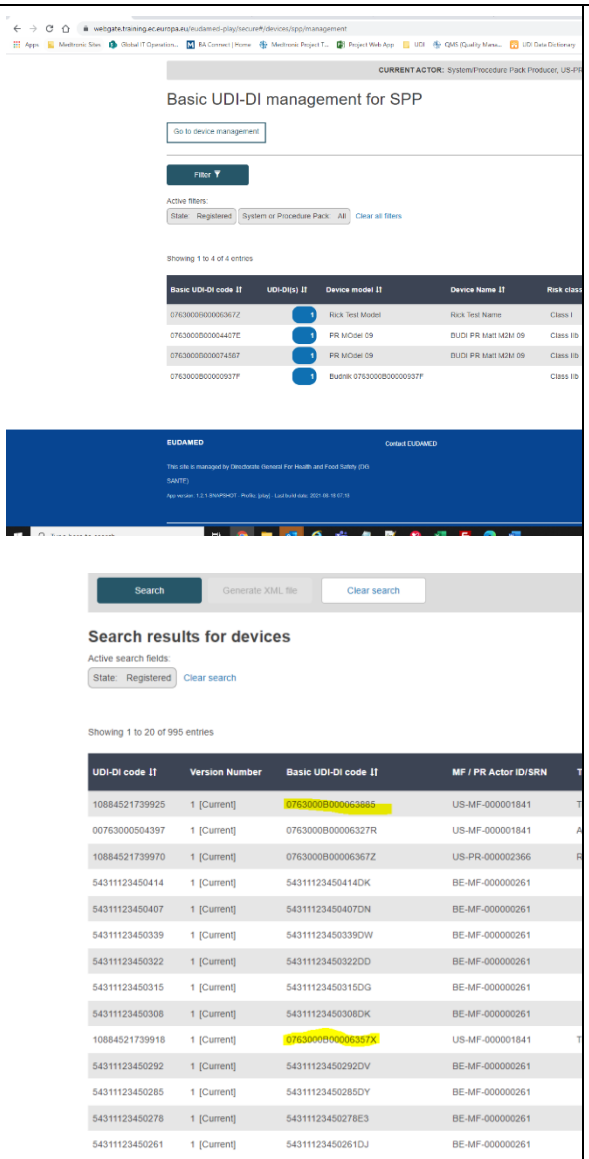
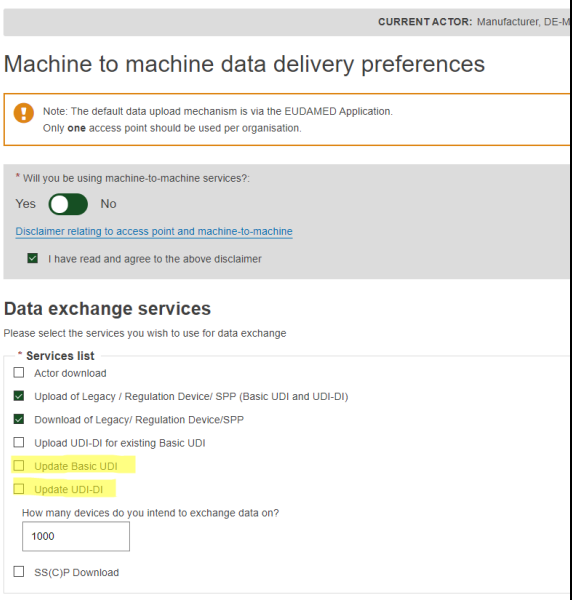
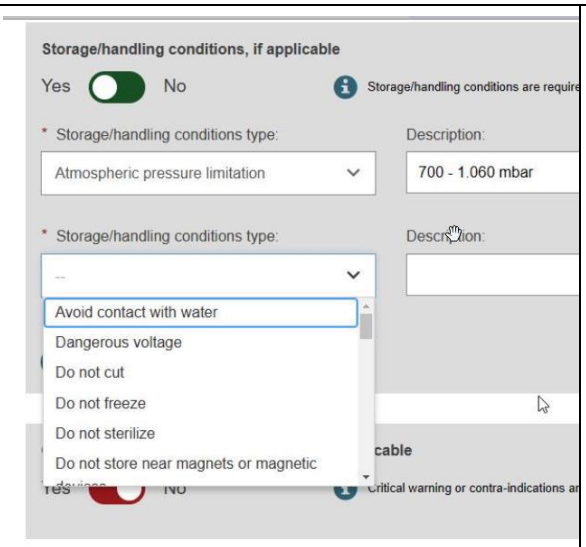
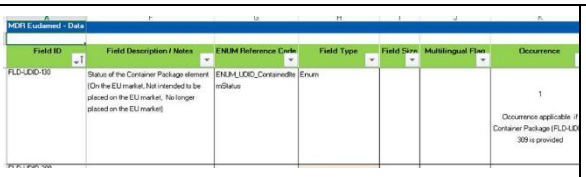
September 2021 MTE feedback v1.2.1 playground with responses from EUDAMED team

#	Title	Item reported	Response
1	Version number to be added when sending updates	The version number of the playground was added in the M2M exchange when sending patches (updates) which is a significant change in functionalities. Any XML files used in the playground should now reference XSD v1.5.1 to avoid triggering an error. This would require proper testing in a new playground before being deployed in Production in EUDAMED.	XSD v1.5.1 was included in the DTX update which was deployed on 24th August, and communication in Circabc included a reference that any other XML samples should be amended to avoid receiving an error.
2	Unit of Use DI	BR-UDID-023: Unit of Use applicable - is not working in the playground anymore if adding DM-DI -no; QTY >1; UoU DI - blanc. This gives error 400 Not being able to be provided later if not initially provided - Data dictionary states that it can be provided at a later stage, but the field is not marked as updateable. If it is possible to update it, then the updateable flag should be set and then this also has to apply to the UoU DI Issuing Agency.	We could reproduce the issue mentioned and we have documented it. Intended to be fixed in production release. Update created for DD- Unit of Use DI - marked as Updatable;
3	POST MARKET_INFO or PUT PACKAGE	Additional DTX services like POST MARKET_INFO or PUT PACKAGE are still missing, not clear whether these services are mandatory for adding new markets or packages or if they are only choices/alternatives for the PATCH UDI_DI (this latter option is preferred). This would require proper testing in a new playground before being deployed in Production in EUDAMED	Services for Update of Market Information and Container Package will be implemented Post- September
4	Update MDR Device UDI-DI having a not valid identifier	Update MDR Device UDI-DI having a not valid identifier (or the identifier or BUDI-DI) does not exist in EUDAMED. After the upload of the XML, a successful message is received for this negative scenario, which normally should have given an error.	We could reproduce the issue mentioned and we have documented it. Intended to be fixed in production release.
5	Searching for System / Procedure pack information	Unable to see either the “System” or “Procedure Pack” that was successfully submitted via M2M to EUDAMED Playground. When manually created a “System” in the playground, we are able to see that device when clicking on the “Manage your Basic UDI-Dis” link on the dashboard. Unable to find these two devices when clicking on the “Manage your Basic UDI-DIs” on the dashboard. (see screenshots below)	We have tried to reproduce the issue but it seems to work fine. Submitting a Device being a system or procedure pack in itself through M2M and previewing the information in Management screen (Basic UDI Management) works ok. When Submitting Devices, being marked as a System which is a Device in itself or a Procedure Pack in itself, then the attribute "*type*" defined in Basic UDI entity needs to have the corresponding value (SYSTEM or PROCEDURE_PACK). In the screens provided - the Management screen is the one of a System or Procedure Pack Producer (PR - US-PR-000002366), whereas the Basic UDI seems to correspond to a Device (not a System or Procedure

			Pack) - registered by a a different Manufacturer (MF -US-MF-000063885).
6	Direct Marking DI equal to UDI-DI	Entering Direct Marking DI gives equal to UDI-DI gives error message 400	We have tested several situation and we could not reproduce the error. Please provide us more some additional information (reproducing steps).
7	Consistency checks performed when linking Devices - UDI-DI for legacy	BR-UDID-702 Consistency checks are dictating what can/cannot be done when performing the linking i.e. which values need to be consistent between the Regulation and Legacy Device. Data attributes of the MDD/AIMDD and MDR also need to be identical in order to be able to link them in EUDAMED i.e. restricted substances (medicinal product: N for MDD, Y for MDR. This prevents manufacturers to be able to use the same UDI-DI for MDD and for MDR device. The system forces to create a EUDAMED DI/ID for a legacy device in order to be able to submit in EUDAMED. In that case the manual linking would not be possible neither.	The link between legacy and regulation devices should be only if there are no significant changes in the design and intended purpose, therefore, main characteristics should remain the same. We will investigate more to determine if such flexibility/possibility could be allowed.

8	BR- CERT- 109 - Certificate type	What is the applicable certificate type for Class II non-implantable device? The related business rule BR- CERT- 109 - Certificate type seems to mix up two different certificate types: Type examination and Technical Documentation assessment certificates: For MDR Devices having device Risk Class IIb non implantable (implantable = false) or Risk Class IIb implantable which are sutures (implantable = true and Staples, Sutures= true) - user will be required to specify if a Technical Examination Certificate is covering the Device and if yes provide the Certificate ID of the Certificate, the Revision Number and the Notified Body Id of the Notified Body that issued the Certificate. For Class IIb non-implantable devices the EU QMS Certificate together with EU technical documentation assessment certificate (for at least one re resentative device per generic device group) should be accepted to comply with MDR requirements.	The Certificate Rule BR- CERT- 109, specifies all the Applicable Certificate types. In Device registration - when submitting a Device and you are required to provide the type of Certificate covering the Device- only Certificate types referenced in the Art 22.4 (MDR Regulation) must be provided - even if the Device can be covered by several. We only ask for this type of certificate as these are the only ones that require confirmation by a NB. We will update our documentation and UI to help outline this clearly.
9	Actor registration setting	M2M preferences need to be changes in the actor module in order to be able to submit patch services for Basic UDI-DI and UDI-DI. This is not described in the related documentation. Please update related guidance. 	Thank you. The guides will be updated to include this in future releases.
10	Storage / handling conditions – value can only be selected once	In the User Interface, only one selection of a specific predefined value for storage/ handling conditions is possible. Once it is selected, it disappears from the next selection. It is inconsistent with the M2M submission where the same value can be submitted multiple times.	Thank you, we have documented it. Intended to be fixed in production release (DTX will have same constraint).

			
11	Certificate type for Regulation devices	Certificate type for Regulation devices: there are 2 types are visible in the portal, but there are more listed in the schema. (for legacy devices the list is consistent what is in the playground vs schema).	The XSD schema contains all the Certificate Types applicable (applicable also in the case of Certificate Module). The type of certificates required to be submitted as Device Certificate Data when submitting a Device are the ones mentioned in the Business Rules for UDI/Device - specific based on the type of Device submitted.
12	Device referenced in a CECP and Product designer organization	BR-UDID-720: When registering a Device for which the Basic UDI has been initially referenced inside a CECP, properties of the Device need to correspond to the ones in CECP" This BR is referenced in the Data Dictionary: FLD-UDID-222 Organisation (When the Product Designer is not already registered as a Manufacturer in EUAMED) Why is this specific to Product designer organistions?	Rule BR-UDID-720 is not specific to Organisation (Product Designer Organisation). Rule that should be referenced in the Organisation section is BR-UDID-718. We have performed an update of that section for DD
13	CI/PS is referenced in the UDI BR on Nomenclature code	BR-UDID-636: Selecting the appropriate Device Nomenclature code CI/PS - Field name in Clinical Investigation: "EMDN nomenclature code"  What's the meaning of having this in the UDI BR?	The same Business Rule is used inside the CI/PS module. It is a mention in regards to the naming of the field inside the CI/PS module.
14	Member States List of Values	UI playground has Turkey but the schema does not contain it.	Turkey will be included
15	Container pack status is not updatable	In the UDID DD 7.1 (sheet 'DD Container Pack'), the Status of the Container Pack (FLD-UDID-130) is no longer marked as 'updatable' (it was updateable in 7.0). It seems to be a mistake.	We have reviewed and updated the DD.

			
16	Packaging info	BR-UDID-430 states that the packaging info is editable but the data dictionary does not mark any of the packaging attributes as updateable. Update data dictionary to match BR.	BR-UDID-430 refers to the fact that any changes to the Container Packages are versioned independently from the UDI-DI (Container Package are versioned independently). Only the status can be versioned inside the Container Package. We have updated the DD to mention this.
17	Device substatus	The link to the device substatus, in data dictionary row 28, should have an occurrence of "0..n" to link all (past) substatuses.	We have reviewed and updated the DD.
18	BR-UDID-818 Special Device Type	Mismatch in the UDI Device Enumeration list v1.2 for special device type (note the applicable regulations for the various device types): Special Device (Software) (MDR,MDD, AIMDD/ IVDR/IVDD) — Software Special Device (Standard soft contact lenses) (MDR,MDD, AIMDD) — Standard_ Special Device (Rigid Gas Permeable (RGP) & Made-to-Order Soft Contact Lenses) (MDR,MDD, AIMDD) — Rigid_Gas_&_Made-Order_Sof Special Device (Orthopaedic) (MDR,MDD, AIMDD) — Orthopaed In BR-UDID-818, the applicable legislations are off for Software and Orthopaedic devices which need to be updated. As per the playground, if applicable legislation is selected as IVDR, then software is the only special device type that can be selected. BR-UDID-818 : Special Device Type - ENUM_UDID_SpecialDevice — RESOLVED Label Software Standard soft contact lenses Rigid Gas Permeable (RGP) & Made-to-Order Soft Contact Lenses Orthopaedic	Final version of the Enumeration for Special Device type will be updated to match the following : Label / Value Software — SOFTWARE Standard soft contact lenses — MDR_STANDARD_SOFT_CONTACT_ Rigid Gas Permeable (RGP) Contact Lenses — MDR_RIGID_GAS_PERMEABLE Made to order soft contact lenses — MDR_MADE_TO_ORDER Spectacle frames — MDR_SPECTACLES_FRAMES Spectacle lenses — MDR_SPECTACLES_LENSES Ready-made reading spectacles — MDR_READY_MADE_SPECTACLES Orthopedic — MDR_ORTHOPEDIC Information has been updated in the BR-UDID-818
19	Clinical size and Unit of Measurement – any linking?	Will there be any relation between the Clinical size type and Unit of Measurement implemented in EUDAMED (after selecting a clinical size type only the related Unit of Measurement will be listed/visible), if yes is the related documentation available?	No validations will be implemented at this moment for Clinical Size and Measure unit selection;
20	Equipment for adipose tissue - typo	In document 14. UDI device enumeration, at p. 28/32, there is a typo error for BR-UDID-812:	Thank you for the remark sent

		<table><tr><td>EQUIPEMNT FOR ADDIPOSE TISSUE</td><td>EQUIPEMNT_F ISSUE</td></tr></table> The correct wording shall be: “equipment for adipose tissue”.	
21	Change log	Change log for the specific doc e.g. data dictionary, enumeration codes’ lists or business rules would be helpful.	Updates to XSDs have been included in the DTX Notes documentation.
22	Error 403 - managing actor	EC suggested to use Firefox (needs to be vendor agnostic) and suggested to set up a new actor to avoid the error. Some specific actor data are causing the error (this issue happened in June- and then in August)	An error with Chrome has been reported in the playground only and has not been detected in production. Some 403 errors were reported that were specific to the playground. These will not apply to production
23	New FAQ for Economic Operators published	There was no communication on updated publication which does not contain a change log listing the updates. https://ec.europa.eu/health/sites/default/files/md_eudamed/docs/md_actor_module_q-a_en.pdf	The last change was that we have Actor ID/SRN instead of just SRN. The term SRN can be used only for actor registered pursuant to MDR Art 31/IVDR Art 28, otherwise it is an Actor ID.