are saved, even those with incorrect data. |

| | | |
|---|-----------------------------------|--|
|  | Download UDI data into a CSV file | This function creates a TAB-separated CSV file that contains the fields. Each column is exported with the technical column identifier. This serves as a control indicator if a new data upload should be made based on this file. Please note the warnings when re-uploading data. |
|---|-----------------------------------|--|



7.5 UDI mass maintenance





In UDI mass maintenance, several data records can be changed at the same time.

7.5.1 Selection screen

First, narrow down the products you want to change. In the data area you select the level in which you want to make your changes. I.e. there is once the "UDI data fields" area, in which the single fields are to be found. And there are the tabular values that you have to select explicitly.

UDI mass maintenance

| | | | | | |
|---------------------|--|----|--------------------------|--|---|
| Organization | <input type="text" value="FDA"/> | | | | |
| UDI relevant | <input type="checkbox"/> | to | <input type="checkbox"/> | |  |
| Primary DI number* | <input type="text"/> | to | <input type="text"/> | |  |
| Labeler DUNS Number | <input type="text"/> | to | <input type="text"/> | |  |
| Data area | <input checked="" type="checkbox"/> ▼ | | | | |
| Material | <input type="text"/> | to | <input type="text"/> | |  |

7.5.2 Field selection

Then all data fields for the selected area will be displayed. Select the field you want to change.

UDI mass maintenance

Field selection

| Field Name | Long Field Label |
|--------------|--------------------------|
| LOCKED | GTIN Trigger locked |
| AGENCY | Issuing Agency* |
| GTIN | Primary DI number* |
| DEV_COUNT | Device Count* |
| GTIN_UOU | GTIN Unit of Use |
| LABELER_DUNS | Labeler DUNS Number |
| BRAND_NAME | Brand Name* |
| MODEL | Version or Model number* |
| CATALOG_NO | Catalog Number |
| DEVICE_DESCR | Device Description |
| PUBLISH_DATE | DI Record Publish Date |

After that, the field with the possible entries appears on the right side.

In the lower part of the screen you will see all the products that you have narrowed down at the beginning.

UDI mass maintenance

Start in test mode Apply changes

Field selection

| Field Name | Long Field Label |
|------------|--------------------|
| AGENCY | Issuing Agency* |
| GTIN | Primary DI number* |
| DEV_COUNT | Device Count* |
| GTIN_UOU | GTIN Unit of Use |

New field value

| Field | Long Field Label | Condition | Locked | Action | NEW:GTIN T |
|--------|---------------------|-----------|--------|--------|------------|
| LOCKED | GTIN Trigger locked | | | | |

Selected records:505

| Organi. | Material | Material Description | Field | Long Field Label | Locked | Message |
|---------|----------|-----------------------------|--------|---------------------|--------|---------|
| FDA | 1018 | Acxis Demo - Bottles | LOCKED | GTIN Trigger locked | | |
| FDA | 1019 | Acxis Demo - Caps | LOCKED | GTIN Trigger locked | | |
| FDA | 1289 | Concrete tie 7x9x9 | LOCKED | GTIN Trigger locked | X | |
| FDA | 1301 | Wood Tie 7x8x8' | LOCKED | GTIN Trigger locked | X | |
| FDA | 1304 | Concrete Tie 7x9x9' | LOCKED | GTIN Trigger locked | | |
| FDA | 1308 | Concrete Tie 7x8x8' | LOCKED | GTIN Trigger locked | X | |
| FDA | 1311 | Automatic Switch Stand # 20 | LOCKED | GTIN Trigger locked | X | |
| FDA | 1312 | Manual Switch Stand # 20 | LOCKED | GTIN Trigger locked | X | |
| FDA | 1313 | Switch Frog # 20 | LOCKED | GTIN Trigger locked | X | |
| FDA | 1316 | Welding Set | LOCKED | GTIN Trigger locked | X | |
| FDA | 1317 | Pandrol Clip | LOCKED | GTIN Trigger locked | | |
| FDA | 1318 | Rail Spikes 7" | LOCKED | GTIN Trigger locked | X | |

You can now enter the new value in the right-hand area of the screen. You also have the option of linking the change to a condition.

With the function "Start in test mode" you can display all affected data fields. These will be marked in green. With "Activate change" the changes are carried out.

7.5.3 UDI master data export (to local drive)

The UDI master data export, generates XML files with all UDI data. These serve as input source for the UDI HL7 Converter (Windows application of Europe IT Consulting GmbH), which converts these data into HL7 SPL files.

However, you can also use the exported data for other processing if you do not have the HL7 Converter. You define your selection in the mandatory selection criteria. It really makes sense to export only released master data. The option "Export changed data" automatically selects all data records that have undergone a change but have not been exported since this change. The change pointer is always reset when transferring data with web service.

When exporting through this program, you can control the resetting with the "Reset indicator after export" option.

UDI master data export

Data export selection criteria

Organizational selection criteria

Organization:

UDI relevant:

released master data

Not submitted data

=> Field "Last Submission" in UDI data must be empty

Material specific selection criteria

Material: to

Changes within selected date/time

Date/time: to

UDI selection criteria

Labeler DUNS Number: to

Primary DI number*: to

DI publish date: to

Commer.Distribut. End date: to

File export path name

Attention: All XML files in the target folder will be deleted

File export path:

Create new sub folder

7.6 UDI Audit trail

The audit trail can be called either via the UDI maintenance transaction or via the audit trail transaction. In the selection area you can limit your search with the available selection criteria.

When outputting the data, you can choose between displaying it in the ALV and outputting it as a PDF file (PDF output is only possible if you are using SAP Adobe Document Service).

UDI audit trail

| | | | |
|------------------|------------|----|------------|
| Organization | FDA | | |
| Object type | | | |
| Material | | to | |
| Table Name | | to | |
| User Name | | to | |
| Transaction Code | | to | |
| Field Name | | to | |
| Date selection | 01.09.2019 | to | 04.10.2019 |

Show in ALV
 Generate PDF output

Available Change Pointer Objects:

| Change Pointer Objects | Meaning |
|------------------------|-----------------------------|
| UDI_DATA | Changes in UDI master data |
| UDI_REL | Changes in the data release |
| UDI_TRANS | UDI data transfers |
| | |

Evaluation of the UDI audit trail as ALV output

UDI audit trail

| Object | Organi. | Doc. no. | Material | Transaction Code | Action | Current Date | Time | User | Table Name | Field Name | New value | Old value |
|-----------|---------|----------|----------|------------------|--------|--------------|----------|--------|------------------|-----------------|-----------------------|------------------------------|
| UDI_DATA | FDA | 101035 | 100-200 | Z_MM_UDI_DATA | U | 11.09.2019 | 19:47:18 | SERKAN | ZMM_UDI_DATA | LABELER_DUNS | 000000000 | 486212074 |
| UDI_REL | FDA | 101036 | 100-200 | Z_MM_UDI_DATA | U | 15.09.2019 | 21:39:55 | SERKAN | ZMM_UDI_RELEASE | FREI_RA | X | |
| UDI_DATA | FDA | 101037 | 100-200 | Z_MM_UDI_DATA | U | 15.09.2019 | 21:42:01 | SERKAN | ZMM_UDI_DATA | LABELER_DUNS | 486212074 | 000000000 |
| UDI_REL | FDA | 101038 | 100-200 | Z_MM_UDI_DATA | U | 15.09.2019 | 21:42:01 | SERKAN | ZMM_UDI_RELEASE | FREI_RA | X | |
| UDI_DATA | FDA | 101039 | 100-200 | Z_MM_UDI_DATA | U | 15.09.2019 | 21:42:26 | SERKAN | ZMM_UDI_DATA | LABELER_DUNS | 000000000 | 486212074 |
| UDI_DATA | FDA | 101040 | 100-200 | Z_MM_UDI_DATA | U | 15.09.2019 | 21:42:52 | SERKAN | ZMM_UDI_DATA | LABELER_DUNS | 486212074 | 000000000 |
| UDI_DATA | FDA | 101041 | 100-200 | Z_MM_UDI_DATA | U | 15.09.2019 | 21:42:52 | SERKAN | ZMM_UDI_DATA | TISSUE_BASED | X | |
| UDI_REL | FDA | 101042 | 100-200 | Z_MM_UDI_DATA | U | 15.09.2019 | 21:43:02 | SERKAN | ZMM_UDI_RELEASE | FREI_RA | X | |
| UDI_DATA | FDA | 101043 | 100-200 | Z_MM_UDI_DATA | U | 15.09.2019 | 21:44:02 | SERKAN | ZMM_UDI_DATA | TISSUE_BASED | | X |
| UDI_REL | FDA | 101044 | 100-200 | Z_MM_UDI_DATA | U | 15.09.2019 | 21:44:02 | SERKAN | ZMM_UDI_RELEASE | FREI_RA | | X |
| UDI_TRANS | FDA | 101045 | 100-200 | Z_MM_UDI_EXPORT | I | 18.09.2019 | 12:52:14 | DEMII | ZMM_UDI_TRANSFER | MATNR | 100-200 | |
| UDI_TRANS | FDA | 101046 | 100-200 | Z_MM_UDI_EXPORT | I | 18.09.2019 | 12:52:14 | DEMII | ZMM_UDI_TRANSFER | ORGANISATION | FDA | |
| UDI_TRANS | FDA | 101047 | 100-200 | Z_MM_UDI_EXPORT | I | 18.09.2019 | 12:52:14 | DEMII | ZMM_UDI_TRANSFER | DATUM | 20190918 | 00000000 |
| UDI_TRANS | FDA | 101048 | 100-200 | Z_MM_UDI_EXPORT | I | 18.09.2019 | 12:52:14 | DEMII | ZMM_UDI_TRANSFER | ZEIT | 125214 | 000000 |
| UDI_DATA | FDA | 101049 | 100-200 | Z_MM_UDI_DATA | U | 18.09.2019 | 12:53:20 | DEMII | ZMM_UDI_DATA | CUST_CONT_PHONE | | +41(781)123456 |
| UDI_DATA | FDA | 101050 | 100-200 | Z_MM_UDI_DATA | U | 18.09.2019 | 12:53:20 | DEMII | ZMM_UDI_DATA | CUST_CONT_EMAIL | | info@europe-it-consulting.ch |
| UDI_TRANS | FDA | 101051 | 100-200 | Z_MM_UDI_EXPORT | I | 18.09.2019 | 12:53:43 | DEMII | ZMM_UDI_TRANSFER | MATNR | 100-200 | |
| UDI_TRANS | FDA | 101052 | 100-200 | Z_MM_UDI_EXPORT | I | 18.09.2019 | 12:53:43 | DEMII | ZMM_UDI_TRANSFER | ORGANISATION | FDA | |
| UDI_TRANS | FDA | 101053 | 100-200 | Z_MM_UDI_EXPORT | I | 18.09.2019 | 12:53:43 | DEMII | ZMM_UDI_TRANSFER | DATUM | 20190918 | 00000000 |
| UDI_TRANS | FDA | 101054 | 100-200 | Z_MM_UDI_EXPORT | I | 18.09.2019 | 12:53:43 | DEMII | ZMM_UDI_TRANSFER | ZEIT | 125343 | 000000 |
| UDI_DATA | FDA | 101055 | 100-200 | Z_MM_UDI_DATA | U | 20.09.2019 | 09:06:32 | DEMII | ZMM_UDI_DATA | LOCKED | | X |
| UDI_DATA | FDA | 101056 | 100-200 | Z_MM_UDI_DATA | U | 20.09.2019 | 09:06:32 | DEMII | ZMM_UDI_DATA | DEV_COUNT | | |
| UDI_DATA | FDA | 101057 | 100-200 | Z_MM_UDI_DATA | U | 20.09.2019 | 09:06:32 | DEMII | ZMM_UDI_DATA | GTIN_UOQ | | 123543535 |
| UDI_DATA | FDA | 101058 | 100-200 | Z_MM_UDI_DATA | U | 20.09.2019 | 09:06:32 | DEMII | ZMM_UDI_DATA | DEVICE_DESCR | EITC - MEDTECH Tube - | EITC - MEDTECH Tube - |
| UDI_TRANS | FDA | 101059 | 100-200 | Z_MM_UDI_DATA | D | 20.09.2019 | 09:40:48 | DEMII | ZMM_UDI_GMDN | MATNR | 100-200 | |
| UDI_DATA | FDA | 101060 | 100-200 | Z_MM_UDI_DATA | D | 20.09.2019 | 09:40:48 | DEMII | ZMM_UDI_GMDN | ORGANISATION | | FDA |
| UDI_DATA | FDA | 101061 | 100-200 | Z_MM_UDI_DATA | D | 20.09.2019 | 09:40:48 | DEMII | ZMM_UDI_GMDN | GMDN | 00000 | 36198 |

Output of the audit trail as PDF in SAP (Adobe Forms)

This feature is only available if you are using Adobe Document Service.

| UDI Audittrail | | | | | | | | | | |
|--------------------|----------|------------------------|--------|---------------------|----------|----------|-----------------|----------------|-------------------------------------|-------------------------|
| Nachname: Demiralp | | Behörde: FDA | | Benutzername: DEMII | | | | | | |
| Vorname: Ismail | | Druckdatum: 18.01.2019 | | Druckzeit: 13:07:30 | | | | | | |
| Objekt | Material | TCode | Aktion | Datum | Zeit | Benutzer | Tabellename | Feldname | neuer Wert | alter Wert |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 23.01.2018 | 15:30:58 | DEMII | ZMM_UDI_DATA | LOCKED | X | |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 23.01.2018 | 15:30:58 | DEMII | ZMM_UDI_DATA | AGENCY | GS1 | HIBCC |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 22.02.2018 | 14:42:01 | DEMII | ZMM_UDI_DATA | LOCKED | | X |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 22.02.2018 | 14:42:01 | DEMII | ZMM_UDI_DATA | KIT | X | |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 22.02.2018 | 14:51:14 | DEMII | ZMM_UDI_DATA | LOCKED | X | |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 22.02.2018 | 14:51:14 | DEMII | ZMM_UDI_DATA | LOT_BATCH | | X |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 11.04.2018 | 14:09:43 | DEMII | ZMM_UDI_DATA | LOCKED | | X |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 11.04.2018 | 14:09:43 | DEMII | ZMM_UDI_DATA | DEV_COUNT | 10 | 1 |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 11.04.2018 | 14:09:43 | DEMII | ZMM_UDI_DATA | GTIN_UOU | 123543535 | |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 11.04.2018 | 14:09:43 | DEMII | ZMM_UDI_DATA | DEVICE_DESCR | EITC - MEDTECH Tube - © X.XL.XXL | EITC - MEDTECH Tube - © |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 11.04.2018 | 14:09:43 | DEMII | ZMM_UDI_DATA | DEV_SUBJECT_DM | X | |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 11.04.2018 | 14:09:43 | DEMII | ZMM_UDI_DATA | DM_DI_DIFF_PI | X | |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 11.04.2018 | 14:11:53 | DEMII | ZMM_UDI_DATA | MRI_SAFETY | UNSPEC | SAFE |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | D | 08.08.2018 | 13:11:20 | DEMII | ZMM_UDI_PRODUCT | MATNR | | 100-200 |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | D | 08.08.2018 | 13:11:20 | DEMII | ZMM_UDI_PRODUCT | ORGANISATION | | FDA |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | D | 08.08.2018 | 13:11:20 | DEMII | ZMM_UDI_PRODUCT | PROD_CODE | | FZT |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | D | 08.08.2018 | 13:11:20 | DEMII | ZMM_UDI_PRODUCT | MATNR | | 100-200 |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | D | 08.08.2018 | 13:11:20 | DEMII | ZMM_UDI_PRODUCT | ORGANISATION | | FDA |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | D | 08.08.2018 | 13:11:20 | DEMII | ZMM_UDI_PRODUCT | PROD_CODE | | GDH |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 29.09.2018 | 12:34:11 | DEMII | ZMM_UDI_DATA | GTIN | 7912345698712 | J999100201 |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 03.10.2018 | 20:33:10 | DEMII | ZMM_UDI_DATA | GTIN | J017BVMKSSC0 | 7912345698712 |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 03.10.2018 | 20:33:57 | DEMII | ZMM_UDI_DATA | GTIN | 889024284456 | J017BVMKSSC0 |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 10.10.2018 | 16:51:52 | DEMII | ZMM_UDI_DATA | GTIN | 889024284456 | 0889024284456 |
| UDI_DATA | 100-200 | Z_MM_UDI_DATA | U | 18.01.2019 | 10:31:39 | DEMII | ZMM_UDI_DATA | LOCKED | X | |

18.01.2019 13:06:52

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7.7 UDI data upload

This function is used to make an initial data upload into the UDI module so that you can upload your collected UDI data from an Excel file. The data upload should only be done with the Excel template provided for this purpose. You will receive this with the UDI module. The Excel template supports the upload of all 62 UDI attributes.

During the upload, the fields are checked by their technical names to see if they also exist in the SAP system.

Attention: If data for the authority/material already exist in the SAP system, they will be overwritten without prompting. Basically, this function is only designed for the initial data upload.

| | A | B | C | D | E | F | |
|----|--------------|----------|------------------|-----------------|-------------|---------------------|-----|
| | Behörde | Material | Materialkurztext | Issuing Agency* | Brand Name* | Labeler DUNS Number | Ve |
| 1 | | | | | | | |
| 2 | ORGANISATION | MATNR | MAKTX | AGENCY | BRAND_NAME | LABELER_DUNS | MC |
| 3 | FDA | 100-200 | Produkt ABC1 | HIBCC | Produkt © | 555555555 | 100 |
| 4 | FDA | 100-201 | Produkt ABC2 | | | | 100 |
| 5 | FDA | 100-202 | Produkt ABC3 | | | | 100 |
| 6 | FDA | 100-203 | Produkt ABC4 | | | | 100 |
| 7 | FDA | 100-204 | Produkt ABC5 | | | | 100 |
| 8 | FDA | 100-205 | Produkt ABC6 | | | | 100 |
| 9 | FDA | 100-206 | Produkt ABC7 | | | | 100 |
| 10 | FDA | 100-207 | Produkt ABC8 | | | | 100 |
| 11 | FDA | 100-208 | Produkt ABC9 | | | | 100 |
| 12 | FDA | 100-209 | Produkt ABC10 | | | | 100 |
| 13 | FDA | 100-210 | Produkt ABC11 | | | | 100 |
| 14 | FDA | 100-211 | Produkt ABC12 | | | | 100 |
| 15 | FDA | 100-212 | Produkt ABC13 | | | | 100 |

The Excel template offers with the help of further sheets all currently valid value lists.

During data upload, the filled target file is specified and displayed in a tabular view. This gives you another opportunity to check the data for accuracy.

The option "Save incorrect data" activates the option to save data in the SAP system, even though they were marked as incorrect during data validation before saving. In the ALV display you have another opportunity to check the data. If you want to correct the data before saving, you must do this in the Excel template and start the upload again.

With the function "Start data upload", the data is now stored in SAP. The lines marked green have been saved. Red lines are not.

Attention: The "Delete UDI master data" function deletes all UDI data for the materials displayed in the list. Restoring the data is no longer possible.

| UDI Datenmigration - Geladene Datensätze: 14 | | | | | | | | | | | | | |
|--|----------|--------------------------|------------|---------|------------|------------|---------------|------------|----------------|------------|----------|-----------|----------|
| Message | Material | Locked | Onl.Status | Organi. | Trans.Date | Trans.Time | Description | Iss.Agency | Prim. DI* | Dev.Count* | GTIN UOU | Lab. DUNS | Descript |
| | 100-200 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC1 | HIBCC | +J099123456789 | 1 | | 55555555 | |
| | 100-201 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC2 | | | 0 | | | |
| | 100-202 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC3 | | | 0 | | | |
| | 100-203 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC4 | | | 0 | | | |
| | 100-204 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC5 | | | 0 | | | |
| | 100-205 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC6 | | | 0 | | | |
| | 100-206 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC7 | | | 0 | | | |
| | 100-207 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC8 | | | 0 | | | |
| | 100-208 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC9 | | | 0 | | | |
| | 100-209 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC10 | | | 0 | | | |
| | 100-210 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC11 | | | 0 | | | |
| | 100-211 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC12 | | | 0 | | | |
| | 100-212 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC13 | | | 0 | | | |
| | 100-213 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC14 | | | 0 | | | |

Warnings and errors after checking the data are signaled with a red icon. When clicking on the message button, the details are displayed.

| UDI Datenmigration - Geladene Datensätze: 14 | | | | | | | | | | | | |
|--|----------|--------------------------|------------|---------|------------|------------|--------------|------------|----------------|-------------|----------|----------|
| Messa... | Material | Locked | Onl.Status | Organi. | Trans.Date | Trans.Time | Description | Iss.Agency | Prim. DI* | Dev.Coun... | GTIN UOU | Lab. DU |
| | 100-200 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC1 | HIBCC | +J099123456789 | 1 | | 55555555 |
| | 100-201 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC2 | | | 0 | | |
| | 100-202 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC3 | | | 0 | | |
| | 100-203 | <input type="checkbox"/> | | FDA | | 00:00:00 | Produkt ABC4 | | | 0 | | |
| | 100-204 | <input type="checkbox"/> | | FDA | | | | | | | | |
| | 100-205 | <input type="checkbox"/> | | FDA | | | | | | | | |
| | 100-206 | <input type="checkbox"/> | | FDA | | | | | | | | |
| | 100-207 | <input type="checkbox"/> | | FDA | | | | | | | | |
| | 100-208 | <input type="checkbox"/> | | FDA | | | | | | | | |
| | 100-209 | <input type="checkbox"/> | | FDA | | | | | | | | |
| | 100-210 | <input type="checkbox"/> | | FDA | | | | | | | | |
| | 100-211 | <input type="checkbox"/> | | FDA | | | | | | | | |
| | 100-212 | <input type="checkbox"/> | | FDA | | | | | | | | |
| | 100-213 | <input type="checkbox"/> | | FDA | | | | | | | | |

Datenupload Fehlermeldungen

Error message

- The material master for material no. 100-201 does not exist (MARA)
- Please enter a value in the field "Issuing Agency"
- The primary di number is missing
- Please enter at least "1" for "device count"
- Missing input: Please enter the "Labor DUNS" number
- Please enter the "brand name".
- Please enter a date in the field "Publish date"
- Please maintain the "FDA Submission Premarket" table
- Please enter all mandatory fields in the table "Product Code"
- Please enter all mandatory fields in the table "GMDN Code"

7.8 UDI data upload with Webservice

This transaction is identical to the UDI data export to a hard disk with the only difference that the data is transferred directly to the web server of Europe IT Consulting GmbH. For you, the transfer process is completed for the time being.

You can see the exact status of the data transfer either in the UDI master data creation transaction (right area in the screen) or in the overview transaction.

To update the data, the Status Update Report must be scheduled as a job. See "UDI GUDID Status Update".

UDI data maintenance for material 100-200

Print UDI protocol Lock GTIN trigger fields Audit trail Check UDI data Data integrity

Material data
 Organization: Material: Actuation: Last data transfer: 20.09.2019 09:58:26

Release status
 Release RA

Overall status

Transfer Status
 Upload time: Submit time:
 Data submitted to GUIDID: Successfully submitted to GUIDID:
 Status Text:
 Device Version:

GUIDID Status
 Public Status: Publish date:
 Record Status: Version date:
 Commerc.Distr. Status:
 Commerc.Distr.End Date: Device Version:

In the right area the status can be seen by Europe IT Consulting GmbH.
 In the left area you can see the status on the GUIDID (productive system only). Note that it takes up to a month for the AccessGUIDID to publish this data.

(WEB address: <https://accessguidid.nlm.nih.gov/>)

UDI submission with web service

Data submission criteria

Organizational criteria
 Organization:
 FDA UDI relevant:
 released records

Material criteria
 Material: to

Changes in selected time period
 Time limitation: to

UDI selection criteria
 Labeler DUNS Number: to
 Primary DI number*: to
 DI publish date: to
 Commer.Distrib. End date: to

UDI data transmission via web service selection screen.

UDI attributes - selected records: 6

Validate data Release RA Save only valid data Save all data Do

| Message | Rel RA | Material | Locked | Onl.Status | Organi. | Transm.Date | Trans.Time | Description | Iss.Agency | Primary DI nu |
|---------|--------------------------|----------|--------------------------|------------|---------|-------------|------------|--------------------|------------|---------------|
| | <input type="checkbox"/> | 100-200 | <input type="checkbox"/> | | FDA | 20.09.2019 | 09:58:26 | Actuation | GS1 | 71215452123 |
| | <input type="checkbox"/> | 100-210 | <input type="checkbox"/> | | FDA | 16.07.2019 | 20:11:23 | Slug for fly wheel | GS1 | 84305911699 |
| | <input type="checkbox"/> | 100-300 | <input type="checkbox"/> | | FDA | 16.07.2019 | 20:11:23 | Hollow shaft | GS1 | 76125468334 |
| | <input type="checkbox"/> | 100-400 | <input type="checkbox"/> | | FDA | 16.07.2019 | 20:11:23 | Electronic | GS1 | 76125468289 |
| | <input type="checkbox"/> | 100-500 | <input type="checkbox"/> | | FDA | 16.07.2019 | 20:11:23 | Bearing case | GS1 | 41234567891 |
| | <input type="checkbox"/> | 100-80 | <input type="checkbox"/> | | FDA | 16.07.2019 | 20:11:23 | Colour | HIBCC | J017EC40M1T |

UDI overview display with the new field for online status

7.9 UDI GUDID status update

This report makes an online query via a service provided by Europe IT Consulting GmbH. On the one hand the GUDID status is queried and on the other hand the processing status during the data transfer to the GUDID.

If you have set the AccessGUDID to be updated in the background (STATUS_UPDATE = 2 or 3), then you must schedule the /UDI/US_UDI_STATUS_READ report for the background job in SAP. Ideally, schedule the job once a day outside of working hours (10:00 pm - 4:00 am).

The runtime of the report depends on the number of records to be updated.

Formula for runtime calculation

Runtime = Number of UDI records x 1 second.

However, you can also run the report directly using transaction /UDI/US_UDI_STATUS_UPD.

The screenshot shows the 'UDI online status update' report selection interface. It is divided into three main sections: 'Organizational selection criteria', 'Material selection', and 'UDI selection criteria'. Each section contains various input fields and checkboxes for filtering the data to be updated.

| UDI online status update | | | |
|---|-----|----|--|
| Selection criteria for data update | | | |
| Organizational selection criteria | | | |
| Organization | FDA | | |
| FDA UDI relevant | ↓ | | |
| <input checked="" type="checkbox"/> Status not up to date | | | |
| If export date is newer than status update date | | | |
| Material selection | | | |
| Material | | to | |
| UDI selection criteria | | | |
| Labeler DUNS Number | | to | |
| Primary DI number* | | to | |
| DI publish date | | to | |
| Commer.Distribut. End date | | to | |