Padova

19

GIUGNO

2026

Navigare il mercato europeo

Strategie di trading, importazione e conformità regolatoria nell'UE

eumed GS1 Italy Solution Partner

med device lab LEADING INNOVATION

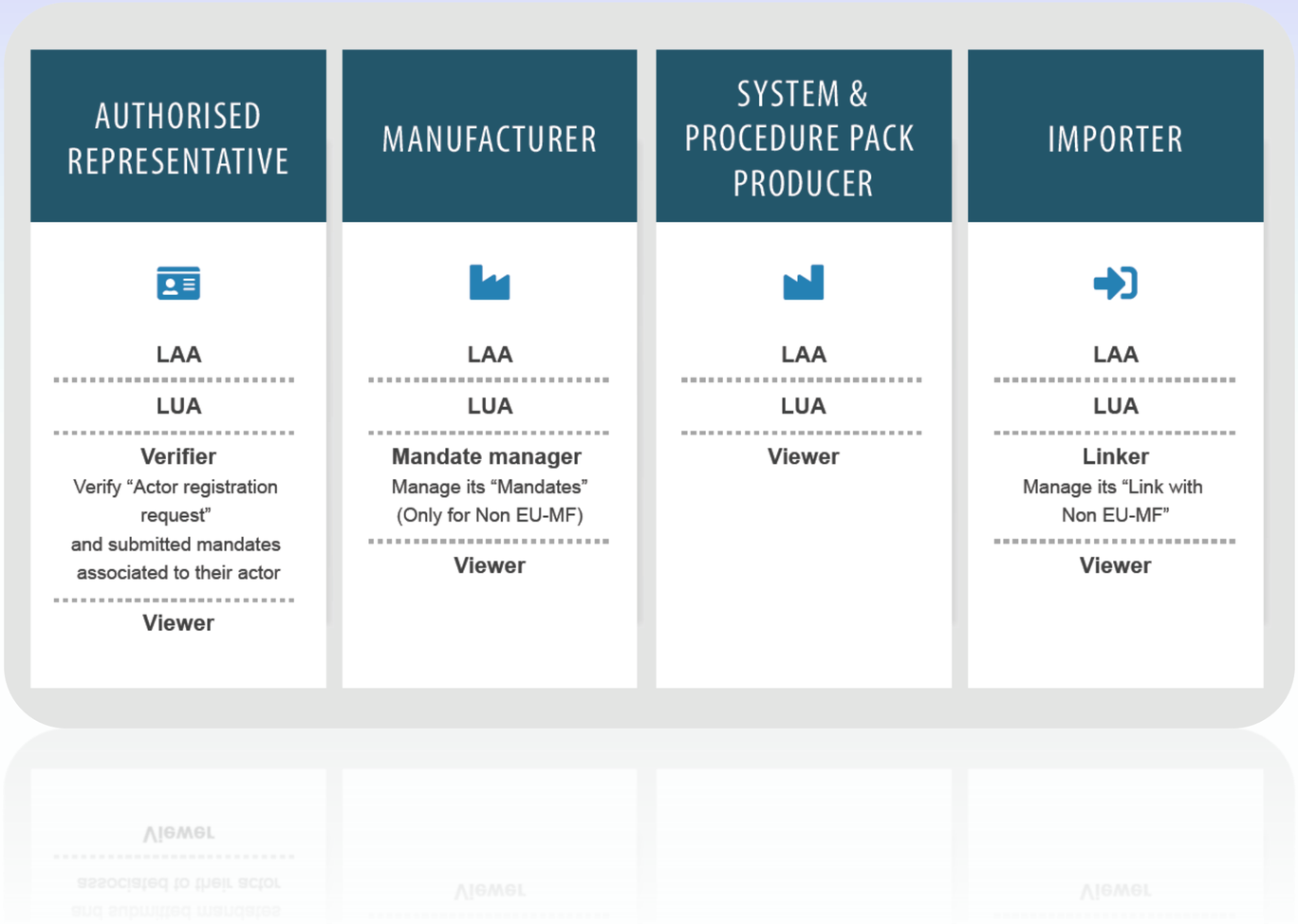
CON IL CONTRIBUTO DI sportello mentore per la competitività

CNA

OBV

Navigare il Mercato Europeo
Strategie di trading, importazione e conformità regolatoria nell'UE

Profili Eudamed



LAA (Local Actor Administrator): Gestisce i dati dell'attore (nome, contatti, indirizzi), indirizzi email per notifiche e tutti i diritti di LUA; è il profilo più alto per tutti gli attori.

LUA (Local User Administrator): Gestisce utenti, richieste di accesso, verifica/gestisce mandati/link a seconda del ruolo attore; comune a tutti gli attori.

Verifier: Solo per Authorised Representative; visualizza + verifica richieste di registrazione di fabbricanti non-EU e mandati associati

Mandate Manager: Solo per Manufacturer non-EU; visualizza + sottopone/gestisce mandati con AR.

Linker: Solo per Importer; visualizza + crea link con fabbricanti non-EU.

Viewer: Per tutti; visualizza solo attori registrati e dettagli propri, senza modifiche.

Registrazione dispositivi EUDAMED

Modalità Registrazione a confronto:

Regulation Device vs Legacy Device

Regulation Devices: MDR 2017/745 e IVDR 2017/746

Legacy Devices: direttive MDD, AIMDD, IVDD

Identificatori

Regulation Devices

- **Basic UDI-DI:** identificatore della famiglia del dispositivo
- **UDI-DI:** identificatore univoco del modello del dispositivo
- Entrambi sempre obbligatori

non è possibile registrare gli UDI-DI senza aver registrato prima il Basic UDI-DI

- Issuing Entity (GS1, HIBCC, ICCBBA, IFA)

Legacy Devices

- **EUDAMED DI:** concettualmente è simile al Basic UDI-DI, ma è UNICO

Costrutto prefisso B-XXXXXXXXXXXXXXX**CD**

- **UDI-DI o EUDAMED ID:** identificatore univoco dispositivo

Come può essere generato?

Opzione 1	Opzione 2
Creazione EUDAMED DI a partire dalla scelta dell'utente	Creazione dell'EUDAMED DI a partire dai codici dell'ente di rilascio
Costrutto prefisso D-XXXXXXXXXXXXXXCD	Costrutto prefisso D-08XXXXXXXXXXXX

STEP 1: Informazioni di Base

Regulation Devices

- Inserimento Basic UDI-DI e scelta regolamento (MDR/IVDR)
- Domanda "Is it a System or Procedure Pack?" (MDR) o "Is it a kit?" (IVDR)
- Selezione classe di rischio
- Device model / Device name

Legacy Devices

- Scelta legislazione applicabile (MDD/AIMDD/IVDD)
- Generazione EUDAMED DI
- Selezione classe di rischio e Device model / name

STEP 2: Certificati

Regulation Devices

- Informazioni relative al certificato (solo se è richiesto l'intervento da parte dell'Organismo notificato).

Le informazioni
certificate Number e Revision vanno inserite **dagli Organismi Notificati.**

La richiesta rimane in «Draft» finché gli **Organismi Notificati (ON)** non approvano/sottomettono i certificati

Legacy Devices

- Tipo di certificato (Allegato), numero NB, numero certificato, scadenza

In fase di registrazione i fabbricanti dei dispositivi Legacy caricano le informazioni dei certificati, qualora applicabile.
Le informazioni obbligatorie sono:
certificate Number e data di scadenza

STEP 3: Identificazione

Regulation Devices

- Issuing Entity e inserimento UDI-DI (univoco)
- UDI-DI Secondario (se applicabile)
- Inserimento EMDN code
- Trade name, Reference/Catalogue number, Direct marking DI, Unit of Use DI

Legacy Devices

- EUDAMED-ID
- Inserimento EMDN code
- Trade name opzionale e lingua
- Reference/Catalogue number e market status

STEP 4: Caratteristiche dispositivo

Regulation Devices

- Clinical size (dimensioni, tipo precisione)
- Single-use / numero riutilizzi
- Presenza lattice
- Sostanze CMR
- sterilità
- Condizioni di stoccaggio (se applicabili)
- Controindicazioni (se applicabili)
- ……

Legacy Devices

- Clinical size (dimensioni, tipo precisione)
- Single-use / numero riutilizzi
- Presenza lattice
- Sostanze CMR
- sterilità
- Condizioni di stoccaggio (se applicabili)
- Controindicazioni (se applicabili)
- ….

Informazioni abbastanza comparabili

STEP 5: Informazioni aggiuntive

Regulation Devices

- Reprocessed/single-use device
- Product original manufacturer (ricerca SRN o manuale)
- Clinical investigation, tessuti/cellule, sostanze

Legacy Devices

- Reprocessed/single-use device
- Product original manufacturer (ricerca SRN o manuale)
- Clinical investigation, tessuti/cellule, sostanze

Informazioni abbastanza comparabili

STEP 6: Informazioni aggiuntive

Regulation Devices

- Reprocessed/single-use device
- Product original manufacturer (ricerca SRN o manuale)
- Clinical investigation, tessuti/cellule, sostanze
- Gestione multilivello packaging
- Ogni livello richiede UDI-DI univoco
- Issuing Entity, quantità, status package

Legacy Devices

- Reprocessed/single-use device
- Product original manufacturer (ricerca SRN o manuale)
- Clinical investigation, tessuti/cellule, sostanze
- Non previsto step separato container package nel flusso principale
- Gestione più semplice rispetto a Regulation
- Nessuna struttura multilivello UDI-DI per package

Un po' meno informazioni per i Legacy Devices

Linking Regulation-Legacy

- Stesso UDI-DI ⟶ linking Automatico
- Link manuale tramite funzione "Link to legacy device"
- Verifica compatibilità caratteristiche Basic UDI-DI / EUDAMED DI
- Possibilità di eliminare link successivamente

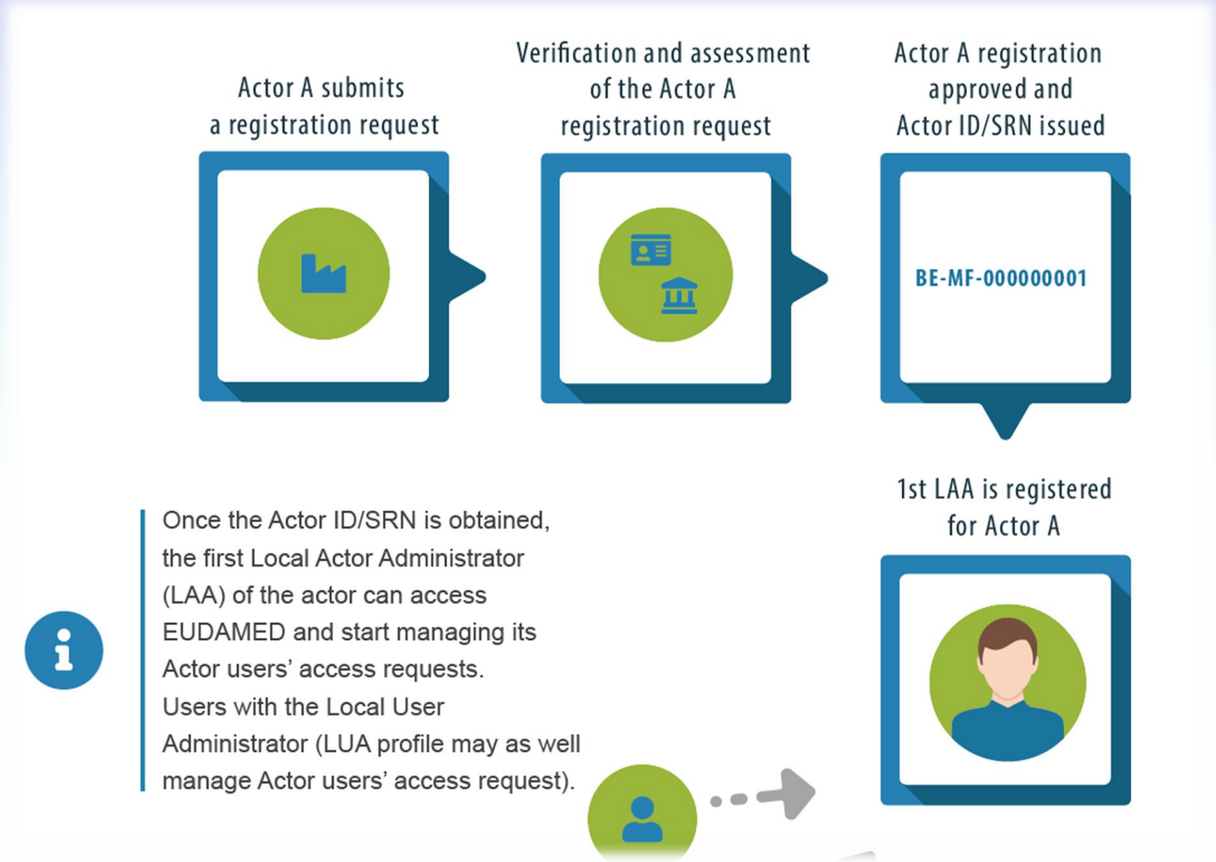
DEVO CARICARE I DOCUMENTI IN EUDAMED?

- IFU?
- ETICHETTE?
- DICHIARAZIONI DI CONFORMITA'?
- CERTIFICATI?

NO! IN EUDAMED NON VANNO RIPORTATI ALLEGATI!

I NOTIFIED BODIES RIPORTERANNO I CERTIFICATI E SSCP!

WORKFLOW – COLLEGAMENTO TRA PROFILI EUDAMED



STEP 1

- ATTORE "A" SOTTOMETTE UNA RICHIESTA ALL'ATTORE "B"

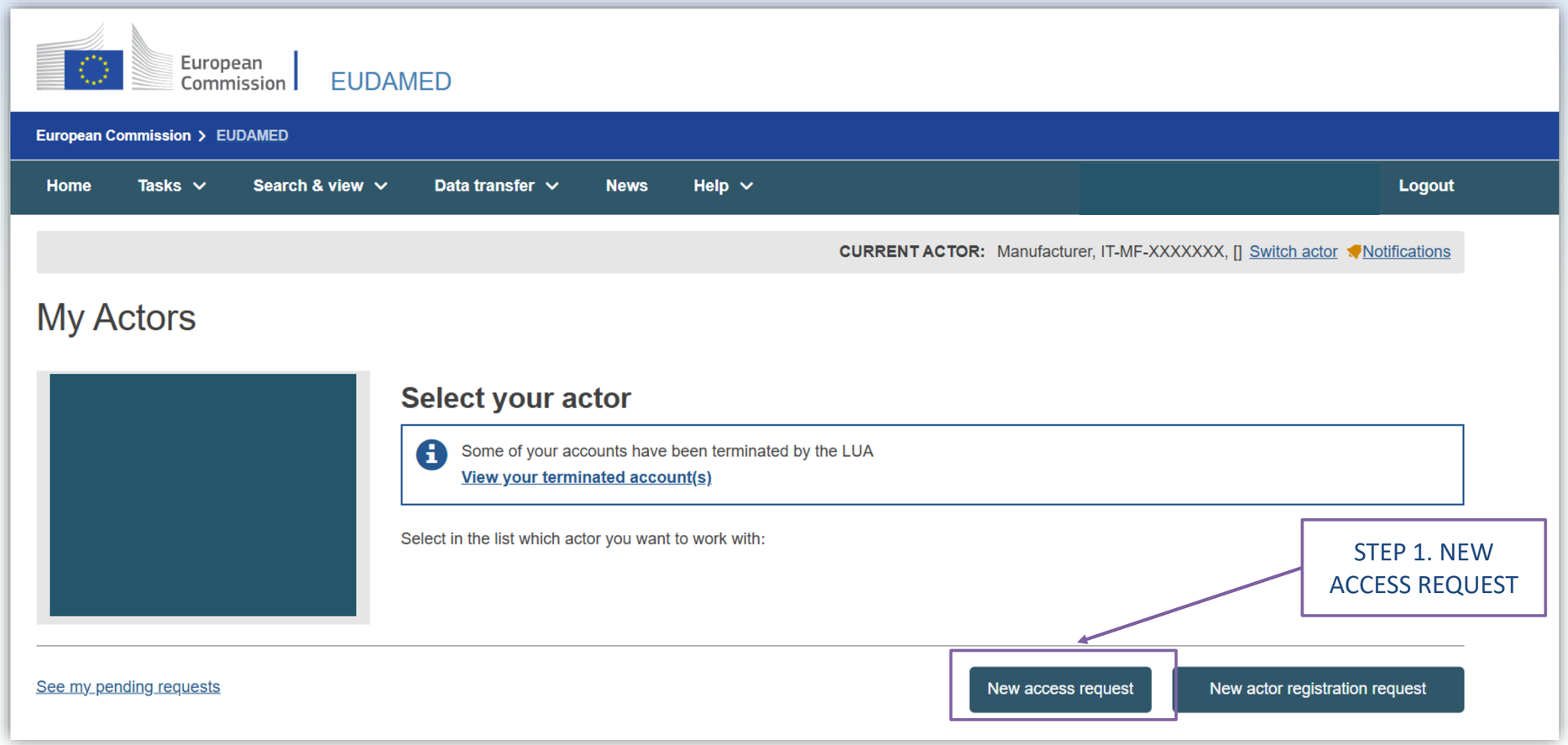
STEP 2

- ATTORE "B" ACCETTA LA RICHIESTA DELL'ATTORE A

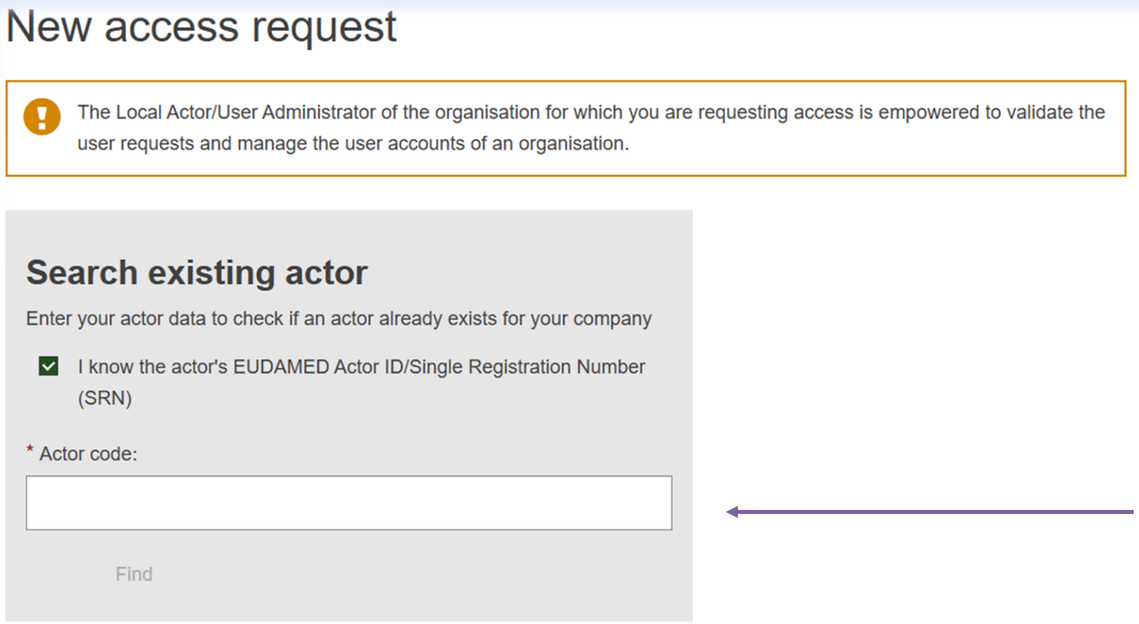
FINAL STEP

- ATTORE "B" AGISCE PER CONTO DI ATTORE "A";

POSSO DELEGARE L'ATTIVITÀ DI REGISTRAZIONE?



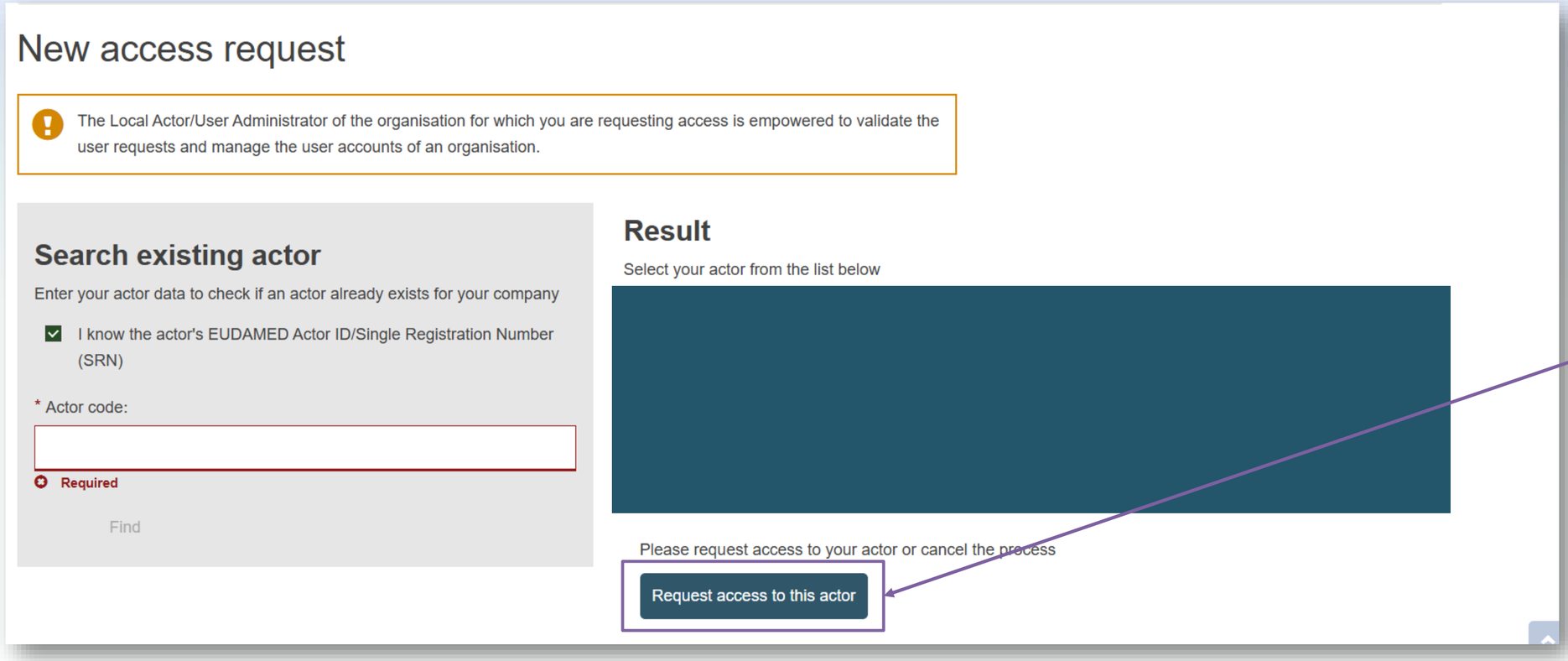
COME POSSO DIVENTARE UN SUB-CONTRACTOR?



STEP 2.

SEARCH EXISTING ACTOR AND TYPE “IT-XXXXXXXXXXX» TO CONNECT WITH ACTOR B

RICHIESTA DI COLLEGAMENTO CON UN ATTORE



STEP 3.

REQUEST ACCESS TO THIS ACTOR

MANUALI DI RIFERIMENTO
UDI-DEVICES

Informazioni Utili

- UDI-DI di base e concetto di UDI-DI
- Categorizzazione dei dispositivi
- Procedura di registrazione

Guida utente

- Guida utente UDI/dispositivi per gli operatori economici

PREREQUISITI ALLA REGISTRAZIONE IN EUDAMED

1. REGISTRAZIONE IN EUDAMED

2. OTTENIMENTO SRN IT-MF-XXXXXXX

Welcome to EUDAMED - European Database on Medical Devices

EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices.

EUDAMED is structured around 6 interconnected modules and a public site.

Starting from May 28, 2026, the use of the first four modules is mandatory:

1. Actor registration,
2. UDI/Devices registration,
3. Notified Bodies and Certificates,
4. Market Surveillance.

Release note 2026-01-27

Release note v 2.22.0

The new version of EUDAMED 2.22.0 has been deployed.

The Information Centre – EUDAMED (Production) provides the full release note document here: EUDAMED Release Note (v2.22) and the full documentation on the release is available as follows: Welcome to the EUDAMED Information Centre.

DTX:

The **XSD schema** for this release has the following version: **3.0.25**. The release affects the XSD version number of the DTX services. You need to adapt the XSD version number in your service requests before using the M2M service or Bulk upload service.

The files of the XSD schema and XML samples are available in the: Technical Documentation. The XML samples files do not contain any more a schema version. Instead, you will have to enter the correct XSD schema version (**3.0.25**) before you can use the sample within the quote: <!-- Schema version here-->.

Warning 2026-02-15

Monday, 16 February 2026, 22:00 CET until Tuesday - 01:55 CET, EUDAMED may not be available due to maintenance reasons. We apologies for the inconvenience.

More news items available today. Go to the news list to view them all.

Tasks

According to your profile per module, consult, verify and/or manage your own and related data (managed by your actor)

UDI-DIs/Device

Register a new Basic UDI-DI

Register a legacy device

Manage your Basic UDI-DIs / EUDAMED DIs

Manage your device details

Legacy Device registration

Manufacturer identification

Organisation name:

Actor ID/SRN:

Address:

Telephone number:

Email:

*** Applicable Legislation**

- ○ IVDD (Directive 98/79/EC on in vitro Diagnostic Medical Devices)
- ○ MDD (Directive 93/42/EEC on Medical Devices)
- ○ AIMDD (Directive 90/385/EEC - Active Implantable Medical Devices)

UDI-DI assigned for the current legacy Device?

Yes ⬤ No

* Issuing Entity: --

* UDI-DI code:

More information about the format requirements

* Generate a EUDAMED-DI based on your UDI-DI code provided above:

Generate

Save & Next ›

Welcome to EUDAMED - European Database on Medical Devices

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UDI-DIs/Device

Register a new Basic UDI-DI

Register a legacy device

Manage your Basic UDI-DIs / EUDAMED DIs

Manage your device details

Legacy device registration

Manufacturer identification

IT-MF-[redacted]

EUDAMED DI identification

Applicable legislation: MDD (Directive 93/42/EEC on Medical Devices)

EUDAMED DI code: B-SDFSDFL5

Issuing Entity: EUDAMED

Is it a System or Procedure Pack which is a Device in itself?

No

Special device type: No

1 EUDAMED DI information — 2 Certificate information — 3 Device identification — 4 Device characteristics — 5 Device information

EUDAMED DI information

* Risk class: --

- Class I
- Class IIa
- Class IIb
- Class III

*** Active device**

Yes No

*** Device intended to administer and/or remove medicinal product**

Yes No

Device model applicable

Yes No

Device model is required by default unless you select the option - No

* Device Model:

Device Name:

Save | Save & Next ›

CURRENT ACTOR: Manu [redacted] actor Notifications

Legacy device registration

Manufacturer identification

IT-MF [redacted]

EUDAMED DI identification

Applicable legislation: MDD (Directive 93/42/EEC on Medical Devices)

EUDAMED DI code: B-SDFSDFL5

Issuing Entity: EUDAMED

Is it a System or Procedure Pack which is a Device in itself?

No

Special device type: No

1 EUDAMED DI information — 2 Certificate information — 3 Device identification — 4 Device characteristics — 5 Device information

Certificate information

Item #1

* Certificate Type:

--

Required

* Enter NB number or name:

Find

* Certificate number:

Revision number:

* Expiry date:

YYYY-MM-DD

Add Directive Certificate Information

Save | Save & Next

CURRENT ACTOR: [redacted] Switch actor Notifications

Legacy device registration

Manufacturer identification

[redacted]

1 EUDAMED DI information ✓ — 2 Certificate information ✓ — 3 Device identification — 4 Device characteristics — 5 Device information

Device identification

EUDAMED DI identification

Applicable legislation: MDD (Directive 93/42/EEC on Medical Devices)

EUDAMED DI code: B-SDFSDFL5

Issuing Entity: EUDAMED

Is it a System or Procedure Pack which is a Device in itself?

No

Special device type: No

Device identification

* Issuing Entity: EUDAMED

* EUDAMED ID code: D-SDFSDFL5

More information about the format requirements

* Enter a nomenclature code (EMDN cod

Advanced search of device nomenclatu

Trade name applicable

Yes / No

* Trade name:

Add a trade name in another langu

* Reference/Catalogue number:

Additional product description:

Select the language: --

Add additional product description in another language

URL for additional information (as electronic instructions for use):

* Device status: On the EU market

Save | Save & Next ›

IDR Eudamed - Data Dictionary

		EA	EA		EA							
Field ID	Field Label	Entity Name	Field Description / Notes	ENUM Reference Code	Field Type	Field Size	Multilingual Flag	Occurrence	Searchable	GDPR Flag	Public Access Flag	
LD-UDID-01	Issuing Entity Basic UDI-DI	BasicUDIData	Assigned Issuing Entities that will generate the DI Codes allocated for all DI`s inside Eudamed (Basic UDI DI, UDI-DI, Unit of Use DI, Secondary Di , Package level DI). The Commission shall designate one or several entities to operate a system for assignment of UDIs ('issuing entity')	ENUM_MDR_IssuingEntity	Enum			1			Y	
LD-UDID-14	Basic UDI- DI code	BasicUDIData	Device Identifier code/value (DI Code). Together with the Issuing Entity creates the uniqness of the element to which they are assigned (Basic UDI-DI , UDI-DI, etc.) The Basic UDI-DI is the primary identifier of a device model.It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity		String	XS		1	Y		Y	
LD-UDID-10	Legal Manufacturer SRN	BasicUDIData	SRN of the									
LD-UDID-11	Applicable Legislation	BasicUDIData	Applicable The device Regulation Directive of Directiv									
LD-UDID-12	Is it a System which is a Device in itself, Procedure pack which is a Device in itself	BasicUDIData	Property d System wh a Device in									
LD-UDID-16	Risk Class	BasicUDIData	Risk Class									
LD-UDID-18	Tissues and cells - Presence of animal tissues or Cells, or their derivates	BasicUDIData	Device Ris Legislation Property d or cells or									
LD-UDID-23	Tissues and cells -	BasicUDIData	Property									

	EA	EA		EA										
Field ID	Field Label	Entity Name	Field Description / Notes	ENUM Reference Code	Field Type	Field Size	Multilingual Flag	Occurrence	Searchable	GDPR Flag	Public Access Flag	Business Rules	Updateable	Field Applicable for MDR	Field Applicable for IVDR	DTX E
D-UDID-178	UDI-DI code	UDIData	The UDI-DI is a unique numeric or alphanumeric code specific to a device and that is also used as the 'access key' to information stored in a UDI database.		String	XS		1	Y		Y	BR-UDID-003 BR-UDID-645		Y	Y	DIIdentifi
D-UDID-291	Issuing Entity UDI-DI	UDIData	Assigned Issuing Entities that will generate the DI Codes allocated for all DI`s inside Eudamed (Basic UDI DI, UDI-DI, Unit of Use DI, Secondary Di , Package level DI). The Commission shall designate one or several entities to operate a system for assignment of UDIs	ENUM_MDR_IssuingEntity	Enum			1			Y			Y	Y	DIIdentifi
D-UDID-145	Basic UDI-DI Identifier	UDIData	Reference to the Basic UDI-DI to which the Device is associated.		Basic UDI-DI FLD-UDID-14, FLD-UDID-01 [DD Basic UDI]			1			Y			Y	Y	UDIDIDat
D-UDID-151	Quantity of Device	UDIData	The base quantity in which the Device is provided. Field has a default value 1.		Number			1			Y			Y	Y	DeviceUDID
D-UDID-156	Containing latex	UDIData	Property defines if the Device contains latex into it`s composition		Boolean			1	Y		Y			Y		MDRUDIDI
D-UDID-163	Reference / Catalogue Number	UDIData	Property stores the Reference or Catalogue Number of the Device		String	XS		1	Y		Y			Y	Y	UDIDIDat
D-UDID-164	Reprocessesed single use device	UDIData	Property defines if the Device is a Reprocessesed single use device or not		Boolean			1	Y		Y			Y		MDRUDIDI
D-UDID-167	Labelled as single use	UDIData	Property defines if the Device is a Labelled as a Single use or not		Boolean			1	Y		Y			Y	Y	DeviceUDID
D-UDID-169	Device labelled sterile	UDIData	Property defines if the UDI-DI is labeled as Sterile or		Boolean			1	Y		Y			Y	Y	UDIDIDat
D-UDID-170	Need for sterilisation before use	UDIData	Property defines if the UDI-DI needs to be sterilised before use or not		Boolean			1	Y		Y			Y	Y	UDIDIDat
D-UDID-130	Device Status	UDIData	Status of the Device (On the EU market, Not intended to be placed on the EU Market, No longer placed on the EU market).	ENUM_UDID_DeviceStatus	Enum			1			Y	BR-UDID-114 BR-UDID-073 BR-UDID-458	Y	Y	Y	UDIDIStat

COME CARICARE ?

	Manual UDI Submission	XML Bulk Upload	M2M
Intervento umano	Sì (manuale)	Sì (semi-manuale)	No (completamente automatico)
Complessità tecnica	Bassa	Medio-bassa	Alta
Costo di implementazione	Contenuto	Contenuto	Elevato
Limite per caricamento	Un UDI alla volta	~25-200 UDI per file	Nessun limite
Ideale per	Meno di 100 UDI	100 – 1.000 UDI	Oltre 1.000 UDI con alta frequenza
Approvazione CE (Commissione Europea) richiesta	No	No	Sì

Use of the XML upload/download implies:

- Cost of adaptation of the existing data to the Eudamed structure (XSD)

Installation and maintenance of Data Exchange with own Access Point implies:

- Cost of infrastructure (hardware)
- Cost of adaptation of existing data to the Eudamed structure (XSD) done by an IT team
- Cost of setting up of an Access Point
- Cost of updating the required software when a new version of Eudamed's Data Exchange is available within a period of 6 months
- Compliance with defined Security Measures

Installation and maintenance of Data Exchange with a Third Party Access Point implies:

- Cost of infrastructure (hardware)
- Cost of adaptation of existing data to the Eudamed structure (XSD) done by an IT team
- Cost of use of a Third Party Provider's Access Point
- Cost of updating the required software when a new version of Eudamed's Data Exchange is available within a period of 6 months
- Compliance with defined Security Measures

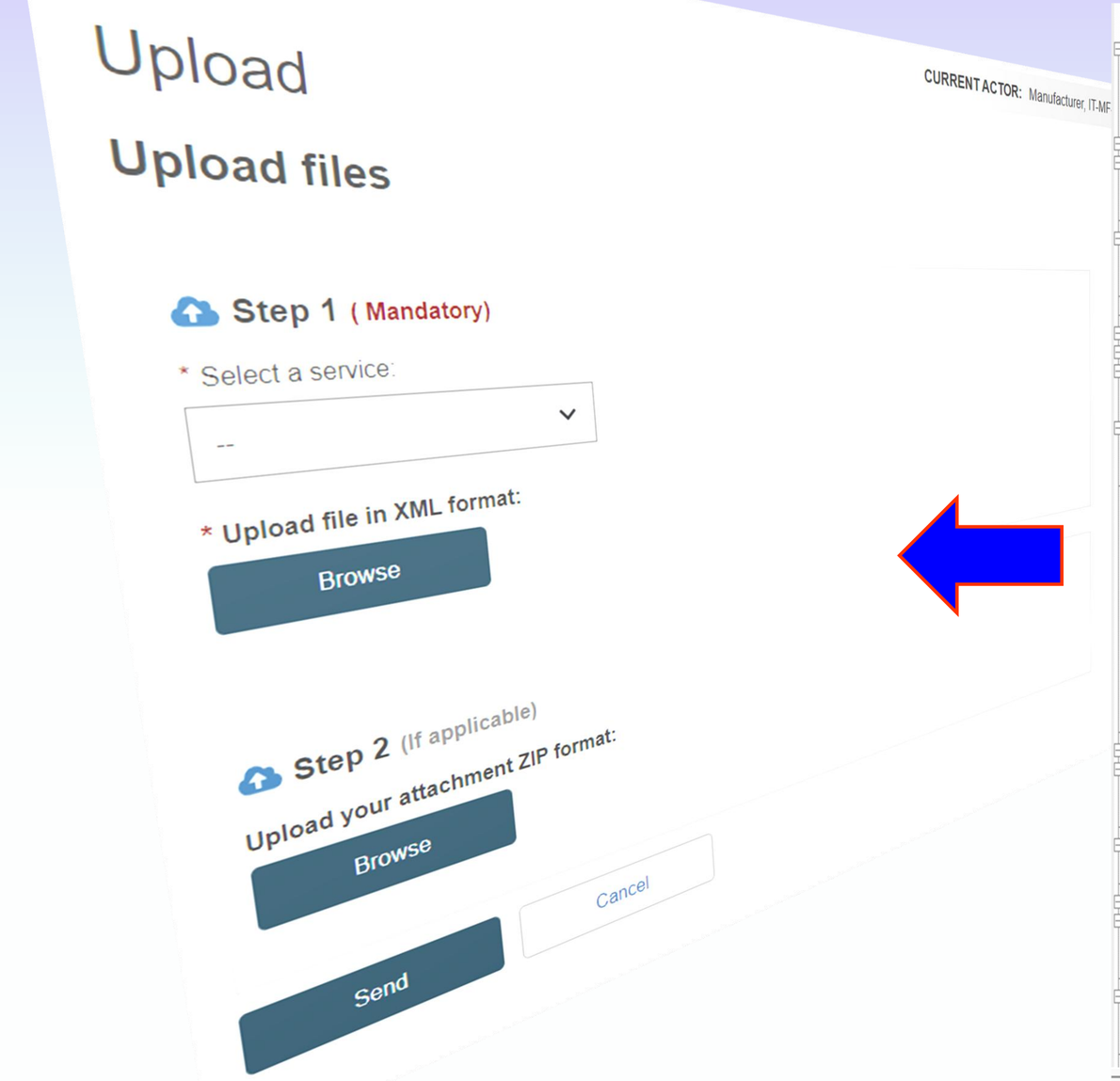
SOLUZIONI

MANUAL UDI SUBMISSION

XML UDI BULK SUBMISSION

EUDAMED M2M

PREDISPOSIZIONE XML




```
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    <m:conversationID>ae6f2f07-6a84-4d01-becd-178d4e7e6e41</m:conversationID>
    <m:correlationID>98971ef5-58ed-4db4-ba19-61bcb07ebec4</m:correlationID>
    <m:creationDateTime>2020-01-23T11:21:58.523108Z</m:creationDateTime>
    <m:messageID>6b5db5cd-715a-490d-9e55-f619c9a64d34</m:messageID>
    <m:recipient>
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            <s:nodeActorCode>EUDAMED</s:nodeActorCode>
            <s:nodeID>eudamed_mdr_acc</s:nodeID>
        </m:node>
        <m:service>
            <s:serviceID>DEVICE</s:serviceID>
            <s:serviceOperation>POST</s:serviceOperation>
        </m:service>
    </m:recipient>
    <m:payload>
        <device:Device xmlns:p37="http://www.w3.org/2001/XMLSchema-instance" p37:type="device:MDRDeviceType">
            <device:MDRBasicUDI p37:type="device:MDRBasicUDIType">
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                <basicudi:identifier>
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```

Markup Language file | length : 10.595 lines : 179 | Ln : 1 Col : 1 Pos : 1 | Windows (CR LF) | UTF-8 | INS

AMBIENTI

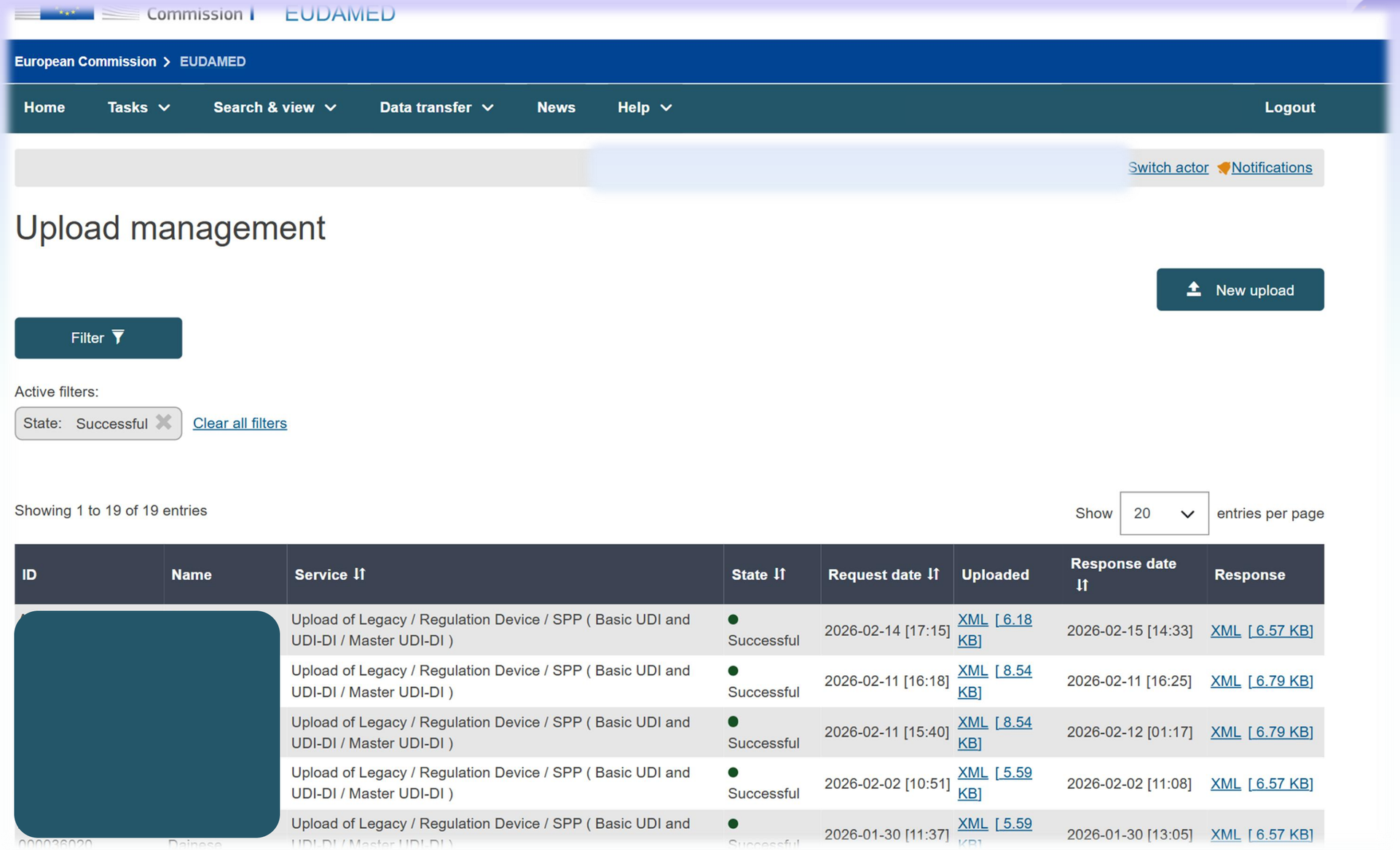
PLAYGROUND (SandBox)

- Actor Registration
- Unique Device Identification (UDI) and Device registration
- Notified Bodies and Certificates
- Clinical Investigations and Performance Studies
- Vigilance and Market Surveillance.

PRODUCTION

- Actor registration
- Unique Device Identification (UDI) and Device registration
- Notified Bodies and Certificates.
- Market Surveillance

REGISTRAZIONE DISPOSITIVI TRAMITE XML



GRAZIE PER L'ATTENZIONE

Dott. ing. Berhanu Petranzan – Eumed S.r.l.