



Switzerland



Czech Republic



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Denmark

GS1 swissdamed Submission Guideline

How to implement UDI submissions for swissdamed via GDSN

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Involved parties

There are several parties involved in the GS1 swissdamed 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 swissdamed. At this moment **GS1 Switzerland, GS1 Denmark, GS1 Czech Republic** and **GS1 Netherlands** are offering a swissdamed 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.

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



Revocation (disclaimer)

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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 swissdamed.

swissdamed is Switzerland's national database for medical devices and in vitro diagnostic medical devices. It is operated by Swissmedic and is based on the Swiss Medical Devices Ordinance (MedDO) and the In Vitro Diagnostic Medical Devices Ordinance (IVDO). The Swiss regulatory framework is closely aligned with Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), reflecting both Swiss and EU requirements.

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

This document serves as a guide for your initial configuration of the Swiss database of medical devices – swissdamed. 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 swissdamed 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 swissdamed by the Legal Manufacturer, Producer or Authorised Representative.

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.

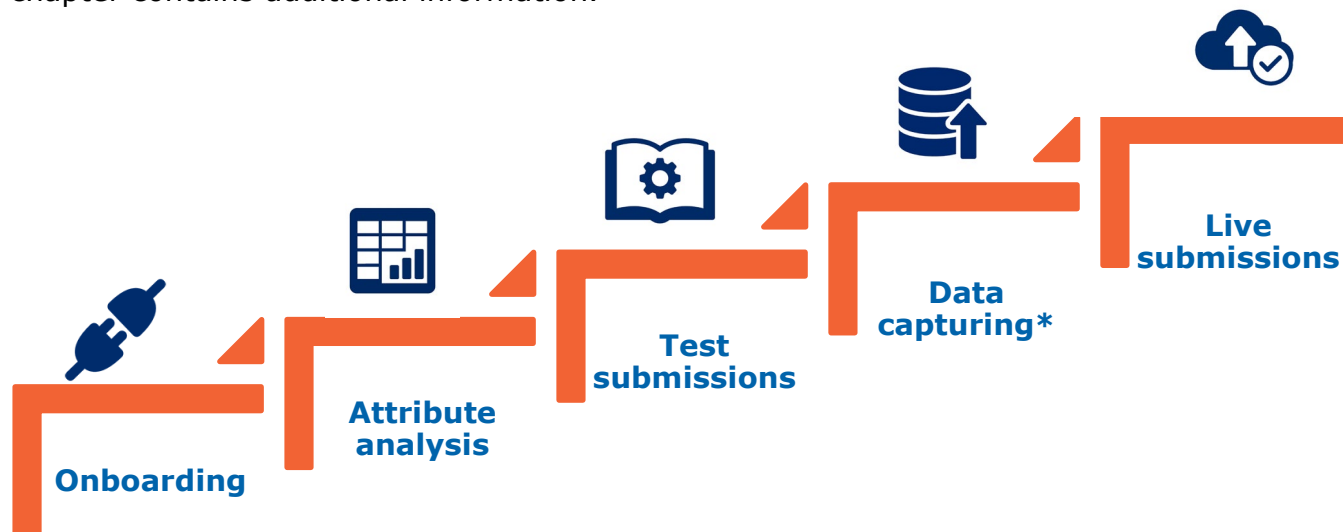
Any services provided by a local Member Organisation of GS1 shall be governed exclusively by the applicable general terms and conditions of the respective local Member Organisation, in their then-current version, as made available by such organisation (e.g. on its website or upon request).

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.

Under the Swiss Medical Devices Ordinance (MedDO), the obligations and data elements for registration in swissdamed are set out in Article 17(5) MepDO (Medical Devices Ordinance, SR 812.213) and the corresponding provisions of the Ordinance on In-Vitro Diagnostic Medical Devices (IvDO). These provisions establish the national responsibilities for swissdamed and differ from the MDR reference to Annex VI, Part A.

1.2 Document and project structure

There are 5 phases to successfully reach the swissdamed 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 Right the First Time**

Figure 1 - UDI submission process

1.3 Only use this service for your UDI data

Because of the technical setup of swissdamed, newly submitting and updating data by using both swissdamed WebUI and API/M2M via GDSN could 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 API/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 swissdamed WebUI and UDI Connector (using swissdamed API interface)

2 Phase 1 - Onboarding Process

swissdamed offers to work with two environments. The first one is a swissdamed 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 swissdamed Production environment representing the official live system where legally binding data must be submitted in compliance with MedDO, IvDO, MDR and IVDR regulations.

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

For the User and Actor registration follow the following steps. A precondition is, your company is registered by a Swiss legal entity in swissdamed Production.

1. Follow this link to swissdamed Playground: <https://playground.swissdamed.ch/>.
2. Sign in with your (*AGOV or CH*) Login or create one if not available. Behind your user your Swiss legal entity from swissdamed Production environment must be assigned.
3. Create a Test Actor request, in the role of *Swiss Manufacturer (MF)*, *Swiss Producer (PR)* or *Swiss Authorised Representative (AR)* with relevant non-Swiss MF/PR mandates.
4. The automatic validation process may take a few minutes. If needed additional support can be found [here](#).

An official source of information is this [swissdamed website](#) which provides a comprehensive information about swissdamed in general and specific the UDI-module.

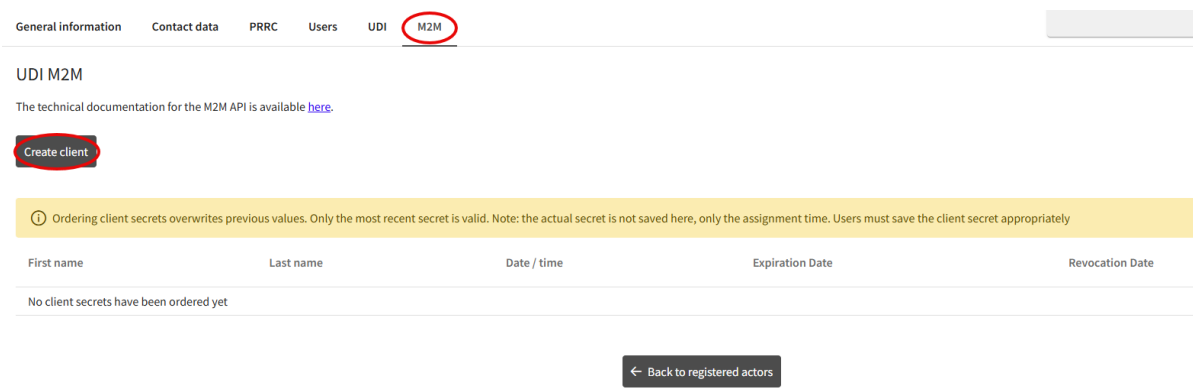
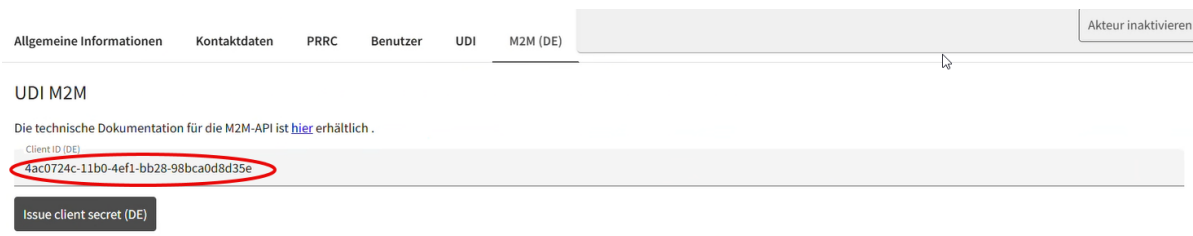
2.1 M2M Client Credentials creation

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

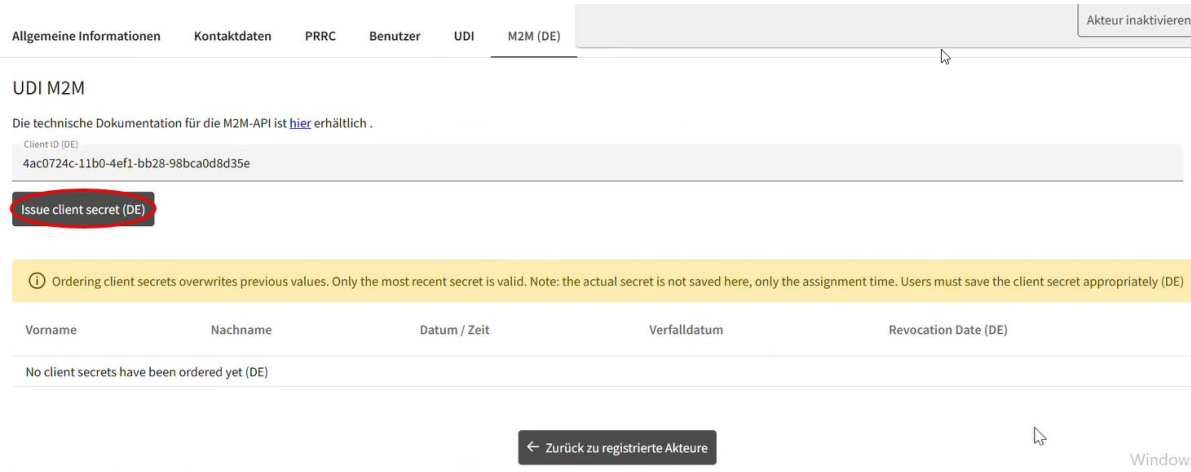
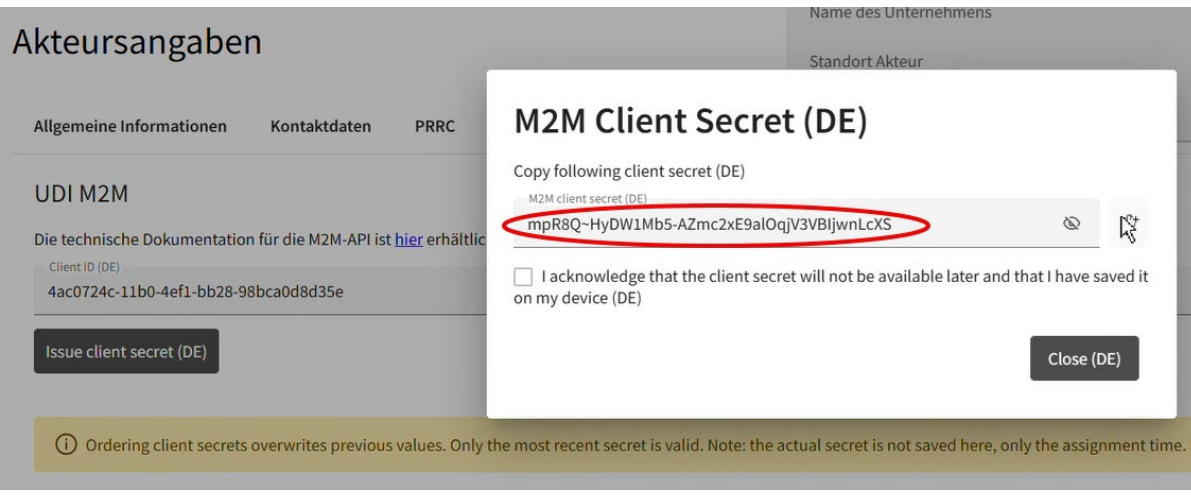
If you wish to activate your M2M services in swissdamed Production environment you must first apply for an AP in swissdamed Playground environment, complete the onboarding and test the service. Please start in the swissdamed Playground and later follow in the swissdamed Production environment.

swissdamed WebUI

(source: [BW630_40_810e_PU swissdamed Machine-to-Machine REST API Documentation](#), sections 7.1 until 7.1.3)

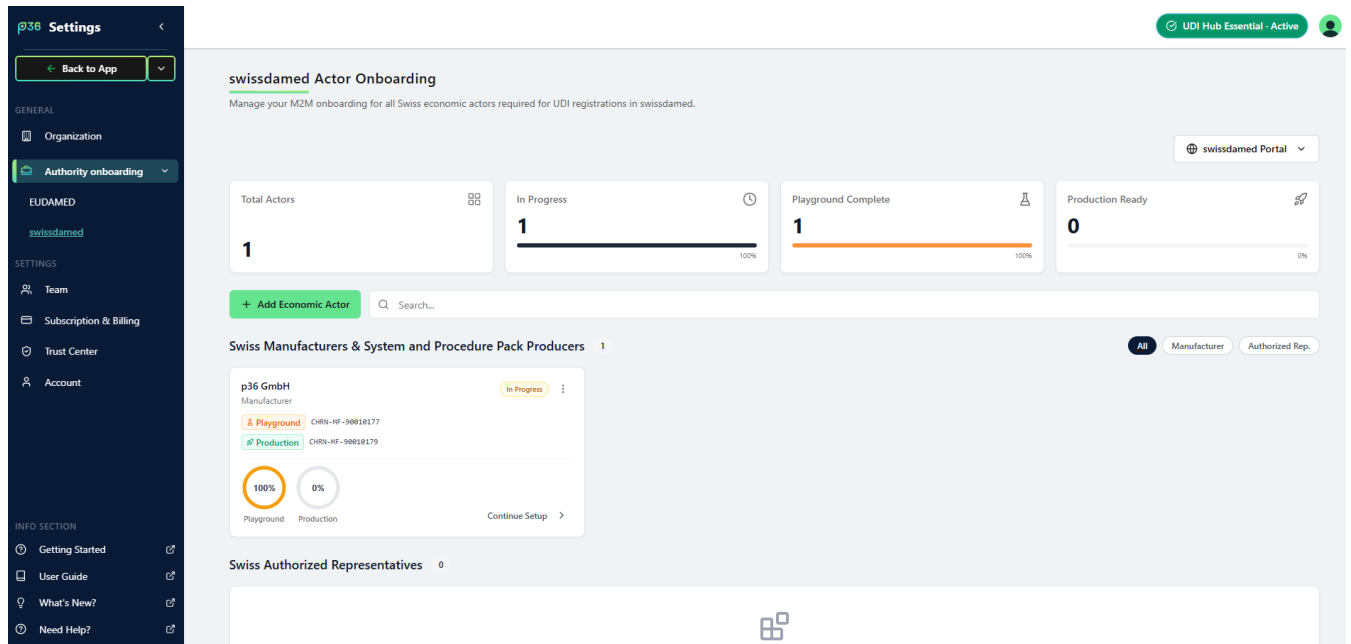
1.	Log into swissdamed as an Actor Admin. Select the relevant actor details. <u>For MF or PR Actors:</u> Under the <i>My actors > Registered actors</i> > Use the magnifying glass icon to select details about the respective MF or PR actor. <u>For Mandates under AR Actors:</u> Under the <i>My actors > Registered actors</i> > Use the magnifying glass icon to select details about the respective AR actor. Under tab "Mandates" > Use the magnifying glass icon to select details about the respective MF or PR actor.
2.	Create new swissdamed client credentials² per Actor/Mandate. Under <u>Registered actor details</u> click on tab M2M > Click on Create client 
3.	The creation of a new client may take up to 2 minutes. During this time no client ID is showing, and no client secret can be ordered. Once the client ID is created, it is displayed in the <i>M2M</i> tab. 

²The **client credentials** (Client ID and Client Secret) are crucial element for authorizing the connection between the legal entity (identified by its Swiss Registration Number – CHRN or by a Mandate ID) and the 3rd Party Provider, and it must be handed over to the provider to enable M2M communication for UDI registration on their behalf.

4.	After the client ID is issued, a client secret can be obtained by clicking the <i>Issue client secret</i> button below the client ID. 
5.	Important note: Please copy and save the client secret, as it will only be displayed at the time it is issued and cannot be viewed at a later time.  If a new client secret is issued, the previous client secret will be invalidated. Client secrets will expire after two years and will then need to be re-generated.
6.	Please forward both client credentials (Client ID and Client Secret): - to a GS1 contact person. - to the 3rd Party Provider p36, see Note #1 at the bottom of this section.
6.	DONE

Note #1

The process described above is very general and follows the mandatory steps in swissdamed Playground/Production. Some 3rd Party 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 swissdamed Actor Onboarding (contact your provider for access). Screen shot below:



The screenshot displays the 'swissdamed Actor Onboarding' interface within the p36 web tool. The interface is divided into a left sidebar and a main content area.

Left Sidebar:

- Settings:** Includes a 'Back to App' button and a dropdown menu.
- GENERAL:** Contains 'Organization' and 'Authority onboarding' (selected).
- EUDAMED:** Includes a link to 'swissdamed'.
- SETTINGS:** Includes 'Team', 'Subscription & Billing', 'Trust Center', and 'Account'.
- INFO SECTION:** Includes 'Getting Started', 'User Guide', 'What's New?', and 'Need Help?'.

Main Content Area:

- Header:** 'swissdamed Actor Onboarding' with a subtitle 'Manage your M2M onboarding for all Swiss economic actors required for UDI registrations in swissdamed.' and a 'swissdamed Portal' dropdown.
- Progress Dashboard:** Four cards showing onboarding progress:
 - Total Actors:** 1
 - In Progress:** 1 (100%)
 - Playground Complete:** 1 (100%)
 - Production Ready:** 0 (0%)
- Buttons:** '+ Add Economic Actor' and a search bar.
- Swiss Manufacturers & System and Procedure Pack Producers:** A list of manufacturers. The first entry is 'p36 GmbH' (Manufacturer), which is 'In Progress'. It shows two progress indicators: 'Playground' (100%) and 'Production' (0%). A 'Continue Setup' button is present.
- Swiss Authorized Representatives:** 0

3 Phase 2 - GDSN Attribute Analysis for UDI Data

To ensure accurate and compliant data submission to swissdamed, users must analyse the alignment between the **swissdamed 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 onboarding 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.

EUDAMED UDI v2.22.0				swissdamed		GDSN v3.1.33 Mappi		Manufacturer's Analysis			
Scope	Field ID	Field Label	Entity Name	MDR Status	Overlap with EUDAMED?	Attribute Name	Example Value	Applicable?	Sample Value	Attribute name in EKP / PIM	Remark
No	Basic-UDI / EUDI Attributes										
Yes	FLD-UID-14	Basic UDI- DI code	BasicUIData	M	Yes	Global model information	Global Model Number (GMN)	Yes	7612345GOLDentest19JG	fmm	
Auto-popul	FLD-UID-01	Issuing Entity Basic UDI-DI	BasicUIData	M	Yes			Yes	7612345GOLDentest19JG	fmm	
Yes	FLD-UID-11	Applicable Legislation / Regulation	BasicUIData	M	Yes	Regulatory act	MDR	Yes	MDR	Legislation	
Yes	FLD-UID-11	Applicable Legislation / Regulation	BasicUIData	M	Yes	Regulatory agency	EU	default=EU			
Yes	FLD-UID-16	Risk Class	BasicUIData	M	Yes	Additional trade item	EU_CLASS_IIB	Yes	CLASS_IIB	Risk Class	
Yes	FLD-UID-16	Risk Class	BasicUIData	M	Yes	Additional trade item	76	default=76			
Yes	FLD-UID-10	Legal Manufacturer SRN	BasicUIData	M	Yes	Additional party identification	SRN / CH-MF-000023141	Yes	DK-MF-000021581	EU Actor	
Yes	FLD-UID-10	Legal Manufacturer SRN	BasicUIData	M	Yes	Contact type code	EMA	default=EMA			
Yes		Legal manufacturer CHRN	CHRN (MF)	M	swissdamed only	Additional party identification	CHRN / CHRN-MF-20010136	No			
Yes		Legal manufacturer CHRN	CHRN (MF)	M	swissdamed only	Contact type code	EMA	Yes			
Yes		Authorised representative CHRN	CHRN (AR)	CM	swissdamed only	Additional party identification	CHRN / CHRN-AR-20010004	No			
Yes		Authorised representative CHRN	CHRN (AR)	CM	swissdamed only	Contact type code	EAR	default=EMA			
Yes	FLD-UID-20	Device Model	BasicUIData	CM	Yes	Additional trade item	MODEL_NUMBER /				
Yes	FLD-UID-22	Device Name	BasicUIData	CM	Yes	Global model description	CompL_MDR_Iib_name				
Yes	FLD-UID-12	Is it a System which is a Device in	BasicUIData	M	Yes	Multi component device type	PROCEDURE_PACK				
Yes	FLD-UID-13	Special Device Type	BasicUIData	O	Yes	Special device type code	SOFTWARE				
Yes	FLD-UID-28	Active Device	BasicUIData	M	Yes	Is active device	false				
Yes	FLD-UID-29	Device Intended to administer and	BasicUIData	M	Yes	Is device intended to administer	true				

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 swissdamed 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 swissdamed can be complicated, because of the requirements from swissdamed. For that reason, it is extra important to have the **Do it Right the First Time** 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.

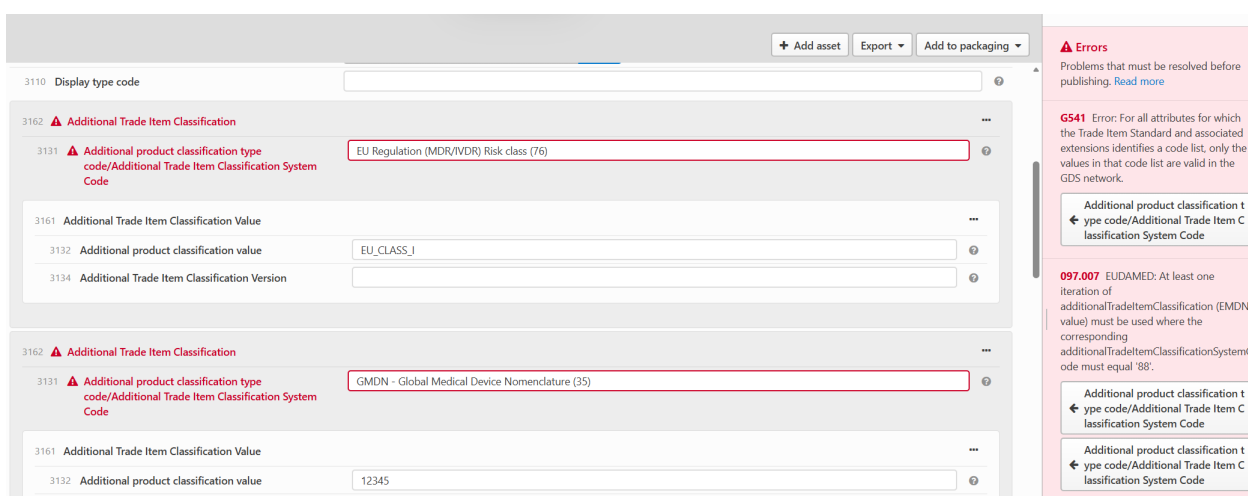
The intention of testing is to make sure, that your M2M solution supports all the scenarios and attributes relevant to your submission of data to swissdamed.

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 \(swissdamed Playground\)](#) explains how to correctly publish data.



The screenshot displays the swissdamed Web-User Interface (Web-UI) for creating a new record. The interface includes a top navigation bar with buttons for '+ Add asset', 'Export', and 'Add to packaging'. The main form area is divided into sections for data entry, with fields for 'Display type code', 'Additional Trade Item Classification', 'Additional product classification type code/Additional Trade Item Classification System Code', 'Additional Trade Item Classification Value', 'Additional product classification value', and 'Additional Trade Item Classification Version'. The form is populated with values such as 'EU Regulation (MDR/IVDR) Risk class (76)', 'EU_CLASS_I', and '12345'. On the right side, there is a red 'Errors' panel with two error messages: 'G541 Error: For all attributes for which the Trade Item Standard and associated extensions identifies a code list, only the values in that code list are valid in the GDS network.' and '097.007 EUDAMED: At least one iteration of additionalTradeItemClassification (EMDN value) must be used where the corresponding additionalTradeItemClassificationSystemCode must equal '88''. The form also includes a '3110 Display type code' field and a '3162 Additional Trade Item Classification' section with a '3131 Additional product classification type code/Additional Trade Item Classification System Code' field.

2. Then check swissdamed 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 \(swissdamed Playground\)](#) 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 swissdamed. Then check swissdamed Response Feedback (CIC - Catalogue Item Conformation) for the records send. Complete the *step 1* again if any mistakes occurred.

4.2 For Machine-to-Machine Users

1. Send your first UDI record through your implemented M2M interface into our UDI Connector service via GDSN or the data validation. How to correctly publish you can read in section [4.4 Publication \(swissdamed Playground\)](#). Then check swissdamed Response Feedback (CIC) for the records send. If there are errors mentioned in the CIC look at [4.6 Error Handling \(swissdamed Playground\)](#) for your guidance. Complete the previous again if any mistakes occurred.
2. Then you can publish all test records in swissdamed.. If there are errors mentioned in the CIC look at [4.6 Error Handling \(swissdamed Playground\)](#) for your guidance. Complete this step for all your chosen test scenarios.

4.3 Registration Process of UDI Submissions in swissdamed

When you send your UDI data to swissdamed, all risk classes will be with no additional involvement of Notified Bodies. The certificate module part is taken care in EUDAMED only and linked in swissdamed. That's why all UDI submissions in swissdamed will be directly registered.

Make sure, that your UDI record has the attribute "UDID medical device market status code" (TC ID 4728) indicated with the initial value "On the market" (code 'ON_MARKET'). The UDI Connector service will put the UDI submission directly with this **Swiss market status** in swissdamed. If all the submitted data is correct, first the UDI record gets the status "Not set" and then after a few minutes "**On the market**" in swissdamed. In GDSN data pool you will get a CIC receipt with the status first "RECEIVED" and after at least 1 minute delay "SYNCHRONISED", and your registration is completed.

4.4 Publication (swissdamed 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 live 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:

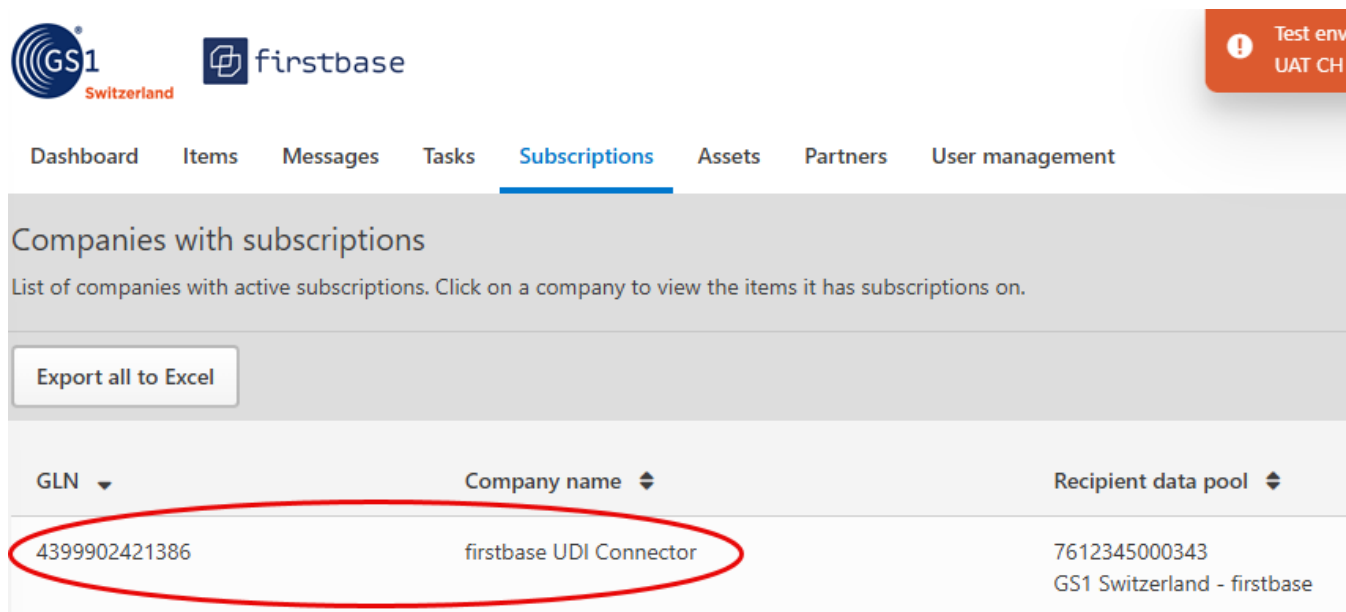
- it is recommended to start with the initial publication of the first UDI-DI belonging to the new Basic UDI-DI.
- after this first submission has succeeded with CIC SYNCHRONISED the follow-up UDI-DIs of the same Basic UDI-DI can be published too.
- repeat this sequencing order of 1+2 above for every first UDI-DI belonging to a Basic UDI-DI and its follow-up UDI-DIs

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

GDSN Data Pool	Member Organisation	Publish To GLN
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 #2

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:



The screenshot shows the 'Subscriptions' tab in the GS1 Switzerland web application. The 'Companies with subscriptions' section lists companies with active subscriptions. The first row is circled in red, showing the following details:

GLN	Company name	Recipient data pool
4399902421386	firstbase UDI Connector	7612345000343 GS1 Switzerland - firstbase

4.5 Submission Flow Scenarios (swissdamed Playground)

After the publication is done, for any UDI submission swissdamed gives direct responses like other UDI databases. As described in [Phase 3 - Learn UDI Upload and Testing](#) the final CIC will be received with the status "SYNCHRONISED" (= "**On the market**" in swissdamed). It is recommended to wait for this initial submission per each Basic UDI-DI. 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 (= "**On the market**" in swissdamed) was provided.

It is highly recommended to make **proper testing** of the specific submission scenarios with swissdamed 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 one or all individual UDI-DIs together with its new Basic UDI-DI, which is not yet submitted or registered. Then successful CIC responses are received: CIC RECEIVED and SYNCHRONISED in quick succession after a few minutes. In swissdamed playground the UDI data get visible per market status "On the market".	A) 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 SYNCHRONISED has been received for a Basic UDI-DI (with the swissdamed status "On the market"), 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. CIC RECEIVED and SYNCHRONISED in quick succession after a few minutes. In swissdamed playground the UDI data get visible per updated Last update date.	A) Same UDI-DI was published with multiple packaging hierarchies one after another. It could lead to a CIC REVIEW with 'Submission blocked error' thereafter. B) Update submission is started before CIC SYNCHRONISED is received. It could lead to a CIC REVIEW with 'Submission blocked error' thereafter. C) 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.

After testing is completed, there is no need to provide any Proof of Test (POT) file to Swissmedic. The full responsibility to ensure sufficient testing lies on the legal entity of UDI submissions (Manufacturer, Producer or Authorised Representative).

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

4.6 Error Handling (swissdamed Playground)

When a CIC REVIEW has been returned, and swissdamed 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 swissdamed because of a service downtime.
- Content error, when the GDSN data pool cannot validate against specific data e.g. a Mandate ID (CHRN) of a foreign Manufacturer.

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

☐	Publication status	CIC Status	GTIN	Description short	Target market	Unit descriptor	Who should see this?
☐	Published	Review View on Synclist	07612345779171	7612345GOLDENtest40J7	EU	Pack or Inner Pack	Restricted View details
☐	Live		07612345779164	7612345GOLDENtest40J7	EU	Base Unit or Each	Restricted View details

Last change date	Status	GTIN	Target market	Data source	Scope	Data recipient
07/11/2025 16:32:35	Review	07612345779133	EU	7612345000435 UDI manufacturer POC/MVP	Public	4399902421386 firstbase UDI Connector
GTIN 07612345779133						
Status code	Status code detail	Description	Corrective action code			
CIC999	Error reported by P36 UDI connect	: elementReport> <message:operationErrorCode>ERR-DTX-EUD-403.01</message:operationErrorCode> <message:operationErrorDetail>Only the owner can update their entities. DE-MF-000005765 is not the owner of: 7612345GOLDENtest38JL GS1.</message:operationErrorDetail> </message:elementReport	ACTION_NEEDED			

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 swissdamed 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.

Synclist

Advanced filter

Filters applied:

GTIN07612345779713

Target marketEU

Clear all

Last change date	Status	GTIN	Target market	Data source	Scope	Data recipient	Customize table
08/12/2025 15:01:07	Review	07612345779713	EU	7612345000435 UDI manufacturer POC/MVP	Public	4399902421386 firstbase UDI Connector	
GTIN 07612345779713							Open in editor
Status code	Status code detail	Description	Corrective action code		Corrective action		
CIC999	Validation at p36 failed.	Submission blocked due to business rules Entity 7612345GOLDENtest46JK is not submittable because of its current state (In Submission)	ACTION_NEEDED		ACTION_NEEDED /		

Note #3

Usually, the error message must be interpreted by the user, as swissdamed responds with specific references like error code, CHRN, 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 swissdamed 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

"GS1_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 affected item must be **re-published**.

5 Phase 4 - Data Capturing and Production Configuration

For Production configuration lookup the steps of [Phase 1 - Onboarding Process](#).

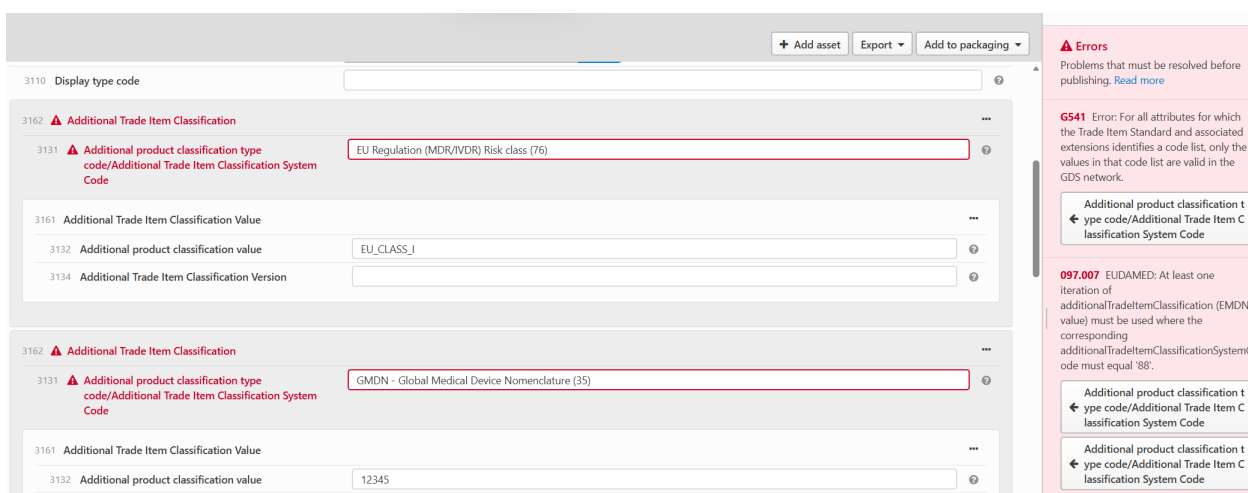
Once you have your configuration in production ready, you can start adding product data for the products you want to register in swissdamed. It is recommended that you identify two user roles to enable working with a 4-eye principle: one person as "Editor", this person adds the relevant data to your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



The screenshot displays the swissdamed web interface for product configuration. It shows two sections for 'Additional Trade Item Classification' (3162). Each section contains fields for 'Additional product classification type code/Additional Trade Item Classification System Code' (3131), 'Additional Trade Item Classification Value' (3161), 'Additional product classification value' (3132), and 'Additional Trade Item Classification Version' (3134). The first section has 'EU Regulation (MDR/IVDR) Risk class (76)' in the 3131 field and 'EU_CLASS_I' in the 3132 field. The second section has 'GMDN - Global Medical Device Nomenclature (35)' in the 3131 field and '12345' in the 3132 field. On the right side, there is an 'Errors' panel with two error messages. The first error, 'GS41 Error', states: 'Error: For all attributes for which the Trade Item Standard and associated extensions identifies a code list, only the values in that code list are valid in the GDS network.' The second error, '097.007 EUDAMED', states: 'At least one iteration of additionalTradeItemClassification (EMDN value) must be used where the corresponding additionalTradeItemClassificationSystemCode must equal 88'. Below each error message are links to 'Additional product classification type code/Additional Trade Item Classification System Code'.

2. After completion publish this first UDI-DI with its Basic-UDI 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.

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	TradeItem	TradeItem
2											
3											
4											
5											
6											
7											
8	GTIN der Artikel	Zielmarkt: Länderc Datenempfänger	Datenverantwort	Artikelebene (307)	Global Model Descr	Global Model Descr	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]
9	07612345778204	097	7612345000435	BASE_UNIT_OR_E	Global Model Descr	Global Model Descr	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]
10	07612345778235	097	7612345000435	CASE	Global Model Descr	Global Model Descr	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]
11	07612345778242	097	7612345000435	PACK_OR_INNER_I	Global Model Descr	Global Model Descr	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]
12	07612345778228	097	7612345000435	CASE	Global Model Descr	Global Model Descr	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]	AdditionalTradeItemIdentification[0]
13											
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4. Then you can publish the records to swissdamed 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 swissdamed, see [Phase 5 - Live Submissions and Error Handling](#).

Note #4

swissdamed 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 swissdamed it can be only done manually manually by checkmarking the affected UDIs.

6 Phase 5 - Live Submissions and Error Handling

6.1 Publication (swissdamed Production)

For details of the instructions look up the information under [Phase 3 - Publication \(swissdamed Playground\)](#).

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

GDSN Data Pool	Member Organisation	Publish To GLN
Synfony	GS1 Czech Republic	8594182509823 Symfony 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

Note #5

In swissdamed Production you can send bulk submissions of UDI's using the same Basic UDI in one upload. There is no need to wait for the initial UDI-DI receive the status CIC SYNCHRONISED.

6.2 Submission Flow Scenarios (swissdamed Production)

For details of the instructions look up the information under [Follow-up Submissions \(swissdamed Playground\)](#) in Phase 3.

6.3 Error Handling (swissdamed Production)

For details of the instructions look up the information under [Error Handling \(swissdamed Playground\)](#) 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 swissdamed system itself, go to <https://www.swissmedic.ch/swissmedic/en/home/medical-devices/medizinprodukte-datenbank/supportswissdamed.html>. Please make sure that you respect their required information.

6.5 Discard

For specific exceptions swissdamed 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 swissdamed it can be only done manually by checkmarking the affected UDIs.

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

1. **swissdamed Web-UI** – please refer to the official documentation provided under <https://www.swissmedic.ch/swissmedic/en/home/medical-devices/medizinprodukte-datenbank/supportswissdamed.html> as user manual named "BW630_40_841e_HB swissdamed User Guide UDI Devices Module.pdf" section **8 Discarden von UDIs**.
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:

Items							
New Item ▾ View Edit Withdraw Templates ▾ Export ▾							
Filters applied: Data source 7612345000435 - UDI manufacturer POC/MVP ✕							
Publication status	CIC Status	GTIN	Description short	Target market	Unit descriptor	Who should see this?	
☒ Published	☒ Accepted View on Syndlist	07612345779201	7612345GOLDENtest41J9	EU	Case	Restricted View details	

7 Sources of Information

7.1 swissdamed WebUI

swissdamed Playground: <https://playground.swissdamed.ch/>

swissdamed Production: <https://swissdamed.ch/>

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 swissdamed Information

swissdamed website: <https://www.swissmedic.ch/swissmedic/en/home/medical-devices/medizinprodukte-datenbank.html>

swissdamed technical documentation
<https://www.swissmedic.ch/swissmedic/en/home/medical-devices/medizinprodukte-datenbank/technische-dokumentation.html>

7.4 Table of Abbreviations

AIMDD	Active Implantable Medical Device Directive 90/385/EEC
AP	Access Point
API	Application Programming Interface (M2M)
CIC	Catalogue Item Conformation
DRIFT	Do it Right the First-Time approach
EC	European Commission
EU	European Union
EUDAMED	European Database on Medical Devices
swissdamed	Swiss 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
IvDO	In Vitro Diagnostic Medical Devices
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
MedDO	Medical Devices Ordinance
MF	Legal Manufacturer (as Economic Operator in swissdamed)
N/A	Not Applicable
POT	Proof of Testing
PR	System/Procedure Pack Producer (as Economic Operator in swissdamed)
PROD	Production (Environment)
SPP	System or Procedure Pack
SRN	Single Registration Number
UAT	User Acceptance Testing
UDI	Unique Device Identification
UDI-DI	Unique Device Identification - Device Identifier
UI	User Interface
Web-UI	Web User Interface

