GS1 EUDAMED Submission Guideline

How to implement UDI submissions for EUDAMED via GDSN

Release 1.2, August 2026

Document Summary

Document Item	Current Value
Document Name	GS1 EUDAMED Submission Guideline[1]
Document Date	August 2026
Document Version	1.2
Document Status	Released

Log of Changes

Release	Date of Change	Summary of Changes
1.0	January 2026	Initial creation and finalisation
1.1	April 2026	Review of process details including minor changes, renaming of chapters and update of Table of contents, review of pictures
1.2	August 2026	Included the sections 4.4. Publication, 4.5 Submission flow scenarios and 4.6 Error Handling under section 4 Phase 3 Learn UDI Upload and Testing (EUDAMED Playground) Changed sections 6.1 – 6.3 by including referencing links to the equivalent sections 4.4 – 4.6 under section 6 Phase 5 - Live Submissions (EUDAMED Production) Added UDI Connector GLNs for PROD under section 6.1 Publication (EUDAMED Production).

Involved parties

There are several parties involved in the GS1 EUDAMED Submission.

- GS1 Member Organisations: your local contact point that offers you the GDSN Data pool for exchanging master data information of your medical devices. And the data pool where you enter the relevant information for GS1 UDI Connector. This data pool also offers automatic validations which helps you to make sure you have the required information for EUDAMED. At this moment **GS1 Switzerland, GS1**

[1] GS1 Member Organisations involved: GS1 Czech Republic, GS1 Denmark, GS1 Netherlands, GS1 Switzerland

Denmark, GS1 Czech Republic and **GS1 Netherlands** are offering a EUDAMED Submission service.

- **Trade Connectors**: The technical party behind the GDSN Data pool solutions that your local GS1 Member Organisation offer.
- **p36**: Technical service provider (access point) for the UDI connect interface. They deliver the integration between the GDSN Data pool and the UDI databases.

Revocation (disclaimer)

Table of contents

1 Introduction - Preconditions

GS1 is an international not-for-profit organisation that offers a solution to share product information of medical devices between manufacturers, distributors and care institutions. This solution is called the Global Data Synchronisation Network (GDSN). Manufacturers also must upload part of this information in EUDAMED.

EUDAMED is the IT system established by Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices. EUDAMED is an integral part of the implementation of the two Medical Devices Regulations.

To support manufacturers in this process the solution that GS1 offers also facilitates the uploading of data in EUDAMED.

This document serves as a guide for your initial configuration of the European database of medical devices – EUDAMED. It is focused on UDI (Unique Device Identification).
The aim is to describe the process of user registration and the registration of an economic operator in the role of Legal Manufacturer (MF) and System/Procedure Pack Producer (PR), for the purpose of configuring Machine-to-Machine (M2M) Connector between EUDAMED and the GS1 GDSN for the UDI submissions.

At the same time, neither GS1 nor any Machine-to-Machine data upload alter or transfer any rights or obligations to other parties beyond those explicitly defined in the MDR (Medical Device Regulation) and IVDR (In Vitro Medical Device Regulation) regulations, which form the legal basis for the obligation to submit medical device data to EUDAMED by the Legal Manufacturer and Producer.

1.1 Regulatory disclaimer

GS1 provides participants with non-binding guidance aimed at applying GS1 standards. Each participating company is responsible for determining how such guidance is applied within its own organisation. GS1 is a neutral organisation providing voluntary recommendations. Participants remain independent entities and are free to define and follow their own procedures. GS1 employees have no authority to act on behalf of regulatory agencies, to interpret legal provisions in a legally binding manner, or to grant exemptions or approvals.

The information contained in this documentation has been developed and compiled by GS1 to the best of its knowledge. GS1 makes no representations or warranties, express or implied, regarding the completeness, accuracy or suitability of this information for any particular purpose.

To the extent permitted by applicable law, GS1 shall be liable only for damages caused by wilful misconduct or gross negligence. Liability for slight negligence is excluded, except where mandatory law provides otherwise.

Each participating company is solely responsible for ensuring compliance with all applicable legal and regulatory requirements.

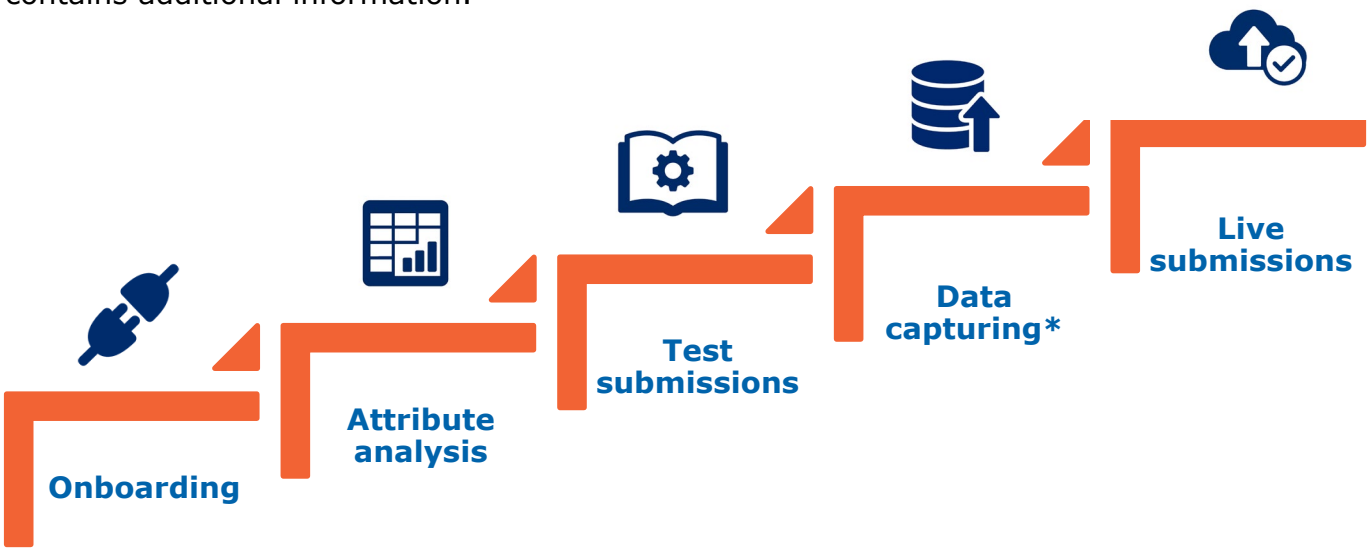
Any services provided by a local Member Organisation of GS1 shall be governed exclusively by the applicable general terms and conditions of the respective local Member Organisation, in their then-current version, as made available by such organisation (e.g. on its website or upon request). The participant alone is responsible for ensuring compliance with all applicable legal and regulatory requirements, including, MDR, IVDR, device registration and synchronization requirements.

For the service that is explained in this document, the general terms and conditions of GS1 are applicable. These are available at the local Member Organisation's website or upon request.

In the MDR regulation the responsibilities regarding EUDAMED are described in Annex VI part A. *https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng*

1.2 Document and project structure

There are 5 phases to successfully reach the EUDAMED submission. These are described in the picture below and in this document in the following 5 chapters. The last chapter contains additional information.



** DRIFT = **Do** it **Ri**ght the **F**irst **T**ime*

Figure 1 - UDI submission process

1.3 Only use this service for your UDI data

Because of the technical setup of EUDAMED, newly submitting and updating data by using both EUDAMED WebUI and DTX/M2M via GDSN will create crucial problems, such as extra error situations, migration efforts and version changes. To get the maximum benefit of this service, it is recommended to only use DTX/M2M via GDSN. Migration of already registered UDIs can cost additional fee depending on your local GS1 Member Organisation.

ATTENTION: Do not use mixed UDI submission methods accross EUDAMED WebUI and UDI Connector (using EUDAMED DTX/M2M interface)

2 Phase 1 - Onboarding Process

EUDAMED offers to work with two environments. The first on is a EUDAMED Playground which is a test environment used for training and verifying system integration, especially for M2M data exchange. It allows users to simulate data submissions without any legal consequences.

In contrast, the second is the EUDAMED Production Environment (PROD) representing the official live system where legally binding data must be submitted in compliance with MDR and IVDR regulations.

In this document the registration phases are explained in a logical and structured manner – EUDAMED Playground first and whenever certain steps differ in the EUDAMED Production, these differences are highlighted.

For the User and Actor registration follow these steps:

1. Follow this link to EUDAMED Playground: *https://webgate.training.ec.europa.eu/eudamed-play/landing-page#/.*
2. Sign in with your EU Login or create one if not available.
3. Create a Test Actor Request, the role of *Legal Manufacturer (MF Actor)* or System or Procedure Pack Producer (PR Actor)
4. Please note that in EUDAMED production environment, all the applications get approved by Competent Authority but in Playground environment, they are approved by EUDAMED application support.
    1. Contact *SANTE-EUDAMED-SUPPORT@ec.europa.eu*.
    2. Provide: country, application ID, manufacturer name, account email address
    3. Kindly ask them with the approval of the test account

European Commission (EC) EUDAMED website:

An official source of information is this *EC EUDAMED website* which provides a comprehensive information about EUDAMED in general and specific the UDI-module.

Refer to EUDAMED information centre (Playground, Production) for more detailed information of the UDI-Module and its setting up and managing M2M data exchange between external systems and the EUDAMED database. This setup is taken care of by the service of GS1's UDI Connector.

It also includes a video explaining the following relevant steps to use of an existing Access Point (AP) in EUDAMED for M2M data exchange with steps like entering the AP Party ID, uploading a 3rd Party Agreement, and submitting technical and legal contact details is found *here*.

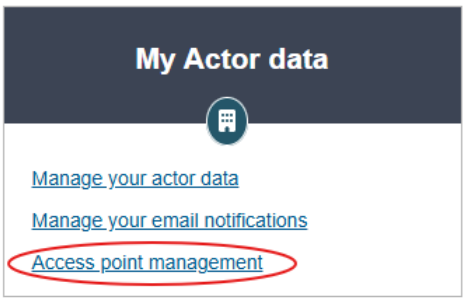
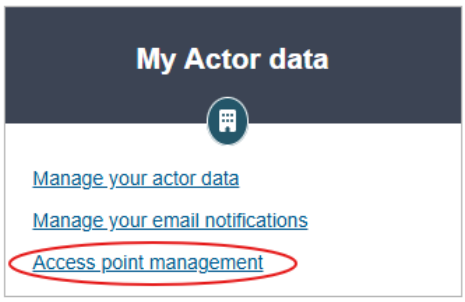
2.1 Access Point Configuration

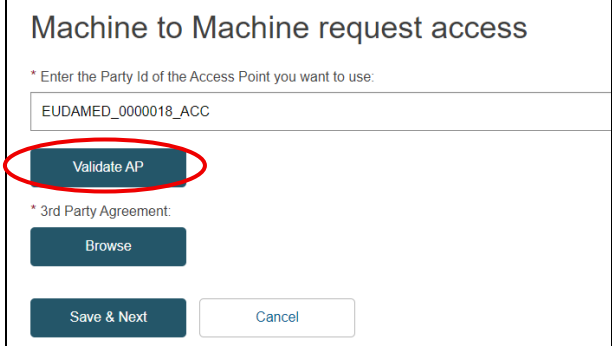
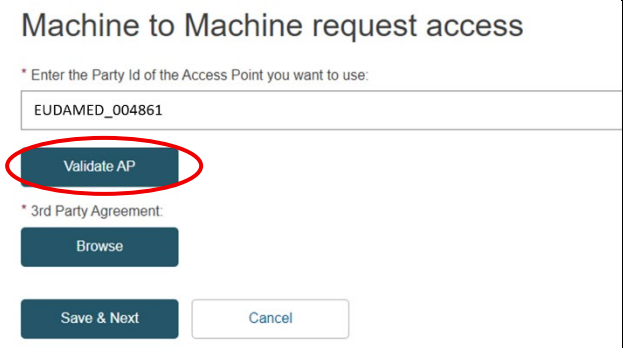
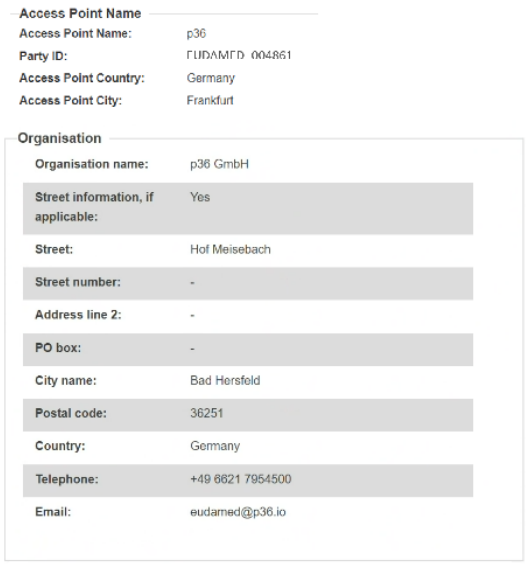
This part provides information on configuring the M2M settings in EUDAMED.

If you wish to activate your M2M services in EUDAMED Production environment you must first apply for an AP in EUDAMED Playground environment, complete the onboarding and test the service. Please start in the EUDAMED Playground and later follow in the EUDAMED Production environment.

Note #1

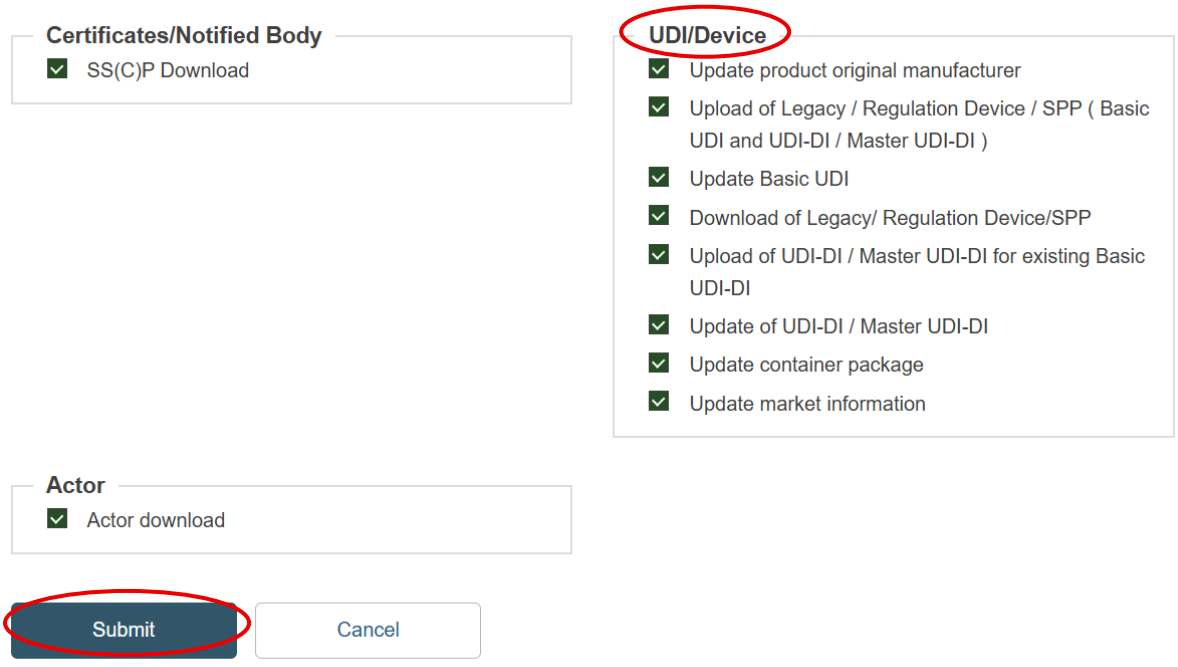
In this part the details of 3rd Party Access Point provider p36 will be provided, as an example of such steps.

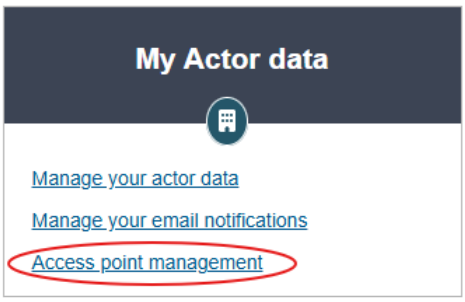
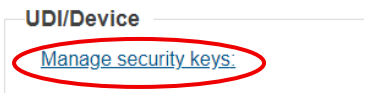
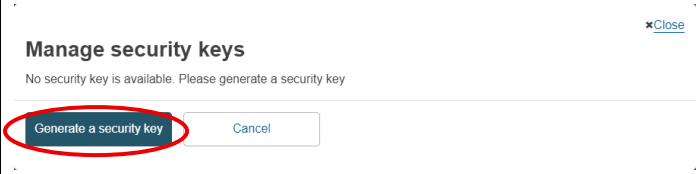
	EUDAMED PLAYGROUND environment	EUDAMED PRODUCTION environment
1.	Log into **EUDAMED Playground** as a Local Actor Administrator (LAA). Under the *My Actor data* section click on the *Access point management* link: 	Log into **EUDAMED Production** as a Local Actor Administrator (LAA). Under the *My Actor data* section click on the *Access point management* link: 
2.	Click on the *Request a new M2M access* button.	
3.	Agree to the disclaimer and click on the *Next* button	
4.	In the next screen select *Yes* to use an existing EUDAMED AP and click on the *Next* button.	

	EUDAMED PLAYGROUND environment	EUDAMED PRODUCTION environment
5.	Enter the following Party ID and click on the *Validate AP* button: Example: p36 Access Point use '*EUDAMED_0000018_ACC'*: 	When Proof-of-Testing is provided enter the following Party ID and click on the *Validate AP* button use '*EUDAMED_004861'*: 
6.	You will be able to view information regarding your selected-Access Point. You will not be able to edit that information. Example: 	You will be able to view information regarding your selected-Access Point. You will not be able to edit that information. Example: 
7.	Sign and upload the **3rd Party Agreement** as a PDF file and click on the *Save & Next* button. A draft to be downloaded *here*. For the signature contact your involved 3rd Party Provider. See also **Note #2** at the bottom of this section.	Sign and upload the **3rd Party Agreement** as a PDF file and click on the *Save & Next* button. A draft to be downloaded *here*. For the signature contact your involved 3rd Party Provider. See also **Note #2** at the bottom of this section.

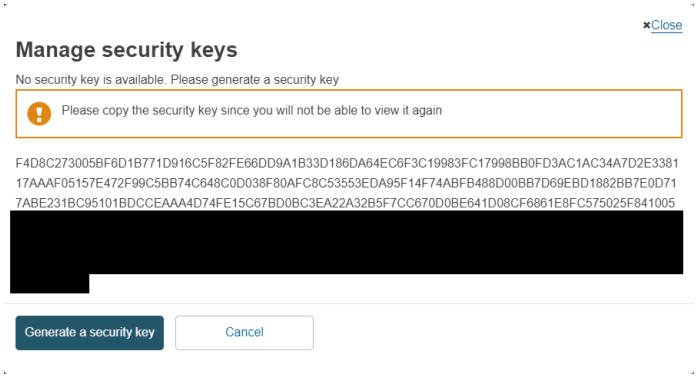
<table>
<tr><th></th><th>EUDAMED PLAYGROUND environment</th><th>EUDAMED PRODUCTION environment</th></tr>
<tr><td>8.</td><td colspan="2">In the next screen fill in the Technical Contact details with the contact information of the Provider of the AP.
Example technical contact (P36): First Name: Pascal, Last Name: Appel, Email:eudamed@p36.io, Phone:+49 6621 968282200.

Or contact your involved 3rd Party Provider for these details.

Fill in also the Legal Contact details. This person must belong to your organisation (Manufacturer) and could be one of your Local Actor Admins in EUDAMED.</td></tr>
<tr><td>9.</td><td>Upload your Business justification as PDF file. You will find the Business justification template here.
Contact your involved 3rd Party Provider OR see Note #2 at the bottom of this section.</td><td>Upload your Proof of testing document as a PDF file which the 3rd Party Provider should have provided to you (EUDAMED Playground step #21) OR see Note #2 at the bottom of this section.</td></tr>
<tr><td>10.</td><td colspan="2">Select all services of the UDI/Device module and click on the Submit button.
 
</td></tr>
<tr><td>11.</td><td colspan="2">Select Yes in the pop-up window to complete the Access Point registration process.</td></tr>
<tr><td>12.</td><td colspan="2">In the next screen you can see a confirmation message and the Access Point Party ID.</td></tr>
</table>

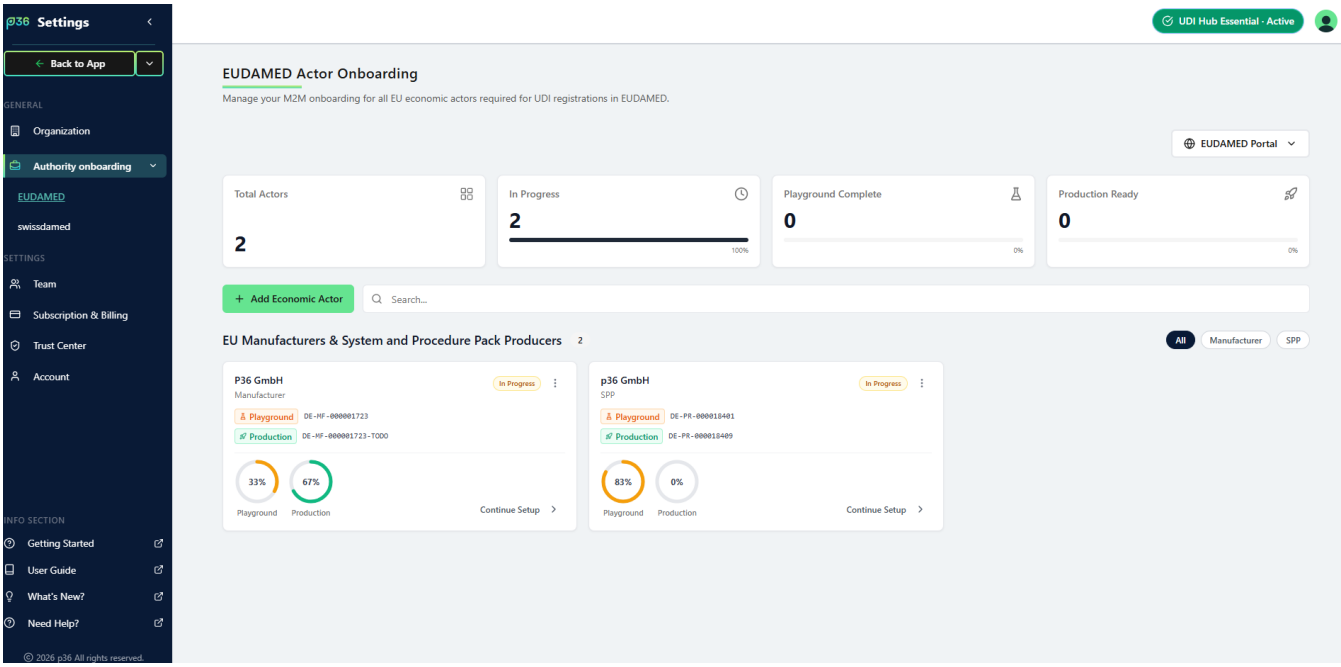
	EUDAMED PLAYGROUND environment	EUDAMED PRODUCTION environment
13.	Click on the *Go back to Access Point Link dashboard* link to manage your AP. As soon as the request has been approved by EC and the AP has the status **'Active'**, you can continue. This can take a few days.	
14.	Under the *My Actor data* section click on the *Access point management* link: 	
15.	In the Access Point management page, you can view all your APs listed in the table. Make sure that the filter is set to *Status: Active.*	
16.	Choose e.g. the p36 AP and click on the *Edit* link under the three dots to view the AP's settings	
17.	In the displayed screen you can view and edit the details you entered regarding the p36 AP. Moreover, you can now change the services attached and manage your **security keys**[2] by clicking on the *Manage security keys* link in the edit mode: 	
18.	In the pop-up window click on the *Generate a security key* button to generate the security key for the UDI/Device module (Notice: Make sure you select the right module): 	

[2]A security key (Token) is a crucial element for authorizing the connection between the legal entity (identified by its Single Registration Number - SRN) and the 3rd Party Provider, and it must be handed over to the provider to enable M2M communication for UDI registration on their behalf.

	EUDAMED PLAYGROUND environment	EUDAMED PRODUCTION environment
19.	In the pop-up window you will be able to view the generated security key:  **Please copy the security key. You will not be able to view your security key after closing the pop-up window.** If you lose your security key, you must regenerate it. **IMPORTANT** Please copy the regenerated security key. You will not be able to view your security key after closing the pop-up window. If you lose your security key, you must regenerate it.	
20.	Please forward the latest generated security key, Actor SRN & and Actor company name: a. to a GS1 contact person. b. to the 3rd Party Provider p36, see **Note #2** at the bottom of this section.	
21.	Continue and follow with the testing phase. Once this phase is successfully completed, ask for a **Proof of testing document (POT) in the PDF format only** for the EUDAMED Production environment setup: 1. via a GS1 contact person. 2. via the 3rd Party Provider p36, see **Note #2** at the bottom of this section.	DONE
22.	The setup for **EUDAMED Playground** is done, go to the *#1* of this Setup and follow the process referring the EUDAMED Production environment.	N/A

Note #2

The process described above is very general and follows the mandatory steps in EUDAMED Playground/Production. Some AP providers may offer more support to efficiently manage the setup. For instance, the *p36 web tool* which digitalizes and half-automates the entire process from the AP Management (contact your provider for access). Screen shot below:



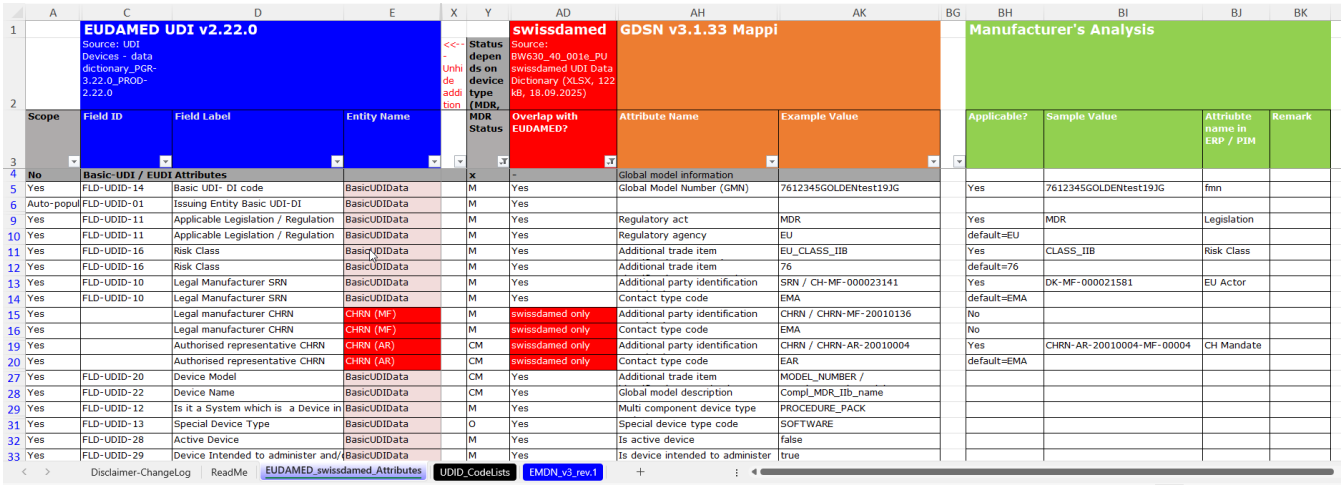
3 Phase 2 - GDSN Attribute Analysis for UDI Data

To ensure accurate and compliant data submission to EUDAMED, users must analyse the alignment between the **EUDAMED UDI Data Dictionary requirements** and the **mapped GDSN Profile**. For this purpose, the prepared document '*GS1_UDI_Connector_Profile_Overview.xlsx'*, which you have received during your on-boarding process, serves as the central reference, providing a comprehensive overview of attribute definitions and code list mappings.

To prepare successful UDI submissions the following tasks should be carried out by the responsible internal experts (e.g. Regulatory Affairs, Master Data Management or IT):

1. Define the scope of relevant device types (MDR, SPP, IVDR, MDD/AIMDD, IVDD).
2. Review the mandatory and optional fields per device type.
3. Compare these requirements with the mapped attributes in the GDSN Profile.
4. Assess the applicability of each attribute against the manufacturer's internal device data in source systems.
5. Identify potential gaps where internal data may not fully meet the requirements.
6. Repeat the same actions for the code list mapping.

For efficient execution, we recommend using the provided '*GS1_UDI_Connector_Profile_Overview.xlsx*'. Add auxiliary columns (highlighted in green) in both tabs 'EUDAMED_swissdamed_Attributes' and 'UDID_CodeLists' document internal notes, responsibilities, or gap resolutions.



	A	C	D	E	X	Y	AD	AH	AK	BG	BH	BI	BJ	BK
1		EUDAMED UDI v2.22.0 Source: UDI Devices - data dictionary_PGR-3.22.0_PROD-2.22.0			<<<- Unhide addition	Status depends on device type (MDR,	swissdamed Source: BW630_40_001e_PU swissdamed UDI Data Dictionary (XLSX, 122 kB, 18.09.2025)	GDSN v3.1.33 Mappi			Manufacturer's Analysis			
2														
3	Scope	Field ID	Field Label	Entity Name		MDR Status	Overlap with EUDAMED?	Attribute Name	Example Value		Applicable?	Sample Value	Attriubte name in ERP / PIM	Remark
4	No	Basic-UDI / EUDI Attributes				x	-	Global model information						
5	Yes	FLD-UDID-14	Basic UDI- DI code	BasicUDIData		M	Yes	Global Model Number (GMN)	7612345GOLDENtest19JG		Yes	7612345GOLDENtest19JG	fmn	
6	Auto-popul	FLD-UDID-01	Issuing Entity Basic UDI-DI	BasicUDIData		M	Yes							
9	Yes	FLD-UDID-11	Applicable Legislation / Regulation	BasicUDIData		M	Yes	Regulatory act	MDR		Yes	MDR	Legislation	
10	Yes	FLD-UDID-11	Applicable Legislation / Regulation	BasicUDIData		M	Yes	Regulatory agency	EU		default=EU			
11	Yes	FLD-UDID-16	Risk Class	BasicUDIData		M	Yes	Additional trade item	EU_CLASS_IIB		Yes	CLASS_IIB	Risk Class	
12	Yes	FLD-UDID-16	Risk Class	BasicUDIData		M	Yes	Additional trade item	76		default=76			
13	Yes	FLD-UDID-10	Legal Manufacturer SRN	BasicUDIData		M	Yes	Additional party identification	SRN / CH-MF-000023141		Yes	DK-MF-000021581	EU Actor	
14	Yes	FLD-UDID-10	Legal Manufacturer SRN	BasicUDIData		M	Yes	Contact type code	EMA		default=EMA			
15	Yes		Legal manufacturer CHRN	CHRN (MF)		M	swissdamed only	Additional party identification	CHRN / CHRN-MF-20010136		No			
16	Yes		Legal manufacturer CHRN	CHRN (MF)		M	swissdamed only	Contact type code	EMA		No			
19	Yes		Authorised representative CHRN	CHRN (AR)		CM	swissdamed only	Additional party identification	CHRN / CHRN-AR-20010004		Yes	CHRN-AR-20010004-MF-00004	CH Mandate	
20	Yes		Authorised representative CHRN	CHRN (AR)		CM	swissdamed only	Contact type code	EAR		default=EMA			
27	Yes	FLD-UDID-20	Device Model	BasicUDIData		CM	Yes	Additional trade item	MODEL_NUMBER /					
28	Yes	FLD-UDID-22	Device Name	BasicUDIData		CM	Yes	Global model description	Compl_MDR_IIb_name					
29	Yes	FLD-UDID-12	Is it a System which is a Device in	BasicUDIData		M	Yes	Multi component device type	PROCEDURE_PACK					
31	Yes	FLD-UDID-13	Special Device Type	BasicUDIData		O	Yes	Special device type code	SOFTWARE					
32	Yes	FLD-UDID-28	Active Device	BasicUDIData		M	Yes	Is active device	false					
33	Yes	FLD-UDID-29	Device Intended to administer and/(	BasicUDIData		M	Yes	Is device intended to administer	true					

Disclaimer-ChangeLog | ReadMe | EUDAMED_swissdamed_Attributes | UDID_CodeLists | EMDN_v3_rev.1

This analysis forms the foundation for a structured implementation, ensuring that all relevant device data is correctly captured, validated, and ready for submission. By systematically comparing EUDAMED field requirements with internal data structures, organizations can proactively address compliance issues and secure efficient UDI registration.

If you have any specific technical or attribute-related questions, please contact your local GS1 Member Organisation.

4 Phase 3 - Learn UDI Upload and Testing

When Phase 2 - GDSN Attribute Analysis for UDI Data is completed, it is time to test upload of your data. It is important to start with a record for one product first and then scale up with the rest of your records afterwards.

Even when having a M2M solution, submitting your data in EUDAMED can be complicated, because of the requirements from EUDAMED. For that reason, it is extra important to have the **D**o it **Ri**ght the **F**irst **T**ime approach (DRIFT). Be very sure the data information is submitted with the right content, by having internal quality assurance steps, all those steps that are possible.

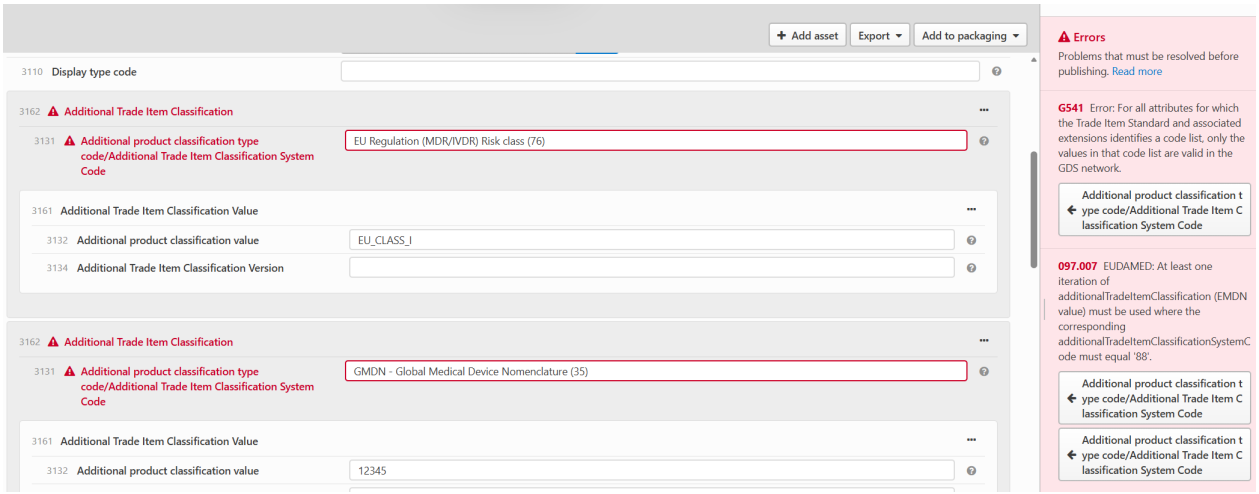
The intention of testing is to make sure, that your M2M solution supports all the scenarios and attributes relevant to your submission of data to EUDAMED.

The recommended number of test submission depends on your range of products. It is recommended to do a test submission for each class in MDR and IVDR that you have in your range of products.

These steps are recommended to follow.

4.1 For Web-User Interface Users

1. Use Editor (Web-UI) to create your first record with all the attributes required for your product. Implemented validation rules will directly control (DRIFT) if your record is affected by any consistency mistake, business rule dependency or error appearance. The screenshot below shows you what that looks like. Publish first UDI when the product has all required attributes. Section *4.4 Publication (EUDAMED Playground)* explains how to correctly publish data.



2. Then check EUDAMED Response Feedback (CIC - Catalogue Item Conformation) for the records sent. If there are errors mentioned in the CIC look at section *4.6 Error Handling (EUDAMED Playground)* for your guidance. Complete the step 1 again if any mistakes occurred.

3. After one successful registered record, that record can be exported in excel. The exported excel file can then be used to fill out other test submissions and be imported into your GDSN service.

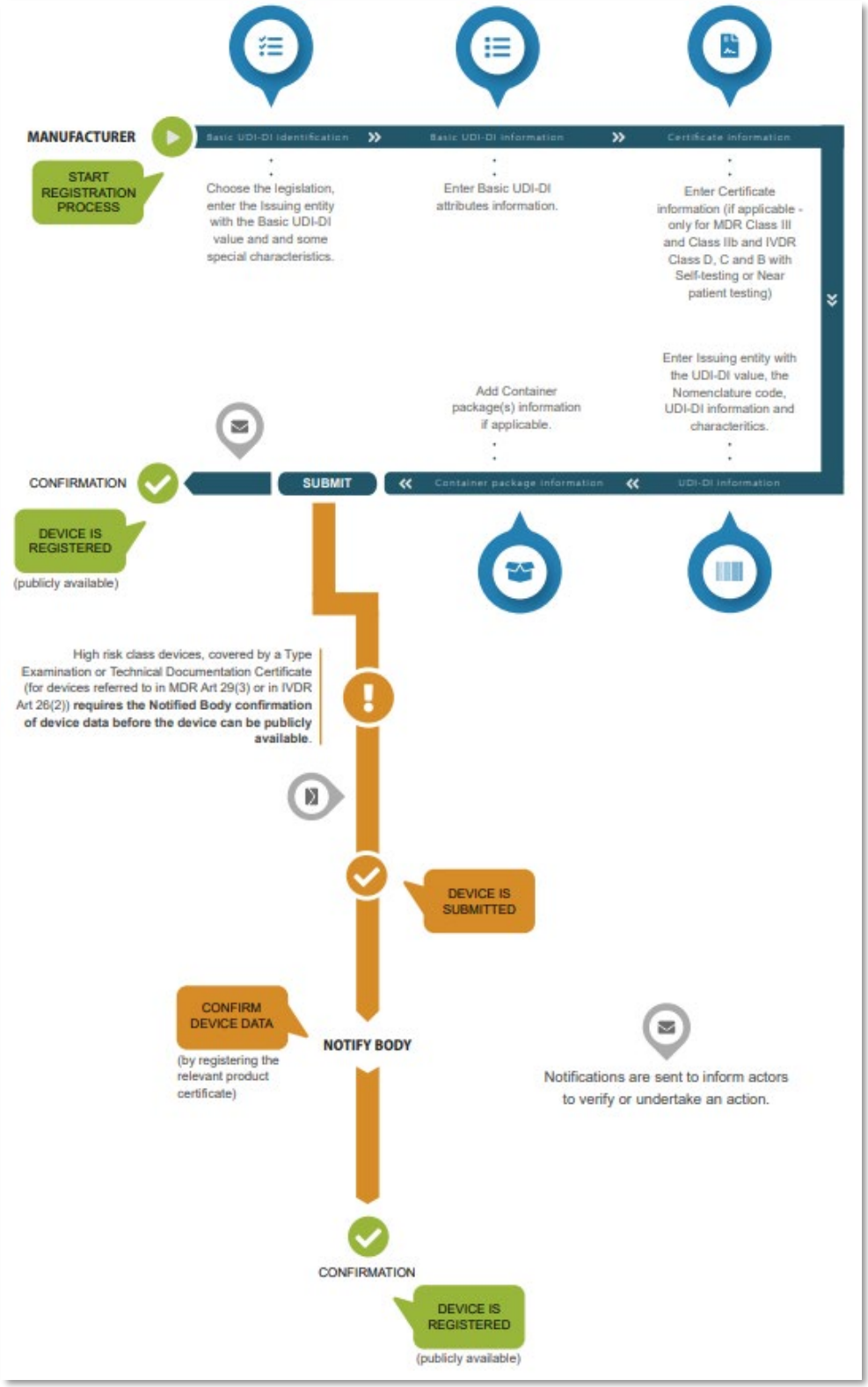
4. Then you can publish all test records in EUDAMED. To avoid blocking errors for 'Follow-up UDI' or 'Update' submissions, please respect the submission flow rules in section *4.5 Submission Flow Scenarios (EUDAMED Playground)*.

4.2 For Machine-to-Machine Users

1. Send your first UDI drafts through your implemented M2M interface into our UDI Connector service via GDSN and see the data validation. How to correctly publish you can read in section *4.4 Publication (EUDAMED Playground)*. Then check EUDAMED Response Feedback (CIC) for the records send. If there are errors mentioned in the CIC look at *4.6 Error Handling (EUDAMED Playground)* for your guidance. Complete the previous step again if any mistakes occurred

2. Then you can publish all test records in EUDAMED. To avoid blocking errors for 'Follow-up UDI' or 'Update' submissions, please respect the submission flow rules in section *4.5 Submission Flow Scenarios (EUDAMED Playground)*. Then complete this step for all your chosen test scenarios.

4.3 EUDAMED UDI Registration Process for Regulation Devices



Source: https://health.ec.europa.eu/document/download/c3231845-228e-437a-8d77-510ecc3a548b_cs?filename=md_eudamed-udi-registration-process_en.pdf

The steps in this part of the process depend on the type of risk class for your products. There will be two levels of risk class:

- **low-risk** class (for MDR: I, IIA, IIB non-implants, for IVDR: D, C, and B with Self-testing or Near patient testing).
- and **high-risk** class (for MDR: IIB implants, III, for IVDR: A or B without Self-testing or Near patient testing).

For **low-risk** class, when you send your data to EUDAMED, there is no involvement of Notified Bodies. The sent data directly gets the status 'Registered' in EUDAMED (and the record gets public). In the UDI Connector service, you will get after a short while a final CIC receipt with the status 'Synchronized', and your registration is completed.

For **high-risk** class (MDR: IIB implants, III) you are only able to send data with status 'Submitted' in EUDAMED and you will get a CIC receipt with the status 'RECEIVED', which means you as MF has a valid submission, but the Notified Body will have to 'confirm' the device data. That will happen when a Notified Body registers the certificate. After approval, status will change to 'Registered' in EUDAMED and you will get a CIC receipt with the status 'Synchronized', and your registration is completed. In the Playground environment this will not happen if no Notified Body is involved for collaboration testing. However this is not required for a Proof of testing.

4.4 Publication (EUDAMED Playground)

When valid draft items are prepared, created or uploaded in the GDSN Data pool and the approval (review by 4 eye-principle) is done, only then **publication** of the first submissions can follow. To avoid additional error handling, it's recommended to go step by step with the following approach.

For MDD/AIMDD/IVDD records:

- the publication can be done per each single UDI-DI (GTIN) submission separately or in bulk.
- Multiple UDI-DI's can be sent in parallel.

For MDR/IVDR/SPP records:

1. it is required to start with the initial publication of the first UDI-DI belonging to the new Basic UDI-DI.
2. after this first submission has succeeded with CIC SYNCHRONISED (**low-risk** class) or CIC RECEIVED (**high-risk** class) the follow-up UDI-Dis of the same Basic UDI-DI can be published too.
3. repeat this sequencing order of 1. + 2. above for every first UDI-DI belonging to a Basic UDI-DI and its follow-up UDI-DIs

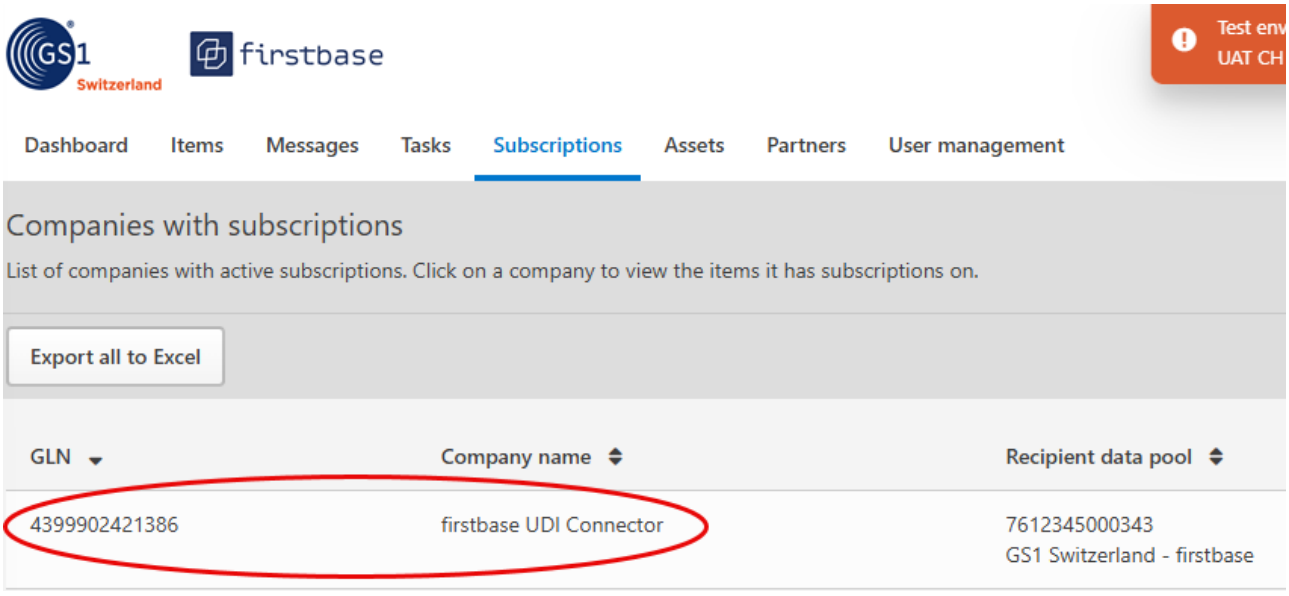
ATTENTION: For high-risk class devices under step 2. don't resubmit the first UDI-DI again, otherwhise it gets an EUDAMED error as CIC REVIEW *': UNAUTHORISED_ERROR: Only the owner can update their entities.* because in EUDAMED it can be only done manually per each single UDI-DI.*SRN XX-MF-00000XXXX is not the owner of Basic UDI-DI Code XXXXXXXXXX GS1'.* In this case, the record cannot be updated if it is not yet registered by the Notified Body.

Use the following Publish to GLNs from your dedicated GDSN Data pool service:

GDSN Data Pool	Member Organisation	Publish To GLN for EUDAMED Playground
Synfony	GS1 Czech Republic	8594182509823 Synfony UDI Connector
GS1Trade Sync	GS1 Denmark	7609999484711 GS1 UDI Link
firstbase	GS1 Switzerland	4399902421386 firstbase UDI Connector
GS1 Data Source	GS1 Netherlands	7609999484728 GS1 Data Source UDI Connector

Note #3

Please make sure, that your GDSN Data pool support has correctly setup the subscription for your participating Information Provider GLN by the relevant UDI Connector service. Only with a valid match between 'Publication' and 'Subscription' ('Pub-Sub-Match') the synchronisation between both partners can be proceeded. Normally this should be the case during the setup and onboarding (*Phase 1 - Onboarding Process*). After the publication is done, the relevant active subscription can be checked under 'subscriptions', for example:



4.5 Submission Flow Scenarios (EUDAMED Playground)

After the initial publication is done EUDAMED gives direct responses like other UDI databases. As described in *Phase 3 - Learn UDI Upload and Testing* the CIC will be received with the status SYNCHRONISED (= 'Registered' in EUDAMED) or RECEIVED (= 'Submitted' in EUDAMED) . It is recommended to wait for this initial submission per each Basic UDI-DI. Only if this initial submission was successful, follow-up submissions for other UDI-DIs can be sent. **Update submissions** for already registered records can **only** be sent if the CIC SYNCHRONISED (='**Registered**' in EUDAMED) was provided.

Note #4

ATTENTION: Please be aware that in EUDAMED Production the Notified Body Approval can take some time. High risk class devices cannot be updated before the 'Registered' state is achieved.

It is highly recommended to make **proper testing** of the specific submission scenarios with EUDAMED Playground. The table below shows the minimum test scenarios. If you need more detailed test scenarios in spreadsheet reach out to your local GS1 Member Organisation.

MDR/ IVDR scenarios	Explanation	Error situations
Initial submission of new Basic UDI-DI	Publish the 1st individual UDI-DI together with its new Basic UDI-DI, which is not yet submitted or registered, **alone**. Then a successful CIC response is received: **low-risk** CIC RECEIVED and SYNCHRONISED in quick succession **high-risk:** CIC RECEIVED and SYNCHRONISED*[3] asynchronously	**A)** User publishes directly multiple UDI-(DI)s (e.g. per bulk upload) belonging to the same new Basic UDI-DI (EUDAMED status is neither 'Registered' nor 'Submitted'). For some UDI-DI(s) the CIC does not turn back correctly or they lead to a CIC REVIEW with 'Submission blocked error' thereafter.

[3] * *In EUDAMED Playground for high-risk class devices, no 'Registered' status, no CIC SYCHRONISED and therefore no update will be possible, as long as no NB approval is involved.*

MDR/ IVDR scenarios	Explanation	Error situations
Follow-up UDI-DI(s) submission of existing Basic UDI-DI	A CIC response of a successfully submitted Basic UDI-DI, which is already in '**Registered**' (**low-risk**) or '**Submitted**' (**high-risk**) status, is received. After that publish a bulk of multiple UDI-DI(s) together with the same linked Basic UDI-DI. Then for all follow-up UDI(s) successful CIC responses are received.	**A)** User does not wait for initial Basic UDI-DI submission success, see above. **B)** Same UDI-DI was published with multiple packaging hierarchies one after another, but not in one bulk publication. There could be a CIC REVIEW with 'Submission blocked error' thereafter. If the affected UDI-DI is still in submission progress, different packages won't be fully published.
Updates to UDI-DI(s) or Basic UDI-DI data	As soon as a CIC SYCHRONISED has been received for a Basic UDI-DI (with the EUDAMED status 'Registered'), changes are made to updatable Basic UDI-DI or UDI-DI attributes for the UDI-DI(s). Subsequently, all associated UDI-DI(s) that have already been published are republished. Then successful CIC SYNCHRONISED responses are received.	**B)** Same UDI-DI was published with multiple packaging hierarchies one after another, see above **C)** Update submission is started before CIC SYNCHRONISED is received. Esp. for not yet 'Registered' **high-risk** Basic UDI-DIs, this will fail without NB's (certificates) approval.*[4] There will be received a CIC REVIEW with *'Only the owner can update their entities. [SRN] is not the owner of: [Basic UDI-DI Code GS1].'* thereafter. **D)** Non-updateable attributes are updated and resubmitted. There will be received a CIC REVIEW with error detail "Submission data invalid according to the authority rules Changing the value of … is a DI Trigger." thereafter.

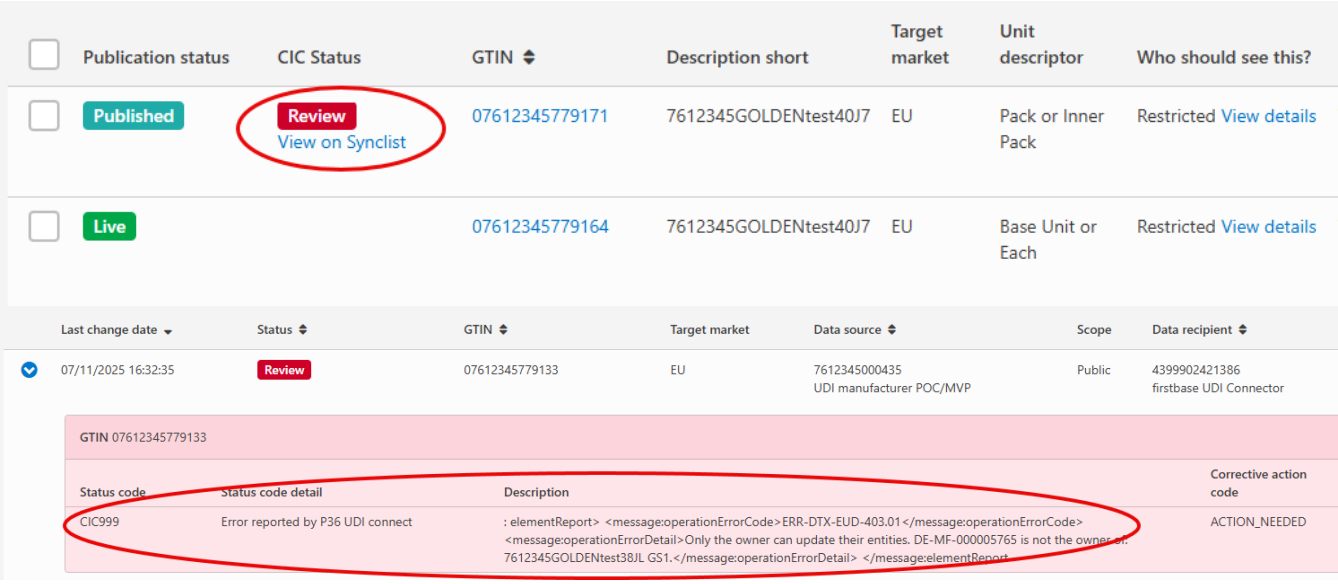
[4] * *In EUDAMED Playground for high-risk class devices, no 'Registered' status, no CIC SYCHRONISED and therefore no update will be possible, as long as no NB approval is involved.*

4.6 Error Handling (EUDAMED Playground)

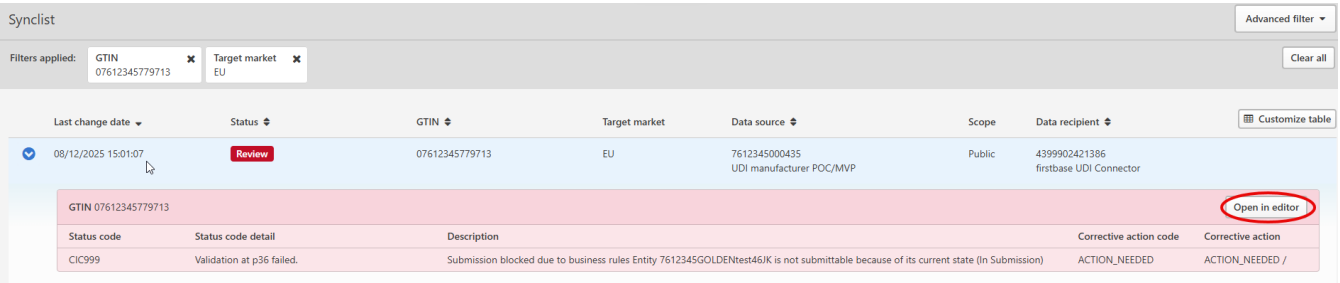
When a CIC REVIEW has been returned, and EUDAMED has responded with an error. This can be the case for several reasons, for instance:

- Issues regarding the access point configuration (Actor settings) e.g. UDI Token is not valid.
- Technical problems in the M2M interface between the UDI Connector service (e.g. p36) and EUDAMED because of a service downtime.
- Content error, when the GDSN Data pool cannot validate against specific data e.g. an invalid Authorised Representative Actor Code (SRN).

In any case click on CIC status 'View on Synclist' link and open the detailed description of the CIC error message.



Important: It is good to know that the communication in GDSN is always related to the top level of trade item packaging hierarchies. Also, here the EUDAMED response message (CIC) is related to the highest level in the packaging hierarchy, e.g. Case unit. If you click on 'Open in Editor', it brings you to the relevant trade item hierarchy, where you can revise the data for error correction.



Note #5

Usually, the error message must be interpreted by the user, as EUDAMED responds with specific references like error code, SRN, Basic UDI-DI Code (GMN) or UDI-DI Code (GTIN) and the related error detail. The detail includes the attribute name or code value in EUDAMED language. If the reader does not find the **error root cause** directly using the Web UI, they could look-up the information in the current 'GS*1_UDI_Connector_Profile_Overview.xlsx'*, which helps to map against the GDSN attribute definitions and code list mappings. If you have any specific error questions, please contact your local data pool support team.

After fixing the error, the item must be **re-published**.

4.7 Proof of Test (POT) for Production Access Point configuration

After testing is completed, it is important to get the **Proof of Test (POT)** file in PDF format and store it in our documentation. The POT file must include the used Actor Code (SRN), DI Codes and successful XML messages from EUDAMED. You can get your POT file from one of the following options:

a) Contact your 3rd Party Provider for POT file.

b) Generate the POT file from p36 'Authority Onboarding' (see *Phase 1 - Onboarding Process* – **Note #2**)

By choosing method b), you will learn more about the service you use, and how it works. Both methods will work fine though.

If you have any questions related to this preparation step, contact your GS1 Member Organisation for support and training.

5 Phase 4 - Data Capturing and Production Configuration

For Production configuration lookup the steps of *Phase 1 - Onboarding Process*.

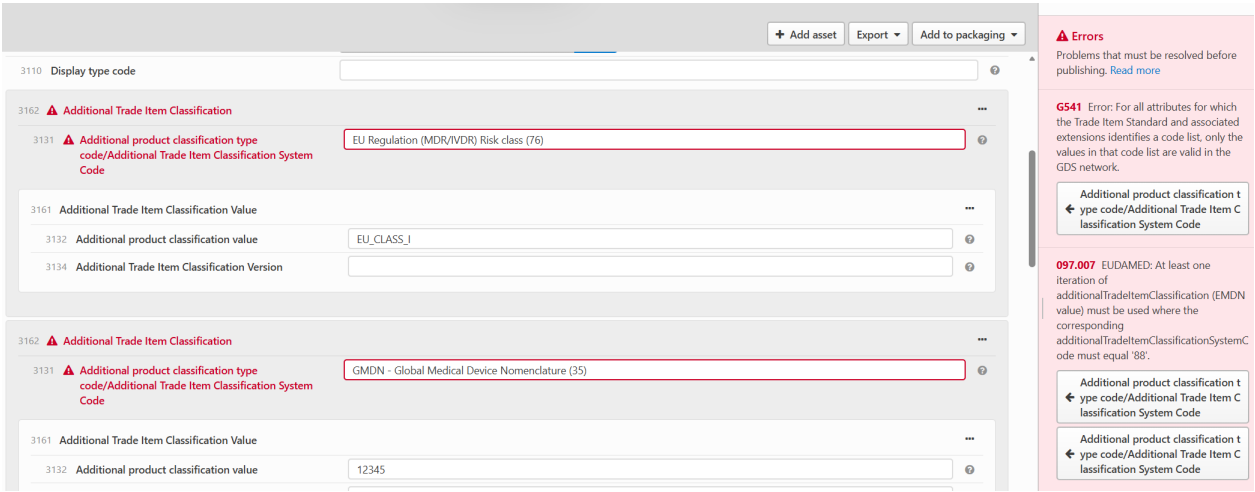
Once you have your configuration in production ready, you can start adding product data for the products you want to register in EUDAMED. It is recommended that you identify two user roles to enable working with a 4-eye principle: one person as 'Editor', this person adds the relevant data to your product. The other person is 'Access control Editor (Publisher)', this person checks the data and publishes the data to EUDAMED. You can identify these roles in the 'users' tab in your GDSN Data pool.

First collect the required UDI data internally, see *Phase 2 - GDSN Attribute Analysis for UDI Data)*. If available, you can also reuse data that was successfully submitted in the TEST environment.

Add the data of one product in your GDSN Data pool. Look for help on the working of the GDSN Data pool here on the website of your local GS1 Member Organisation. The following steps are recommended.

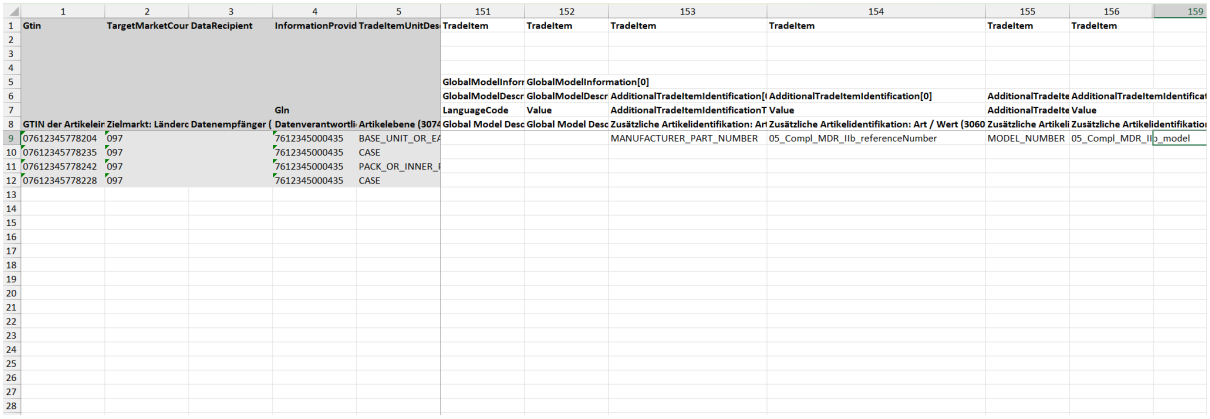
5.1 For Web-User Interface Users

1. Use the Editor role to create a first product (UDI-DI) under a Basic UDI-DI and enter all the attributes required for that product. As mentioned in the previous step under testing, it's recommended to follow DRIFT. Implemented validation rules (errors) will support that and directly control if your record is affected by any missing mandatory, consistency mistake or other business rule dependency. The screenshot below shows you what that looks like.



2. After completion publish this first UDI-DI with its Basic UDI-DI data to your targeted 'UDI Connector' GLN (Publish to GLNs see *Phase 5 - Live Submissions and Error Handling, Publication section*). Make sure that this first publication of a Basic UDI-DI with its first UDI-DI succeeds with CIC SYNCHRONISED or RECEIVED.

3. After one successful registered record, this first UDI can be exported in excel to multiply the records for all other UDI-DI's that fall under the same Basic UDI-DI. Use the downloaded excel template with the relevant attributes. The exported excel file can then be used to copy the relevant data to the other UDI-DI's and then imported back into GDSN.



	1	2	3	4	5	151	152	153	154	155	156	159
1	Gtin	TargetMarketCour	DataRecipient	InformationProvid	TradeItemUnitDes	TradeItem	TradeItem	TradeItem	TradeItem	TradeItem	TradeItem	
2												
3												
4												
5						GlobalModelInfor	GlobalModelInformation[0]					
6						GlobalModelDescr	GlobalModelDescr	AdditionalTradeItemIdentification[(	AdditionalTradeItemIdentification[0]	AdditionalTradeIte	AdditionalTradeItemIdentifica	
7				Gln		LanguageCode	Value	AdditionalTradeItemIdentificationT	Value	AdditionalTradeIte	Value	
8	GTIN der Artikeleir	Zielmarkt: Länderc	Datenempfänger (	Datenverantwortli	Artikelebene (3074	Global Model Desc	Global Model Desc	Zusätzliche Artikelidentifikation: Ari	Zusätzliche Artikelidentifikation: Art / Wert (3060	Zusätzliche Artikeli	Zusätzliche Artikelidentifikatio	
9	07612345778204	097		7612345000435	BASE_UNIT_OR_EA			MANUFACTURER_PART_NUMBER	05_Compl_MDR_IIb_referenceNumber	MODEL_NUMBER	05_Compl_MDR_IIb_model	
10	07612345778235	097		7612345000435	CASE							
11	07612345778242	097		7612345000435	PACK_OR_INNER_							
12	07612345778228	097		7612345000435	CASE							

4. Then you can publish the records to EUDAMED using the 'publishing' role to apply the 4-eyes principle. See *Phase 5 - Live Submissions and Error Handling, Publication section*.

5.2 For Machine-to-Machine Users

Use your installed process to publish to EUDAMED, see *Phase 5 - Live Submissions and Error Handling*.

Note #6

EUDAMED only allows manual corrections for most of the data so make sure your data is correct.

ATTENTION: The discard functionality should be only used in exceptional circumstances, because in EUDAMED it can be only done manually per each single UDI-DI.

6 Phase 5 - Live Submissions and Error Handling

6.1 Publication (EUDAMED Production)

For details of the instructions look up the information under Phase 3 - Publication (EUDAMED Playground).

Use the following Publish to GLNs from your dedicated GDSN Data pool service:

GDSN Data Pool	Member Organisation	Publish To GLN for EUDAMED Production:
Synfony	GS1 Czech Republic	8594182509823 Synfony UDI Connector
GS1Trade Sync	GS1 Denmark	7609999484742 GS1 UDI Link
firstbase	GS1 Switzerland	7609999484735 firstbase UDI Connector
GS1 Data Source	GS1 Netherlands	7609999484759 GS1 Data Source UDI Connector

6.2 Submission Flow Scenarios (EUDAMED Production)

For details of the instructions look up the information under *Submissions Flow Scenarios (EUDAMED Playground)* in Phase 3.

Note #7

ATTENTION: Please be aware that in EUDAMED Production the Notified Body Approval can take some time. High risk class devices cannot be updated before the 'Registered' state is achieved.

6.3 Error Handling (EUDAMED Production)

For details of the instructions look up the information under *Error Handling (EUDAMED Playground) in Phase 3.*

6.4 Support

If the error is misunderstood or for any kind of user question in your GDSN Data pool, please don't hesitate to contact your **local GS1 Member Organisation for support** or training. See *Data Pool Resources* section for links to relevant information.

If the error, its root cause or the user question is related to the EUDAMED system itself, please contact *SANTE-EUDAMED-SUPPORT@ec.europa.eu*. Please make sure that you respect their required information.

6.5 Discard

For specific exceptions EUDAMED allows to withdrawal and discard existing UDI registrations. This 'escape-out' should be only used, when the submitted data is incorrect and non-updateable fields cannot be changed after successful registration. As an example, a Basic UDI-DI codes were wrongly entered and linked to its UDI-DI (GTIN).

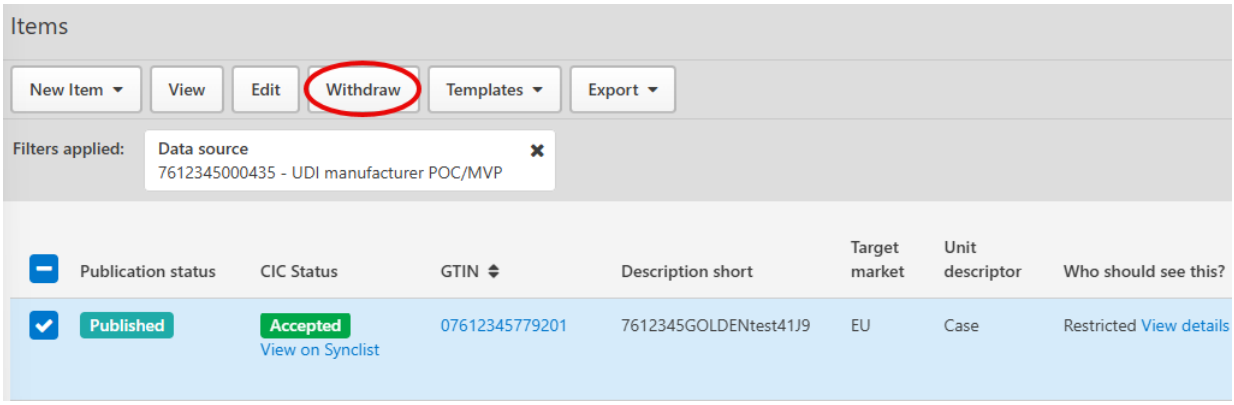
ATTENTION: The discard functionality should be only used in exceptional circumstances, because in EUDAMED it can be only done manually per each single UDI-DI.

It is very important to follow the discard process in the following three interfaces:

1. **EUDAMED Web-UI** – please refer to the official documentation from *https://webgate.ec.europa.eu/eudamed-help/en/documentation/user-guides-and-templates.html and Devices: UDI Devices*: Section 5.2.7 Discard registered UDI-DIs/EUDAMED IDs (and their Basic UDI-DI/EUDAMED DI)

2. Discard the submission under the **3rd Party Provider's** (e.g. p36) **interface**. steps to follow will be detailed here very soon, probably later in 2026.

3. Or use the item withdrawal process of **GDSN Data pool**, e.g. by using the button **'Withdraw'** to be clicked for the published item – but only in these kinds of exceptional situations:



7 Sources of Information

7.1 Required Templates for Access Point Configuration

EUDAMED Playground: *Business justification*, *Third-party agreement*

EUDAMED Production: *Third-party agreement*

7.2 Data Pool Resources (e.g. User Manuals)

p36 web tool: *https://app.udiconnect.io/*

GS1 Czech Republic Synfony: *https://synfony.cz/*

GS1Trade Sync: *GS1Trade Sync | Product data exchange made easy*

GS1 Netherlands Data Source: *https://www.gs1.nl/producten-services/data-exchange/gs1-data-source/gezondheidszorg/*

GS1 Switzerland firstbase: *https://www.firstbase.ch/de/support*

7.3 EUDAMED Information

EC's EUDAMED Website: *https://health.ec.europa.eu/medical-devices-eudamed_en?prefLang=de*

Information Centre - EUDAMED Playground: *https://webgate.ec.europa.eu/eudamed-play-help/en/welcome-to-the-eudamed-information-centre.html*

Information Centre - EUDAMED Production: *https://webgate.ec.europa.eu/eudamed-help/en/welcome-to-the-eudamed-information-centre.html*

7.4 Table of Abbreviations

AIMDD	Active Implantable Medical Device Directive 90/385/EEC
AP	Access Point
CIC	Catalogue Item Conformation
DRIFT	Do it Right the First-Time approach
DTX	Data Exchange
EC	European Commission
EU	European Union
EUDAMED	European Database on Medical Devices
GDSN	Global Data Synchronisation Network
GLN	Global Location Number
GMN	Global Model Number
GTIN	Global Trade Item Number
GUDID	Global Unique Device Identification Database
IFU	Instructions for Use
IVDD	In Vitro Medical Device Directive 98/79/EC
IVDR	In Vitro Diagnostic Regulation (EU) 2017/746
LAA	Local Actor Administration
M2M	Machine-to-Machine
MDD	Medical Device Directive 93/42/EEC
MDM	Master Data Manager
MDR	Medical Device Regulation (EU) 2017/745
MF	Legal Manufacturer (as Economic Operator in EUDAMED)
N/A	Not Applicable
POT	Proof of Testing
PR	System/Procedure Pack Producer (as Economic Operator in EUDAMED)
PROD	Production (Environment)
SPP	System or Procedure Pack
SRN	Single Registration Number
swissdamed	Swiss Database on Medical Devices
UAT	User Acceptance Testing
UDI	Unique Device Identification
UDI-DI	Unique Device Identification - Device Identifier
UI	User Interface
Web-UI	Web User Interface
XML	eXtensible Markup Language