COSMO UNIQUE DEVICE IDENTIFICATION

Online Help PDF

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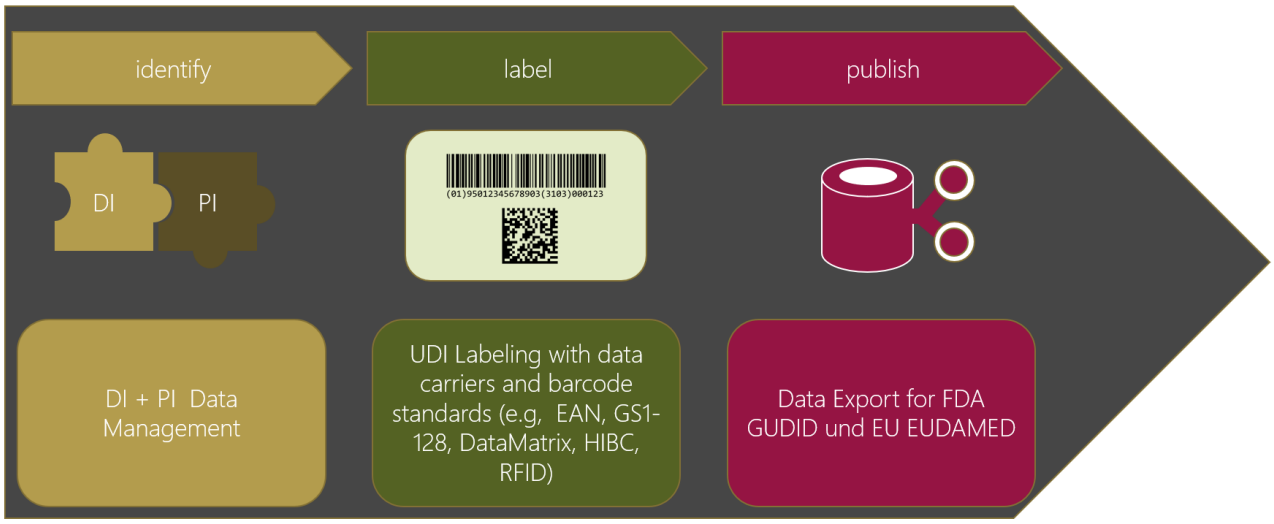
COSMO Unique Device Identification

COSMO Unique Device Identification (UDI) is mandatory for medical device manufacturers when the European Medical Device Regulation (MDR) is in force. In many countries, such as the USA, the UDI system is already mandatory. The main objective of UDI is to ensure that medical devices can be clearly identified and traced throughout their entire distribution and use cycles. The UDI requirements stipulate, among other things, that medical devices worldwide must bear a unique product number (Device Identifier), which is printed on the product itself or on its outer packaging by means of a barcode or data matrix. In addition, dynamic product information (Product Identifier), such as the serial/batch number, the expiry date or the date of manufacture must also be applied. COSMO UDI supports you in meeting the requirements of the new labeling regulations.

Since the requirements of the American authorities, such as the U.S. Food and Drug Administration (FDA), differ fundamentally from the requirements of the EU Medical Device Regulation, COSMO UDI offers two separate areas of application. For each application area, the static product/device information or attributes can be recorded, reviewed, and used. The system enables data management at both item and variant level.

The following figure illustrates an overview of the UDI Components.



Key Features

- Integrated UDI product data management according to FDA and EU MDR
- Management of relevant master data and attributes for classification and identification of medical devices (basic DI, DI, direct marking, alternative DI, other additional product attributes)
- PI data directly from the ERP system
- Label printing support for GS1 / HIBC standards

- Printing processes incl. the print data as well as prepared interface for the connection of label printing software, such as NiceLabel
- Simple XML export as a basis for data upload to the GUDID or EUDAMED database
- Intelligent user interface through dynamic display/hiding of necessary data entries including logical data checks
- Complete integration into Microsoft Dynamics 365 Business Central

COSMO Unique Device Identification functionalities are accessed using the Tell Me feature in Microsoft Dynamics 365 Business Central. Choose the icon, enter the page name, and then choose the related link.

Document References

Title / Version	Link	Short description
Microsoft Docs: Online help for using Microsoft Dynamics Business Central	Welcome to Microsoft Dynamics 365 Business Central - Business Central (Microsoft Docs)	Online Help, Microsoft Dynamics 365 Business Central
Validation Toolkit URS RAS100.050_001 Unique Device Identification		User Requirement Specification

Feedback

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Getting Started

This section covers the app installation, licensing, registration, and activation processes required to use COSMO Unique Device Identification. Additionally, the role center that provides the most efficient user experience is described.

The following table describes a sequence of tasks, with links to the topics that describe them.

To	See
Install COSMO Unique Device Identification in a SaaS or OnPremises environment.	App Installation
License and register COSMO Unique Device Identification.	App Licensing and Registration
Make pages and controls visible for the app.	App Activation
Learn about the role center that can be assigned to users to provide the most efficient COSMO Unique Device Identification user experience.	Role Center

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App Installation

This section covers the installation of the COSMO Unique Device Identification app. Typically an installation is only performed once by an administrator and is not executed by the user. The installation differs for SaaS and On-Premises (OnPrem) environments.

To install in SaaS environment

In SaaS environments, the app can be installed from Microsoft AppSource either from Business Central or directly from the Microsoft site. All dependencies are installed automatically.

Depending on the current Microsoft upgrade policy, you may not have the most current version of the app. To upgrade to the most current version, go to the Dynamics 365 Business Central admin center and perform the app upgrade for your environment.

Business Central

1. In Business Central, choose the icon, enter Microsoft AppSource apps, and then choose the related link.
2. If a message opens asking to allow the request to an external service, choose whether to Allow Always or Allow Once and then choose the OK button.
3. In the Microsoft AppSource apps page, search for and choose COSMO Unique Device Identification.
4. In the App overview page, choose the Install App action.

   > **Note**
   > **If you choose the View on AppSource action, you're taken to the Microsoft AppSource Site.**

5. Follow the wizard instructions to complete the installation.
6. After installation, go to the Business Central home page and license/register the app.

Microsoft AppSource Site

1. Open the Microsoft AppSource site.
2. Choose the Free trial button.
3. You will be forwarded to a page where you must log in with your Business Central user credentials and select an environment to install the app to.
4. Follow the wizard instructions to complete the installation.
5. After installation, go to the Business Central home page and license/register the app.

To install in on-premises environment

To install the COSMO Unique Device Identification app and its requirements in an on-premises environment, you can find the app files in the App Versions (Download Area) of the COSMO CONSULT Solution Store. Check the technical specifications of the version to find the minimum dependent version of *Business Central* and the *Base Application*. For customer installations without a Business Central developer license, you must create and install a runtime package of the app (Microsoft Documentation).

Besides the Business Central Base Application, the app depends on additional apps that must be installed in the correct order first.

1. COSMO Licensing app
2. COSMO Unique Device Identification app

See Also

App Activation
Role Center

Feedback

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App Licensing and Registration

This section covers the licensing, registration, and license check of the COSMO Unique Device Identification app. When installing the app, COSMO Licensing is automatically installed. After installing the app, you need to register it either with a license activation code or a trial license.

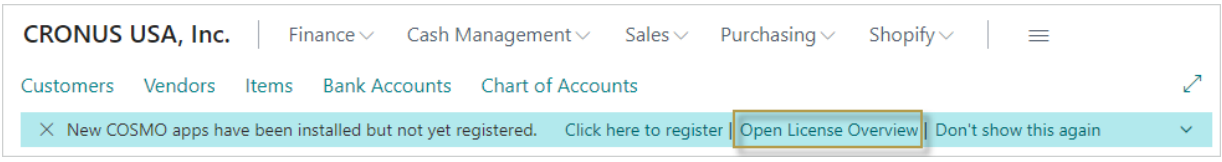
> **Note**
> **App registration by activation code is available if COSMO Licensing version 2.2 or higher is installed. Customers who purchase new COSMO product subscriptions through our Marketplace will receive an activation code.**
> **If you do not have the option to enter an activation code or have not received an activation code, follow the steps in the Register the app with a trial license section.**
> **After you have registered, you can contact appsource@cosmoconsult.com to convert your 30-day trial license to a full license.**

To assign licensing permission set

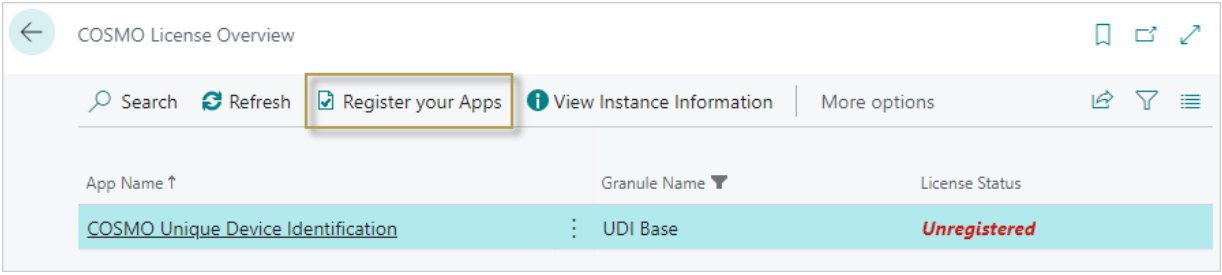
The COSMO Licensing app provides an extension permission set with Role ID = *CCS LIC ALL*. This permission set must be assigned to all users in the database to allow access to the COSMO License Overview page and, more importantly, to the licensed COSMO CONSULT apps. App-specific permission set(s) must be assigned to users in the database to allow access to the licensed functionality.

To open the COSMO License Overview

1. If the registration notification does not show in the notification bar, refresh the environment.



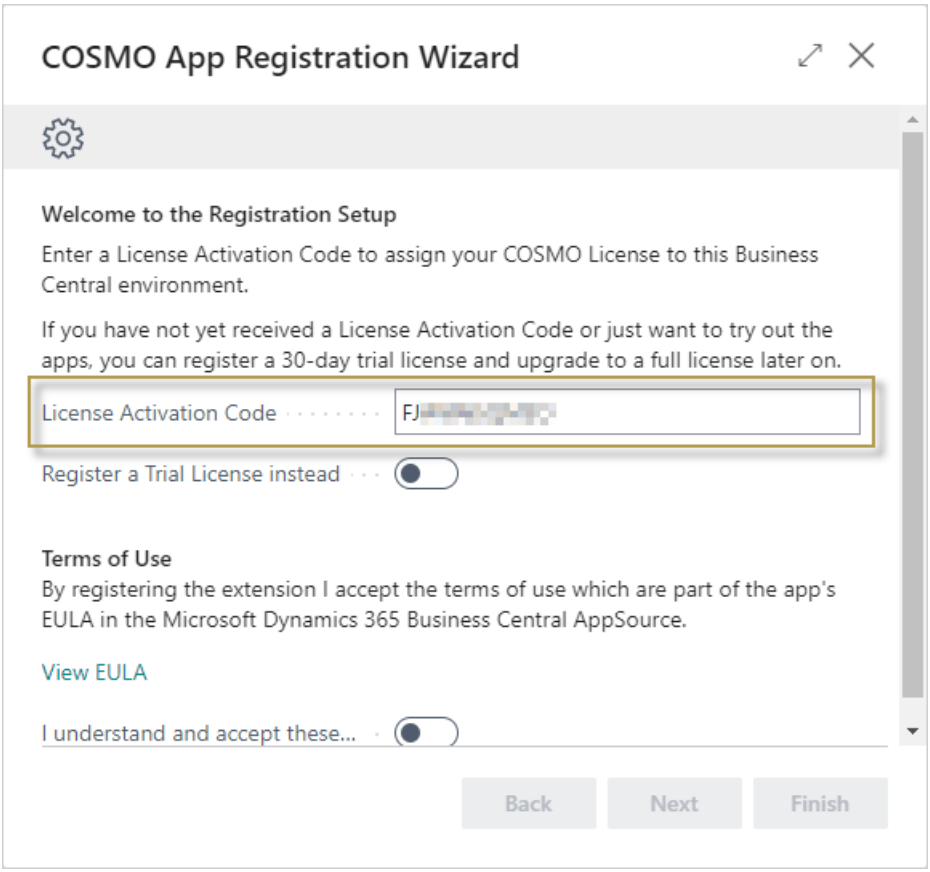
2. On the notification line, choose Open License Overview.
   The app is listed in the COSMO License Overview page with Status = *Unregistered*.



3. Choose the Register your Apps action.
   The COSMO App Registration Wizard opens with the registration options.

To register the app with license activation code

1. If you purchased the Business Central app through our Marketplace, you will have received an activation code by email.
   Enter this activation code in the License Activation Code field on the first page of the COSMO App Registration Wizard.

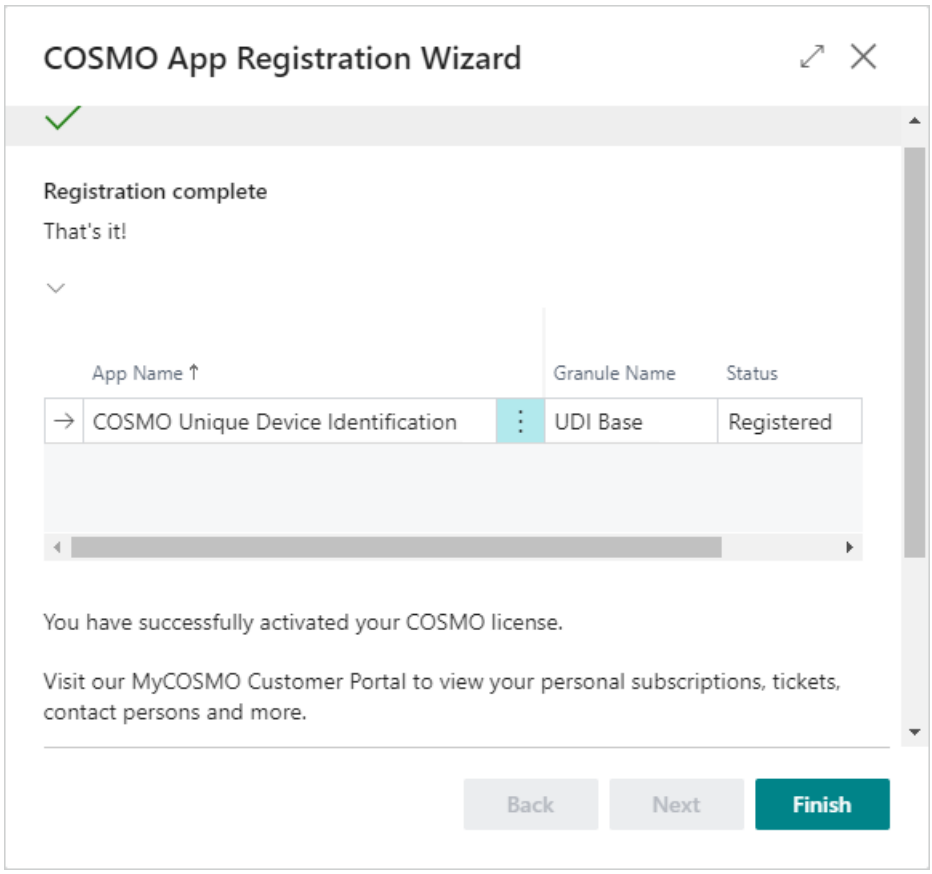


Note

In SaaS environments, an activation code can be used for exactly one production system. The same activation code can additionally be used in multiple SaaS environments (sandbox environments, e.g., test/demo/development environments).

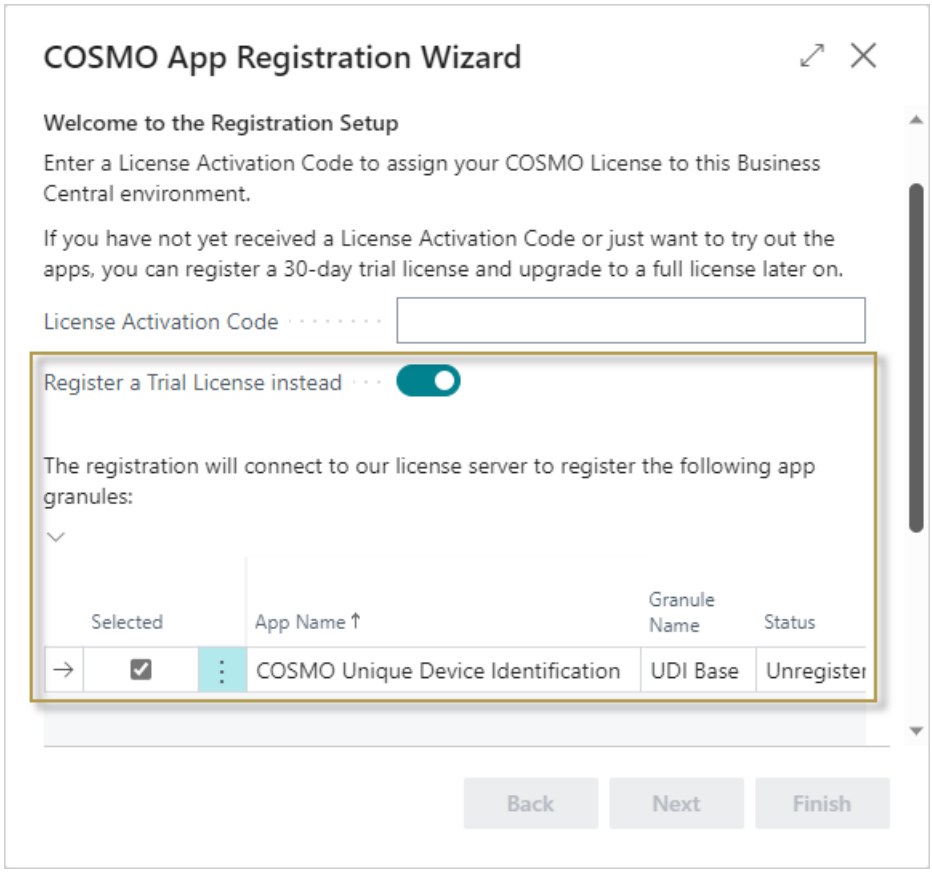
For On-premises, there is no technical distinction between *Production* and *Sandbox*, so the activation code is instead connected to the serial number of the Business Central license (.flf / .bclicense) with which it was first activated. Therefore, it is possible to use it On-premises multiple times with the same Business Central license (to allow use in test/demo/development environments). Once it has been redeemed, it cannot be used in BC environments with another BC license.

2. In order to agree to the Terms of Use, scroll down, turn on the I understand and accept these terms toggle, and then choose the Next button.
3. You have successfully registered your app. Choose the Finish button to close the wizard.
   The license connected to the entered activation code will then be automatically retrieved.



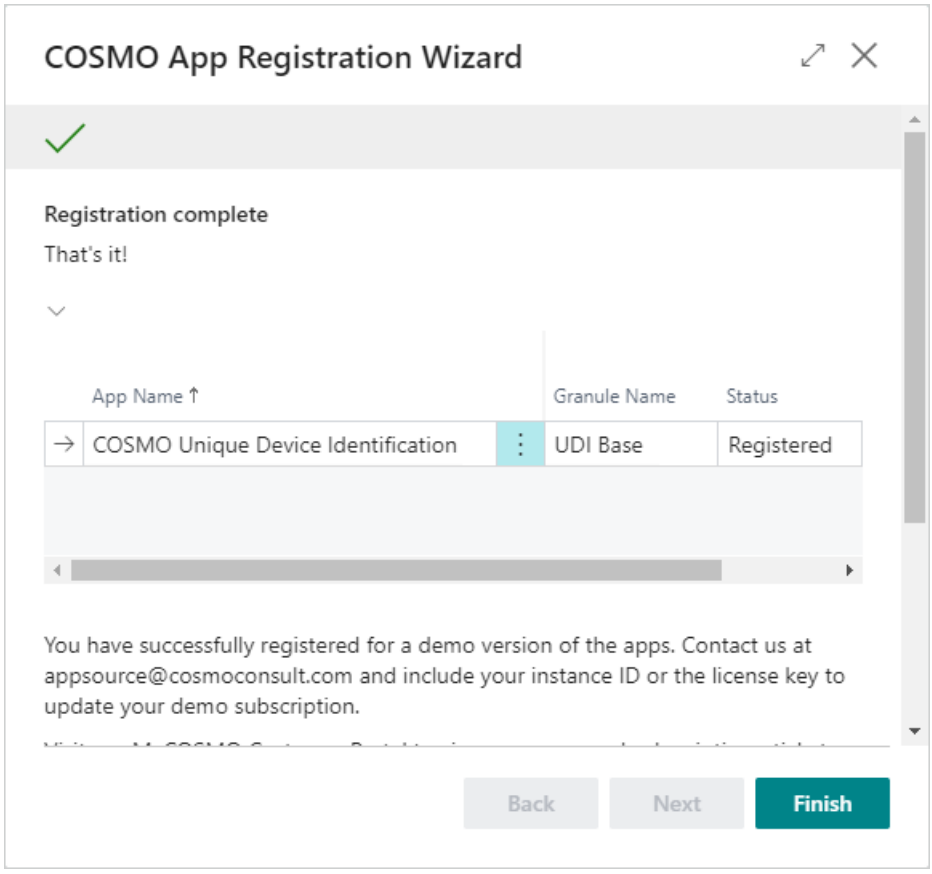
To register the app with a trial license

1. If you turn on the Register a Trial License instead toggle on the first page of the COSMO App Registration Wizard, the app granule to be registered is displayed.



2. In order to agree to the Terms of Use, scroll down, turn on the I understand and accept these terms toggle, and then choose the Next button.
3. Enter your customer name. The name is used to identify the company. For test purposes, enter any Cronus-related name.
4. Choose the Next button to sign into the COSMO Platform to link the registration with your account. The COSMO Platform opens in a new browser tab. After signing in you can close this tab and return to the final page of the COSMO App Registration Wizard.

   To skip this step, choose the Skip Login button.
5. You have successfully registered for a 30-day trial version of the app. Contact appsource@cosmoconsult.com and use the displayed license key to update your trial subscription.
6. The app has Status = *Registered*. Choose the Finish button to close the wizard.



7. The status for the app is updated in the COSMO License Overview page. Leave the COSMO License Overview page to return to the Role Center.

> **Note**
> **You can register the app and perform other administrative licensing tasks from the COSMO License Overview page.**

To check the license

The COSMO License Overview page lists the license status of the COSMO app and is accessed using the Tell Me feature.

1. Choose the icon, enter COSMO License Overview, and then choose the related link. This page can also be opened from the UDI Setup page (Related > App Licensing) and from the last page of the COSMO App Registration Wizard by choosing Open License Overview.
2. In the COSMO License Overview page, the app can be registered if not done on the Role Center notification bar. Other administrative tools are available as well.
3. Hover over an action on the COSMO License Overview page to read a short

description.

See Also

App Installation
App Activation
Role Center
UDI Setup

Feedback

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App Activation

COSMO Unique Device Identification has its own activation button in the setup page that makes pages and controls visible for the product. Opening the UDI Setup page automatically activates the app. However, you must determine which application area (FDA/EU) to activate.

> **Note**
> **Turning on the toggle in the setup pages will require logged in users to restart the application.**

1. Choose the icon, enter UDI Setup, and then choose the related link.
2. On the General FastTab, choose which database is needed for exporting your devices:
   - Turn on the Activate FDA Appl. Area toggle to export to the GUDID database in the USA.
   - Turn on the Activate EU Appl. Area toggle to export to the EUDAMED database in Europe.
3. Close the page or continue with further setup (see UDI Setup).

See Also

App Installation
App Licensing and Registration
Role Center

Feedback
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Role Center

COSMO Unique Device Identification has a special Role Center that is used with the *UDI Manager* Profile (Role). This Role Center provides the most efficient COSMO Unique Device Identification user experience.

This Role Center provides quick access to pages relating to UDI administration and label printing as well as links to FDA UDI-DIs, Basic UDI-DIs, EU UDI-DIs, Items, and Audit Trails.

The Activities part uses cues to provide a visual overview of the number of open, released, and blocked FDA UDI-DIs, Basic UDI-DIs, and EU UDI-DIs.

To apply this role center

1. Choose the icon and then select My Settings from the menu. Alternatively, you can use the Tell Me feature.
2. In the Role field, choose the ellipsis button.
3. In the Available Roles page, select *UDI Manager* and then choose the OK button.
4. Choose the OK button to close the My Settings page and save your changes.

You can also assign roles directly to users in the User Settings page.

See Also

App Installation
App Licensing and Registration
App Activation
Microsoft Documentation

Feedback
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Setting Up UDI

Further steps are needed to set up COSMO Unique Device Identification.

The following table describes a sequence of tasks, with links to the topics that describe them.

To	See
Set up UDI.	UDI Setup
Set up UDI Status Permissions	UDI Status Permissions
Set up UDI Notified Bodies.	UDI Notified Bodies
Set up UDI Languages.	UDI Languages
Set up UDI GMDN Codes.	UDI GMDN Codes
Set up Clinical Sizes.	UDI Clinical Sizes Setup
Set up UDI Symbol Codes.	UDI Symbol Codes
Set up UDI Storage and Handling Types.	UDI Storage and Handling Types
Set up UDI Sterilization Methods.	UDI Sterilization Methods
Set up UDI Packaging Types.	UDI Packaging Types
Set up FDA Product Codes	FDA Product Codes
Set up EU EMDN Codes.	EU EMDN Codes
Set up UDI Certificate Types.	UDI Certificate Types

Tip

Menu items and fields beginning with FDA or EU are specific to that public agency. For example, there is no need to maintain EU data for FDA UDI-DIs.

Feedback

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UDI Setup

The UDI Setup page contains all the necessary configurations for COSMO Unique Device Identification. The UDI Setup page is accessed using Tell Me. Choose the icon, enter UDI Setup, and then choose the related link.

On the general setup page, general configurations are set which are required in the context of the UDI master data and marking processes.

On opening the UDI Setup page, some fields are set by default but can be adjusted as needed.

General FastTab

The general required setup fields are described in the following table.

Field	Description
Issuing Agency	Specifies the default issuing agency for new UDI-DIs. Can be updated on each UDI-DI individually.
Importer Contact No.	Specifies the default importer contact number for new UDI-DIs. Can be updated on each UDI-DI individually.
Distributor Contact No.	Specifies the default distributor contact number for new UDI-DIs. Can be updated on each UDI-DI individually.
Check Permission for UDI Status	Specifies whether users need a special setup on the UDI Status Permissions page to change the UDI Status of UDI-DIs.
GS1 Company Prefix	Specifies a numeric, 7- to 9-digit GS1 Company Prefix. It is used to generate GTINs for items, variants, and UDI-DIs, and to calculate GMNs for basic UDI-DIs. For more information, see Generate GTINs.
GTIN Nos.	Specifies the number series that will be used to generate GTINs for items, variants, and UDI-DIs. The value is considered only if the field is not specified on the item level. The assigned numbers can have a maximum length of 13 minus the GS1 Company Prefix length. For more information, see Generate GTINs.

Field	Description
Activate FDA Appl. Area	Specifies whether FDA controls shall be displayed (see App Activation). Refresh the page after a change.
Activate EU Appl. Area	Specifies whether EU controls shall be displayed (see App Activation). Refresh the page after a change.
Skip Export Data Update	Specifies whether file exports for UDI-DIs should skip updating any fields. When enabled, export files are generated normally but no changes are made to UDI-DIs (e.g., Submission Version No., Version No., Exported DI No.). This setting is intended for testers and developers to verify export file contents and should never be enabled in production environments.

FDA FastTab

The fields in the FDA FastTab only need to be maintained if you manage FDA UDI-DIs and want to send them to the GUDID.

Field	Description
Customer Contact No.	Specifies the default contact for new UDI-DIs. Can be updated on each UDI-DI individually.
Customer Contact Name	Specifies the name of the default contact (read-only).
Sender DUNS	Specifies your labeler or third-party DUNS number that is part of your GUDID account. It will be used as the default labeler DUNS for new UDI-DIs. For UDI-DIs not labeled by yourself, the labeler DUNS can be updated on each UDI-DI individually.
English UDI Language Code	Specifies the UDI Language Code that represents the English language. It is required for exports to the FDA GUDID.

EU FastTab

The fields in the EU FastTab only need to be maintained if you manage EU UDI-DIs and want to send them to the EUDAMED database.

Field	Description
Model Reference Nos.	Specifies the code for the number series that will be used on GS1 global model number (GMN) calculation for basic UDI-DIs. The assigned numbers may have a maximum length of 23 minus GS1 company prefix length.
Our Manufacturer SRN	Specifies the single registration number (SRN) provided by EUDAMED to act as a manufacturer.
Our SPP Producer SRN	Specifies the single registration number (SRN) provided by EUDAMED to act as a system or procedure pack (SPP) producer.
Default XSD Version	Specifies the default XSD version number. It is used to export to EUDAMED, unless a custom XSD version is populated.
Custom XSD Version	Specifies the custom XSD version to replace the default XSD version. Enter the value in the same format as the default XSD value.

Labels FastTab

Print labels using reports or connect to a label software. For more information, see Labels Overview.

Field	Description
Use Legacy HTTP Request Management	Determines whether the old or new HTTP Request Management is used. - For installations prior to the 5.2 release, turning off this toggle will enable the HTTP request management using the Rest Client module. Once turned off, it cannot be turned back on. - For installations using the 5.2 release or later, the new HTTP request management is used and this setting cannot be changed. With the new HTTP Request Management, whenever printing UDI labels or communicating with the label software, the application generates HTTP requests using the standard Rest Client module. This provides enhanced security and communication error message handling.
HTTP Timeout	Specifies the duration in milliseconds to wait before an HTTP request times out. If none is specified, the Business Central default timeout of 100 seconds is used. In the cloud, you can set a maximum value of 5 minutes (300,000 milliseconds).
Default Layout GS1	Specifies the default label layout for GS1 UDI-DIs.

Field	Description
HIBC LIC	Specifies the 4-digit, alphanumeric Labeler Identification Code (LIC) assigned by the HIBCC. It identifies the labeler on HIBC barcodes.
Default Layout HIBCC	Specifies the default label layout for HIBC UDI-DIs.
Label Public Agency	Specifies from which public agency UDI data will be fetched on UDI label print. If not specified, the user will be prompted to choose the public agency individually on every print (unless reprinting from the UDI Label Entries page, or the document to print involves only UDI-DIs of the same public agency).
COSMO Barcode Auth. Method	Specifies which authentication method the COSMO barcode requires.
COSMO URL Barcode	Specifies the COSMO URL to return a barcode image for reports. Additionally, set an authentication key by choosing More options > Actions > Labels > COSMO Barcode.
Label Software Usage	Specifies whether and how label software is used for printing. For values other than *None*, a corresponding API URL must be provided. Possible values: - *None*: Printed using reports - *Print*: Labels are printed on printers of the label software. - *Preview*: Returns the labels as PDF files. The printer setup is irrelevant for this. - *Print Job*: For test purposes only. Returns the printer specific data. For more information, see Set up Label Printing.

Actions

Menu	Action	Description
Home	UDI Status Permissions	Opens the UDI Status Permissions page to set up permissions for changing UDI Statuses.
Information	About	Shows the current product version and copyright information.

Menu	Action	Description
Actions	Labels > COSMO Barcode Labels > Label Software	Opens submenus to manage label-related actions. For more information, see Set up Label Printing.
	Insert Default Codes	Inserts default symbol codes, sterilization method codes, size types, and measure units. Existing codes will not be updated.
Related	Information > Company Information	Opens the Company Information page to set up your company details.
	App Licensing > License Overview	Opens the COSMO License Overview page, which lists the license status of the COSMO app and allows you to register the app and perform other administrative licensing tasks. For more information, see App Licensing and Registration.

Feedback

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UDI Status Permissions

The UDI Status Permissions controls which user is allowed for which status changes. These permissions apply to UDI-DIs of all public agencies (FDA, EU).

The UDI Status Permissions page is accessed using Tell Me. Choose the icon, enter UDI Status Permissions, and then choose the related link.

Field	Description
User ID	Specifies the ID of the user for whom the permission is to apply.
From UDI Status	Specifies from which UDI Status the user can change. <Blank> is interpreted as *all*.
To UDI Status	Specifies to which UDI Status the user can change. <Blank> is interpreted as *all*.

Note

A warning is shown if the permission entries are inactive due to the current UDI Setup settings.

Feedback

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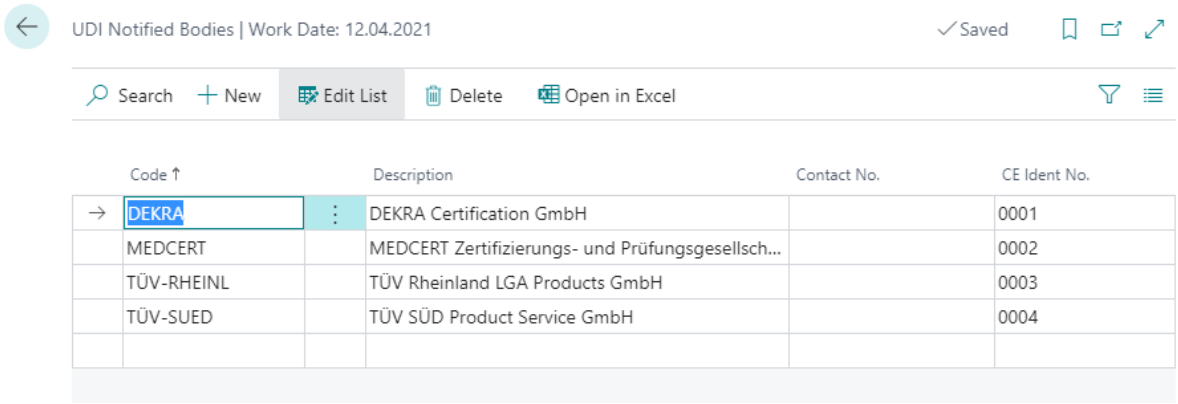
UDI Notified Bodies

Every medical device sold in Europe will require a valid approval certificate in accordance with MDR and IVDR. This certification is carried out by a notified body. This notified body must be assigned to the respective certificate. The notified bodies can be stored as master data.

The UDI Notified Bodies page is accessed using Tell Me. Choose the icon, enter UDI Notified Bodies, and then choose the related link.



Field	Description
Code	Specifies a notified body code that you can select.
Description	Specifies a text to describe the notified body.
Contact No.	Specifies the number of the contact that provides further data such as the address.
CE Ident No.	Specifies the four-digit identification number required for printing CE marks for basic UDI-DI data.

Feedback

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UDI Languages

According to the EUDAMED implementation guideline, the language in which the data is available or in which the data is published must be identified when uploading the data. For this purpose, the UDI languages can be set up accordingly and linked to the respective EUDAMED language code.

In addition, UDI languages are required in the definition of brand names for all public agencies.

Field	Description
Code	Specifies a unique language code that you can choose.
Description	Specifies the description of the language.
Is English	Specifies that the language code represents the English language. The English language is required for exports to the FDA GUDID. Only one language can be marked as English.
EUDAMED Code	Specifies the language code defined by EUDAMED. Only translations into languages with a EUDAMED code will be exported to EUDAMED.

Feedback

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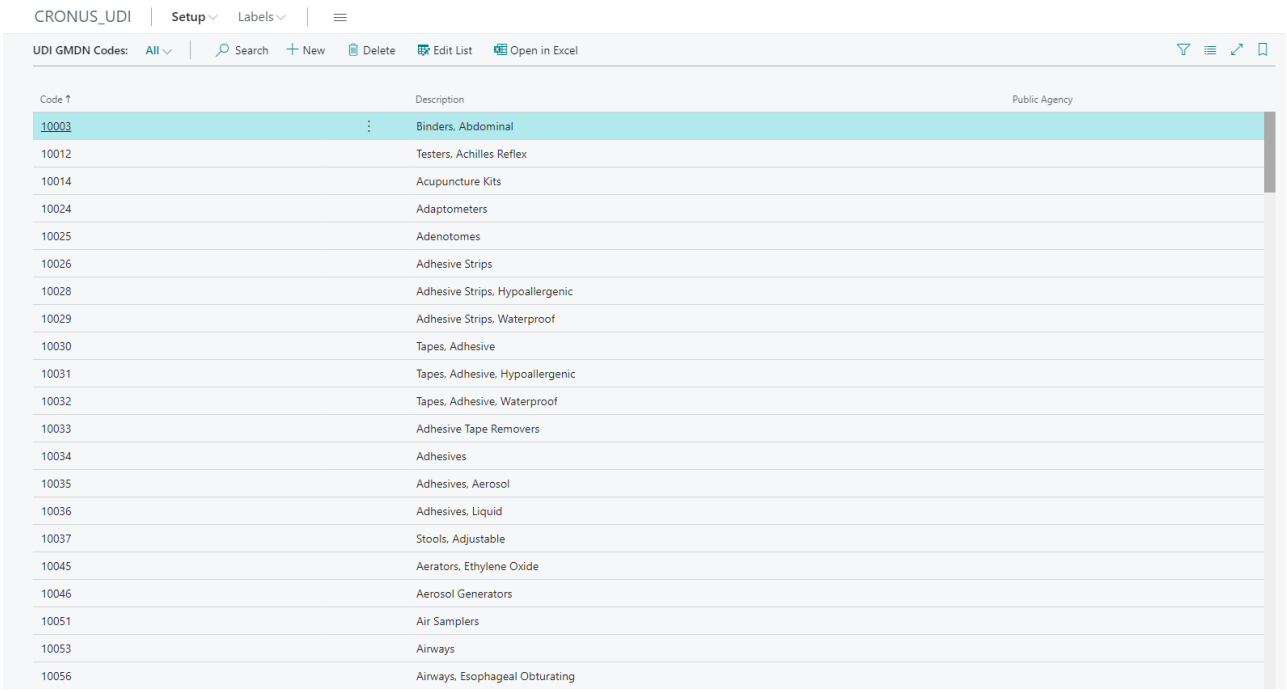
UDI GMDN Codes

Global Medical Devices Nomenclature (GMDN) is the standard for naming and grouping medical devices. The GMDN Codes are required by the FDA UDI System. The system is hierarchical. It divides the medical devices into classes and assigns codes to these classes.



Field	Description
Code	Specifies a 5 digit numeric GMDN code that you can select.
Description	Specifies a text to describe the GMDN.
Public Agency	Specifies the public agency this GMDN is created for. Leave blank in order to apply to all public agencies.

Feedback

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UDI Clinical Sizes Setup

For the specification of clinically relevant sizes, the structuring into categories and attributes is necessary. The setup of Clinical Sizes uses standard item attributes and categories as well as UDI settings for size types and unit measurements, as of which are needed when exporting to EUDAMED.

The following table lists the setup needed for clinical sizes with links to the topics that describe them.

To	See
Set up the size types, which are used to classify clinical sizes and attributes.	UDI Size Types
Set up the unit in which the values of the respective clinical variable are to be specified and evaluated.	UDI Measure Units
Set up the clinical sizes using standard Item Attributes.	UDI Clinical Sizes
Set up the categorization of the clinical sizes.	UDI Clinical Sizes Categories

Feedback

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UDI Size Types

UDI Size Types are a sub-category of the clinical size categories and are used to classify clinical sizes and attributes. Each size type is assigned a corresponding interface code to the FDA GUDID database and EU EUDAMED database.

The Size Types page is accessed using Tell Me. Choose the icon, enter Size Types, and then choose the related link.

The fields are described in the following table.

Field	Description
Code	Specifies a unique code for the UDI Size Type.
Description	Specifies a description for the UDI Size Type.
Category	Specifies the UDI size category the record belongs to.
FDA Code	Specifies the code that will be used for exports to GUDID. It must begin with "C", followed by digits. If no FDA code is defined, then the size type is not considered for export.
EU Code	Specifies the code that will be used for exporting clinical sizes to the EUDAMED database, but not for exporting storage and handling conditions. The code must begin with "CST", followed by digits. The default value for custom size types is CST999. If no EU code is defined, then the size type is not considered for exporting clinical sizes.

The UDI Size Types are partly predefined value codes that are assigned to clinical sizes and also to storage and handling types. Users can add default codes, delete unused default codes, and add their own codes.

Tip

Use the predefined views to filter the page to *Default* or *Custom* codes.

With the setup of the concrete item attributes and their characteristics, the respective UDI Size Types are assigned accordingly.

Insert Default Codes

Choose the Insert Default Codes action to insert size type codes of different categories predefined by the app.

If there is already a code with an identical name, it will not be updated. This means that accidentally deleted default codes can be restored at any time with this function.

Note

Default size types can also be created by choosing Actions > Insert Default Codes on the Unique Device Identification Setup page. However, this function also adds UDI Symbol Codes, UDI Sterilization Methods, and UDI Measure Units.

Feedback

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UDI Measure Units

UDI Measure Units indicate the unit in which the values of the respective clinical variable are to be specified and evaluated.

The Measure Units page is accessed using Tell Me. Choose the icon, enter Measure Units, and then choose the related link. Choose the New action to add a measure unit or Edit List action to edit existing measure units.

Field	Description
Code	Specifies a unique code for the UDI measure unit.
Description	Specifies a description for the UDI measure unit. For custom codes to be exported to EUDAMED, the description must be in English.
Category	Specifies the UDI size category the record belongs to.
FDA Code	Specifies the code that will be used for export to GUDID. If no FDA code is defined, then the measure unit is not considered for export.
EU Code	Specifies the code that will be used for exporting to the EUDAMED database. It must begin with "MU", followed by digits. The default value for custom measure units is MU999. If no EU code is defined, then the measure unit is not considered for export.

The UDI Measure Codes are used in clinical sizes, storage and handling types, and UDI-DI storage conditions. Users can add default codes, delete unused default codes, and add their own codes.

Tip

Use the predefined views to filter the page to *Default* or *Custom* codes.

Insert Default Codes

Choose the Insert Default Codes action to insert measure unit codes of different categories predefined by the app.

If there is already a code with an identical name, it will not be updated. This means that accidentally deleted default codes can be restored at any time by using this function.

Note

Default measure units can also be created by choosing Actions > Insert Default Codes on the Unique Device Identification Setup page. However, this function also adds UDI Symbol Codes, UDI Sterilization Methods, and UDI Size Types.

Feedback

Submit feedback for this page .

UDI Clinical Sizes

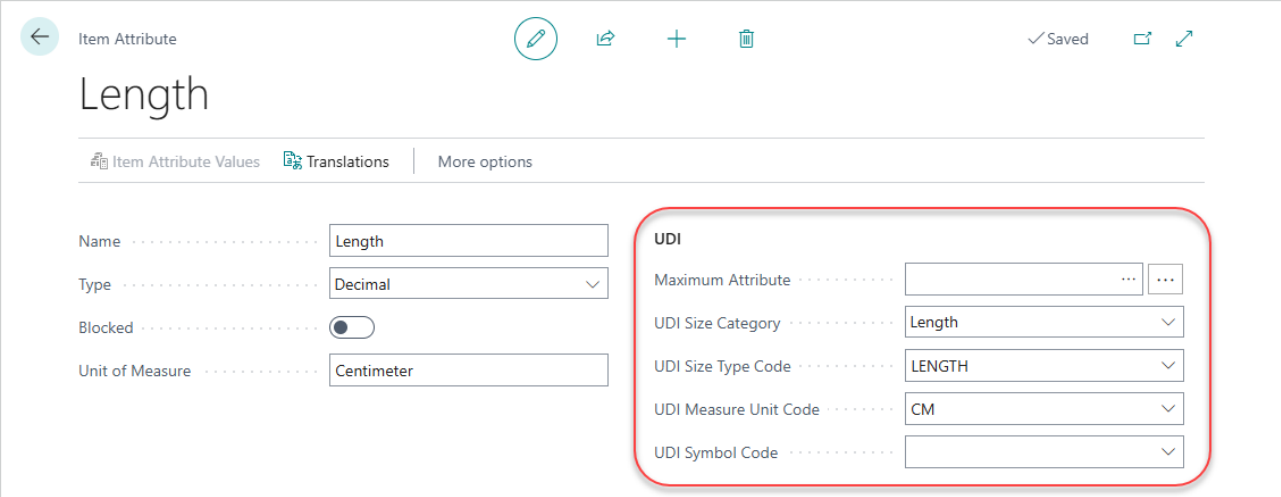
To set up the clinical sizes, standard Item Attributes are used. The setup of clinical sizes parameters can thus be used flexibly.

Important

Only Item Attributes with Type = *Text*, *Integer*, or *Decimal* can be used as clinical sizes. UDI-related fields are only visible when one of these types is selected.

The Item Attributes page is accessed using Tell Me. Choose the icon, enter Item Attributes, and then choose the related link.

Clinical sizes can be added or changed directly in the Item Attributes list page; however, UDI specific fields are only accessible by choosing the Edit action to open the Item Attribute page.



The fields in this page are described in the following table.

Field	Description
Name	Specifies the name of the item attribute.
Type	Specifies the type of the item attribute. If *Text*, *Integer*, or *Decimal* is chosen, the UDI relevant fields are displayed.
Blocked	Specifies that the attribute cannot be assigned to an item. Items to which the attribute is already assigned are not affected.
Unit of Measure	Specifies the name of the item or resource's unit of measure, such as piece or hour. This field is only a text field and has no further functionality.

Field	Description
Maximum Attribute	Specifies another attribute to form a numeric range, whereas the current attribute marks the minimum. You can choose from non-blocked attributes of the same type and unit of measure, and without any assignment as minimum or maximum value. Shown when Type = *Integer* and *Decimal*.
UDI Size Category	Specifies a general size category (e.g., length) to facilitate the choice of the UDI Size Type and the UDI Measure Unit. This field references the Category field on the Size Types and Measure Units pages. Shown when Type = *Text*, *Integer*, and *Decimal*.
UDI Size Type Code	Specifies a size type according to the size category. You can only choose Size Types that are connected to the category you choose in the UDI Size Category field. If the UDI Size Category field is empty, the lookup for this field will be empty. Shown when Type = *Text*, *Integer*, and *Decimal*.
UDI Measure Unit Code	Specifies a measure unit according to the size category. You can only choose Measure Units that are connected to the category you choose in the UDI Size Category field. If the UDI Size Category field is empty, the lookup for this field will be empty. Shown when Type = *Integer*.
UDI Symbol Code	Specifies the symbol code the clinical size is linked to. Clinical sizes with a symbol code will be added to the symbol set entries upon printing. Shown when Type = *Text*, *Integer*, and *Decimal*.

Tip

To form a numeric value range for EUDAMED, combine two item attributes of the same type, by entering the "higher" item attribute name into the Maximum Attribute field of the "lower" item attribute. The EU codes of the lower attribute will be exported.

CAUTION: Item attributes that are part of a range are not considered for exports to GUDID.

Feedback

Submit feedback for this page .

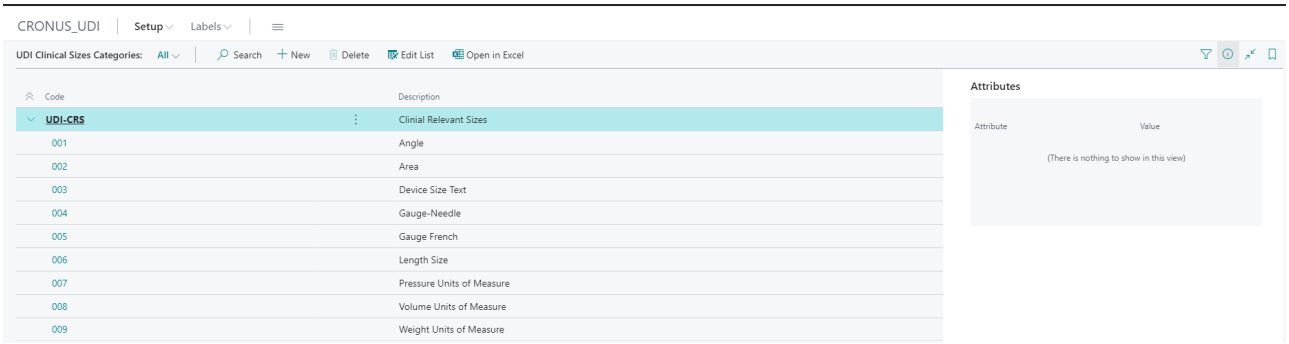
UDI Clinical Sizes Categories

Clinical Sizes Categories are an optional setup feature that allows you to group and manage clinical size attributes. They provide a convenient way to add multiple item attributes (clinical sizes) to a UDI-DI by specifying a single Clinical Sizes Category Code. After selecting a category, users can add or modify the attribute values in a subsequent step, unless they are already predefined in the category.

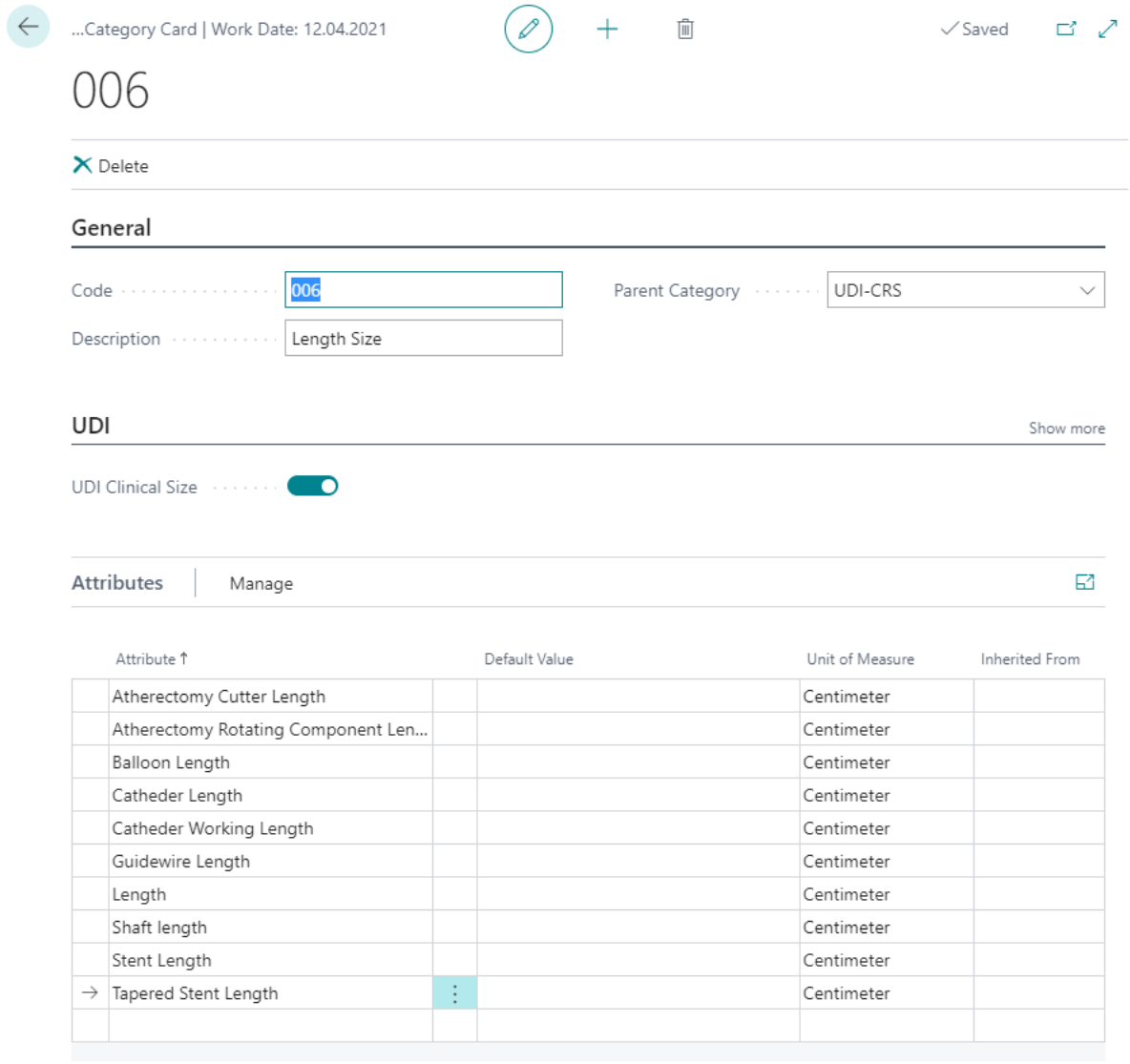
Clinical sizes categories are specified in Business Central by using the standard Item Categories functionality.

To designate an item category as a UDI relevant category, turn on the UDI Clinical Size toggle in the UDI FastTab. This setting automatically filters the Clinical Sizes menu items/pages to show only these UDI categories. Conversely, clinical sizes are hidden on the Item Categories page.

The Clinical Sizes Categories page is accessed using Tell Me. Choose the icon, enter Clinical Sizes Categories, and then choose the related link.



Choose the Edit List action to open the card.



Field	Description
Code	Specifies the item category.
Description	Specifies a description of the item category.
Parent Category	Specifies the parent item category that this item category belongs to. Item attributes that are assigned to a parent item category also apply to the child item Category.
UDI Clinical Size	If the toggle is turned on, it specifies that the item category is used as clinical relevant size and, therefore, reserved for UDI purposes. Item attributes that belong to a parent item category also apply to the child item category.
Attribute	Specifies the attribute which is chosen for this item category.
Default Value	Specifies the value of the item attribute.

Field	Description
Unit of Measure	Specifies the unit of measure code of the item attribute.
Inherited From	Specifies the parent item category that the item attributes are inherited from.

Feedback

Submit feedback for this page .

UDI Symbol Codes

Use symbol codes to:

- manage any number of symbol pictures for labels.
- link them to sterilization methods and storage and handling conditions.
- set mandatory and additional information for the UDI-DI Storage & Handling Conditions page.

For information about setting up UDI Symbol Codes, see UDI Symbol Codes.

Feedback

Submit feedback for this page .

UDI Storage and Handling Types

The storage and handling types are used to be able to represent the storage / handling conditions at DI level. The storage and handling types represent the predefined ranges or conditions which are expressed in a certain unit of measure (for example, temperature in degree Celsius). The storage and handling types can also be linked to a concrete medical symbol which is used when creating the UDI labels for this storage condition type.

Field	Description
Code	Specifies a storage and handling type code that you can select.
Description	Specifies a text to describe the storage and handling type.
UDI Size Type Code	Specifies a predefined UDI size type.
UDI Measure Unit Code	Specifies the default UDI measure unit code that will be populated when selecting this storage and handling type in a UDI-DI storage and handling condition. The populated value can be edited later.
Public Agency	Specifies the public agency this reference is created for. Leave blank to apply to all public agencies.
Special Condition Test	Specifies the default special condition text that will be populated when selecting this storage and handling type in a UDI-DI storage and handling condition. The populated value may be edited later.
Symbol Code	Specifies the symbol to be printed on UDI labels if this storage and handling type is used. Verify a picture has been uploaded on the UDI Symbol page.
Value Format	Specifies a format number (e.g., *2*) or an individual format string (e.g., *<Sign><Integer Thousand><Decimals>°C*) for values printed on labels. If no value is specified, the standard local formatting will be applied.

Tip

Call the lookup of the value format field to test the format expression based on some sample numbers. The page must be open in Edit mode.

Caution

Value formats can only be maintained if a symbol code is assigned with Min. Value Usage or Max. Value Usage not equal to *None* is assigned.

Feedback

Submit feedback for this page .

UDI Sterilization Methods

The sterilization methods are preconfigured with the Insert Default Codes action and assigned to a UDI DI data set. A sterilization method is assigned to the UDI DI data record if the item is packaged as a sterile product or if sterilization is required before the item is used.

> **Note**
> **Default sterilization methods can also be created by choosing Actions > Insert Default Codes on the UDI Setup page. However, this function also adds UDI Symbol Codes, UDI Size Types and UDI Measure Units.**

The UDI Sterilization Methods page is accessed using Tell Me. Choose the icon, enter UDI Sterilization Methods, and then choose the related link.

Field	Description
Code	Specifies a sterilization method code that you can select.
Description	Specifies a text to describe the sterilization method.
FDA C-Code	Specifies the code that will be used for exports to GUDID.
Symbol Code	Specifies the symbol to be printed on UDI labels if this sterilization method is used. Verify a picture has been uploaded on the UDI Symbol page.

Feedback

Submit feedback for this page .

UDI Packaging Types

The packing types are used in the definition of the packing structures and identify the type of packing, for example, whether it is a box or a carton or similar. The packing type setup is flexible and can be done individually by the customer.

Field	Description
Code	Specifies the code for the Packaging Type.
Description	Specifies a text to describe the Packaging Type. Filled descriptions are transferred during the GUDID export and must then be maintained in English.

Feedback

Submit feedback for this page .

FDA Product Codes

The name and three-digit product code identify the generic category of a device for FDA. The product code assigned to a device is based upon the medical device product classification.

Field	Description
Code	Specifies a 3-digit FDA product code that you can select.
Description	Specifies a text to describe the FDA product code.

Feedback

Submit feedback for this page .

EU EMDN Codes

The European Medical Device Nomenclature (EMDN) codes are used to reflect the design and intended purpose of EU UDI-DIs. All EU UDI-DIs (that are not a parent package) must have at least one EMDN code from the EU EMDN Codes page assigned.

The EMDN system is hierarchical. It divides the medical devices into classes and assigns codes to these classes. The nomenclature prescribes a length of 3 to 14 characters for the EMDN codes. The first character must be an uppercase letter, all subsequent characters are numeric.

Important

Enter only codes that are lowest level in the tree-like hierarchy of EMDN. Other codes will fail to import into the EUDAMED database.

Tip

Refer to EUDAMED Devices Nomenclature Finder to search for lowest-level EMDN codes, and to enter them into the page along with their description. Note that the Browse nomenclatures link below the search box will also show upper-level codes; however, these are not eligible for assignment.

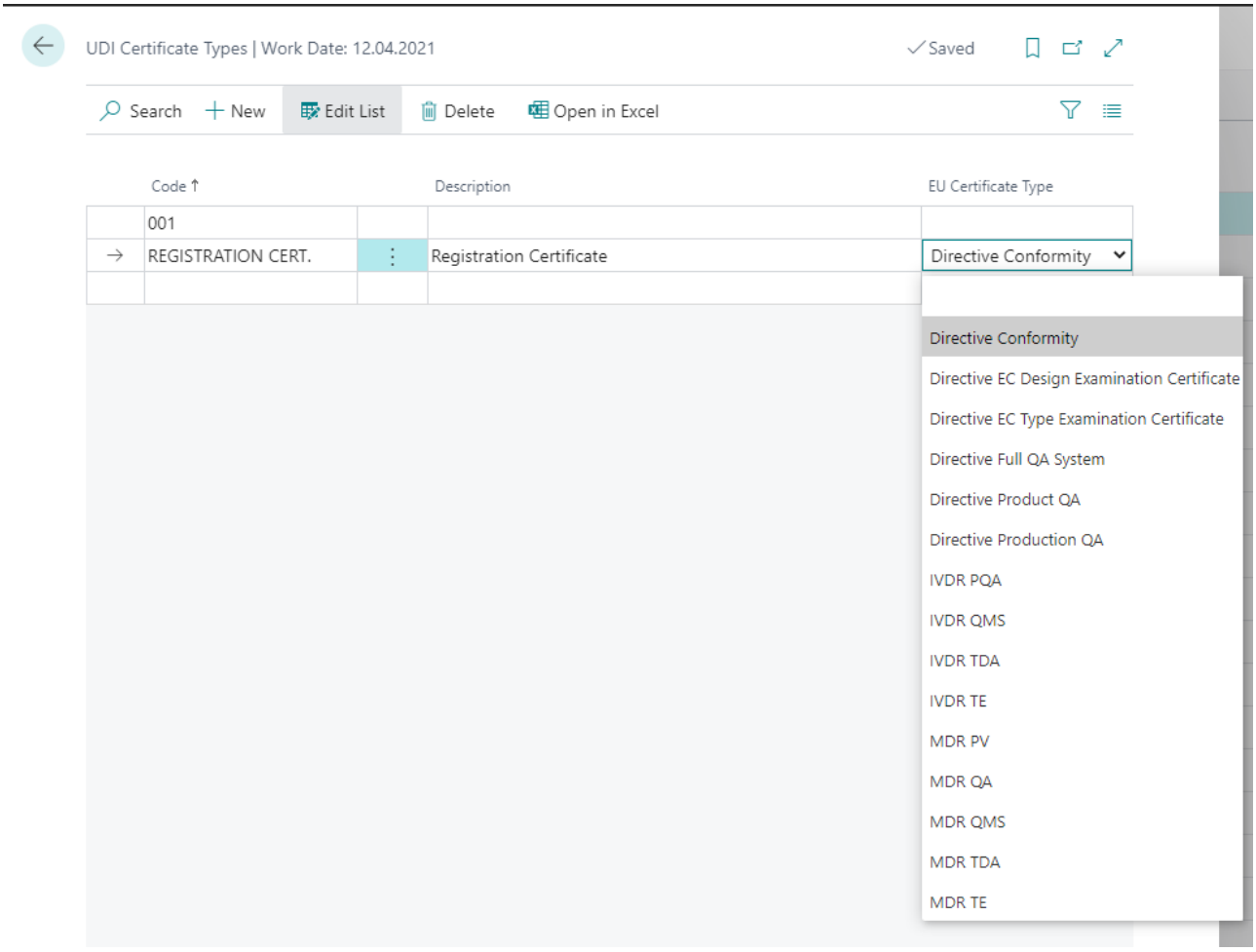
Feedback

Submit feedback for this page .

UDI Certificate Types

Every medical device sold in Europe requires a valid approval certificate in accordance with MDR 2017/745 and IVDR 2017/746. It certifies that the product meets all regulatory requirements of a medical device. By combining a product group into a Basic UDI-DI, only one certificate is required for a product group instead of for each item within a product group. The certificate type specifies the type of the product certificate associated with the device.

UDI certificate types are currently not relevant for the FDA.



Field	Description
Code	Specifies a certificate type code that you can select.
Description	Specifies a text to describe the certificate type.
EU Certificate Type	Specifies the certificate type that will be used when exporting to EUDAMED.

Feedback

Submit feedback for this page .

UDI-DIs

All relevant information of medical devices is managed in so-called UDI-DIs, which are assigned to an Item or an Item variant. UDI-DIs aim to be exported to the central database of the respective public agency after they have been registered and approved. This is done in the case of FDA UDI-DIs to the GUDID, and in the case of EU UDI-DIs to the EUDAMED.

A separate UDI-DI is maintained for each public agency. This means that several UDI-DIs can be assigned to one item or one item variant. The registration is largely independent of each other.

Important

Depending on the public agency (FDA, EU), the application area must be activated to be visible. This is done in the UDI setup by setting the fields Activate FDA Appl. Area or Activate EU Appl. Area.

Create and edit UDI-DI

To create a new UDI-DI or edit existing ones, you can use the corresponding actions on the following pages:

Page	Actions
Item	Item > FDA UDI-DI Item > EU UDI-DI
Item Card	Item > FDA UDI-DI Item > EU UDI-DI
Item Variants	FDA UDI-DI EU UDI-DI

After confirming, the new record opens. Depending on the setup, the first fields of the UDI-DI card are already filled.

Tip

In the new Item variants UDI-DIs, choose the Copy from Item action to copy data from another UDI-DI of the same public agency. These can then be added to.

Data maintenance

UDI data entry is supported by the system in terms of error reduction and user convenience. Already during data entry, important plausibilities are checked and the user is guided through the necessary data entry with dynamically displayed fields.

The following table describes a sequence of tasks, with links to the topics that describe them.

Public Agency	To	See
FDA	Set up FDA UDI-DI Card	FDA UDI-DI Card
EU	Set up Basic UDI-DI Card	Basic UDI-DI Card
EU	Set up EU UDI-DI Card	EU UDI-DI Card
All	Set up Packaging Lines	UDI-DI Packaging Lines
All	Set up Storage and Handling Conditions	UDI-DI Storage & Handling Conditions

Tip

While a UDI-DI is still empty, you can use the Copy from UDI-DI action to copy data from another UDI-DI of the same public agency. Source DI table data can be selected individually. The copy function will skip the DI No. and UDI Status fields, among others. This action is enabled for non-parent UDI-DIs with an open UDI Status only.

Release

Upon release, all mandatory fields and dependencies are checked again. This results in a list which contains warnings and errors.

- Warnings can be ignored. The data set can be released despite existing warnings.
- Error messages prevent the release of the data set.

Export

After successful approval, UDI-DIs can be exported to the public agency database.

The following table describes a sequence of tasks, with links to the topics that describe them.

Public Agency	To	See
FDA	Export data	Data Export to GUDID

Public Agency	To	See
EU	Export data	Data Export to EUDAMED

Feedback

Submit feedback for this page .

Generate GTINs

A Global Trade Item Number (GTIN) is a unique and internationally recognized identifier for products in the global supply chain. In COSMO Unique Device Identification, the GTIN is located on the Item Card, Item Variants, and UDI-DI Cards (EU, FDA, and Basic) in the GTIN, DI No. or Primary DI No. fields, depending on the usage.

GTINs can be created manually or automatically via the Generate GTIN action on the Item Card, Item Variants, and EU/FDA UDI-DI Cards. GTINs created on items and item variants will be transferred to EU/FDA UDI-DI Cards that are created from the items/item variants.

GTIN Number Series

To generate GTINs, a number series must be assigned to the GTIN Nos. field in UDI Setup page (to be used as the default) or the Item Card (which overrides the default from UDI Setup).

The assigned numbers can have a maximum length of 13 minus the GS1 Company Prefix length that is specified in the UDI Setup page, but must be between 3-6 digits.

For example, if you have 9-digit GS1 Company Prefix and need to have a 13-digit GTIN, create a 3-digit No. Series. The final digit will be randomly selected from the GTIN generator.

GS1 Company Prefix	No. Series	Generated Result	Explanation
405401236	123	4054012361235	Company Prefix (405401236) / No. Series (123) / Random Number (5)

GTIN Generator

The fields in the GTIN Generator request page are described in the following table.

Field	Description
Indicator Digit	User-defined, optional number to indicate packaging level (1-8) or that the product is variable measure (9). Indicator digits are used for GTIN-14 only.
GS1 Company Prefix	Automatically populated from UDI Setup.

Field	Description
No. Series Code	Automatically populated from the Item Card when using from Item or Item Variant, or from UDI Setup if not specified in the Item Card. An alternative number series can be selected as needed.
GTIN	Displays the generated GTIN.

To generate a GTIN

1. Open the Item Card, Item Variant, EU UDI-DI Card, or FDA UDI-DI Card.
2. Choose the Generate GTIN action:
   - on the Item menu from the Item Card.
   - on the action bar for Item Variants.
   - on the Actions menu for UDI-DI Cards.
3. Fill in the Indicator Digit field as needed.
4. Update the No. Series Code field as needed.
5. Choose the OK button.

The calculated GTIN (from 12- to 14-digits) is copied to the GTIN, DI No., or Primary DI No. fields.

> **Note**
> **When new UDI-DIs are created from an Item Variant, the GTIN will be stored as the UDI-DI's (Primary) DI No.**

FDA UDI-DI Card

On the FDA UDI DI Card, all relevant information and master data required by the FDA regarding to the UDI requirements is available.

For each Item or Item Variant card a corresponding UDI record can be created by choosing Item > FDA UDI-DI.

If the GTIN has already been entered in the GTIN field on the Item page and GS1 has been defined as the Issuing Agency in the UDI Setup, the GTIN is adopted as the DI number when the UDI data record is created. When creating the data record, the system checks whether the GTIN to be created is already used. If it is already used, there will be an error message and the system stops creating the FDA UDI-DI Data. For more information, see Generate GTINs.

Tip

Entries on several, subordinate pages are required. These pages can be accessed both through actions and drill-downs to fields that start with *Number* or *No.* in their names. It is best to edit all fields one after the other.

Fields

Certain fields are marked with a red asterisk. The red asterisk means that the field must be filled to complete a certain process that uses the field, such as releasing the FDA UDI-DI.

Tip

Choose the Toggle instructional texts action on the Actions menu to get additional note texts for FastTabs and groups of fields. You can remove them by choosing them again.

General FastTab

Field	Description
Is Parent Package	Specifies whether the current DI is supposed to contain other DIs. If the toggle is turned on, specify the child DIs in the packaging lines. Parent package DIs require only very few information. They are not directly exported to GUDID, but indirectly by exporting the DIs they contain.
UDI Status	Specifies whether the UDI-DI is ready to be uploaded to the GUDID.

Field	Description
Blocking Date	Specifies the date on which the UDI Status was set to *Blocked*.
DI Record Publish Date	Specifies the date the DI Record was first published to GUDID and made available via public search.
Submission Set ID	Specifies the globally unique identifier for the device that will used by GUDID to link subsequent versions with previous versions. If you leave it blank, it will be automatically populated during release and should not be changed ever after.
Submission Version No.	Specifies an internal counter that is increased on every export to GUDID, unless the Skip Export Data Update field is enabled in the UDI Setup page.
Exported DI No.	Specifies the value that the Primary DI No. was exported as. GTINs are exported with leading zeros until 14 digits are reached. This field is automatically updated during export, unless the Skip Export Data Update field is enabled in the UDI Setup page.
Created At	Specifies the date and time when the UDI-DI data were created.
Created By	Specifies the user who created the UDI-DI data.
Modified At	Specifies the date and time when the UDI-DI data were last modified.
Modified By	Specifies the user who last modified the UDI-DI data.

DI Information FastTab

Field	Description
Brand Name	Specifies the English proprietary/trade name of the medical device as used in the labeling or catalog. This information is mandatory.
Version or Model	Specifies the version or model number found on the device label or accompanying packaging used to identify a category or design of a device. The version or model identifies all devices that have specifications, performance, size, and composition within limits set by the labeler.
In Commercial Distribution	Specifies whether the device is currently offered for sale. This field is intended for internal use only, and it is not exported to GUDID.

Field	Description
Commercial Distribution End Date	Specifies the date the device is no longer held or offered for sale. The device may or may not still be available for purchase in the marketplace.
Catalog No.	Specifies the catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.
Long Device Description	Specifies the English long description of the device.
Issuing Agency	Specifies the organization accredited by FDA to operate a system to issue UDIs for devices.
Primary DI No.	Specifies an identifier that is the primary lookup for a medical device. The primary DI will be located on label of the base package. For medical devices without packaging, the primary DI number and full UDI may be on the device itself. For more information, see Generate GTINs.
Device Count	Specifies the number of medical devices in the base package (the lowest package level of a medicinal device containing a full UDI). If the number is greater than one, at least a unit of use or a direct marking DI must be specified.
Labeler DUNS	Specifies the labeler company number issued by Dun & Bradstreet (D&B). It was initialized from the UDI setup submitter DUNS, but it may be updated to any other DUNS that is part of the GUDID account as labeler DUNS.
No. of FDA Listing Nos.	Specifies the number of 7-character listing numbers assigned by the FDA. At least one listing number is required for all medical devices, except for HCT/P, kits and licensed IVDs. Medical devices that are HCT/P products with a BL premarket number may not have listing numbers.

Device Characteristics FastTab

Field	Description
MRI Safety Status	Specifies the information the labeling contains about whether the device is compatible with magnetic resonance imaging (MRI) procedures.
Contains Natural Rubber	Specifies whether the device or packaging contains natural rubber that contacts humans. *Natural rubber* includes natural rubber latex, dry natural rubber, and synthetic latex or rubber that contains natural rubber.

Field	Description
Produced without Natural Latex	Specifies that natural rubber latex was not used as material in the manufacture of the medical product and container and the device labeling contains this information. Not all medical products that are NOT made with natural rubber latex are so marked.
For Single Use	Specifies that the device is intended for one use or on a single patient during a single procedure.
Prescription Use (Rx)	Specifies whether a prescription is required.
Over the Counter (OTC)	Specifies whether the device is sold over the counter.
Kit	Specifies a collection of products, including medical devices, that are packaged together to achieve a common intended use.
Combination Product	Specifies whether the product is comprised of two or more types of medical products, such as a drug and a medical device.
HCT/P	Specifies that the product contains or consists of human cells or tissues that intended for implantation, transplantation, infusion, or transfer into a human recipient.
No. of GMDN Codes	Specifies the number of Global Medical Device Nomenclature (GMDN) codes as device types. At least one code must be provided.
No. of FDA Product Codes	Specifies the number of 3-character products codes assigned by the FDA. At least one product code is required for all medical devices, except for kits and licensed IVDs (indicated by a premarket number beginning with BL).
Exempt from Premarket Submission	Specifies if an FDA premarket submission is not required for this device. It can be selected only if the device does not contain human tissue (HCT/P).
No. of FDA Premarket Submission Nos.	Specifies the number of premarket submission numbers assigned by the FDA.
Licensed IVD	Specifies whether the device is a licensed in vitro diagnostic product, as indicated by a premarket number beginning with BL.
Packaged as Sterile	Specifies whether the device is packaged to be free from viable microorganisms.

Field	Description
No. of Sterilization Methods	Specifies how many sterilization methods have been set up for the device. If at least one method is attached, GUDID interprets that sterilization is required prior to use.
No. of SH Conditions	Specifies how many storage & handling conditions have been set up for the device.
Clinical Sizes Category Code	Specifies the category of clinical sizes that the EU UDI-DI belongs to. Clinical sizes categories also contain any assigned attributes.

Alternative and Additional Identifiers FastTab

Field	Description
Is Parent Package	Specifies whether the current DI is supposed to contain other DIs. If the toggle is turned on, specify the child DIs in the packaging lines. Parent package DIs require only very few information. They are not directly exported to GUDID, but indirectly by exporting the DIs they contain.
No. of Parent Package DIs	Specifies the number of packaging units that contain the current package DI. Opens the UDI-DI Packaging Lines page.
Secondary Issuing Agency	Specifies the agency that issues the secondary DI number. It must differ from the primary issuing agency.
Secondary DI No.	Specifies an optional device identifier that may be an alternate lookup to the primary DI.
Unit of Use DI No.	Specifies a number of the same issuing agency as the primary DI number.
Direct Marking required	Specifies whether a direct marking is required. This internal information is not exported to GUDID.
Excepted from Direct Marking	Specifies if the device is subject to direct marking under 21 CFR 801.45, but is excepted.
Alternative DM DI required	Specifies whether an alternative direct marking DI is required.
DM Issuing Agency	Specifies the agency that issues the direct marking DI number. It may be the same as the primary issuing agency.
DM DI No.	Specifies the alternative direct marking DI number.
Lot or Batch No.	Specifies that the lot or batch number is required as part of the PI. The value is read from the item tracking code of the item the UDI-DI is attached to.

Field	Description
Serial No.	Specifies that the serial number is required as part of the PI. The value is read from the item tracking code of the item the UDI-DI is attached to.
Primary Tracking Identifier	Specifies which tracking numbers are used as part of the UDI-PI if both lot/batch and serial number tracking apply. The options are *All Tracking Numbers*, *Lot Number*, and *Serial Number*. This field can be edited only when the UDI Status field is set to *Open* and if both Lot or Batch No. and Serial No. fields are set to *Yes*. The value from this field is copied to Label Item Entries to be considered on label barcodes and is considered on UDI export.
Expiration Date	Specifies whether expiration date is required as part of the PI.
Manufacturing Date	Specifies whether the manufacturing date is required as part of the PI.
Donation Identification No.	Specifies for a HCT/P regulated device, whether the distinct identification code by 21 CFR 1271.290(c) is required as part of the PI.

Customer Contact FastTab

The fields on the Customer Contact FastTab indicate how patients and consumers with device-related questions can contact the device company.

Field	Description
Contact No.	Specifies the number of the contact who is responsible for this device. The contact number is not passed to GUDID.
Contact Name	Specifies the name of the contact who is responsible for this device.
Contact Phone No.	Specifies the phone number of the contact who is responsible for this device. The format should be in +0xx(xx)xxx format and cannot exceed 20 signs.
Contact E-Mail	Specifies the e-mail of the contact who is responsible for this device.

Additional Classification FastTab

All fields of the Additional Classification FastTab are not relevant for the GUDID.

Field	Description
Product Risk Class	Specifies the product risk class according to 21 Code of Federal Regulations.

Field	Description
Measurement Function	Specifies that the device has a measurement function.
Active	Specifies whether the device is an active device.
Implant	Specifies whether the device is an implant.
Reusable Surgical instrument	Specifies whether the device is a reusable surgical instrument.
Reprocessed	Specifies whether the device is a reprocessed device.
Contains Medication	Specifies that the product contains a medication.
Contraindication Text	Specifies the product's contraindication.

Labels FastTab

Here data is stored which controls the printing of data and symbols on labels. They are not relevant for GUDID.

Field	Description
Label Layout Code	Specifies which layout will be considered when printing a label for the current UDI-DI.
Device Description	Specifies a short description to be printed on labels.
Importer Contact No.	Specifies the number of the contact who imported this device. The contact number is not passed to GUDID.
Distributor Contact No.	Specifies the number of the contact who distributed this device. The contact number is not passed to GUDID.
Country of Manufacture	Specifies a two letter or three letter country code to be printed as a symbol on labels. If no code is specified, the symbol will not be printed.
Date Symbol	Specifies whether to print the date symbol on labels.
Liquid Filter Pore Size	Specifies the value to be printed as a symbol on labels, e.g., *15 µm*. If no value is specified, the symbol will not be printed.
No. of Additional Symbols	Specifies the number of additional or electrical symbols to be printed on labels.

Field Values & Dependencies

Some fields are considered mandatory because of the value of another field. The table below lists the most important dependencies.

Field / Value	Description of Dependencies
Unit of Use	If the Device Count > 1, the Unit of use needs to be filled.

Field / Value	Description of Dependencies
Exempt from Premarket Submission	If a premarket submission is linked to the FDA UDI-DI data, the field value cannot be set to *Yes*.
Donation Identification No.	If HCT/P = *Yes* the Donation Identification No. needs to be filled.
Direct Marking	If a direct marking is necessary for a device, the following dependencies exist: Direct Marking = *Yes* Excepted from Direct Marking = *No* Alternative DM DI required = *Yes* DM Issuing Agency - Needs to be filled DM DI No. - Needs to be filled
Secondary Issuing Agency	If a secondary DI No. is needed, the secondary issuing agency needs to be different from the primary issuing agency.

Actions

The actions on the FDA UDI-DI Card are described in the following table.

Menu	Action	Description
Release/Reopen/Block	Release	Releases the UDI-DI to allow export. You must reopen the UDI-DI before you can make changes to it.
	Reopen	Reopens the UDI-DI to change it after it has been released. Exported UDI-DIs have the *Released* status and must be opened before they can be changed.
	Block	Blocks the UDI-DI to avoid any further changes or exports.
Export	Create GUDID export file	Creates and downloads a GUDID export file.
Actions	Copy from Item	Copies FDA UDI-DI values and related tables from the item that the variant is attached to. The action is visible only for UDI-DIs attached to item variants.

Menu	Action	Description
	Copy from UDI-DI	Copies FDA UDI-DI values and related tables from another FDA UDI-DI. The action is visible only for non-parent FDA UDI-DIs not attached to item variants.
Actions	Generate GTIN	Assigns a new GTIN to the Primary DI No. field. For more information, see Generate GTINs.
	Toggle instructional texts	Shows/hides additional note texts for FastTabs and field groups.
Related > DI Information	Brand Names	Opens the UDI-DI Brand Names page where existing brand names can be viewed or new brand names can be edited. The entry of the brand names is language code dependent and depends on the respective public agency to which the data set is to be exported. Therefore, it is possible to enter both FDA or GUDID relevant brand names as well as EUDAMED relevant brand names.
	FDA Listing Nos.	Opens the FDA Listing Nos. page where existing FDA Listing No. can be viewed or new FDA Listing No. can be edited.
Related > Device Characteristics	GMDN Codes	Opens the UDI-DI GMDN Codes page where existing GMDN Codes can be viewed or new GMDN Codes can be edited. For more information, see UDI GMDN Codes.
	FDA Product Codes	Opens the FDA Product Codes page where existing FDA Product Codes can be viewed or new FDA Product Codes can be edited. For more information, see FDA Product Codes.
	FDA Premarket Submission Nos.	Opens the FDA Premarket Submission Nos. page where existing FDA Premarket Submission Nos. can be viewed or new FDA Premarket Submission Nos. can be edited.

Menu	Action	Description
	Sterilization Methods	Opens the UDI Sterilization Methods page where existing sterilization methods can be viewed or new sterilization methods can be edited. For more information, see UDI Sterilization Methods.
	Storage & Handling Conditions	Opens the UDI-DI Storage & Handling Conditions page where existing storage and handling conditions can be viewed or new storage and handling conditions can be edited.
	Clinical Sizes	Opens the Clinical Sizes page where existing clinical sizes can be viewed, or new clinical sizes can be edited. The Clinical Sizes gives Information about the Size Type, the Attributes and belonging Size Values.
Related > Alternative and Additional Identifiers	Packaging Lines	Opens the UDI-DI Packaging Lines page. This action is only available if the Is Parent Package toggle is turned on.
Related > Labels	Print Label Preview	Prints a label preview based on the current UDI data, and using dummy item tracking data. The Label Layout Code must be specified.
	Additional Symbols	Opens the UDI-DI Symbols page. Here you can maintain additional or electrical symbols that are to be printed on labels. This data is not relevant for GUDID.
Related > History	Show Change History	Opens the Change Log Entries page which is filtered to the belonging Basic UDI-DI Date Item. The page shows all Changes of that Basic UDI-DI Data, which should be recorded. All changes are displayed with date and time stamp, user ID, table description, field description, type of change, old value and new value. The action is only active if change log entries exist.

Clinical Sizes FactBox

The Clinical Sizes FactBox displays the UDI-DI related clinical sizes. The clinical size relevant attributes and related values are displayed in the FactBox. Choose the Edit action of the FactBox to directly edit the belonging clinical sizes attributes and values.

Feedback

Submit feedback for this page .

Data Export to GUDID

COSMO Unique Device Identification supports the upload of UDI data to the FDA GUDID database. The connection to the GUDID is not a machine-to-machine connection, but a manual upload based on a generated XML data set.

To create XML files for one or more UDI-DIs, open a list of released FDA UDI-DIs.

1. Select the records you need and then choose the Create GUDID export file action.
2. Confirm the dialog by choosing the Yes button.
3. A zipped export folder will be downloaded to the Downloads folder on your computer. The folder contains one subfolder per UDI-DI named according to the name of the UDI-DI Item No., Variant Code and Submission Version No. Within this folder, another subfolder with the spl name has been created, which contains the actual XML file. This folder structure was defined by the FDA.
4. To upload the file, follow the instructions for using the GUDID database.

> **Note**
> **The Create GUDID export file action is only active if the selected UDI-DI has the *Released* status.**

Feedback

Submit feedback for this page .

Basic UDI-DI Card

Basic UDI-DIs are required to register EU UDI-DIs. The Basic UDI-DI represents the primary identifier of a product model or product group. It is used to identify the product and is assigned at the usage unit level. Thus, it is independent of packaging units and at the same time the most important classification criteria for data records in the EUDAMED database.

Fields

Certain fields are marked with a red asterisk. The red asterisk means that the field must be filled to complete a certain process that uses the field, such as releasing the Basic UDI-DI. Once a Basic UDI-DI has been marked as registered in EUDAMED - indicated by the Version No. field being greater than 0 - certain fields are not editable.

General FastTab

Field	Description
Code	Specifies a code that you can select.
Description	Specifies the description of the Basic UDI-DI.
UDI Status	Specifies whether the UDI-DI is ready to be uploaded to the EUDAMED database.
Used in No. of EU UDI-DIs	Specifies the number of EU UDI-DIs that are using the current basic UDI-DI code.
Blocking Date	Specifies the date on which the UDI Status was set to *Blocked*.
Created At	Specifies the date and time when the UDI-DI data were created.
Created By	Specifies the user who created the UDI-DI data.
Modified At	Specifies the date and time when the UDI-DI data were last modified.
Modified By	Specifies the user who last modified the UDI-DI data.

Identification FastTab

Field	Description
Issuing Agency	Specifies the agency that issues the DI number.
DI No.	Specifies the device identifying number for the basic UDI-DI. In case of the GS1 issuing agency, a GS1 global model number (GMN) is expected. You can assign a GMN either manually, or run the Create GMN action.

Field	Description
Device Model Code	Specifies the code of the device model.
Device Model Name	Specifies the name of the device model.
Legacy	Specifies whether a legacy application legislation (MDD, AIMDD, IVDD) is applied. Legacy devices cannot be exported to the EUDAMED database.
Application Legislation	Specifies the applicable legislation of the device; either medical device regulation (MDR) or in vitro diagnostic regulation (IVDR).
MDR Device Type	Specifies whether the basic UDI-DI represents a standard device, a system or procedure pack. A system means a combination of products, either packaged together or not, which are intended to be inner-connected or combined to achieve a specific medical purpose. A procedure pack means a combination of products packaged together and placed on the market to achieve a specific medical purpose.
System Device	Specifies if the basic UDI-DI is referring to a system which is a device in itself. A system means a combination of products, either packaged together or not, which are intended to be inner-connected or combined to achieve a specific medical purpose.
Procedure Pack Device	Specifies if the basic UDI-DI is referring to a procedure pack which is a device in itself. A procedure pack means a combination of products packaged together and placed on the market to achieve a specific medical purpose.
Special Device	Specifies if the basic UDI-DI is a special device type, and if so, the type of the special device type.
Kit Device	Specifies whether the basic UDI-DI is part of a kit. If set, a related Basic UDI-DI must be populated.
No. of Medical Purposes	Specifies the number of medical purposes. For system or procedure packs, at least one purpose must be provided.
Manufacturer SRN	Specifies the single registration number (SRN) of the manufacturer that registers the device. The value is read from the Our Manufacturer SRN field on the UDI Setup page.
SPP Producer SRN	Specifies the single registration number (SRN) of the system or procedure pack (SPP) producer that registers the device. The value is read from the Our SPP Producer SRN field on the UDI Setup page.

Field	Description
Auth. Represent. Contact No.	Specifies the contact number of the authorized representative associated with the basic UDI-DI. For manufacturers which are not established in the European Union, providing the authorized representative is required. Only a contact with a EUDAMED SRN can be chosen.

Regulatory FastTab

Field	Description
Application Legislation	Specifies the applicable legislation of the device; either medical device regulation (MDR) or in vitro diagnostic regulation (IVDR).
MDR Risk Class	Specifies the product class regarding the medical device regulation.
IVDR Risk Class	Specifies the product class regarding the in-vitro diagnostic regulation.
CE Mark Notified Body	Specifies the notified body involved in the CE conformity assessment procedure. A value is required to print the CE mark on labels, but not for submission to EUDAMED.
CE Ident No. required	Specifies whether the notified body's identification number is required whenever the CE mark is printed. The field is visible as soon as a CE Mark Notified Body is indicated.
No. of Certificates	Specifies the number of product certificates covering the Basic UDI-DI.
No. of Clinical Investigations	Specifies the number of clinical investigations performed for the Basic UDI-DI.

UDI Characteristics FastTab

Field	Description
Animal Tissues/Cells	Specifies whether the device has presence of animal tissues or cells or their derivates.
Human Tissues/Cells	Specifies whether the device has presence of human tissues or cells or their derivates.
Human Product	Specifies if the device contains substances which may be considered medicinal product derived from human blood or plasma.
Contains Medicinal Substances	Specifies if the device contains substances which may be considered medicinal product, but not derived from human blood or plasma.

Field	Description
Active Device	Specifies if the basic UDI-DI corresponds to an active device or not. Active device means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device.
Administer Medicinal Substances	Specifies whether the device is used to administer or remove a medicinal substance.
Implantable	Specifies if the basic UDI-DI corresponds to a device that is implantable or not. Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device.
Implantable Exceptions	Specifies if the registered device is sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates wires, pins, clips and connectors.
Measuring Function	Specifies if the device has a measuring function or not.
Reusable Surgical Instrument	Specifies if the device is a reusable surgical instrument or not. Reusable surgical instrument means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.
Microbial Substances	Specifies if the device contains presence of substances of microbial origin.
Reagent	Specifies if the device is a reagent or not.

Field	Description
Companion Diagnostic	Specifies if the device corresponds to a device that has a role of companion diagnostic device or not. Companion diagnostic means a device which is essential for the safe and effective use of a corresponding medicinal product to: identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.
Instrument	Specifies if the device is an instrument or not.
Near Patient Testing	Specifies if the device is near patient testing or not. Device for near-patient testing means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional.
Professional Testing	Specifies if the device is designed to be used for professional testing or not.
Patient Self-Testing	Specifies if the device is a patient self-testing device or not. Device for self-testing means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services.

EUDAMED Version FastTab

If a device has already been registered in EUDAMED, then all fields in the EUDAMED Version FastTab should be manually populated to reflect the current state. The values can be edited at any time.

The Version State and Version Date fields are used for informational purposes only. They are automatically updated during export, unless the Skip Export Data Update field is enabled in the UDI Setup page.

The Version No. field determines whether certain fields are editable or not, and how the export file will be created. The Version No. is automatically increased by the application after every export, unless the Skip Export Data Update field is enabled in the UDI Setup page.

Field	Description
Version State	Specifies the state of the version in the EUDAMED database.

Field	Description
Version No.	Specifies the number of the version in the EUDAMED database. Any number greater than 0 indicates that the Basic UDI-DI was already registered in EUDAMED. Since Legacy devices cannot be exported, their Version No. is always 0.
Version Date	Specifies the date when the version was last updated in the EUDAMED database.

Field Values & Dependencies

Some fields are considered mandatory because of the value of another field. The table below lists the most important dependencies.

Field / Value	Description of Dependencies
Application Legislation = *MDR*	If the Application Legislation = *MDR*, then MDR Device Type needs to be filled
MDR Device Type = *Standard*	If MDR Device Type = *Standard*, then Special Device needs to be filled. Also the UDI Characteristics FastTab is displayed and the following mandatory fields needs to be filled: - Animal Tissues/Cells - Human Tissues/Cells - Procedure Pack Device - System Device - Human Product - Medicinal Product - Active Device - Administer Medicinal Product - Implantable - Measuring Function - Reusable Surgical Instrument
MDR Device Type = *Procedure Pack*	If MDR Device Type = Procedure Pack then Medicinal Purpose and Producer Contact No. needs to be filled.
Application Legislation = *IVDR*	If the Application Legislation = *IVDR* then Special Device Type and Kit Device needs to be filled.

Field / Value	Description of Dependencies
Application Legislation = *IVDR*	If Application Legislation = *IVDR* then UDI Characteristics FastTab is displayed and the following mandatory fields needs to be filled: - Animal / Tissues / Cells - Human Tissues / Cells - Microbial Substances - Reagent - Companion Diagnostic - Instrument - Near Patient Testing - Professional Testing - Patient Self-Testing
Kit Device = *Yes*	If Kit Device = *Yes* than Related Basic UDI – DI needs to be filled.
Application Legislation = *IVDR*	If Application Legislation = IVDR then other Product Risk (IVDR Risk Class) classes can be chosen.

Actions

The actions on the Basic UDI-DI Card are described in the following table.

Menu	Action	Description
Release/Reopen/Block	Release	Releases the UDI-DI to allow export. You must reopen the UDI-DI before you can make changes to it. When executing the function, the system checks the setup of the respective user permissions. If no suitable authorization to change to the desired status is set up, the system responds with an error message and the status change is canceled. For more information, see UDI Status Permissions.
	Reopen	Reopens the UDI-DI to change it after it has been released. Exported UDI-DIs have the Released status and must be opened before they can be changed.
	Block	Blocks the UDI-DI to avoid any further changes or exports.

Menu	Action	Description
Export	Create EUDAMED export file	Creates and downloads a EUDAMED export file. The action is available only for already EUDAMED registered Basic UDI-DIs (having a Version No. greater than 0).
Actions	Copy from UDI-DI	Copies Basic UDI-DI values and related tables from another Basic UDI-DI.
Related	Medical Purposes	Opens the Medical Purposes page to view or edit the medical purposes.
	Certificates	Opens the Certificates page where existing certificates can be viewed or new certificates can be edited. For more information, see Certificate Types.
	Clinical Investigations	Opens the Clinical Investigations page where existing clinical investigations can be viewed or new clinical investigations can be edited.
Related > History	Show Change History	Opens the Change Log Entries page which is filtered to the belonging Basic UDI-DI Date Item. The Change Log Entries page shows all Changes of that Basic UDI-DI Data, which should be recorded. All changes are displayed with date and time stamp, user ID, table description, field description, type of change, old value and new value. The action is only active if change log entries exist.

Data Changes on Basic UDI-DI Data Entries

Some information is transferred from the Basic UDI DI records to the linked EU UDI DI records. If changes are to be made to already released Basic UDI-DI data sets, all associated EU UDI-DI data sets must first be set to the *Open* status. No changes to the base UDI-DI data set are possible if there are linked released EU UDI-DI data sets. Also the status of the base UDI-DI cannot be reset from *Released* to *Open* if linked released EU UDI-DI records exist.

Submit feedback for this page .

EU UDI-DI Card

In accordance with the Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR) requirements, COSMO Unique Device Identification supports both the management of the Basic UDI data and the requirement relating to the UDI-DI data.

For each Item or Item Variant card, a EU UDI-DI record can be created by choosing Item > EU UDI-DI.

If the GTIN has already been entered in the GTIN field on the Item page and GS1 has been defined as the Issuing Agency in the UDI Setup, the GTIN is adopted as the DI number when the UDI data record is created. When creating the data record, the system checks whether the GTIN to be created is already used. If it is already in use, an error message is displayed and the creation of the EU UDI-DI data is stopped. For more information, see Generate GTINs.

Tip

Entries on several, subordinate pages are required. These pages can be accessed both through actions and drill-downs to fields that start with *Number* or *No.* in their names. It is best to edit all fields one after the other.

Fields

Certain fields are marked with a red asterisk. The red asterisk means that the field must be filled to complete a certain process that uses the field, such as releasing the EU UDI-DI.

General FastTab

Field	Description
Is Parent Package	Specifies whether the current DI is supposed to contain other DIs. If the toggle is turned on, specify the child DIs in the Packaging Lines.
UDI Status	Specifies whether the UDI-DI is ready to be uploaded to the EUDAMED database.
Blocking Date	Specifies the date on which the UDI Status was set to *Blocked*.
Language Code	Specifies the language in which textual information (such as special storage condition texts and critical warnings) is provided. For further information, see UDI Languages.

Field	Description
Created At	Specifies the date and time when the UDI-DI data were created.
Created By	Specifies the user who created the UDI-DI data.
Modified At	Specifies the date and time when the UDI-DI data were last modified.
Modified By	Specifies the user who last modified the UDI-DI data.

Identification FastTab

Field	Description
Issuing Agency	Specifies the agency that issues the DI No., Package DI No. and Unit of Use DI No..
DI No.	Specifies the device identifying number for the EU UDI-DI. If GS1 is used as the Issuing Agency, the GTIN is used at the DI No. For more information, see Generate GTINs.
Basic UDI-DI Code	Specifies the Basic UDI-DI to which the device is associated.
Legacy	Specifies whether a legacy application legislation (MDD, AIMDD, IVDD) is applied. The value is inherited from the Basic UDI-DI. Legacy devices cannot be exported to the EUDAMED database.
No. of Additional Descriptions	Specifies the number of additional product descriptions. These are mandatory for systems or procedure packs, for standard devices being marked as a system or procedure pack, or for kits.
Device Type	Specifies the device type according to the basic UDI-DI. It is used internally for dynamic field visibility control.
Secondary Issuing Agency	Specifies the agency that issues the secondary DI number.
Secondary DI No.	Specifies an optional device identifier that may be an alternate lookup to the primary DI.
Direct Marking required	Specifies whether direct marking is required.

Field	Description
Alternative DM DI required	Specifies whether an alternative direct marking DI is required.
DM Issuing Agency	Specifies the agency that issues the direct marking DI number.
DM DI No.	Specifies the alternative direct marking DI number.
Unit of Use DI No.	Specifies a virtual identifier to associate the use of a device to/on a patient when a base package contains more than one device.

Device Name FastTab

Field	Description
No. of Brand Names	Specifies the number of translated brand names.
Catalog No.	Specifies the reference or catalog number of the device.
Info URL	Specifies the website of the Manufacturer or Labeler where additional information about the device can be available.

Manufacturer/Designer FastTab

Field	Description
Product Designer Contact No.	Specifies the contact number of another legal or natural person who designed or manufactured the device. After an upload to EUDAMED, the Product Designer Contact No. cannot be changed. EUDAMED allows the correction of contact data, but not the addition, change, or removal of the product designer itself. For more information, see Update Product Designer Information.

Packaging FastTab

Field	Description
Is Parent Package	Specifies whether the current DI is supposed to contain other DIs. If the toggle is turned on, specify the child DIs in the Packaging Lines.
No. of Packaging Lines	Specifies the number of Packaging Lines set up for the current UDI-DI.
No. of Parent Package DIs	Specifies the number of packaging units that contain the current package DI.

Field	Description
Base Quantity	Specifies the base quantity in which the device is provided. The default value is 1.

Regulatory FastTab

Field	Description
Device Status	Specifies the status of the device concerning the EU market. The options are: - *On the EU Market* - *No longer on the EU Market* - *Not Intended for EU Market*
Device Status Date	Specifies the date when the device status was last updated.
No. of Market Info	Opens the UDI-DI EU Market Info page. Specifies the number of EU countries the device is or was made available on the market.
No. of EMDN Codes	Opens the UDI-DI EMDN Codes page. Specifies the number of assigned European Medical Device Nomenclature (EMDN) codes to reflect the design and intended purpose of the device. At least one code must be assigned.
New Device	Specifies if the device can be considered a new device. It should be considered to be new if: (a) there has been no such device continuously on the EU market during the previous three years for the relevant analyze or another parameter, (b) the procedure involves analytical technology not continuously used in connection with a given analyze or other parameter on the EU market during the previous three years.
Reprocessed Single Use	Specifies if the device is a reprocessed single use device.

Characteristics FastTab

Field	Description
Lot Specific Tracking	Specifies that the lot or batch number is required as part of the PI. The value is read from the item tracking code of the item the UDI-DI is attached to.
SN Specific Tracking	Specifies that the serial number is required as part of the PI. The value is read from the item tracking code of the item the UDI-DI is attached to.

Field	Description
Primary Tracking Identifier	Specifies which tracking numbers are used as part of the UDI-PI if both lot and serial number specific tracking apply. The options are *All Tracking Numbers*, *Lot Number*, and *Serial Number*. This field can be edited only when the UDI Status field is set to *Open* and if both Lot Specific Tracking and SN Specific Tracking fields are set to *Yes*. The value from this field is copied to Label Item Entries to be considered on label barcodes and is considered on UDI export.
Expiration Date Mandatory	Specifies whether expiration Date is required as part of the PI.
Manufacturing Date Mandatory	Specifies whether the manufacturing date is required as part of the PI.
Software Version Mandatory	Specifies whether the software version is required as part of the PI. The field is visible only if the linked basic UDI-DI is set up as a *Software* in the Special Device field.
No. of SH Conditions	Specifies how many storage & handling conditions have been set up for the device.
Clinical Sizes Category Code	Specifies the category of clinical sizes that the EU UDI-DI belongs to. Clinical sizes categories also contain any assigned attributes.

Safety Info FastTab

Field	Description
Sterile	Specifies if the UDI-DI is labeled as sterile or not.
Sterilization	Specifies if the UDI-DI needs to be sterilized before or use or not.
No. of Reuses	Specifies the maximum number of reuses applicable for the device. Use the -1 value when no maximum number of reuses is defined.
Contains Latex	Specifies if the device contains latex into its composition.
No. of Medicinal or Human Substances	Specifies the number of medicinal or human substances.

Field	Description
No. of CMR or Endocrine Substances	Specifies the number of CMR or endocrine-disrupting substances.
Electrical Brain Stimulation	Specifies whether the device is intended for brain stimulation that applies electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.
Contact Lenses	Specifies whether the device is intended to be introduced into or onto the eye.
EMR	Specifies whether the device emits high intensity electromagnetic radiation (e.g., infra-red, visible light and ultra-violet) intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
Filling By Injection	Specifies whether the substance or item is intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
Product in Body	Specifies whether the device is intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
Equipment for Adipose Tissue	Specifies whether the equipment is intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

Labels FastTab

Here data is stored which controls the printing of data and symbols on labels. They are not relevant for GUDID.

Field	Description
Label Layout Code	Specifies which layout will be considered when printing a label for the current UDI-DI.
Product Description	Specifies an additional description to be printed on labels.
Importer Contact No.	Specifies the number of the contact who imported this device. The contact number is not passed to GUDID.

Field	Description
Distributor Contact No.	Specifies the number of the contact who distributed this device. The contact number is not passed to GUDID.
Country of Manufacture	Specifies a two letter or three letter country code to be printed as a symbol on labels. If no code is specified, the symbol will not be printed.
Date Symbol	Specifies whether to print the date symbol on labels.
Liquid Filter Pore Size	Specifies the value to be printed as a symbol on labels, e.g., *15 µm*. If no value is specified, the symbol will not be printed.
No. of Sterilization Methods	Opens the UDI-DI Sterilization Methods page. Specifies how many sterilization methods have been set up for the device.
No. of Additional Symbols	Specifies the number of additional or electrical symbols to be printed on labels.

EUDAMED Version FastTab

If a device has already been registered in EUDAMED, then all fields in the EUDAMED Version FastTab should be manually populated to reflect the current state. The values can be edited at any time.

The Version State, Version Date, and Exported DI No. fields are used for informational purposes only. They are automatically updated during export, unless the Skip Export Data Update field is enabled in the UDI Setup page.

The Version No. field determines whether certain fields are editable or not, and how the export file will be created. The Version No. is automatically increased by the application after every export, unless the Skip Export Data Update field is enabled in the UDI Setup page.

Field	Description
Version State	Specifies the state of the version in the EUDAMED database.
Version No.	Specifies the number of the version in the EUDAMED database. Any number greater than 0 indicates that the EU UDI-DI was already registered in EUDAMED. Since Legacy devices cannot be exported, their Version No. is always 0.
Version Date	Specifies the date when the version was last updated in the EUDAMED database.

Field	Description
Exported DI No.	Specifies the value that the DI No. was exported as. GTINs are exported with leading zeros until 14 digits are reached.

Actions

The actions on the EU UDI-DI Card are described in the following table.

Menu	Action	Description
Release/Reopen/Block	Release	Releases the UDI-DI to allow export. You must reopen the UDI-DI before you can make changes to it. When executing the function, the system checks the setup of the respective user permissions. If no suitable authorization to change to the desired status is set up, the system responds with an error message and the status change is canceled. For more information, see UDI Status Permissions.
	Reopen	Reopens the UDI-DI to change it after it has been released. Exported UDI-DIs have the Released status and must be opened before they can be changed.
	Block	Blocks the UDI-DI to avoid any further changes or exports.
Export	Add or Update UDI-DI	Creates and downloads a EUDAMED export file that is used to add or update the UDI-DI to EUDAMED. The action is available only for released EU UDI-DIs that have both the Is Parent Package and Legacy toggles turned off.
	Update Market Information	Creates and downloads a EUDAMED export file to update market information.
	Update Product Designer	Creates and downloads one or more EUDAMED export files to update the product designer of selected UDI-DIs.
	Update Container Packages	Creates and downloads a EUDAMED export file that contains the complete package structure of the root UDI-DI, and not just the updated packages.

Menu	Action	Description
Actions	Copy from Item	Copies EU UDI-DI values and related tables from the item that the variant is attached to. The action is visible only for UDI-DIs attached to an item variant.
	Copy from UDI-DI	Copies EU UDI-DI values and related tables from another EU UDI-DI. This action is visible only for non-parent EU UDI-DIs not attached to item variants.
	Generate GTIN	Assigns a new GTIN to the DI No. field. For more information, see Generate GTINs.
Related > Identification	Additional Descriptions	Opens the UDI-DI Additional Descriptions page where additional information about the product or details about specific features of the device can be viewed or edited.
Related > Device Name	Brand Names	Opens the UDI-DI Brand Names page where existing brand names can be viewed or new brand names can be edited. The entry of the brand names is language code dependent and depends on the respective database to which the data set is to be exported. Therefore, it is possible to enter FDA or GUDID relevant brand names as well as EU EUDAMED relevant brand names in the UDI Item Brand Names table.
Related > Packaging	Packaging Lines	Opens the UDI-DI Packaging Lines page. This action is only available if the Is Parent Package toggle is turned on.
Related > Regulatory	EMDN Codes	Opens the UDI-DI EMDN Codes page where EMDN codes assigned to the device can be viewed or edited.
	EU Market Info	Opens the UDI-DI EU Market Info page where EU countries where the device is or was available can be viewed or edited.
Related > Characteristics	Storage and Handling Conditions	Opens the UDI-DI Storage & Handling Conditions page where existing storage and handling conditions can be viewed or new storage and handling conditions can be edited.

Menu	Action	Description
	Clinical Sizes	Opens the Clinical Sizes page where existing clinical sizes can be viewed, or new clinical sizes can be edited. The Clinical Sizes gives Information about the Size Type, the Attributes and belonging Size Values.
Related > Safety Info	Medicinal or Human Substances	Opens the UDI-DI Medicinal or Human Substances page (see UDI-DI Medicinal or Human Substances).
	CMR or Endocrine-Disrupting Substances	Opens the UDI-DI CMR or Endocrine Substances page (see CMR Substances or Endocrine Disruptors).
Related > Labels	Print Label Preview	Prints a label preview based on the current UDI data, and using dummy item tracking data. The Label Layout Code must be specified.
	Sterilization Methods	Opens the Sterilization Methods page where existing sterilization methods can be viewed or new sterilization methods can be edited. These are relevant for label printing only. For more information, see UDI Sterilization Methods.
	Additional Symbols	Opens the UDI-DI Symbols page. Here you can maintain additional or electrical symbols that are to be printed on labels. This data is not relevant for GUDID.
Related > History	Show Change History	Opens the Change Log Entries page which is filtered to the belonging Basic UDI-DI Date Item. The page shows all Changes of that Basic UDI-DI Data, which should be recorded. All changes are displayed with date and time stamp, user ID, table description, field description, type of change, old value and new value.

UDI-DI Medicinal or Human Substances

If a medical device is approved according to MDR and it is a standard product (not a procedure pack or system product), then the Medicinal or Human Substances can be recorded for the product. To edit the medicinal or human substances, choose Related >

Safety Info > Medicinal or Human Substances.

Field	Description
Item No.	Specifies the item number that the record is linked to.
INN	Specifies the International Nonproprietary Name of the substance.
Type	Specifies the type of the substance. The options are: - *Medicinal Product* - *Human Product*

CMR Substances or Endocrine Disruptors

If a medical device is approved according to MDR and it is a standard product (not a procedure pack or system product), then the CMR substances and endocrine Disruptors can be recorded for the product. To edit the CMR substances, choose Related > Safety Info > CMR or Endocrine-Disrupting Substances.

Field	Description
Item No.	Specifies the item number that the record is linked to.
CAS No.	Specifies the Chemical Abstracts Service (CAS) number of the substance.
EC No.	Specifies the European Community (EC) number of the substance in the format XXX-XXX-X.
Type	Specifies the type of the substance. The options are: - *<Blank>* - *1A CMR* - *1B CMR* - *Endocrine-Disrupting*

Clinical Sizes FactBox

The Clinical Sizes FactBox displays the UDI-DI related clinical sizes. The clinical size relevant attributes and related values are displayed in the FactBox. Choose the Edit action of the FactBox to directly edit the belonging clinical sizes attributes and values.

Basic UDI-DI Details FactBox

The Basic UDI-DI Details FactBox displays the UDI-DI related Basic UDI-DI Details. All data from Basic UDI-DI Card are shown in the FactBox for better information.

Feedback

Submit feedback for this page .

Data Export to EUDAMED

COSMO Unique Device Identification supports the upload of UDI data to the EU EUDAMED database. The connection to the EUDAMED is not a machine-to-machine connection, but a manual upload based on a generated XML data set.

Depending on how many records you selected and how the EUDAMED requires them to be grouped, either one XML file or a zip file with multiple XML files will be downloaded to the Downloads folder on your computer. Each XML file name begins with *EUDAMED*, followed by the actor single registration number (SRN), an operation description, and a timestamp.

To upload the file(s), see Upload to EUDAMED.

Basic UDI-DIs and EU UDI-DIs that have already been submitted to EUDAMED are called *registered* devices in COSMO Unique Device Identification.

Tip

To see which records are exportable on the Basic UDI-DIs and EU UDI-DIs list pages, select a view name beginning with *Exportable*.

EUDAMED Version FastTab

In the EUDAMED database, records for registered devices hold a version state (such as *Submitted*), a version number (such as *1*) and a version date.

Both the Basic UDI-DI Card and EU UDI-DI Card hold corresponding fields in the EUDAMED Version FastTab and need to be manually adjusted.

Note

Devices with a Version No. set to 0 are regarded as *unregistered*, and devices with a Version No. greater than 0 as *registered*.

Once the Version No. is set to a value greater than 0, certain fields are no longer editable.

Setting the Version No. to value 0 on a Basic UDI-DI will automatically pass the value to all attached EU UDI-DIs.

Important

It is essential to keep the Version No. field up-to-date.
Every time (unless the Skip Export Data Update field is enabled in the UDI Setup

page) the Create EUDAMED export file or Add or Update UDI-DI action is invoked and confirmed, the Version No. counter for all included devices will be automatically increased by 1 to reflect the future version number in the EUDAMED database.

Export Basic UDI-DIs

To create XML files for one or more Basic UDI-DIs, open a list (or card) of released and registered Basic UDI-DIs.

1. Select the records you need and then choose Export > Create EUDAMED export file.
2. Confirm the dialog by choosing the Yes button.

Note

The Create EUDAMED export file action is only active if the selected UDI-DI has the *Released* status and was already registered.

You cannot directly export new Basic UDI-Ds. Instead, export one or more unregistered EU UDI-DIs attached to the Basic UDI-DIs.

Export EU UDI-DIs

To create XML files for one or more UDI-DIs, open a list (or card) of released EU UDI-DIs.

1. Select the records you need and then choose Export > Add or Update UDI-DI.
2. Confirm the dialog by choosing the Yes button.

Note

The Add or Update UDI-DI action is only active if the selected UDI-DI has the *Released* status, is a base package (the Is Parent Package toggle is turned off), and the Legacy toggle is turned off. Parent packages are automatically included in export files for their base packages.

Update Market Information

When only market information needs to be updated for an EU UDI-DI, you can create and download an export file for this specific task.

To create XML files for one or more UDI-DIs, open a list (or card) of released EU UDI-DIs.

1. Select the records you need and then choose Export > Update Market Information.
2. Confirm the dialog by choosing the Yes button.

> **Note**
> **The Update Market Information action is only active if the selected UDI-DI has the *Released* status, is a base package (the Is Parent Package toggle is turned off), the Legacy toggle is turned off, and the UDI-DI has been already uploaded to EUDAMED, hence the Version No. is greater than zero. The market information update is always exported with version number 1.**

Update Product Designer Information

Once you have submitted an EU UDI-DI to EUDAMED (Version No. > 0), the Product Designer Contact No. cannot be changed because EUDAMED allows the correction of contact information, but not the addition, change or removal of the product designer itself.

If you need to update the contact information, you must use the Update Product Designer export function. The Add or Update UDI-DI action *does not* include any product designer data.

Empty Product Designer Contact No. Warning

When a new EU UDI-DI is released, an empty Product Designer Contact No. field will generate a warning because the information cannot be changed after an upload to EUDAMED. Regardless of whether there is a product designer number or not, the EU UDI-DI will be released:

- If there is no product designer number, you can ignore the message.
- If there is a product designer number, you must reopen the EU UDI-DI, add the product designer number, and then release it again.

Product Designers without Single Registration Number

In the UDI FastTab of the Contact Card, the product designer's single registration number (SRN) is stored in the EUDAMED SRN field. The contact information from this SRN is used when exporting the product designer information. For product designers without an SRN, the information from the fields within the EUDAMED Product Designer field group will be exported.

When an EU UDI-DI is released, an empty EUDAMED SRN field in the related Contact Card will generate a warning and the fields in the EUDAMED Product Designer field group will be tested. The message states that the EUDAMED SRN field is empty and that the

contact's EUDAMED Product Designer data will be exported instead. The release depends on whether issues are found in the contact information:

- If no issues are found, the EU UDI-DI will be released.
- If issues are found, the fields with errors will be listed. You must correct the field(s) in the UDI FastTab of the Contact Card and then release the EU UDI-DI again.

Create Upload File with Product Designer Changes

On the EU UDI-DI Card page, choose the Update Product Designer action on the Export menu to create an upload file with contact data changes, which can be uploaded to the EUDAMED website using the "Update product original manufacturer" upload service.

If run from the EU UDI-DIs page, one or more update files can be created for the selected UDI-DIs.

Update Container Packages

An export is required after container package changes, such as, after adding new parent packages, or changing the Device Status of existing parent packages. After the changes, the root UDI-DI needs to be selected for export.

On the EU UDI-DI Card page, choose the Update Container Packages action on the Export menu to create the export file, named EUDAMED_PUT_PACKAGE_UDI*.xml, which contains the complete package structure of the root UDI-DI, and not just the updated packages.

Note

The Update Container Package action is enabled only for the following UDI-DIs: released, already uploaded to EUDAMED, no legacy device, and no parent package.

The EUDAMED also requires a new container version number added to the file. The system calculates it per root UDI-DI by finding the highest Version No. in any of its parent packages to export, and then it increases it by one. After the export, all exported parent packages are set to the increased version number, unless the Skip Export Data Update field is enabled in the UDI Setup page.

Important

Whenever a (non parent package) EU UDI-DI is set to Device Status = *No longer placed on the EU market* or *Not intended for the EU market*, all its direct or indirect parent packages will be automatically set to the same value. If that UDI-DI was

already uploaded to EUDAMED, an immediate export and upload to EUDAMED is required (Export > Add or Update UDI-DI, but not Export > Update Container Packages). Although not included in the resulting EUDAMED_PATCH_UDI_DI*.xml export file, EUDAMED will also automatically update the status of all packages within a new container packages version.

When changing to Device Status = *No longer placed on the EU market*, all DI EU Market Info valid to the current work date and beyond, are set to Ending Date = work date minus 1.

Upload to EUDAMED

1. In EUDAMED, choose: Data transfer > Bulk Upload > New upload.
2. Select the required service according to the export file name:

Export file name contains	EUDAMED service
PATCH_BASIC_UDI	Update Basic UDI
PUT_PACKAGE	Update container package
PUT_MARKET_INFO	Update market information
PATCH_UDI_DI	Update of UDI-DI / Master UDI-DI
PUT_PRODUCT_DESIGNER	Update product original manufacturer
POST_DEVICE	Upload of Legacy / Regulation Device / SPP (Basic UDI and UDI-DI / Master UDI-DI)
POST_UDI_DI	Upload of UDI-DI / Master UDI-DI for existing Basic UDI-DI

Feedback

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UDI-DI Packaging Lines

Each standard packaging of a product is mapped in Business Central as an item or as an item variant to enable correct pricing, inventory management as well as correct inventory valuation. Thus, each packaging is also assigned to a separate UDI-DI data record. This applies to both FDA UDI DI's and EU UDI DI's.

Starting from the packaging product, the underlying packaging structure can be recorded in the system. This is recorded in the Packaging Lines which are assigned to the UDI-DI data record. However, to be able to identify a packaging item as such, the Is Parent Package toggle must be turned on in the UDI-DI data record card in advance. Once the toggle is turned on, the assigned packaging lines can be registered. All non-relevant UDI-DI fields are dynamically hidden for the capture of the packaging UDI-DI data.

To enter the Packaging Lines, choose Related > Alternative and Additional Identifiers > Packaging Lines, or choose No. of Packaging Lines.

Field	Description
Public Agency	Specifies the public agency for this line.
Item No.	Specifies the item number of the parent package DI.
Variant Code	Specifies the variant code of the parent package DI.
Starting Date	Specifies the date from which the record is valid.
Ending Date	Specifies the date to which the record is valid.
Type Code	Specifies the packaging type. For more information, see UDI Packaging Types.
Packaging DI No.	Specifies the DI number of the parent UDI-DI.
Child Package DE	Specifies the child package DI.
Quantity per Package	Specifies how many units of the child package DI are included in one unit of the parent package DI.

Feedback

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UDI-DI Storage and Handling Conditions

According to the requirements for FDA & EU MDR, statements or instructions for the use of the product must also be issued on the UDI label. For this purpose, the Unique Device Identification app offers the possibility to store corresponding storage and handling conditions for each UDI-DI data record.

To enter the Storage & Handling Conditions, choose Related > Device Characteristics > Storage & Handling Conditions, or choose the No. of S&H Conditions field.

Field	Description
Item No.	Specifies the item number that the record is linked to.
Variant Code	Specifies the variant code that the record is linked to.
Storage & Handling Type Code	Specifies a storage and handling type code used to pre-populate fields and to determine which symbol to print on labels. For more information, see UDI Storage & Handling Types.
Min. Value	Specifies the minimum value that must be met.
Max. Value	Specifies the maximum value that may be achieved
UDI Measure Unit Code	Specifies the UDI measure unit for the minimum and maximum values.
Special Condition Text	Specifies an additional, textual description for a special storage or handling condition that can also be printed on labels. For exports to GUDID, it is considered only if the UDI Measure Unit Code is set to *TEXT SH*.
Public Agency	Specifies the public agency this record is created for. Leave blank in order to apply to all public agencies.
Symbol Code	Specifies the symbol code assigned to the storage and handling type. You cannot add two storage and handling types that share the same symbol code.
EU S&H Condition Type	Specifies the condition type inherited from the symbol code. Only records with a populated value will be exported to EUDAMED as a storage and handling condition.
EU Critical Warning Code	Specifies the critical warning inherited from the symbol code. Only records with a populated value will be exported to EUDAMED as a critical warning.

Note

The Storage and Handling Conditions can only be entered if the UDI-DI isn't marked as a Parent Package.

Feedback

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Labels

Further steps are required to set up label printing in COSMO Unique Device Identification.

The following table describes a sequence of tasks, with links to the topics that describe them.

To	See
Set up Label Printing	Set up Label Printing
Print Labels	Label Printing
Understand Label Entries and reprint Labels	UDI Label Entries

Feedback

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Set Up Label Printing

Labels can be printed using reports or external label software. This can be changed in the settings at any time and for all users at the same time. First of all, some settings are necessary.

Overview and First Steps

To set up label printing, we recommend the following steps.

Order	To	See
1	Create symbol codes for symbols on labels including file.	UDI Symbol Codes
2	Manage different label layouts. If you use label software, you also need the layout code according to the provider.	UDI Label Layouts
3	Complete the general UDI setup.	UDI Setup
4	Specify on which printers the labels will be printed.	UDI Printer Selections

UDI Setup

Identification of the UDI-DIs

For an item, there can be several UDI-DIs from different public agencies (FDA, EU) at the same time. By default, therefore, with each new print (not reprint), the user is asked from which UDI-DI the data should be retrieved. To suppress this query and automatically always define the same public agency, choose the Label Public Agency in the Labels FastTab of the UDI Setup accordingly.

Note

If the Label Public Agency field is empty in UDI Setup but one public agency is found in all UDI-DIs that are attached to the Production Order lines, then this public agency will be selected automatically.

Without Label Software

In order for the label reports to print barcodes according to GS1 or HIBCC standard, a COSMO Azure function must be used.

Important

To obtain a customer-specific authentication key and URL, contact COSMO CONSULT - Andy.Buchmann@cosmoconsult.com.

In the UDI Setup page, the following information is also required in the Labels FastTab.

Field	Default value
COSMO Barcode Auth. Method	*Authentication key*
COSMO URL Barcode	Enter the URL provided to you by COSMO CONSULT.
Label Software Usage	*None*

The authentication key must be entered via Actions > Labels > COSMO Barcode > Set Authentication Key.

With Label Software

To use label software, the following settings must be made on the UDI Setup page in the Label Software FastTab.

Field	Description	Label Software Usage
Label Software Usage	Relevant values: - *Print*: Labels are printed on printers of the label software. - *Preview*: Returns the labels as PDF files. The printer setup is irrelevant for this. - *Print Job*: For test purposes only. Returns the printer specific data.	
Label Software Auth. Method	Specifies which authentication method the label software requires. In addition, set an authentication key via Actions > Labels > Label Software > Set Authentication Key.	
API URL Send Symbols	Specifies the label software API URL to send all symbol codes and symbol pictures to.	
API URL Symbols Report	Specifies the API URL that will return a PDF file with all symbols sent to the label software. It is also necessary to specify the Preview File Path.	Symbol Report
API URL Print	Specifies the label software API URL to print directly.	*Print*

Field	Description	Label Software Usage
API URL Preview	Specifies the label software API URL that will return a PDF file. It is also necessary to specify the Preview File Path.	*Preview*
Preview File Path	Specifies the dot separated path within the response JSON to the symbols report or preview PDF file. Example: "Response.Preview".	*Preview*, Symbol Report
API URL Print Job	Specifies the label software API URL to return a printer specific code. Such code can be sent directly to the target printer for test purposes.	*Print Job*
API URL Printer Names	Specifies the label software API URL to return a list of all available printers on the UDI Printer Selections page. It is also necessary to specify the Printer Name Path.	Printer
Printer Name Path	Specifies the dot separated path within the response JSON to a printer name. Example: "Response.Printer".	Printer

Important

The authentication method, authentication key, and all URLs and paths can be obtained from your label software partner.

Send Symbols

After setting up or changing your UDI Symbol Codes, they must be sent to the label software in bundled form.

To do this, choose Actions > Labels > Label Software > Send Symbols.

You can request a report from the label software at any time for control purposes, listing all imported symbols. To do this, choose Actions > Labels > Label Software > Download Symbols Report.

Tip

The actions are also available on the UDI Symbol Codes page under Actions > Label Software .

Submit feedback for this page .

UDI Symbol Codes

The COSMO Unique Device Identification app enables the printing of UDI labels including the administration of necessary medical symbols. The most important symbols are predefined and only need to be supplemented with a symbol picture.

Existing symbol codes cannot be renamed, only deleted and recreated. Any number of your own symbol codes of all categories can be added.

The UDI Symbol Codes page is accessed using Tell Me. Choose the icon, enter UDI Symbols, and then choose the related link.

Tip

Switch to the *Tall Tiles* or *Tiles* layout option on the page to see all imported symbol code pictures.

Insert Default Codes

Choose the Insert Default Codes action to insert symbol codes of different categories predefined by the app. Then complete them with a symbol picture to print on labels.

If there is already a code with identical name, it will not be updated. That means, accidentally deleted default codes can be restored at any time by means of this function.

Note

Default symbol codes can also be created by choosing Actions > Insert Default Codes on the UDI Setup page. However, this function also adds UDI Sterilization Methods, UDI Size Types and UDI Measure Units.

Fields

Field	Description	Required Categories
Code	Specifies the unique Symbol Code.	
Description	Specifies a description of the symbol.	
Category	Specifies the Symbol Category, see Categories.	

Field	Description	Required Categories
Min. Value Usage	Specifies whether the user can or must enter a Min. Value for UDI-DI storage and handling conditions using the symbol, e.g., for temperatures.	Storage Handling
Max. Value Usage	Specifies whether the user can or must enter a Max. Value for UDI-DI storage and handling conditions using the symbol, e.g., for temperatures.	Storage Handling
Special Condition Text Usage	Specifies whether the user can or must enter a *Special Condition Text* for UDI-DI storage and handling conditions using the symbol, e.g., for an instruction.	Storage Handling
No. of Source Fields	Specifies how many fields have been assigned to determine on label print whether the symbol is required or not. Use the drill-down to open the Symbol Source Fields page.	Source Field
EU S&H Condition Type	Specifies the EU storage and handling condition type to be copied into the UDI-DI storage and handling conditions using the symbol.	Storage Handling
EU Critical Warning Code	Specifies the EU critical warning code to be copied into the UDI-DI storage and handling conditions using the symbol.	Handling Source Field Electrical Additional
Symbol Code Picture (FactBox)	Shows the imported picture for the symbol code. The picture can be imported, exported or deleted.	

Categories

Symbol categories are used for overview and regulate which symbols are available on which pages and when symbols should be printed. Depending on the category, further details are required. It is not possible to create additional categories.

Category	Description
<Blank>	No category selected. Symbols of this category are not considered by the application.
On All Labels	The symbol is automatically assigned to each label.

Category	Description
Source Field	The symbol is assigned to a label if a field stored under Source fields action is filled, see Symbol Source Fields.
Storage	Symbols of this category can be selected on the UDI Storage & Handling Types page, see Storage and Handling.
Handling	Symbols of this category can be selected on the UDI Storage & Handling Types page, see Storage and Handling.
Sterilization Methods	Symbols of this category can be selected on the UDI Sterilization Methods page.
Electrical	This category summarizes symbols of the electrical and electronics area. The symbols must be assigned to the UDI-DIs individually.
Additional	Symbols of this category must be assigned to UDI-DIs individually.

Tip

Use the predefined views to filter the page to a single category. Fields that are not relevant for the current category are automatically hidden.

Symbol Source Fields

The Symbol Source Fields page uses table field references to control under which conditions a symbol is assigned to a label, and whether a value (e.g., a formatted date or temperature limit) should be printed next to the symbol.

Field	Description
Table No.	Specifies the number of the source table. Only certain tables are supported. These are displayed when using the Field Lookup.
Table Caption	Specifies the source table caption.
Field No.	Specifies the source table field. With the lookup, all fields of the table are available.
Field Caption	Specifies the source field caption.
Is Setting	Specifies whether the field determines to print the symbol or not. The evaluation is carried out taking into account the field type, e.g., the *Yes* value must be present for Boolean fields, or the text field must be filled so that the symbol is assigned to the label.

Field	Description
Is Value	Specifies whether the field value will be printed next to the symbol. Field values are always formatted as text. The formatting can be controlled with the Value Format field.
Value Format	Specifies a format number (e.g., *2*) or an individual format string (e.g., "<Year4>-<Month,2>-<Day,2>") for a *non-textual field value* to be printed. If no value is specified, the standard local formatting will be applied.

Several table fields may be defined as Is Setting. This corresponds to an OR operation, which means that the symbol is assigned to the label as soon as at least one of these fields is filled.

Is Setting and Is Value may be set at the same time. This is usually only useful for text fields.

Important

The same table can be used only once per symbol code.

At least one table field must be marked as Is Setting.

A maximum of one table can be used as Is Value. If, nevertheless, several tables are defined, only the last one found will be taken into account.

To add a symbol to a label item tracking entry, an item tracking specific table must be used for both Is Setting and Is Value settings. The current list of item tracking specific tables includes: 32 Item Ledger Entry, 337 Reservation Entry, 6504 Serial No. Information, 6505 Lot No. Information.

Tip

Call the lookup of the value format field to test the format expression based on some sample values matching the data type of the field. The page must be open in Edit mode.

Tip

For clarification, consider the source fields of the *DATE* standard code:

If the Date Symbol toggle is turned on when printing an EU UDI-DI or an FDA UDI-DI, then the *DATE* symbol will be assigned to the label, and the Created date from the UDI label entries will be printed next to the symbol.

Storage and Handling

The Min. Value Usage, Max. Value Usage and Special Condition Text Usage fields define whether the Min. Value, Max. Value and Special Condition Text fields must or may be filled when maintaining UDI-DI Storage & Handling Conditions. Permitted values are:

- *None*
- *Permitted*
- *Required*

Feedback

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UDI Label Layouts

Each UDI-DI is assigned a label layout. Each label layout is linked to a report and, if necessary, with a reference to the layout of the label software provider.

By default, the app delivers a report for demo purposes: 5559063 UDI Label. This is based on the Label Item Entries.

All data to be printed (with the exception of address data) can be taken directly from the Label Item Entries, the Label Item Tracking Entries and the Symbol Set Entries.

> **Tip**
> **To create new reports, use Report 5559063 (UDI Label) incl. layout as a copy template.**

The UDI Label Layouts page is accessed using Tell Me. Choose the icon, enter UDI Label Layouts, and then choose the related link.

Field	Description
Code	Specifies a label layout code that you can select.
Issuing Agency	Specifies the issuing agency the label will be created for. Only layouts with matching issuing agency can be assigned on UDI DIs.
Default for Issuing Agency	Specifies if this label layout is used when updating the issuing agency on UDI-DIs. Only one label layout per issuing agency can be set as the default. It is best to set the field by choosing the Use as default layout action.
Report ID	Specifies the object ID of the report. It must be provided if labels are not printed by a label software.
Report Caption	Specifies the display name of the report.
Code Label Software	Specifies the layout code as defined in the label software. An entry is only required when printing with the label software.

UDI Printer Selections

To print labels from reports, set up the Printer Selections default page as usual.

Printing with label software, on the other hand, requires setting up the printer names on the separate Label Software Printer Selections page. This works similarly to the default page, whereby no field is mandatory.

Tip

From the Label Software Printer Selections page, switch to the default Printer Selections page by choosing the linked note text at the top of the page or by choosing the Report Printer Selection action.

Important

When outputting labels in preview mode (i.e. as a PDF download), label software printer selections are ignored.

The Label Software Printer Selections page is accessed using Tell Me. Choose the icon, enter Label Software Printer Selections, and then choose the related link.

Field	Description
User ID	Specifies the ID of the user for whom you want to define a printer. Leave blank to apply to all users.
Label Layout Code	Specifies the UDI Label Layout code the printer is assigned to. Leave blank to apply to all label layouts.
Label Software Layout Code	Specifies the label software layout code the printer is assigned to. The value is calculated using the UDI Label Layout record.
Printer Name	Specifies the printer of the label software on which the report is to be printed. If the label software supports a standard layout, the printer name may be left blank. Enter the printer name directly or use the lookup. It may take some time to determine the available printer names the first time you open the page.

Prioritization

If, based on the setup, several printers are applicable at the same time, they are prioritized

in the following order.

Priority	User ID	Label Layout Code
1	filled	filled
2	filled	blank
3	blank	filled
4	blank	blank

Tip

Define a standard printer for all label prints by creating a new record and specifying only the printer name. If additional records are created for specific users or label layouts, these will take precedence.

Feedback

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Label Printing

One of the aims of the UDI system is to simplify the identification of medical devices and to enable tracking. In this context, manufacturers are obliged to label their products. Important elements in relation to the labeling obligations are the Device Identifier (DI) data and the Production Identifier (PI) data. The data carriers used (for example, a label) must be both human- and machine-readable. This also applies to any outer packaging. In addition to the UDI system itself, the labeling requirements according to the Medical Device Regulation must also be met. These include, among other things, the presentation of information on use, symbols, or instructions for handling the products. The COSMO Unique Device Identification app supports you in printing product labels in two ways. On the one hand, you can generate a label using the standard report output, on the other hand, there is a prepared interface that can be used to connect to external label printing programs. Depending on the complexity and variety of the labels to be printed, one of the two solutions is used.

Print a Label Preview from UDI-DIs

The Print Label Preview action on FDA and EU UDI-DI pages allow users to print a label preview based on the current UDI data (specifically on the Label Layout Code field), and using dummy item tracking data.

The preview printing is tracked in label entries, just as other label prints are. Their Label Entries can be identified by the Source Record ID being a *CCS UDI FDA UDI-DI* or *CCS UDI EU UDI-DI* record.

Print UDI Labels from Production Orders

The label printing function is implemented in Firm Planned Production Orders, Released Production Orders and Finished Production Orders.

The print function for the UDI label can be executed for the entire production order by choosing the document-based action Reports > Print UDI Labels. In this case, a corresponding UDI label is created for all item tracking lines stored in the production order lines, depending on the quantity in the item tracking specification.

If a UDI label is to be printed only for a specific production order line and thus for the item tracking lines stored in the line, the line-based function can be used by choosing Line > Functions > Print UDI Labels.

Important

Using the print function results in an error message if no item tracking is stored in a Firm Planned or Released Production Order line despite having a remaining quantity, if a Finished Production Order still has a remaining quantity, or if there is no UDI-DI for the item or the item variant.

If HIBC is used as the UDI standard, the following restrictions apply when assigning lot/serial numbers:

- **Only a maximum of 18 characters are permitted.**
- **Alphanumeric characters can be used, but no special characters are allowed.**

History and Reprint of Labels

The Label Entries are the data basis for printing product labels or for transferring the print data to external labeling software. The entries are generated each time the print function is used in the production order. In addition, the label entries enable the reprint of labels.

For more information, see UDI Label Entries.

Feedback

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UDI Label Entries

A new label entry is created for each label printing job, which documents:

- who submitted the print job from which page and when
- for which public agency the UDI data was retrieved according to UDI Label Item Entries
- whether and how label software has been used
- whether all labels could be printed successfully

The label layout and data intended for printing on the label can be found in the Label Item Entries and Label Item Tracking Entries.

> **Note**
> **The entries cannot be edited. For performance reasons, it may sometimes be the case that the Entry No. is not sequential, i.e., for example, 21 is followed by 24. Gaps do not indicate deleted data.**

The UDI Label Entries page is accessed using Tell Me. Choose the icon, enter UDI Label Entries, and then choose the related link.

Label Item Entries and Label Item Tracking Entries

There are one or more label item entries for each label entry. A new label item entry is created for each item number. A new label item tracking entry is created for each serial number and lot number. The data mostly originates from the source document (e.g., the item number and lot number) and the UDI-DI used (e.g., quantity, DI number, symbols).

You can show or hide additional fields in the label item entries by choosing Functions > Toggle Source Field Visibility. These fields are used as source fields for UDI Symbol Codes.

> **Note**
> **The Quantity (Base) as an item or item tracking quantity indicates how often the label was printed.**

Reprint of Labels

An entire print job or individual labels from it can be reprinted from the UDI Label Entries

page. To do this, choose

- Report > Reprint Labels at the top of the page
- or Functions > Reprint Labels on the label item entries and label item tracking entries.

Because a reprint is considered a new print job, new items are created as a copy of the previous ones. Only the following data is determined anew for each print job and can therefore deviate from the original print:

- Source Page
- Label Software Usage
- Print Status
- Layout and Label Software Printer Name
- Company Information
- Address or Contact Data (contact numbers are maintained, but the contact is read again)
- Picture files for symbols
- Item data (Description, Description 2, Translations)

Note

It is not possible to select a subset of the Quantity (Base) when reprinting individual labels. The entire quantity is always printed.

Tip

You can recognize reprints in the label entries by their Source Page ID *5559105 (Label Entries)*, *5559081 (Label Item Entries)* and *5559083 (Label Item Tracking Entries)*.

Send to Label Software

When printing with label software, the data from label entries and label data entries are converted to a JSON file and sent to the label software.

To view this JSON file and exchange it with the label software provider if necessary, choose the Create JSON action. Because this does not result in the printing of a label, no new item is created. This action is also available if no label software is connected.

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