

firstbase User Manual

for data providers using the UDI Connector

firstbase – the industry solution for standardised product master data exchange

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1 Introduction

1.1 How is this manual structured?

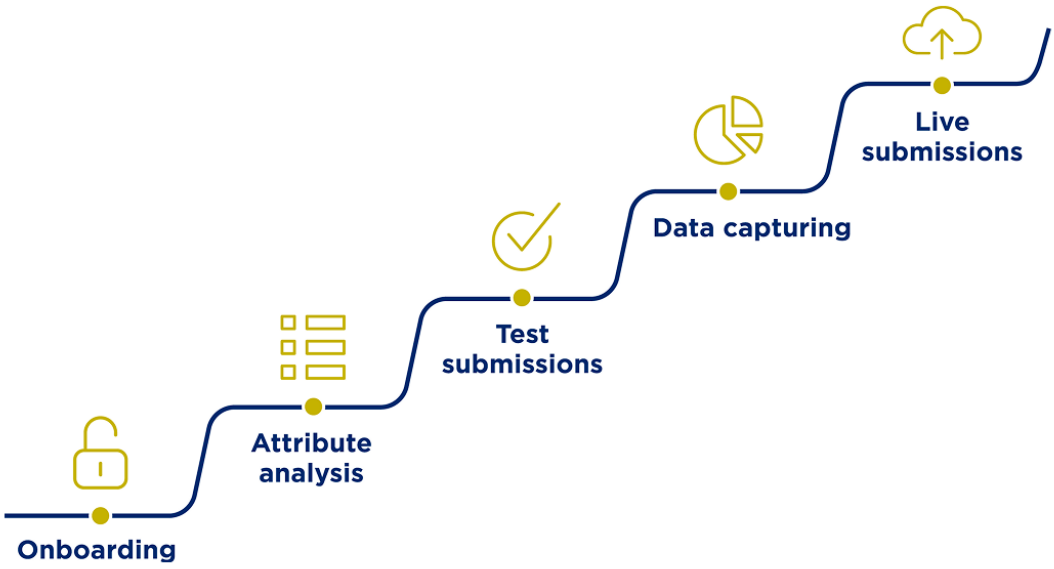
This manual guides you step by step using the UDI Connector service in firstbase. It covers the use of the user interface (WebUI) for capturing and transmitting medical device master data to be registered in the relevant UDI database, e.g. EUDAMED or swissdamed. This manual describes the practical use of the firstbase WebUI for the UDI Connector. It assists you with creating individual UDI records, working with Basic UDI-DI item templates, importing and exporting via Excel, and verifying the submission to the relevant UDI database.

1.2 Target audience

Depending on the UDI database, this handbook is intended for all economic operators acting as manufacturers, producers, importers or Swiss authorised representatives (CH-REP) who have subscribed to the 'UDI Connector' service.

1.3 Scope and limitations

The UDI onboarding process describes preparatory work and the five sequential stages or phases (see diagram) and is not covered in this handbook. It is explained on our UDI onboarding website at *https://www.firstbase.ch/en/support/onboarding-udi*. Alternatively, you can read the detailed explanation of the five phases in the relevant **'GS1 UDI Connector Submission** Guideline'. Completing all five stages is strongly recommended to ensure the successful submission of your UDI registrations. The relevant **EUDAMED** or **swissdamed guideline** can be downloaded from*https://www.firstbase.ch/en/support/manuals-and-tutorials*.



Furthermore, this manual does not describe any (M2M) interfaces. Information on the interfaces can be found on our firstbase website under the Support *> Manuals & Tutorials.*

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1.4 Glossary

GLN

A GLN (Global Location Number) is a globally unique identification number that identifies a clearly defined legal entity, function or a physical location. It ensures that this legal entity can be identified unambiguously and uniquely across all GS1 systems, supply chains and digital platforms.

SRN

An SRN is a European registration number issued to a manufacturer, producer, importer or authorised representative of medical devices when they register with the EU system *EUDAMED*. It serves as a unique identifier for a company within the EU.

CHRN

The Swiss registration number issued to a manufacturer, producer, importer or authorised representative (CH-REP) when they register with the Swissmedic system, swissdamed. It is the Swiss equivalent of the SRN.

UAT (User Acceptance Testing)

UAT refers to a test environment in which real users check whether a system or piece of software is functioning correctly.

PROD

PROD refers to a system's production environment – in other words, the 'real' live version in which actual work is carried out.

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2 Checks on UDI Connector configurations

In the first phase of UDI onboarding, the firstbase team at GS1 Switzerland will set up your account with the necessary access rights and settings. You should therefore check the following aspects and the associated settings before you start the actual UDI data collection and transmission in the firstbase WebUI. This check is a prerequisite for the successful transmission of your UDI data to the relevant UDI database.

The following settings and configuration steps should have been implemented in practice in collaboration with the firstbase team during Phase 1 of the onboarding process before you proceed:

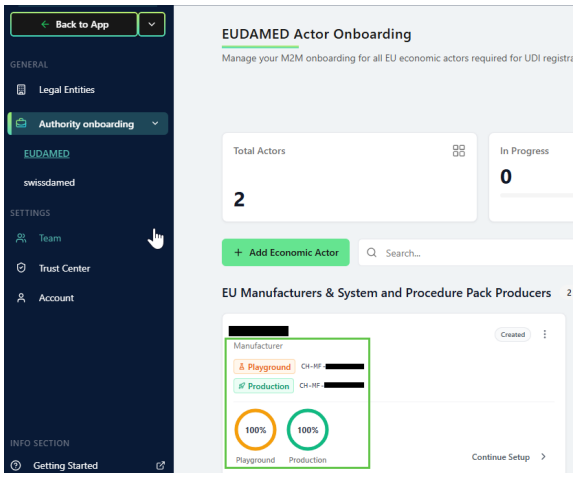
☐ You have registered your **user account** with GS1 Switzerland (Single Sign-On) and successfully logged in to the UAT environment at *https://test-firstbase.gs1.ch/Account/Login*.
→ This is where Phase 3 takes place.

☐ You have registered your **user account** with GS1 Switzerland (Single Sign-On) and successfully logged in to the PROD environment at *https://firstbase.gs1.ch/Account/Login*.
→ Phases 4 and 5 take place here.

☐ For each environment, the logged-in account is displayed in the top-right corner of the 'User Account' menu. Under 'Company Settings' in the 'Default Settings' tab, check whether the 'UDI Registry' sector has been set up.

☐ The relevant **Actors** in the required roles are available in the respective **UDI database environment** (e.g. *swissdamed Playground*, *swissdamed Production*) and have been set up by you for M2M as described in the guideline, e.g. 'GS1_swissdamed_Guideline.pdf', Phase 1.

☐ All relevant information for the configured actors (e.g. ID, SRN, UDI token) has been provided and **fully configured** (by the firstbase team) **in UDI Connect** at *https://app.udiconnect.io/id/sign-in*.

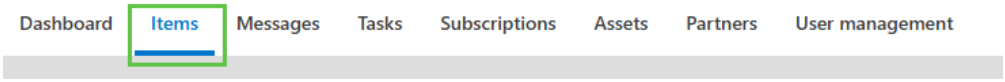


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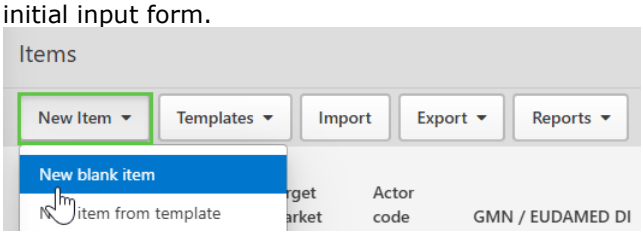
3 Creating UDI records using the editor

3.1 Create an initial UDI draft

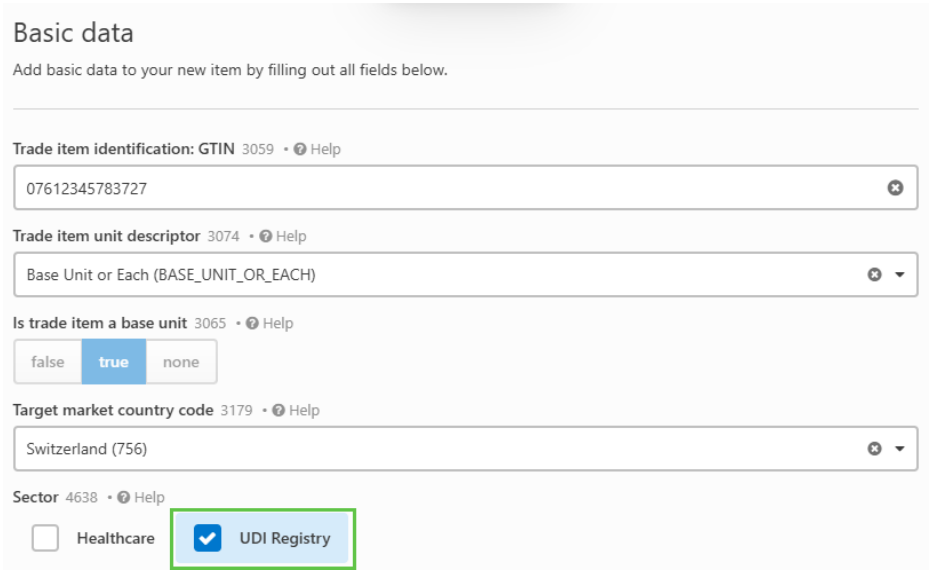
1. Log-in to firstbase.
2. Switch to the 'Items' tab.



3. To create a new item (UDI record), select 'New Item' and **'New blank** Item'; this will open the initial input form.



4. Fill in the initial mandatory attributes (marked in red) as follows:
   a. **GTIN of the** (primary) **UDI-DI**; this must be a 14-digit number with a valid check digit, with a leading '0' if necessary.
   b. 'Trade item unit descriptor' by code: BASE_UNIT_OR_EACH for the UDI-DI as a base item
   c. Depending on the UDI database, select, for example, 756 for swissdamed, 097 for EUDAMED, etc., under 'Target market country code'.
   d. For 'Sector', select **'UDI Registry**'.
   e. Leave all other attributes pre-filled and click **'Next'** three times to proceed through the initialisation screen. This will generate the draft and open the 'Draft' editor mode.



5. In the case of EUDAMED or swissdamed, save the draft by **clicking** 'Save' and exit the item's input editor by clicking the 'Exit' button. Before continuing, first create the **Basic UDI-DI for the first item** (see *EUDAMED/swissdamed: Creating your first Basic UDI-DI*).
6. You can then continue entering data in 'Draft' mode – or, in the case of other UDI databases such as AusUDID (target market = Australia 036) – until all required attributes have been completed.
7. Finally, save your changes by clicking the **'Save'** button.

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3.2 EUDAMED/swissdamed: Creating your first Basic UDI-DI

The **Basic UDI-DI** is the model or family reference for a product group covered by the EU MDR and IVDR, and groups together similar UDI records in EUDAMED or swissdamed. Within the model hierarchy of a Basic UDI-DI, certain key regulatory attributes are the same and must be populated consistently for all UDI records linked to it. The identification code of the Basic UDI-DI is recorded in firstbase under attribute 3183 **Global Model Number** (GMN for short):



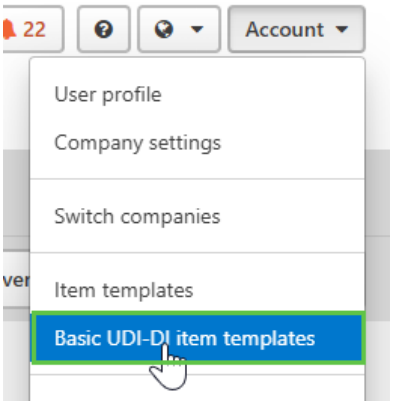
In firstbase, all Basic UDI-DI attributes can generally be recorded together with the individual UDI-DI data records at the base item level. At all other packaging levels ('Package UDI-DIs'), only attribute 4767 **Global Model Number (GMN)** is linked.

To ensure flawless transmission to EUDAMED or swissdamed, it is essential that all Basic UDI-DI attributes – e.g. actor SRN or risk class – are consistently populated within the same product group. firstbase therefore offers the option of creating Basic UDI-DI records separately as a template and inheriting the relevant attributes to the linked individual items (UDI-DI). **Before** creating all the UDI-DIs belonging to a Basic UDI-DI, we therefore recommend creating the respective **'Basic UDI-DI item** template'.

First, check in your firstbase (TEST or PROD) environment by going to the 'Account' and 'Company Settings' menu in the top right-hand corner, then select the 'Services' tab to see whether the **'Basic UDI-DI** Items' feature has been set up under 'Additional services'. If it has not been set up and you wish to use this feature, please contact us via our *contact form*.

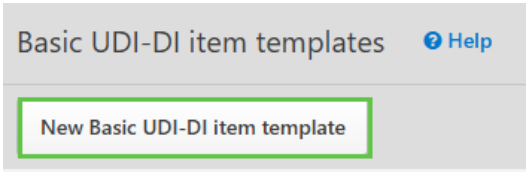
Once it has been set up, proceed as follows:

1. Click on **'Basic UDI-DI item** templates' in the top-right corner of the 'Account' menu.

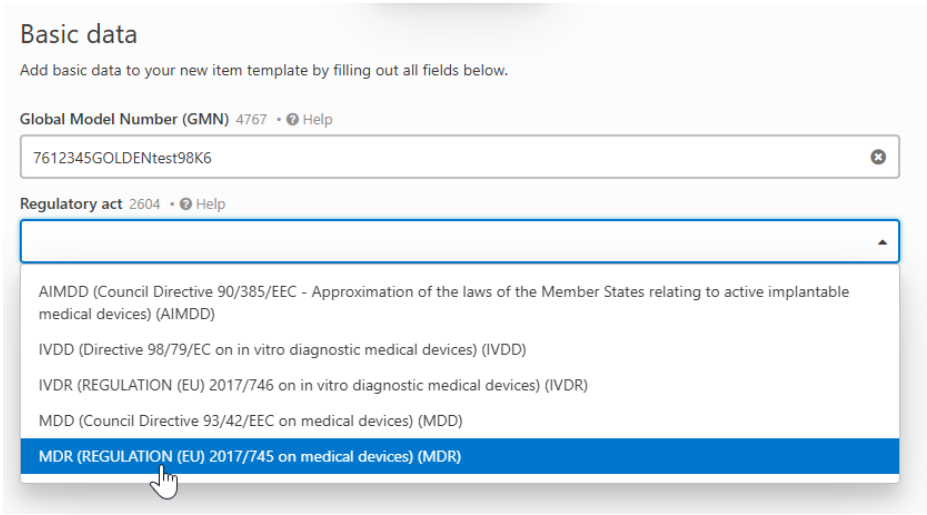


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2. To create a new Basic UDI-DI record, select **'New Basic UDI-DI item** template'; this will open the initial input form.



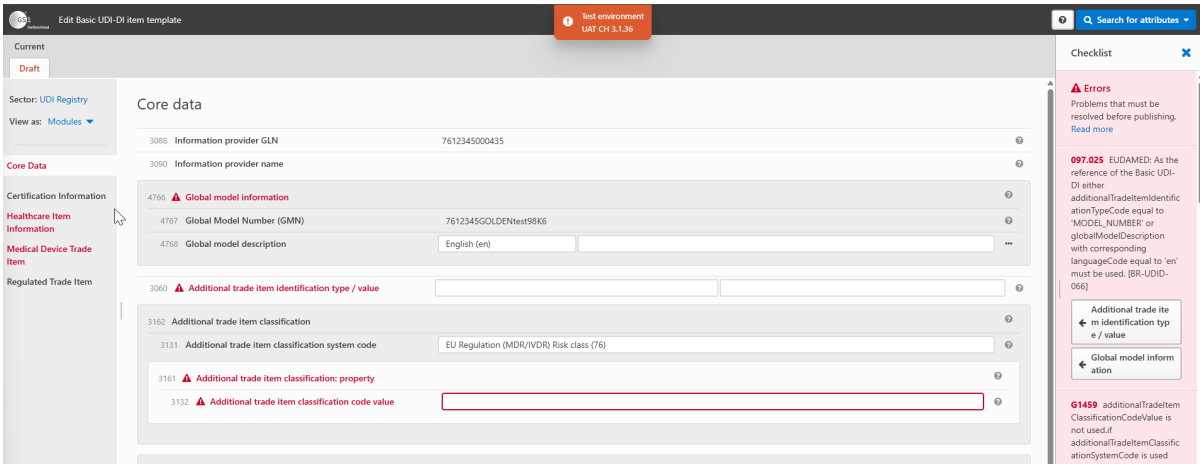
3. Fill in the initial mandatory attributes (marked in red) as follows:
   a. **The Basic UDI-DI GMN**; it must be valid with two check digits and can be generated at *https://www.gs1.org/services/check-character-calculator*
   b. Select the applicable legislation under 'Regulatory act' by code, e.g. **MDR** or **IVDR**



Note:

If 'Legacy Device' records subject to the MDD, AIMDD or IVDD legislation are to be checked for consistency between EUDAMED and swissdamed using a template, a Basic UDI-DI item template can also be generated for each GTIN. Please note that, in this case, attribute 4767 Global Model Number (GMN) must be entered under 3a. with the value 'B-[GTIN]', e.g. 'B-07612345783727'.

4. To generate the template, click on **'Create template**'. This will generate the draft and open the 'Draft' editor mode.
5. Fill in all the required attributes under the relevant legislation, taking care to address the validation errors displayed under the **'Checklist**':

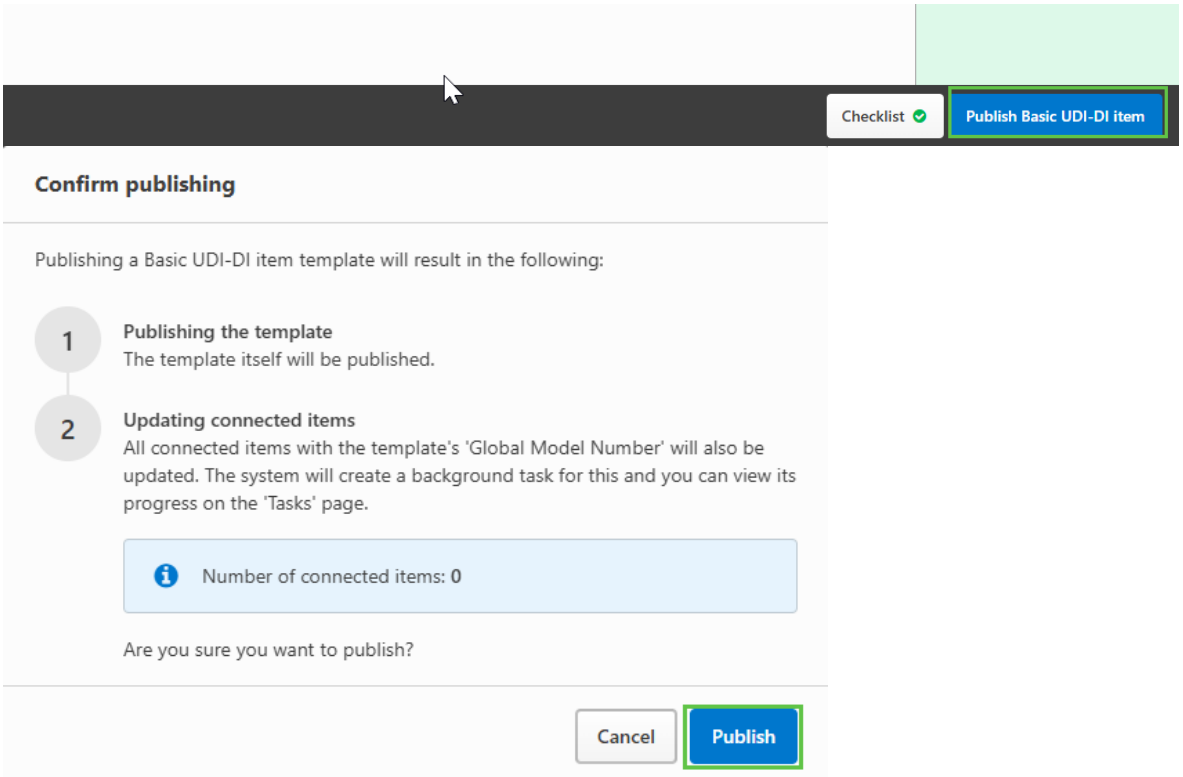


6. In the input form, all attributes are validated 'globally' using **EUDAMED validation rules**. If the same 'Basic UDI-DI item template' with the same GMN is also to be used for swissdamed UDI

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records, add the attribute 3183 'Additional company identification: Type / Value' with your **CHRN** below the SRN in the corresponding attribute 3182 'Contact: Code', using the value 'Manufacturer (MF) (EMA)' or 'System/procedure pack producer (PR) (EMA)', depending on your role.

7. Finally, click the 'Save' button and publish the template using the **'Publish Basic UDI-DI item'** button. Confirm the whole process again under 'Confirm publishing'.

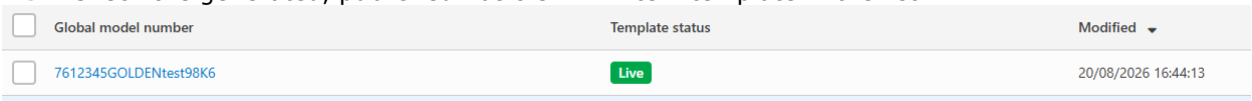


For the Basic UDI-DI template, the publication process will start briefly in the background and your template status will change to 'Live'.

Note:

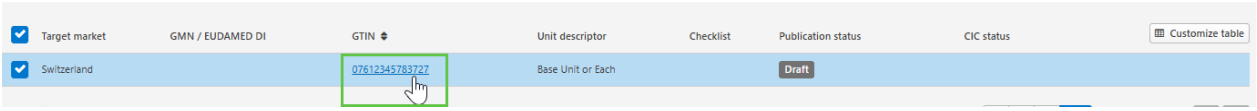
As long as no linked items (UDI-DI records) have yet been published using the created Basic UDI-DI as the Global Model Number (GMN), no data will be transmitted to the UDI Connector at this stage. Only when items have the 'Live' publication status will the publication of the Basic UDI-DI item template trigger a re-publication of the individual UDI data record. See also *Publishing to the UDI database via the UDI Connector*.

8. Check the generated, published Basic UDI-DI item template in the list:

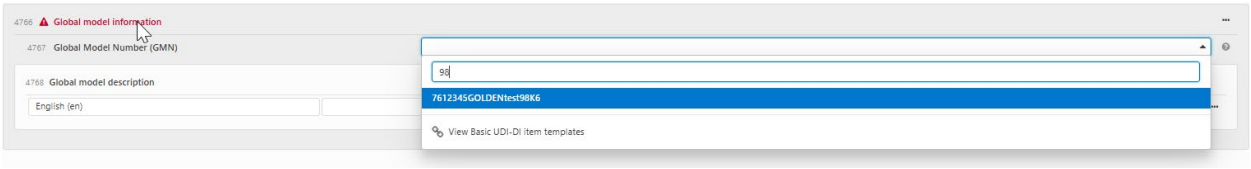


3.3 EUDAMED/swissdamed: Finalising the first UDI draft

1. Go back to the 'Items' tab.
2. Open the 'Draft' editor mode for the item you created earlier, e.g. by clicking on the GTIN:



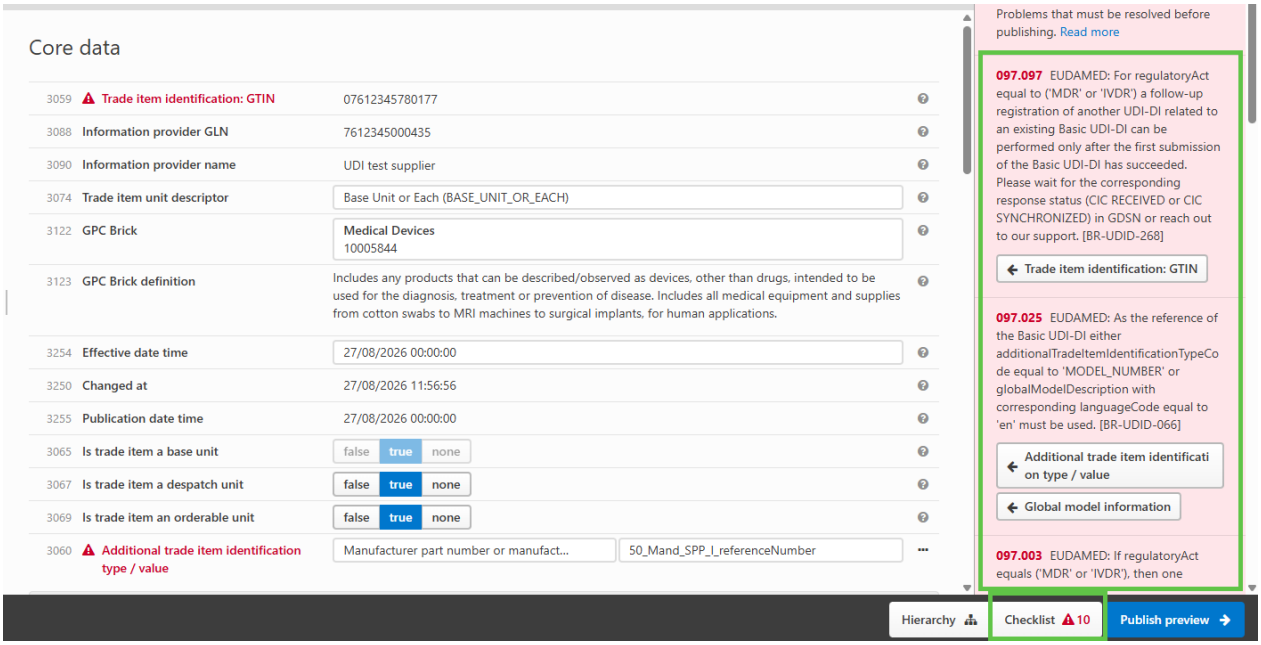
3. Go to attribute **4767 Global Model Number (GMN)** and select your previously created and published Basic UDI-DI item template by entering the GMN:



4. Once selected, all attributes belonging to the Basic UDI-DI item template are transferred or inherited by the item and appear with a 'chain symbol' because they are linked to the Basic UDI-DI record.



5. Complete all required attributes in accordance with the relevant legislation, taking care to address any validation errors displayed under the **'Checklist'**:



6. Save the item.

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3.4 Publishing to the UDI database via the UDI Connector

Once you have entered and validated the product information, you publish the UDI record. Only then is the data transmitted via the UDI Connector to the desired UDI database.

3.4.1 Publishing in the item editor (draft mode)

1. Open the relevant item in draft mode by clicking on the GTIN.
2. Then click on 'Publish preview'.
3. Under 'Who should see this?', select the 'Restricted' option and, under 'Data recipients', select the GLN of the UDI Connector (UAT: **4399902421386** / PROD: **7609999484735**).
4. Click 'Save'.
5. To publish the items, click on 'Publish'.



Note:

Particularly relevant for EUDAMED: Before proceeding with further UDI records, wait until the published UDI record has been successfully transmitted to EUDAMED. You can check this via the 'CIC status' in the product overview; the status must read **'Synchronised'**. If the 'CIC status' column is not displayed in the item overview, add it via 'Customise table'.



Note:

Only products without validation errors can be published.

4 Bulk processing via the Excel template

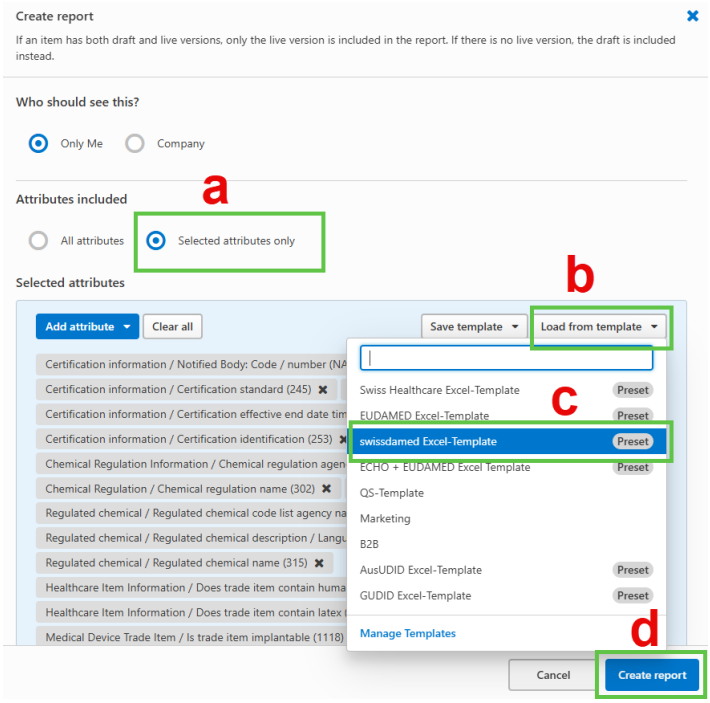
This chapter explains how to download the UDI records in Excel, enter the data in Excel (large quantities) and upload them.

Please note that you should only proceed with this step once the UDI has been successfully submitted to the required regulatory database (must have the status **'Synchronised'**).

4.1 Downloading UDI records to Excel

1. Log in to firstbase.
2. Go to the 'Items' tab.
3. Click on 'Reports' and select the option 'Filtered items to Excel, complete data set'. You will now need to configure a few settings.
   a. Give the report **a name, e.g. based on the Basic UDI-DI (GMN).**
   b. Select the option 'Product data + Access control'.
   c. Select the option 'Selected attributes only'.
   d. Use the 'Load from template' button to select the **'swissdamed** Excel template' or **'EUDAMED** Excel template'.
   e. Click on 'Create report'.

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Note:

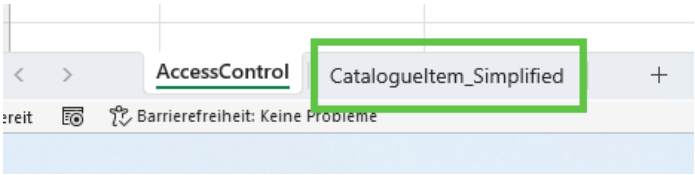
Download the items as reports each time. This has several advantages: the report can be given a name so that it can be found in the 'Tasks' tab with a timestamp. Downloads via 'Export' are not recorded in the history and therefore cannot be traced.

Note:

Download only one BUDI per report. This helps you to maintain an overview and avoid accidentally mixing up BUDIs.

4.2 Entering UDI records in the Excel template

1. Open the Excel template you downloaded earlier.
2. Switch to the 'CatalogueItem_Simplified' worksheet.



3. The BUDI that has already been successfully registered will now be displayed here. You can now enter all the UDIs belonging to the same BUDI below it. You can use the BUDI as a guide for this.
4. Once you have entered all required UDI-DI records, save the file.

Note:

Numbers must always be entered in the Excel template using the 'Standard' format. You can recognise this by the green triangle in the relevant field.

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4.3 EUDAMED/swissdamed: Importing Basic UDI-DI item templates via an Excel template

When performing a bulk upload with multiple Basic UDI-DI adjustments, the following generally applies:

New or updated '**Basic UDI-DI item template**' must be created or generated by 'importing' an Excel template before the bulk upload of the associated items is carried out under 'Items > Import'. Following this two-step procedure ensures that the 'Basic UDI-DI item template' and all linked items remain consistent and up to date.

The following applies to the Excel import under 'Basic UDI-DI item templates':

A single Excel file may contain several items linked to a Basic UDI-DI.

For each Basic UDI-DI, only the values from the first row of a linked base item – based on attribute 4767 **Global Model Number (GMN)** – are used to create or update the corresponding 'Basic UDI-DI ttem templates'. Any further rows with the same Global Model Number are ignored by the import.

If the import encounters an entry linked to a different Global Model Number, the values from the first occurrence of this Basic UDI-DI are used to create or update the corresponding 'Basic UDI-DI item templates'.

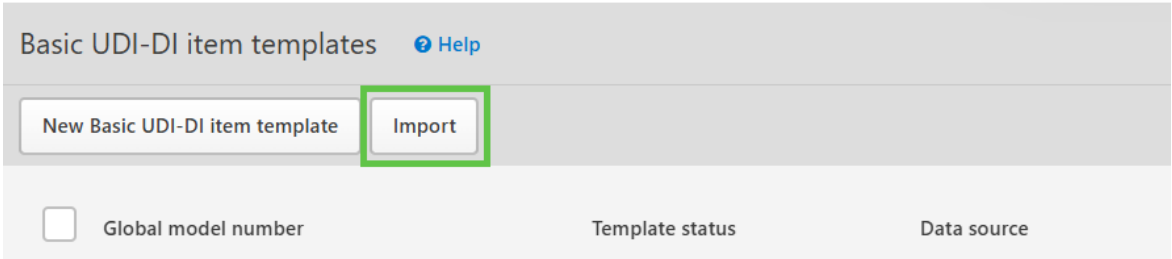
Example (basic items only):

- Line 1 → Basic UDI-DI A → Basic UDI-DI item template A created or updated
- Line 2 → Basic UDI-DI A → Ignored
- Line 3 → Basic UDI-DI A → Ignored
- Line 4 → Basic UDI-DI B → Basic UDI-DI item template B created or updated
- Line 5 → Basic UDI-DI B → Ignored
- Line 6 → Basic UDI-DI C → Basic UDI-DI item template C created or updated

This ensures that template-driven attributes remain consistent across all items linked to the same Basic UDI-DI.

Specific procedure for **creating** new 'Basic UDI-DI item templates' where these are missing:

1. First, import the same Excel template that you downloaded from 'Items' (and edited if necessary) using the **'Import'** button under the **'Basic UDI-DI item templates'** menu.

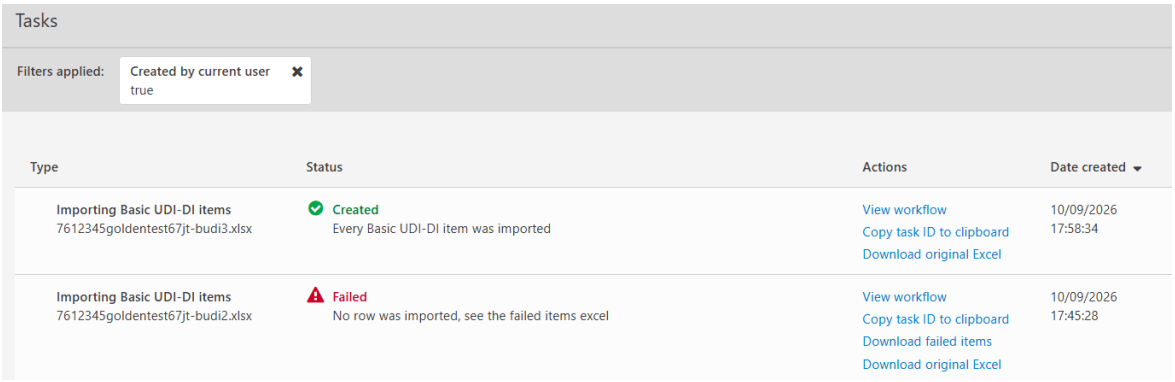


Note:

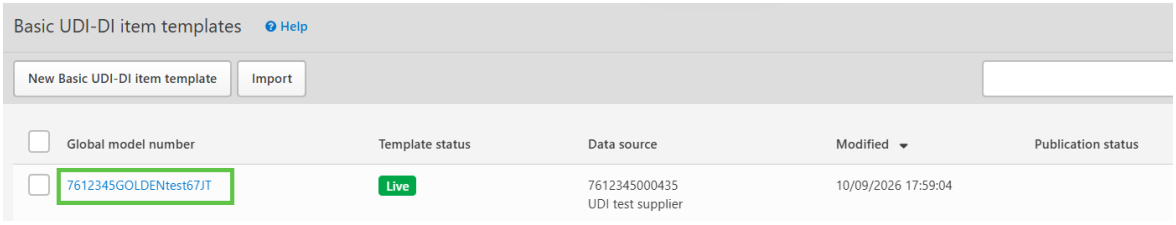
The Excel template must contain no more than 1,000 rows of data (items), and the .xlsx file must not exceed 20 MB in size.

2. You can monitor the import process under 'Tasks' and, in the event of an error, troubleshoot under 'Download failed items'.

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3. Once the import has been successful, you can click on individual imported Basic UDI-DIs under 'Basic UDI-DI item templates' using the **'Global Model** Number' and carry out spot checks on their values.



4. The new items (UDI-DIs) are then also imported and published via the standard process under 'Items' using the 'Import' button. (See also *Importing UDI records from an Excel template* and *Publication via bulk upload*)

Step-by-step procedure for **making changes** to existing 'Basic UDI-DI item templates'

1. To change one of the few editable attributes of a 'Basic UDI-DI item templates', before republishing, import the same Excel template that you would import under 'Items' via the **'Basic UDI-DI item templates**' menu using the **'Import'** button.
2. Subsequently (only if necessary), the same Excel template can be imported again under 'Items' using the 'Import' button should further adjustments to the existing items (UDI-DIs) be required.

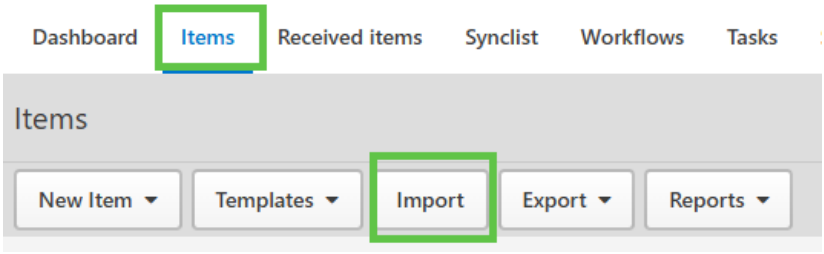
Note:

If you change details relating to the Basic UDI-DI attributes of existing **'Basic UDI-DI item templates**' in the Excel template, these will be ignored during import under the 'Items' menu; in other words, they will not be uploaded and will not be applied to the corresponding items. Return to step 1.

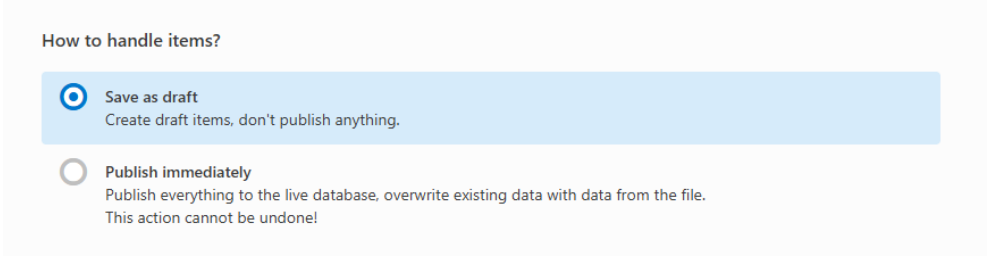
3. Once the import has been successfully completed, you can click on individual imported Basic UDI-DIs under 'Basic UDI-DI item templates' using the **'Global Model Number (GMN)**' and perform spot checks on the amended values.
4. Tick the box next to the verified draft of a 'Basic UDI-DI item template'. Publish this using the **'Publish Basic UDI-DI item**' button. Confirm the whole process again under 'Confirm publishing'. For the 'Basic UDI-DI item templates', the publication process starts briefly in the background and their template status changes to 'Live'.

4.4 Importing UDI records from an Excel template

1. Go back to firstbase.
2. Switch to the 'Items' tab.
3. Click on the 'Import' option.



4. Select the desired file using the 'Browse' button.
5. Specify that you want to 'Save as draft' the UDI data.



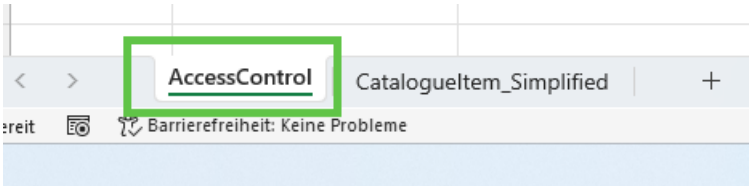
6. Click on 'Import'.

Note:

If the **'Basic UDI-DI item templates'** feature is enabled and you amend details relating to the Basic UDI-DI attributes in the Excel file, these will not be uploaded or updated during import under the 'Items' menu. To change one of the few updatable attributes of 'Basic UDI-DI item templates', the adjustments must be made separately in the relevant menu using the editor or via an Excel import before republishing. (See also *EUDAMED/swissdamed: Creating your first Basic UDI-DI* or *EUDAMED/swissdamed: Importing Basic UDI-DI item templates via an Excel template*)

4.5 Publication via bulk upload

If you wish to publish a large number of items, you can do so via an Excel upload. To do this, use the 'Access Control' tab in Excel. This was downloaded as part of the initial download. In the UDI context, this method is used for follow-up submissions and bulk updates.



1. The following details must be provided:
   a. GTIN (column A)
   b. Target market (Column B). For swissdamed, this is always '756'; for EUDAMED, it is '097'.
   c. Item level (Column C). Please note that in the case of hierarchies (products with multiple packaging levels, such as smallest unit, carton, outer packaging, etc.), the GTIN of the highest level must always be entered. If all levels were entered, errors would occur during transmission as the correct order would not be maintained.

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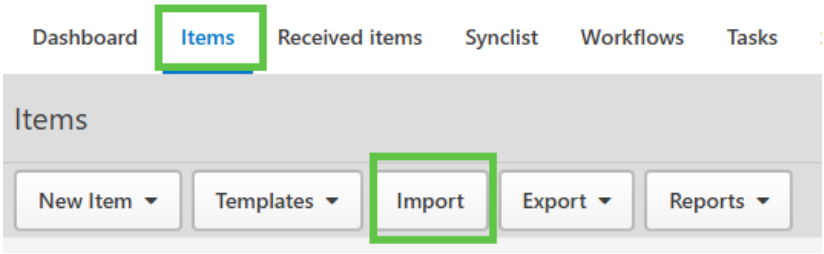
d. Recipient GLN (column G). Always enter the GLN for the UDI Connector (UAT: **4399902421386** / PROD: **7609999484735**).

	A	B	C	D	E	F	G	H
1	Gtin	TargetMarketCountryCode	TradeItemUnitDescriptorCode	DescriptionShort	PublishToTargetMarket	AccessControlGroupName	Gln[0]	
2	Gtin (NaN)	TargetMarket Country Code	Trade Item Unit Descriptor Code	Trade Item Description Short	Publish To TargetMarket	Access Control Group Name	Publish to Gln	
3	07320451393241	756	BASE_UNIT_OR_EACH				4399902421386	
4	07320451438164	756	BASE_UNIT_OR_EACH				4399902421386	
5	07320451391834	756	BASE_UNIT_OR_EACH				4399902421386	
6	07320451450746	756	BASE_UNIT_OR_EACH				4399902421386	
7	07320451438140	756	BASE_UNIT_OR_EACH				4399902421386	
8								
9								
10								

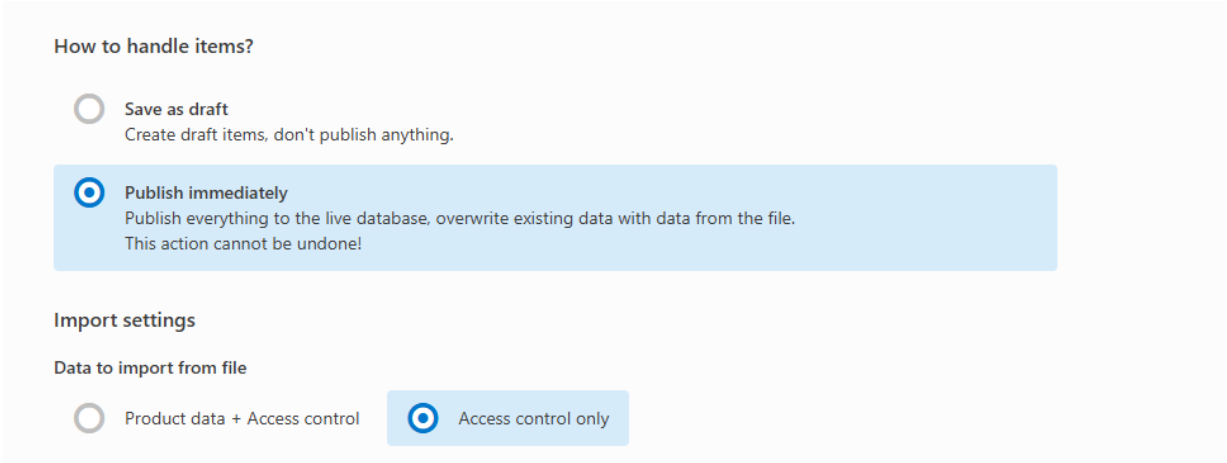
Note:

You can copy and paste the information from the 'CatalogueItem_Simplified' tab.

2. Save the file.
3. Switch to the 'Items' tab.
4. Click on the 'Import' option.



5. Select the desired file using the 'Browse' button.
6. Specify that you want to 'Publish immediately' the items and upload them with 'Access control only'.



7. Click 'Import'.

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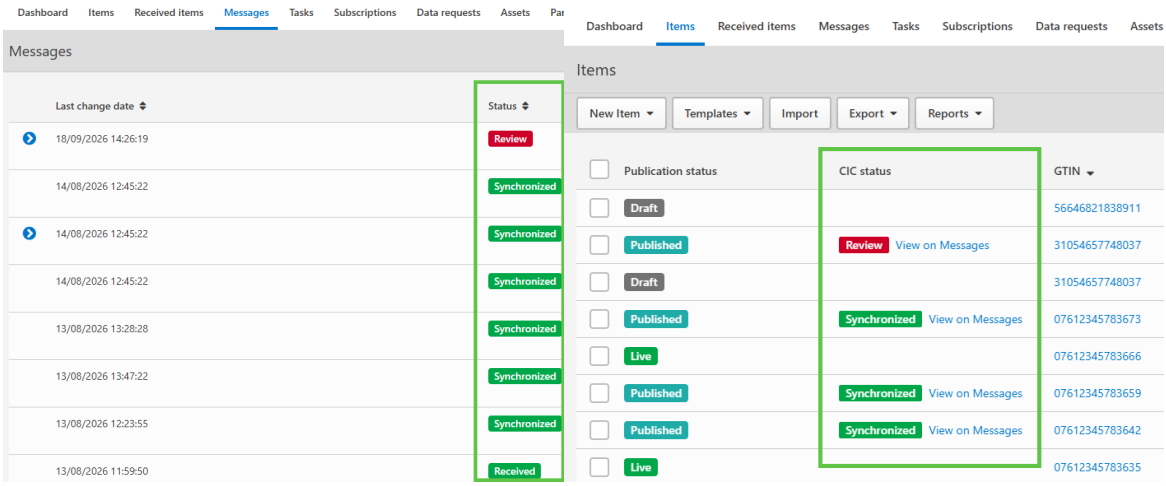
5 Check transmission to the UDI database

Once the items have been published either manually or via upload, you must check whether the data has been successfully transmitted.

You can check the items in the item overview under the 'Items' tab or the 'Messages' tab. Depending on the CIC status received, the transmission was either successful or not. The following statuses apply:

- 'CIC ACCEPTED' is only provided 'internally' by the recipient data pool as soon as data has been sent. No 'external' responses from the UDI Connector or the UDI database are available yet.
- 'CIC RECEIVED' is sent by the UDI database immediately after successful transmission. During this time, the item may temporarily be in 'Submitted' status and will not be updated until then.
- 'CIC SYNCHRONISED' is sent by the UDI database after a delay once the final status has been reached. These items are fully "Registered" in the UDI database. Updates can now be made.
- 'CIC REVIEW' is sent immediately if an error occurs during transmission via the UDI Connector or in the UDI database. The error can be viewed in detail under 'View in Messages' and, if necessary, corrected in the data record.

CIC messages are displayed as follows:



In the case of a 'CIC REVIEW', the blue arrow in the 'Messages' tab can be used to view why the item could not be registered or submitted.

Please correct the error and resubmit the item.

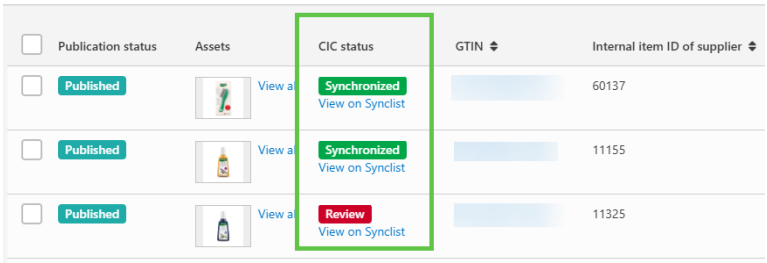
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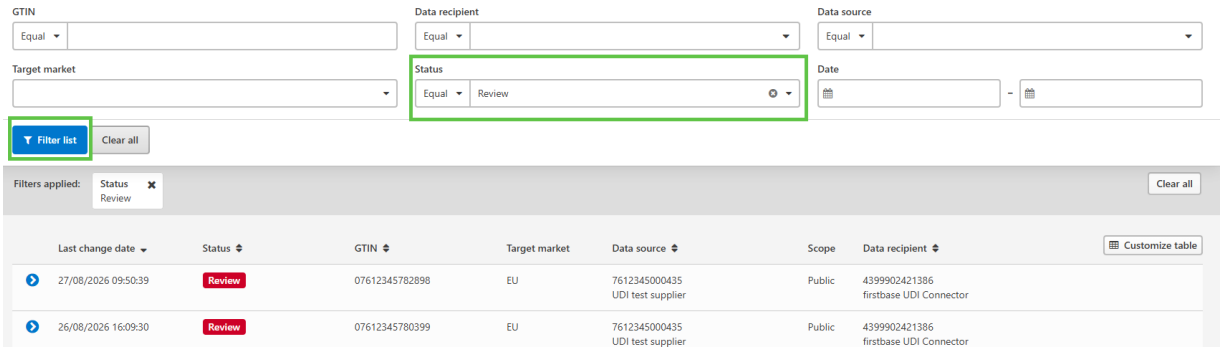
6 Dealing with error responses

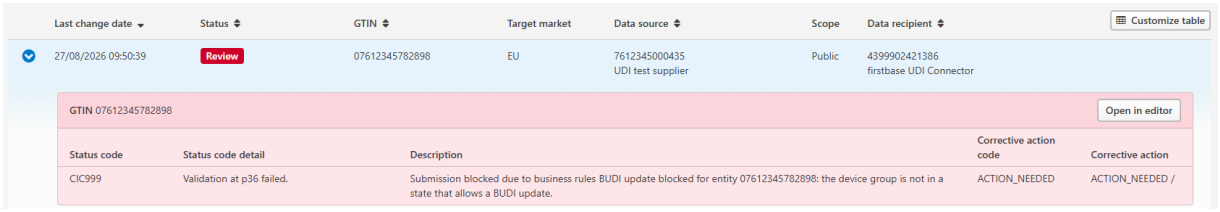
If you receive a CIC 'Review' for one or more products, this may be for various reasons:

- Problems with the configuration of the 'access point' (under 'Actor settings'), e.g. if the UDI token is invalid.
- Technical issues in the M2M interface between the UDI Connector service (e.g. p36) and EUDAMED due to a service outage.
- Content errors, where the GDSN data pool is unable to validate certain data, e.g. an invalid authorised representative code (SRN).

In all cases, click on the 'View on Synclist' link in the 'CIC status' column and open the detailed description by clicking the blue arrow next to the CIC error message.







Note:

It is worth noting that communication within the GDSN always refers to the top level of the packaging hierarchies for retail items. Here too, the EUDAMED response message (CIC) refers to the highest level of the packaging hierarchy, e.g. the carton unit. If you click on 'Open in Editor', you will be taken to the relevant trade item hierarchy, where you can amend the data to resolve the error.

Note:

As a rule, the error message must be interpreted by the user, as EUDAMED responds with specific details such as the error code, SRN, Basic UDI-DI code (GMN) or UDI-DI code (GTIN), as well as the associated error details. The details include the attribute name or the code value in the EUDAMED language. If the reader is unable to determine the actual cause of the error directly via the web user interface, they can refer to the information in the current file 'GS1_UDI_Connector_Profile_Overview.xlsx', which helps with reconciliation against the GDSN attribute definitions and code list mappings. For specific queries regarding errors, please contact our *support team*. Once the error has been rectified, the item must be republished.

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7 Support & Contact Details

Do you have any questions about the firstbase application?

In the 'Support' section of our website, you'll find everything you need to help you work with firstbase: a user manual, tutorials, information on the GDSN standard, support contact details and much more.

Our support team will be happy to assist you with any questions.

To ensure you receive prompt and efficient support, please describe the issue as precisely as possible. Ideally, you should include screenshots with your description.

You are welcome to submit your enquiry via our *contact form*.

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