



# **Registration obligations for operators and devices**

Information on the swissdamed medical devices database

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*Welcome!*

*Please note the registration obligation*



Improve  
transparency  
and traceability

  
European Commission

### Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR)

The European Commission has adopted 2 new Regulations – the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR) – bringing EU legislation up to date with medical advances and to ensure better protection of public health and patient safety.

#### THE NEW

-  Increase clinical monitoring risk to ensure patient safety
-  Improve surveillance and management of the entire MDR and IVDR life cycle
-  Improve transparency and traceability
-  Reduce ambiguity with clearer classifications and definitions

#### SOME OF THE NEW FEATURES:

-  Unique Device Identifiers (UDIs)
-  European Database on Medical Devices EUDAMED
-  An implant card for patients, with information on implanted medical devices
-  Stricter pre-market control for high risk devices

#### SOME THINGS TO KEEP IN MIND...

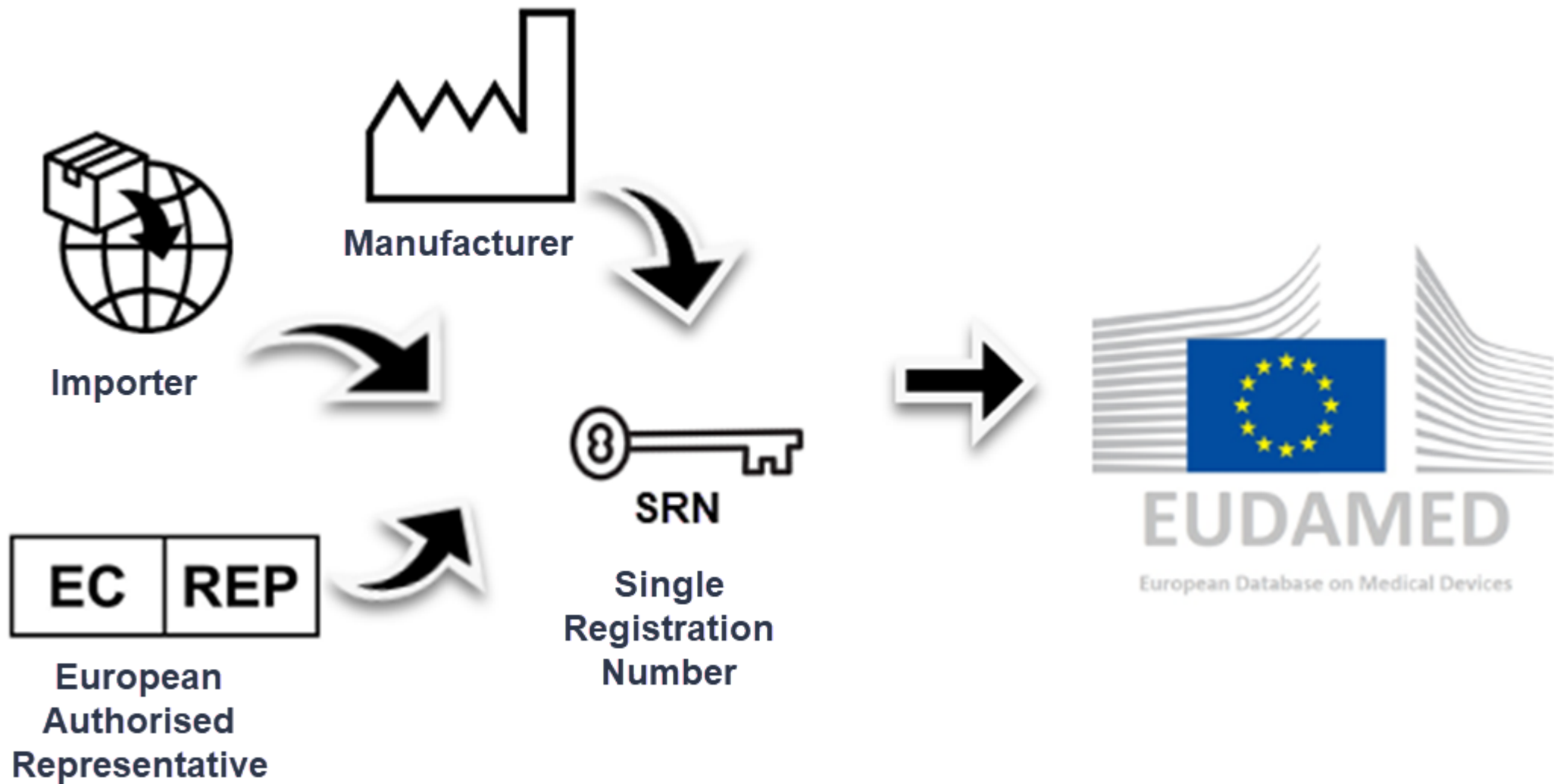
- Manufacturers**  
The new Regulations better reflect recent scientific and technological advancements and will strengthen the image and value of CE marked devices
- Procurement ecosystem**  
The procurement of Directive-compliant devices can continue until the transition ends (2021)
- Authorities in non-EU/EEA states**  
All actors impacted by the Regulations must be informed of the changes and timelines in order to avoid any disruption on the market
- Reprocessing of single-use devices**  
Strict conditions have been introduced in the case of reprocessing single-use medical devices
- Healthcare professionals and health institutions**  
Healthcare professionals and health institutions will benefit from improved transparency on clinical and vigilance data through EUDAMED
- Patients**  
Patients will benefit from the increased safety and performance of devices, and from more information on surveillance and transparency on devices on the EU market

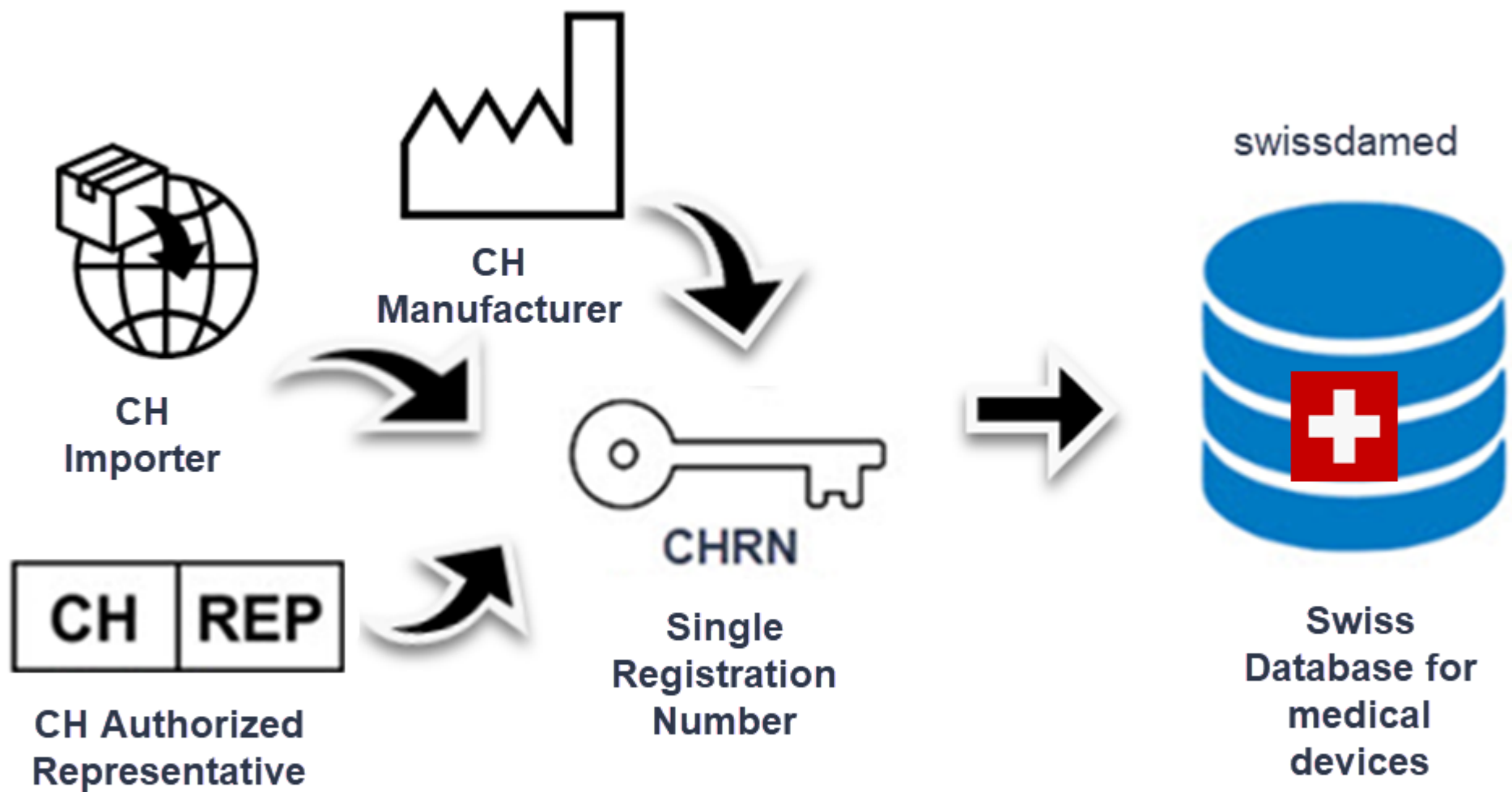
For a complete overview of the impact of the new Regulations and the roles and responsibilities of all stakeholders, check the Medical Devices section in the [European Commission website](#)

Funded under the Third EU Health Programme



European Database  
on Medical Devices  
EUDAMED

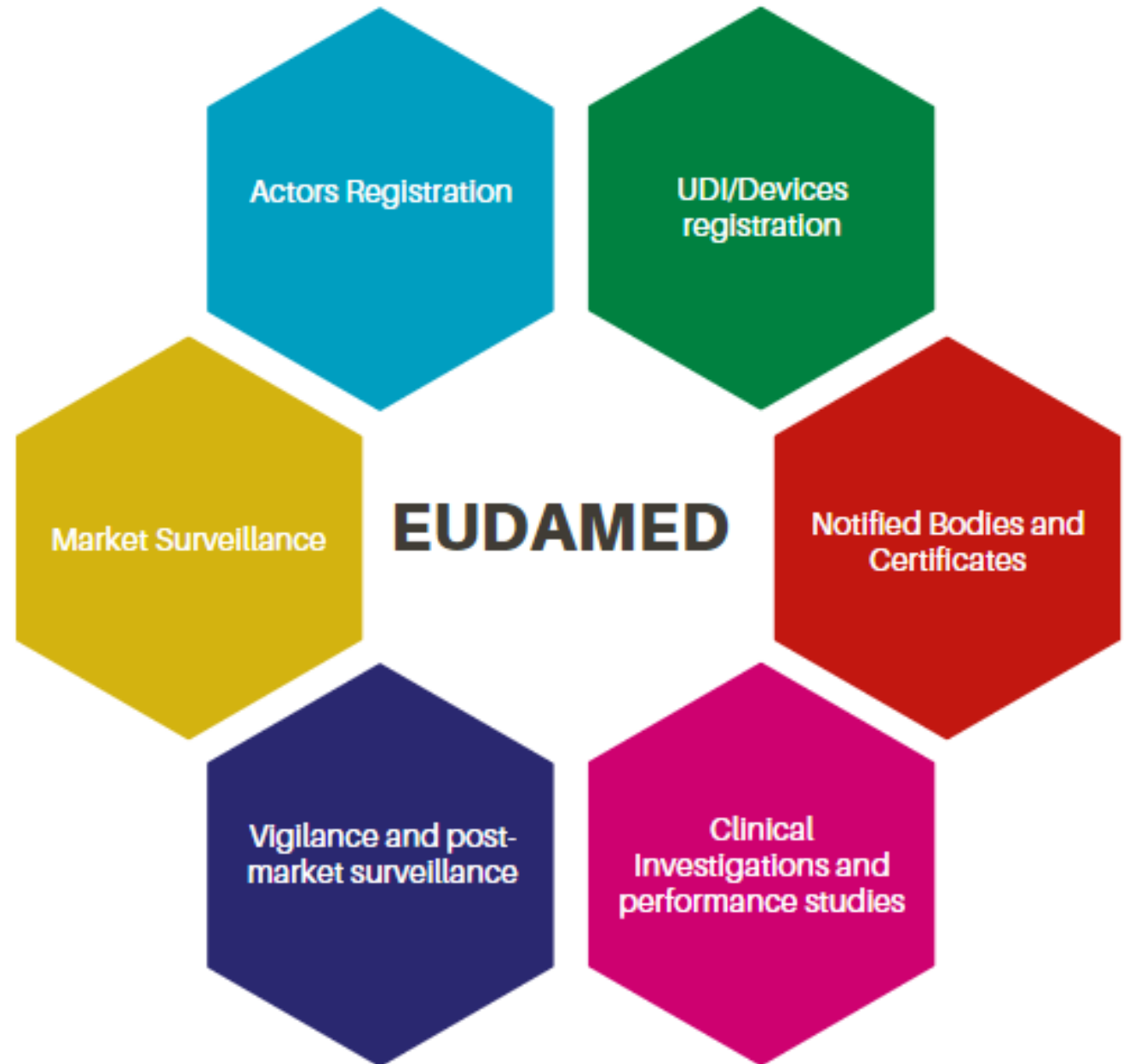




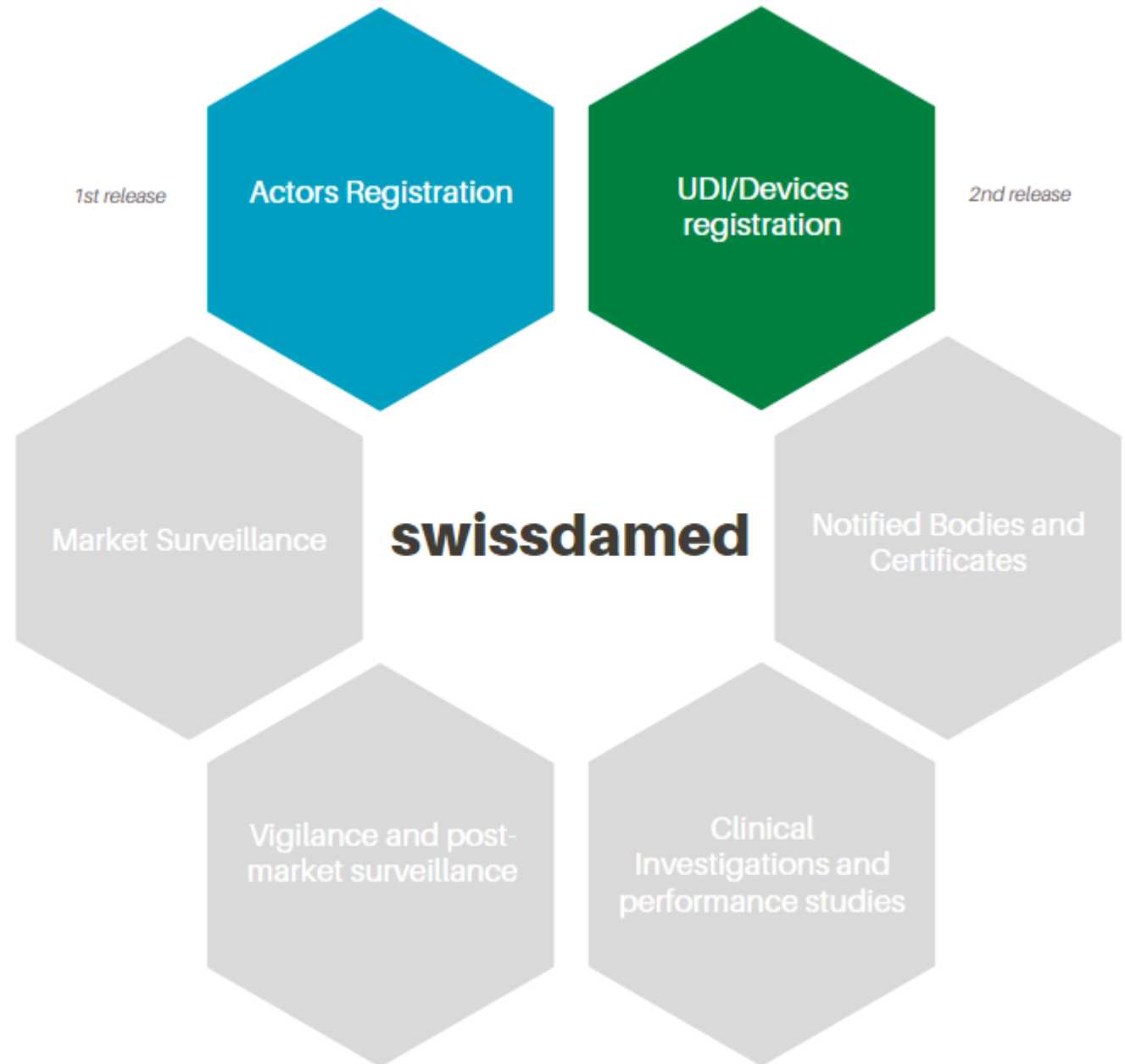
# What is swissdamed?



# EUDAMED MODULES



# swissdamed MODULES



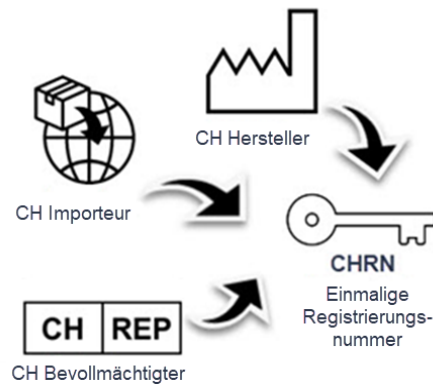


**What are my obligations as an economic operator?**

Registration as an operator



# Why do I have to register?



Clear identification of all economic operators in the MD area



## swissdamed public domain

Increased transparency



## swissdamed restricted

All information accessible for economic operators and Swissmedic



## Legislation

Art. 55 MedDO and Art. 48 IvDO

# How do I register?

Forms available on the website

[www.swissmedic.ch](http://www.swissmedic.ch)

Home > Medical devices > Market access >  
Unique identification no. (CHRN)

## Order forms



 BW630\_11\_001defi\_FO Registration application single registration no. in accordance with Art. 55 MedDO (PDF, 1 MB, 25.06.2021)

 BW630\_12\_002defi\_FO Change of registration message in accordance with Art. 55 MedDO (PDF, 1 MB, 26.05.2021)

 BW630\_11\_003e\_FO Mandate registration form (PDF, 1 MB, 04.08.2021)



Form  
Application CHRN

DE FR IT EN

## Application CHRN (Swiss Single Registration Number)

Before submitting forms, you are required to ensure that you are using the latest version of the forms, which can be downloaded at any time from our website.

If you wish to receive information automatically on forms that have just become available on the internet, you can subscribe to the Swissmedic newsletter specifically for medical devices.

<https://www.swissmedic.ch/swissmedic/en/home/news/news.html>

### Important

Hard-copy applications and scanned forms will be rejected. All details from an application form are transferred into the Swissmedic business case processing system via XML import.

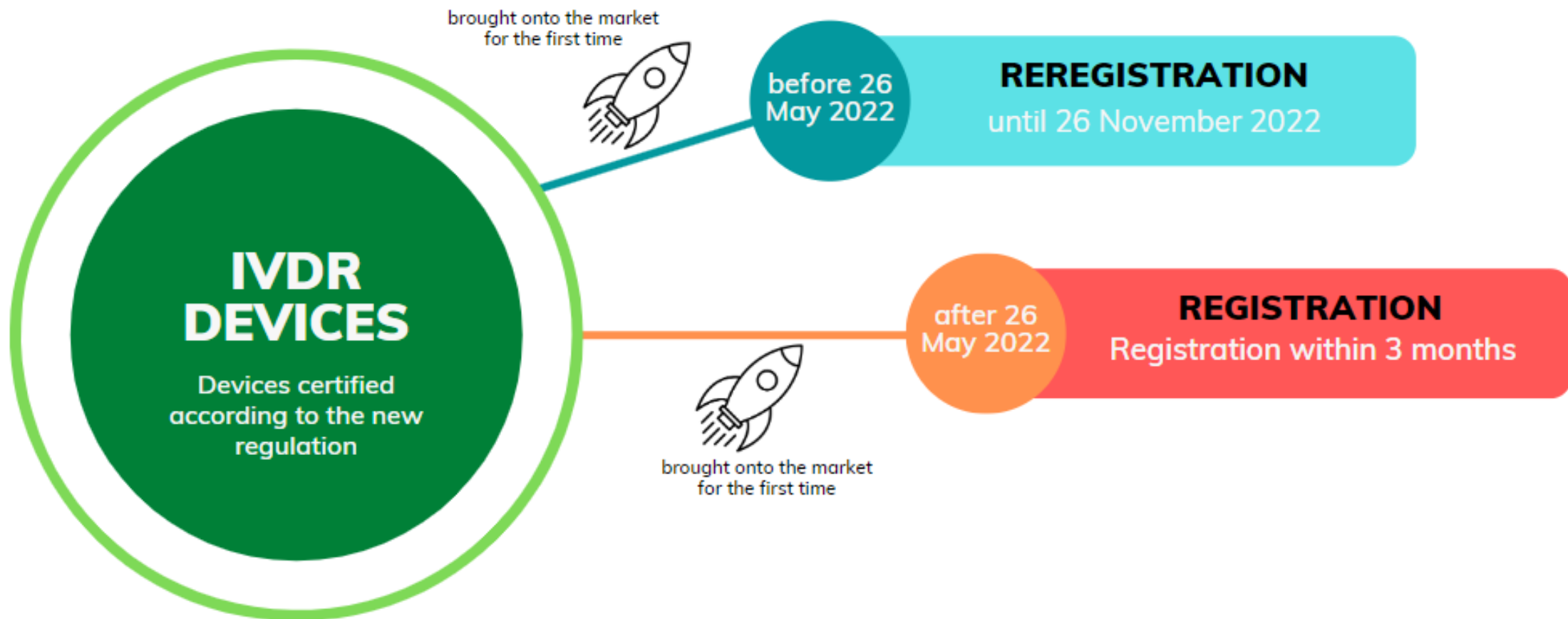
## Role of economic operator

<input checked="" type="radio"/> Manufacturer	<input type="radio"/> Authorised representative for Switzerland	<input type="radio"/> Importer	<input type="radio"/> Manufacturer of systems and procedure packs
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## Details of economic operator

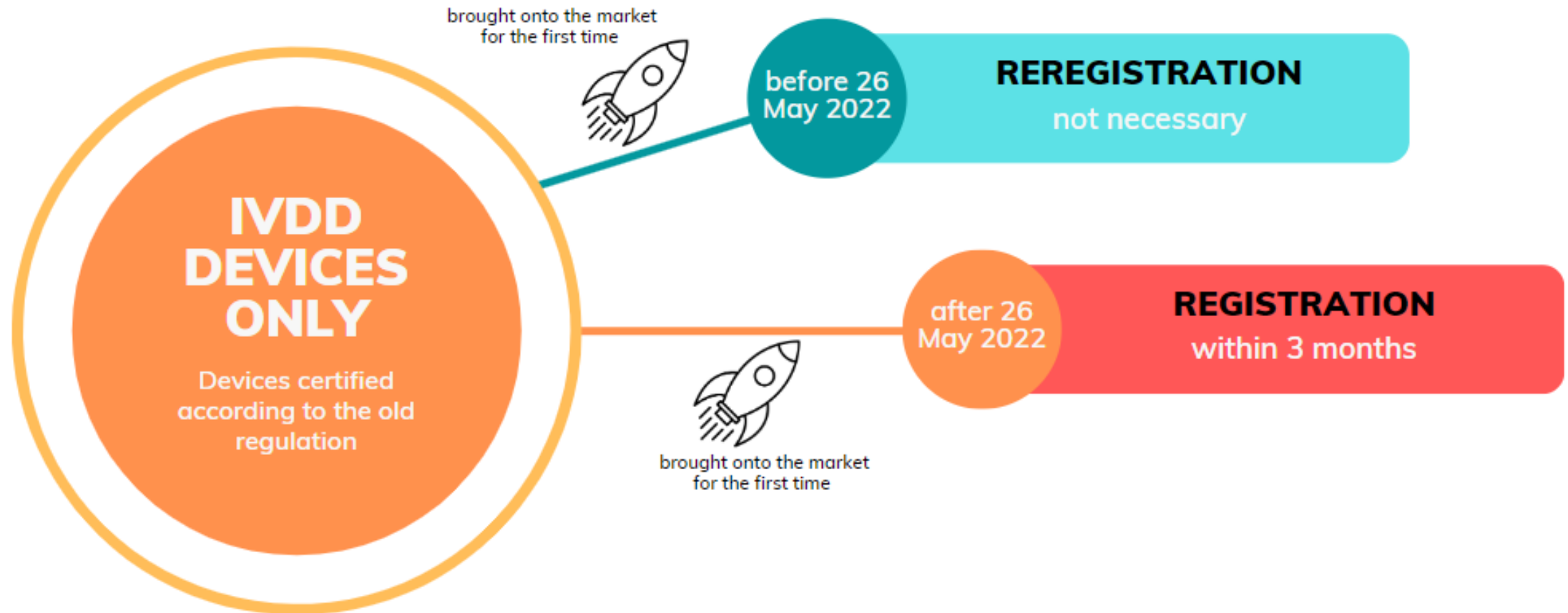
Company	<input type="text"/>	
Commercial register	<input type="text"/>	<a href="#">Link to the UID-Register</a>
P.O. Box	<input type="text"/>	
Street	<input type="text"/>	No. <input type="text"/>

# From when?



# From when?

Briefly elaborate on what you want to discuss.

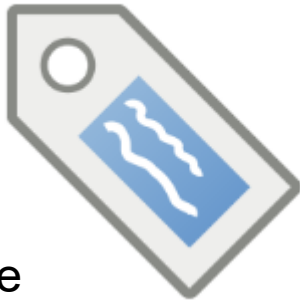


**What are my obligations as an economic operator?**

Device registration



# Why do I have to register my device?



Clear device  
identification – better  
traceability and  
surveillance



## **swissdamed public domain**

Increased transparency



## **swissdamed restricted**

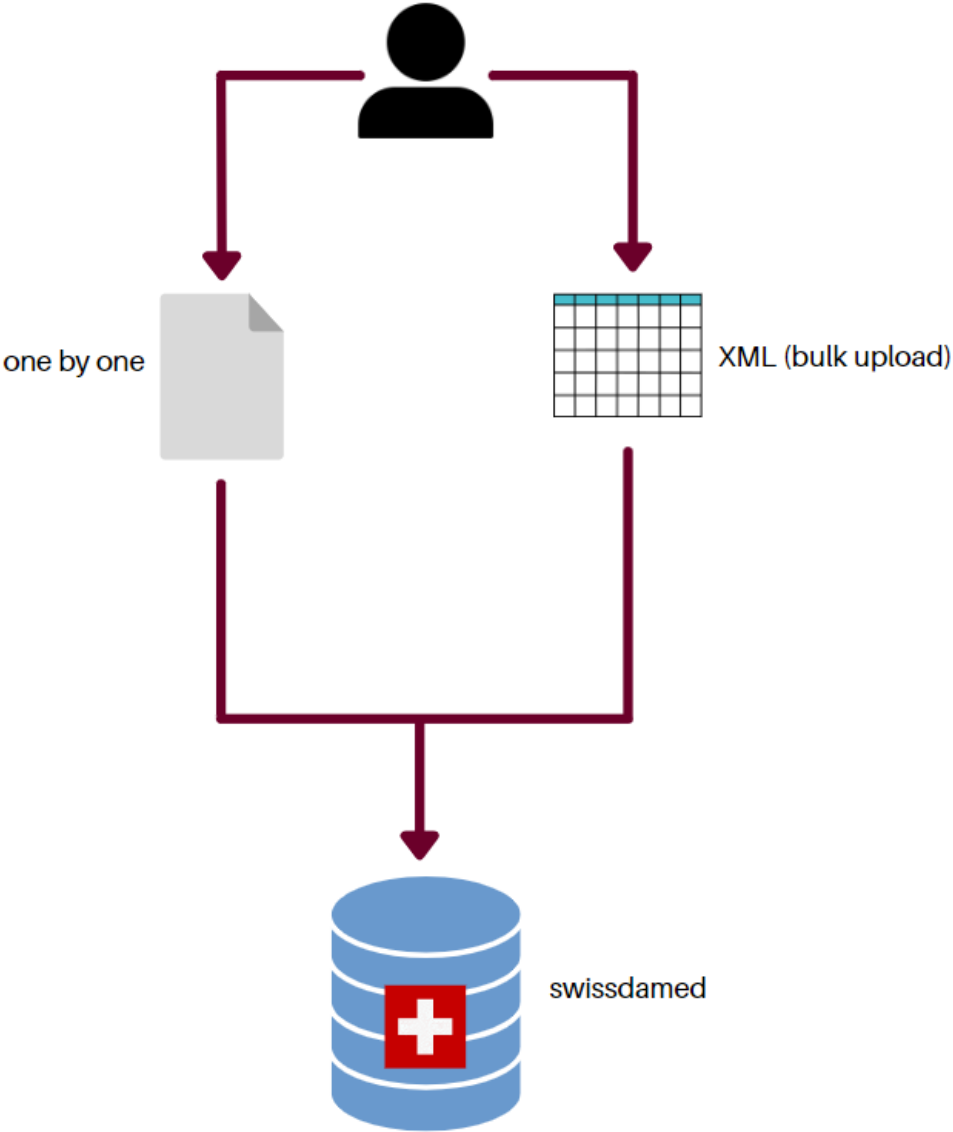
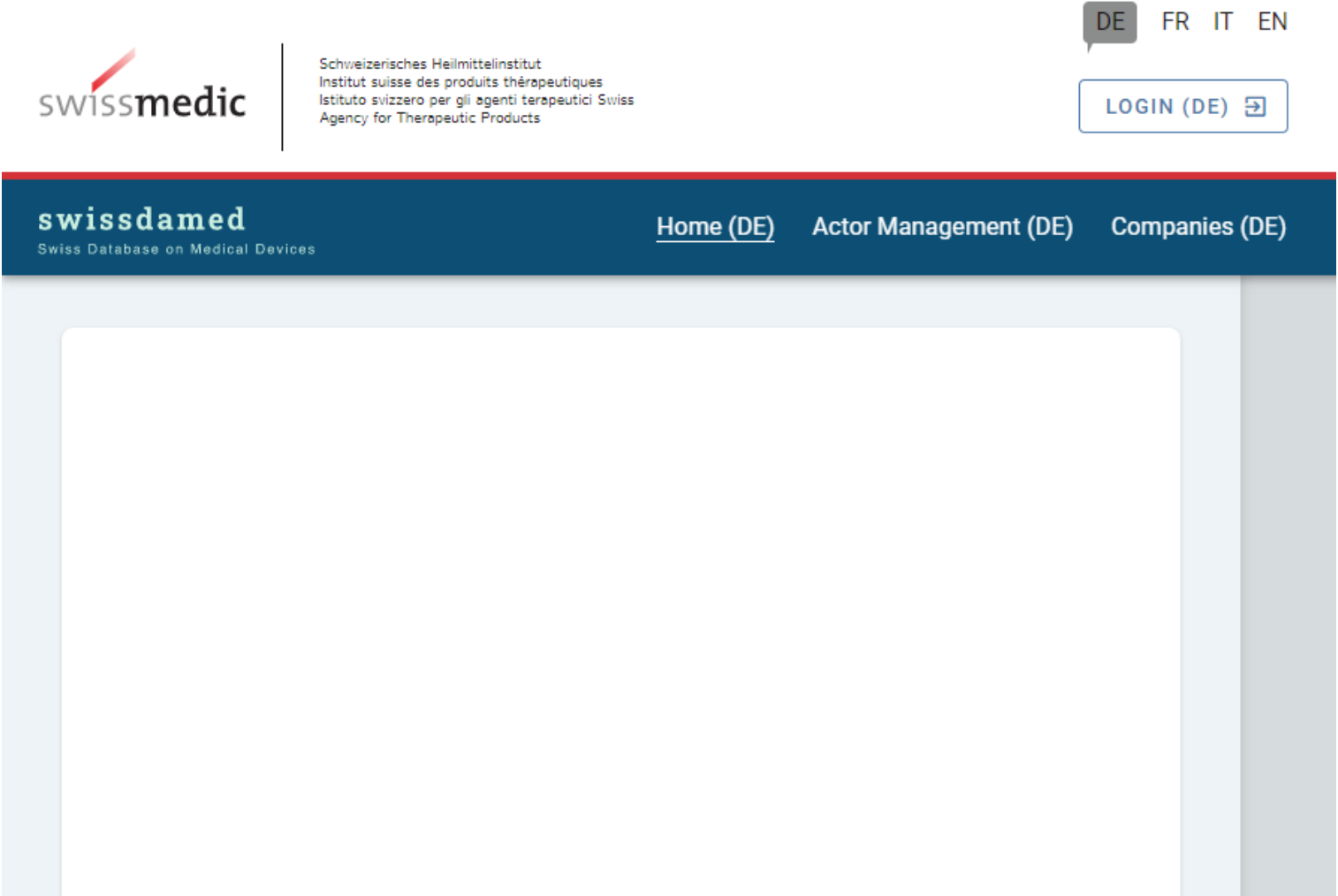
All information accessible for economic  
operators and Swissmedic



## **Legislation**

Art. 17 MedDO and Art. 16 IvDO

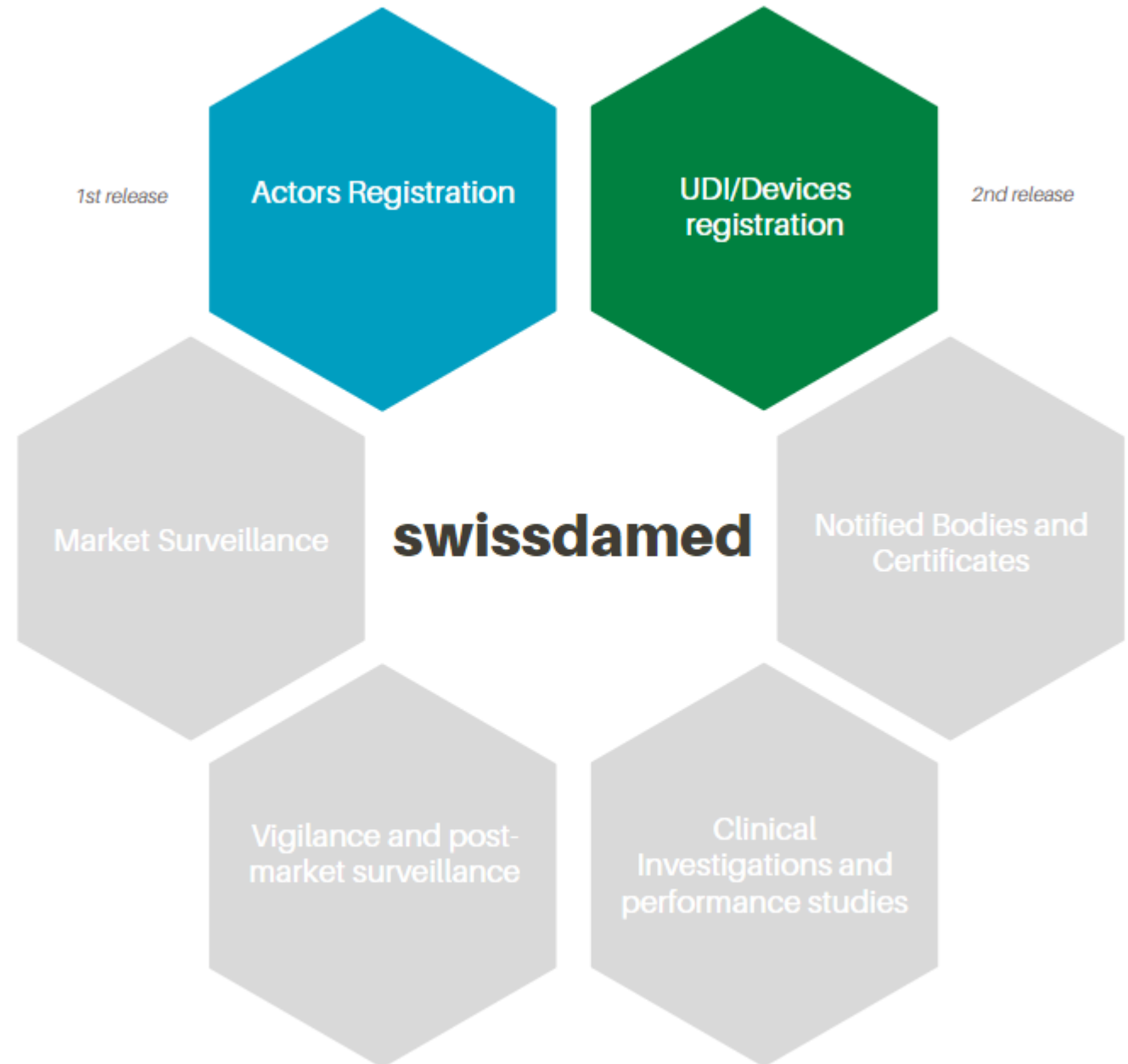
# How do I register my device?





# From when?

Go-live planned for 2023



# Questions

- I am a manufacturer (or CH-REP or importer) both of in vitro diagnostic devices and of medical devices that are not IVD devices (“classic MDs”). Do I have to register twice?
  - No, you need only register once. You can inform Swissmedic of any changes (e.g. to your address) by means of a change notification.