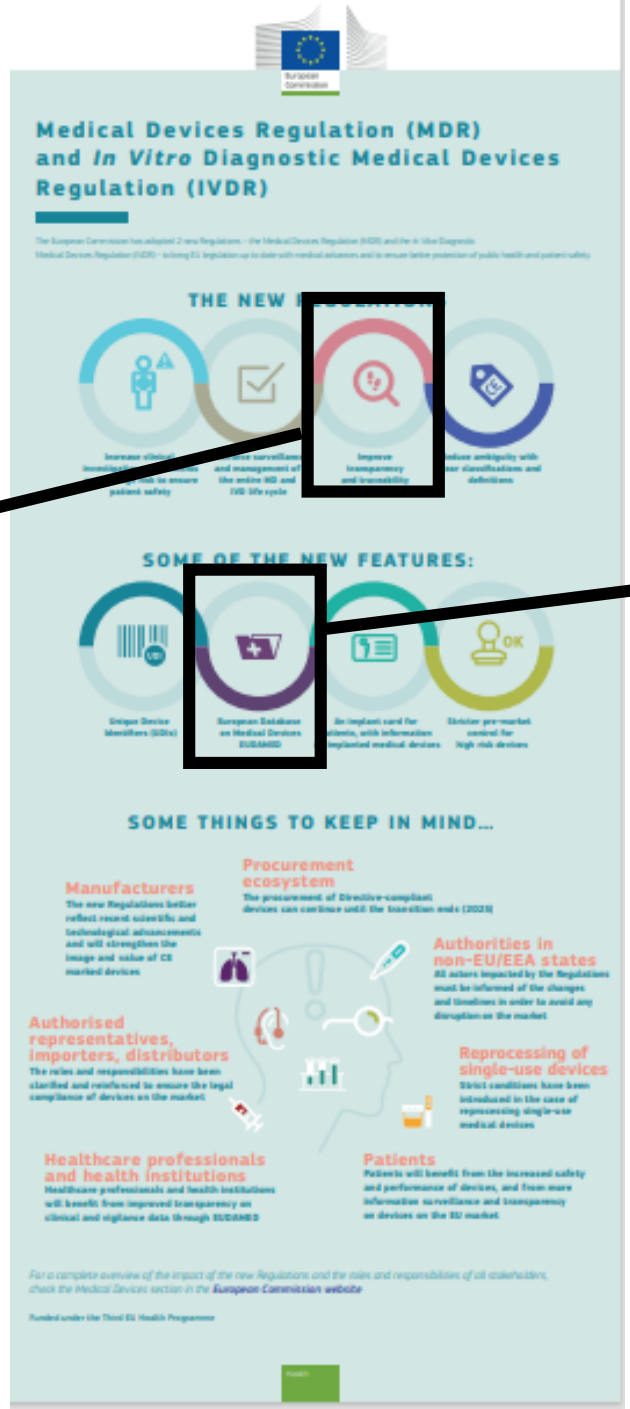
Registration obligations for operators and devices

Information on the swissdamed medical devices database

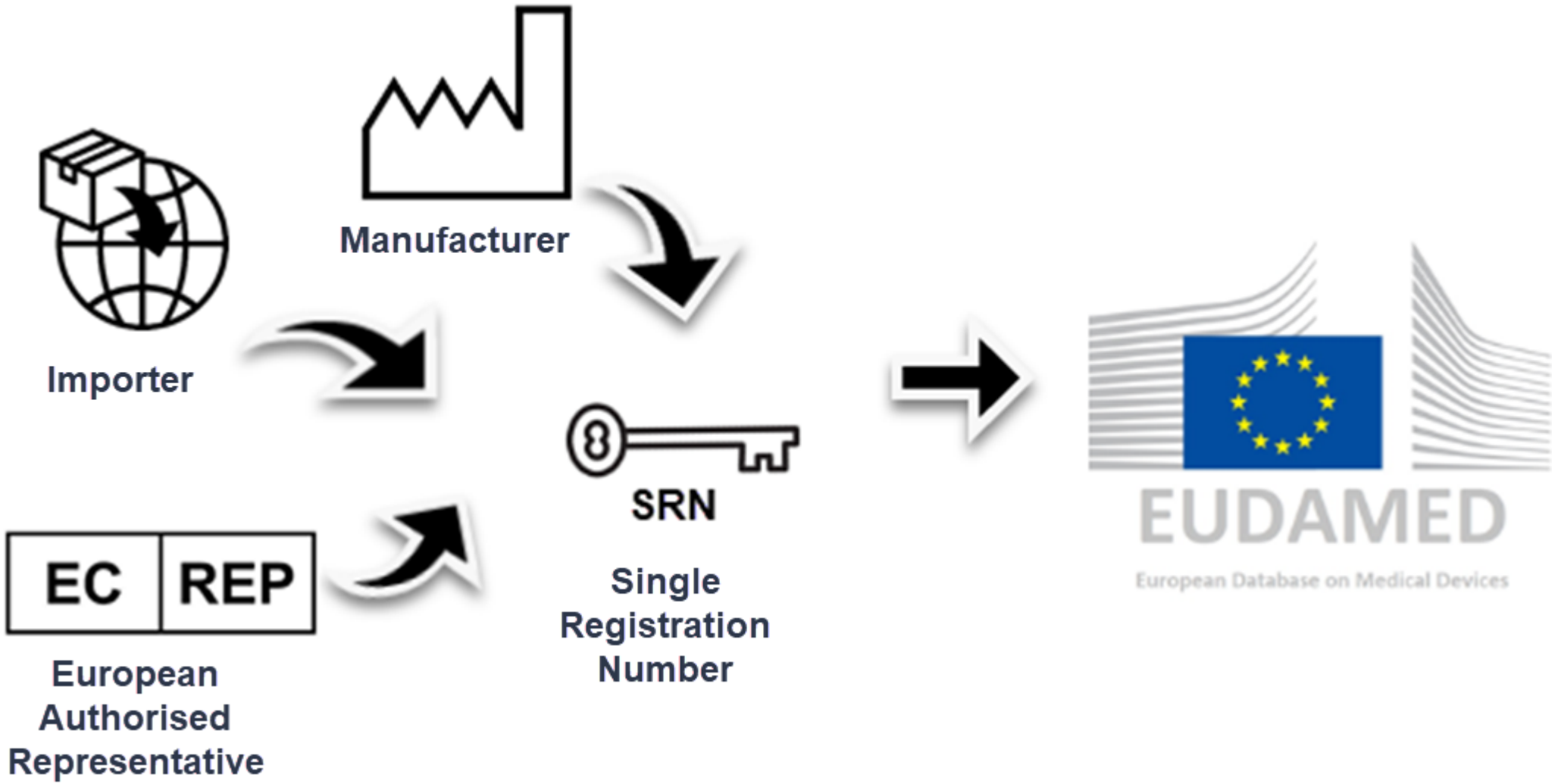
Dr Janine Conde
Head of Medical Devices Operations & Hospitals

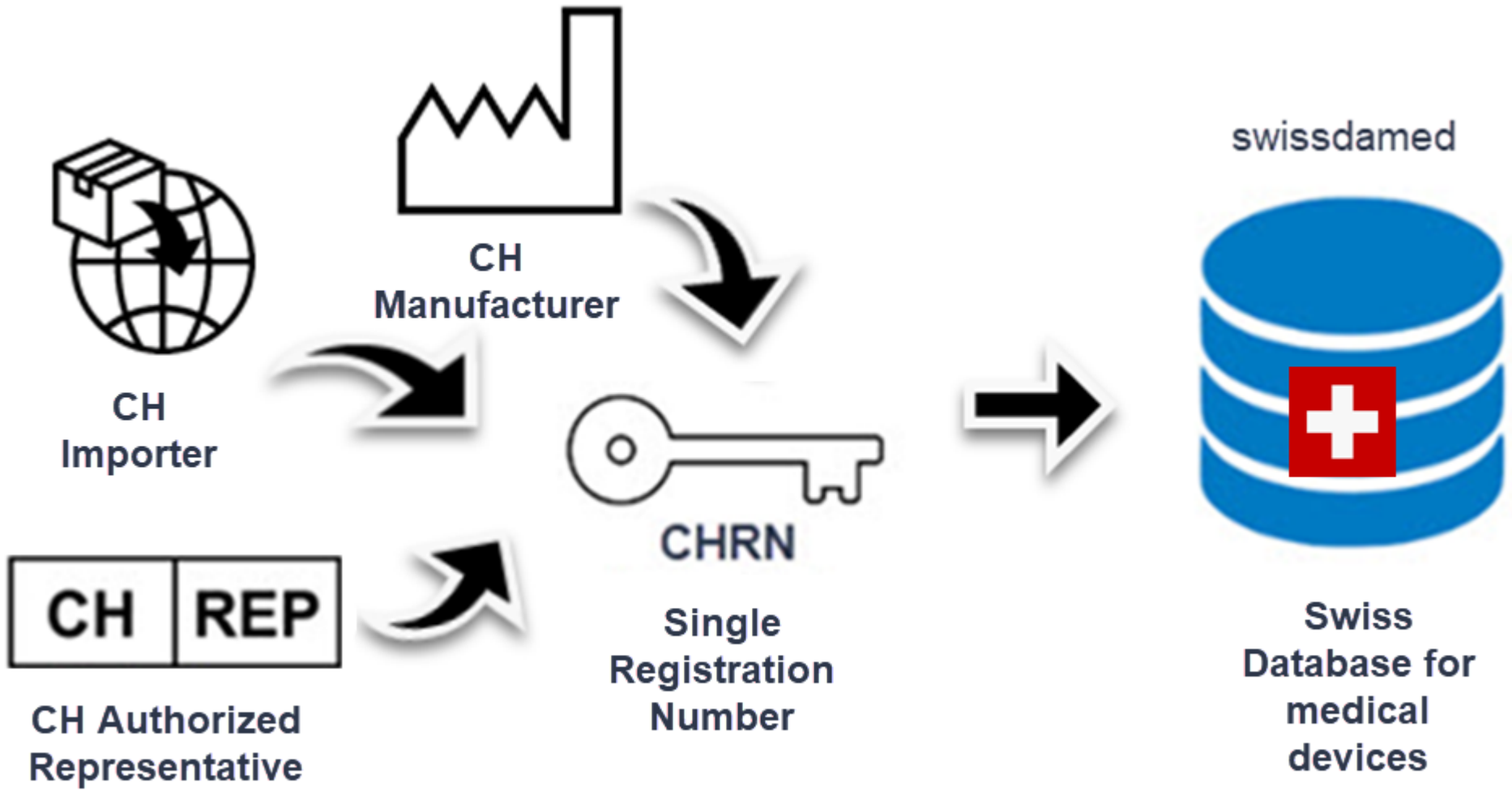

Welcome!
Please note the registration obligation


Improve
transparency
and traceability


Medical Devices Regulation (MDR)
and In Vitro Diagnostic Medical Devices
Regulation (IVDR)
THE NEW
SOME OF THE NEW FEATURES:
SOME THINGS TO KEEP IN MIND...
Manufacturers
Procurement ecosystem
Authorities in non-EU/EEA states
Authorised representatives, importers, distributors
Reprocessing of single-use devices
Healthcare professionals and health institutions
Patients

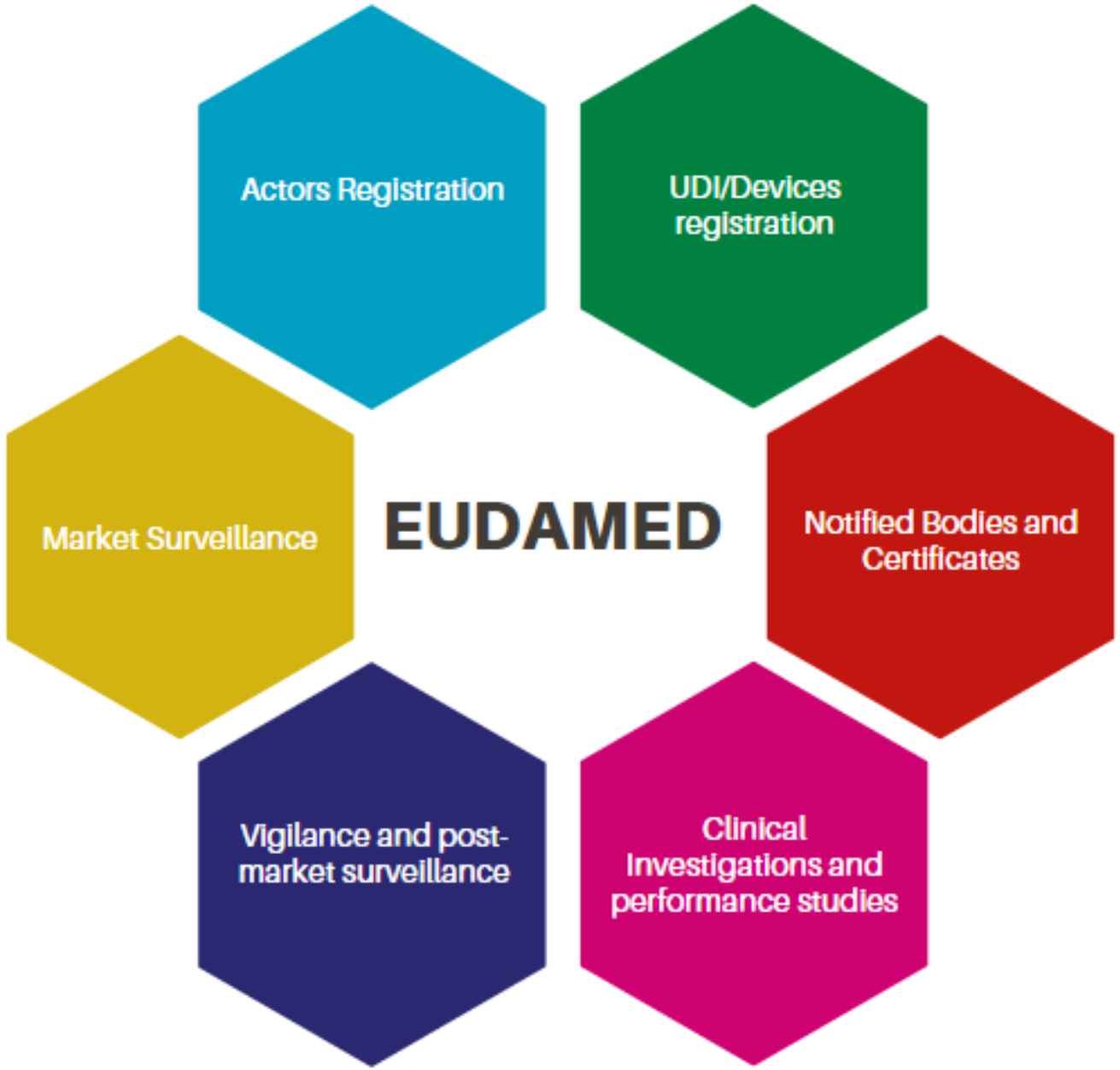

European Database
on Medical Devices
EUDAMED


Manufacturer
Importer
SRN
Single
Registration
Number
EC
REP
European
Authorised
Representative
EUDAMED
European Database on Medical Devices

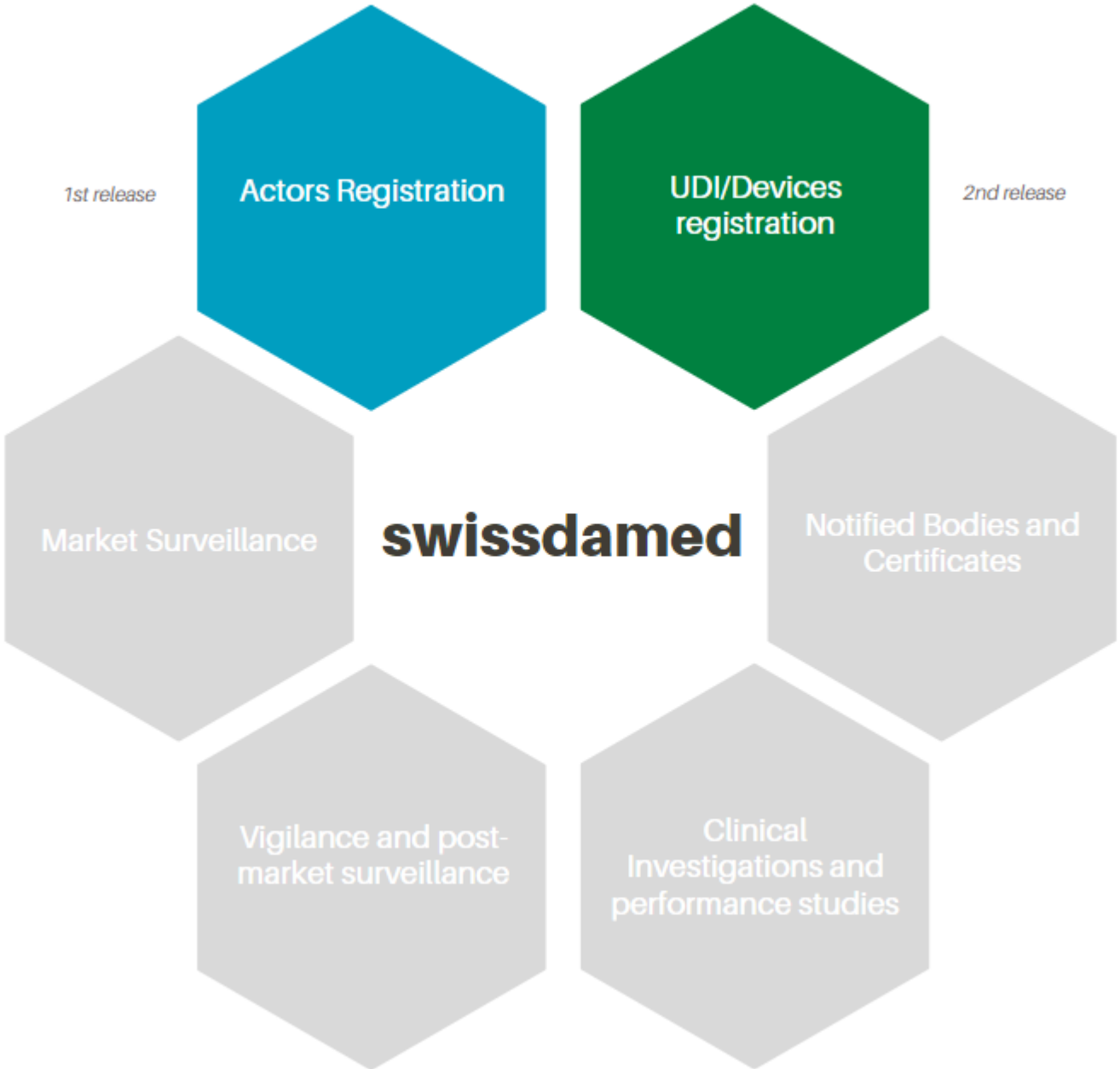

CH
Manufacturer
CH
Importer
CH
REP
CH Authorized
Representative
CHRN
Single
Registration
Number
swissdamed
Swiss
Database for
medical
devices

What is swissdamed?

EUDAMED MODULES



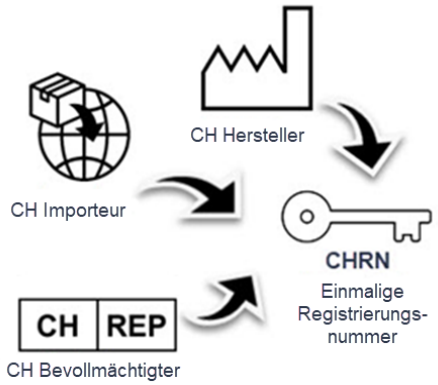
swissdamed MODULES



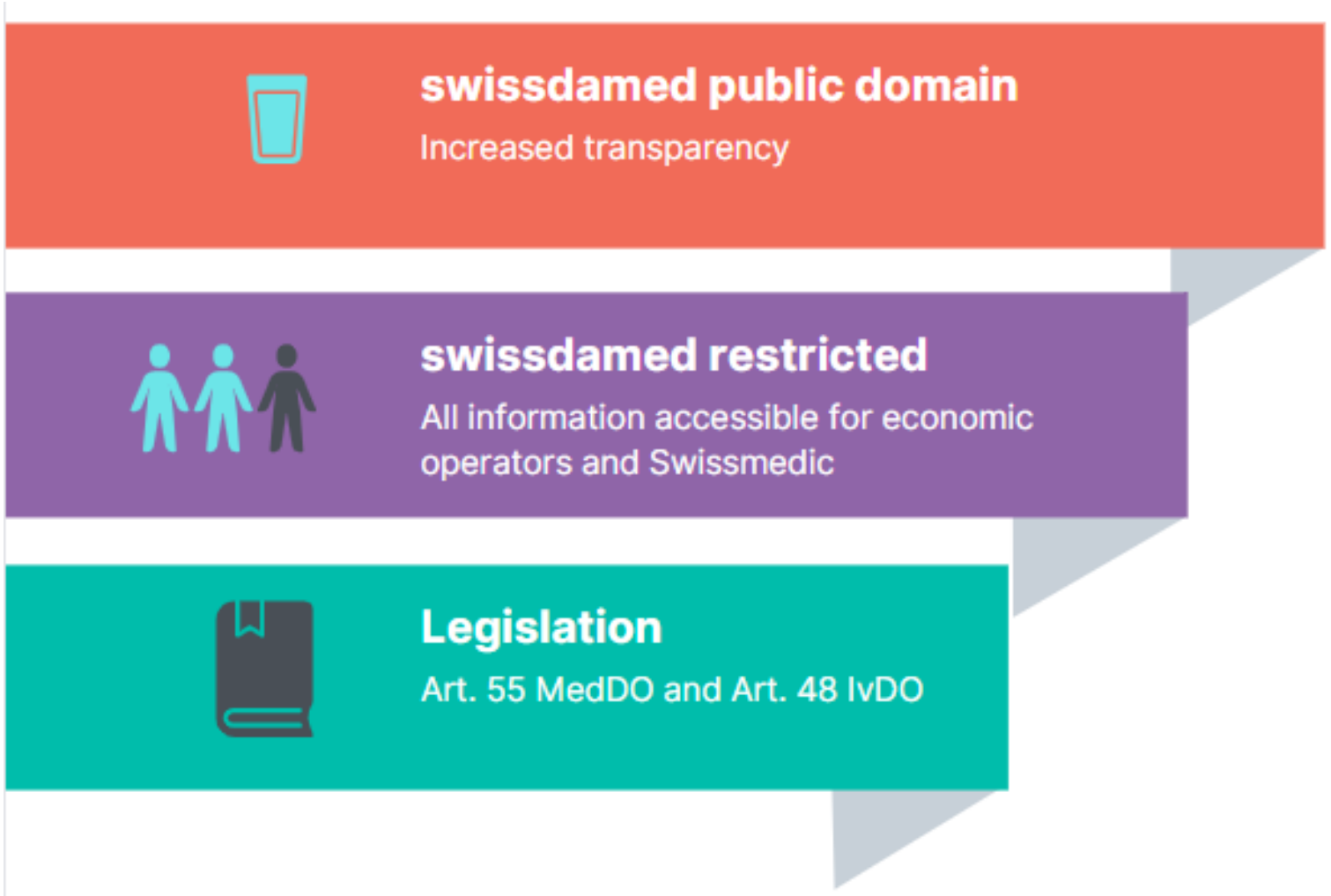
What are my obligations as an economic operator?

Registration as an operator

Why do I have to register?



Clear identification of all economic operators in the MD area



How do I register?

Forms available on the website

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)

swissmedic

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

○ Manufacturer ○ Authorised representative for Switzerland ○ Importer ○ Manufacturer of systems and procedure packs

Details of economic operator

Company

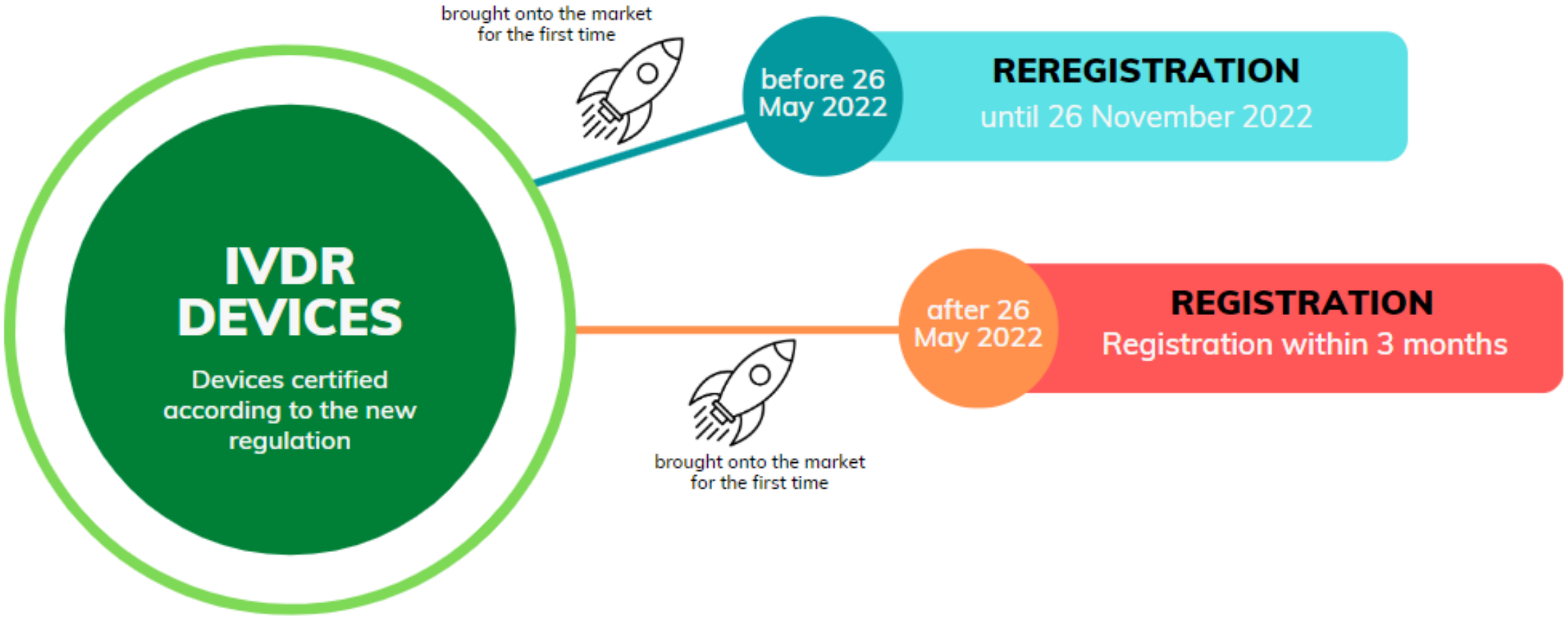
Commercial register — Link to the UID-Register

P.O. Box

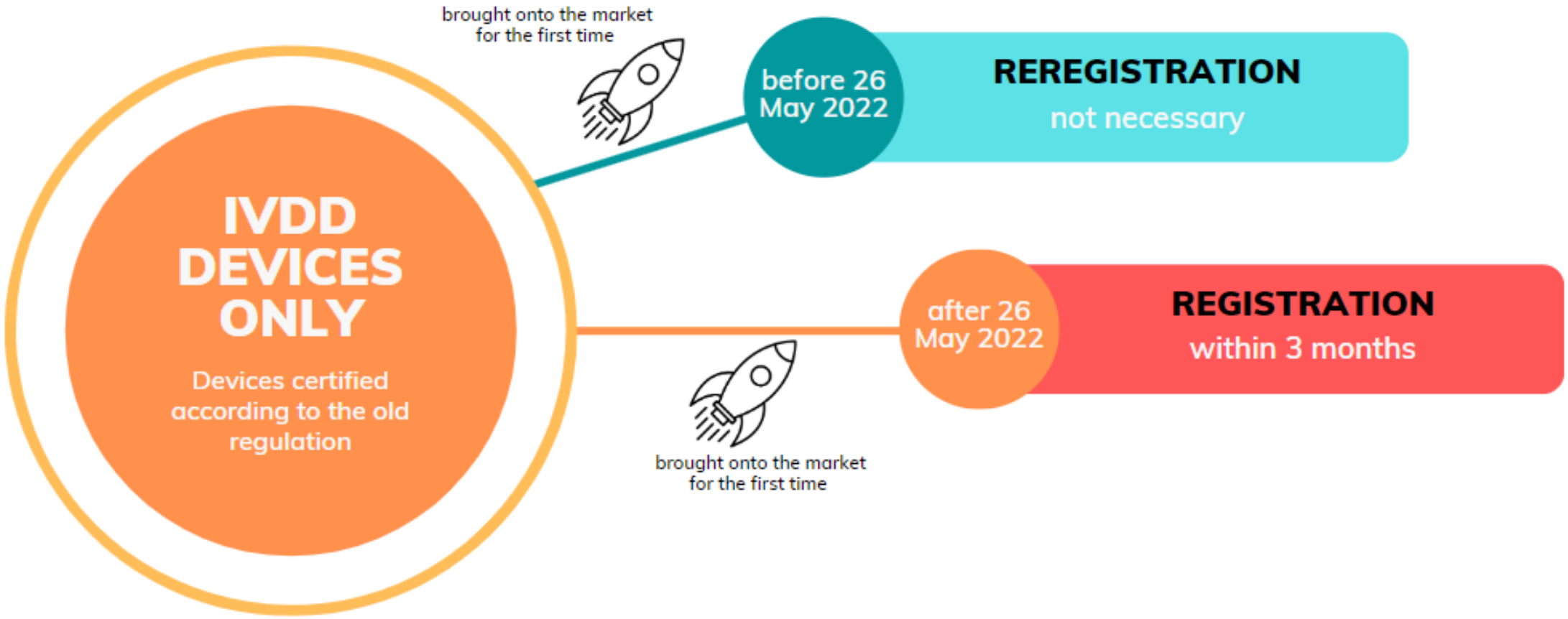
Street — No.

swissmedic 20 Jahre 2002 - 2022

From when?


brought onto the market
for the first time
before 26
May 2022
REREGISTRATION
until 26 November 2022
IVDR
DEVICES
Devices certified
according to the new
regulation
after 26
May 2022
REGISTRATION
Registration within 3 months
brought onto the market
for the first time

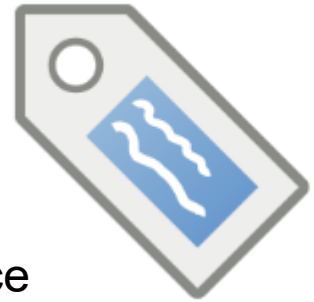
From when?


brought onto the market for the first time
before 26 May 2022
REREGISTRATION
not necessary
IVDD DEVICES ONLY
Devices certified according to the old regulation
after 26 May 2022
REGISTRATION
within 3 months
brought onto the market for the first time

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

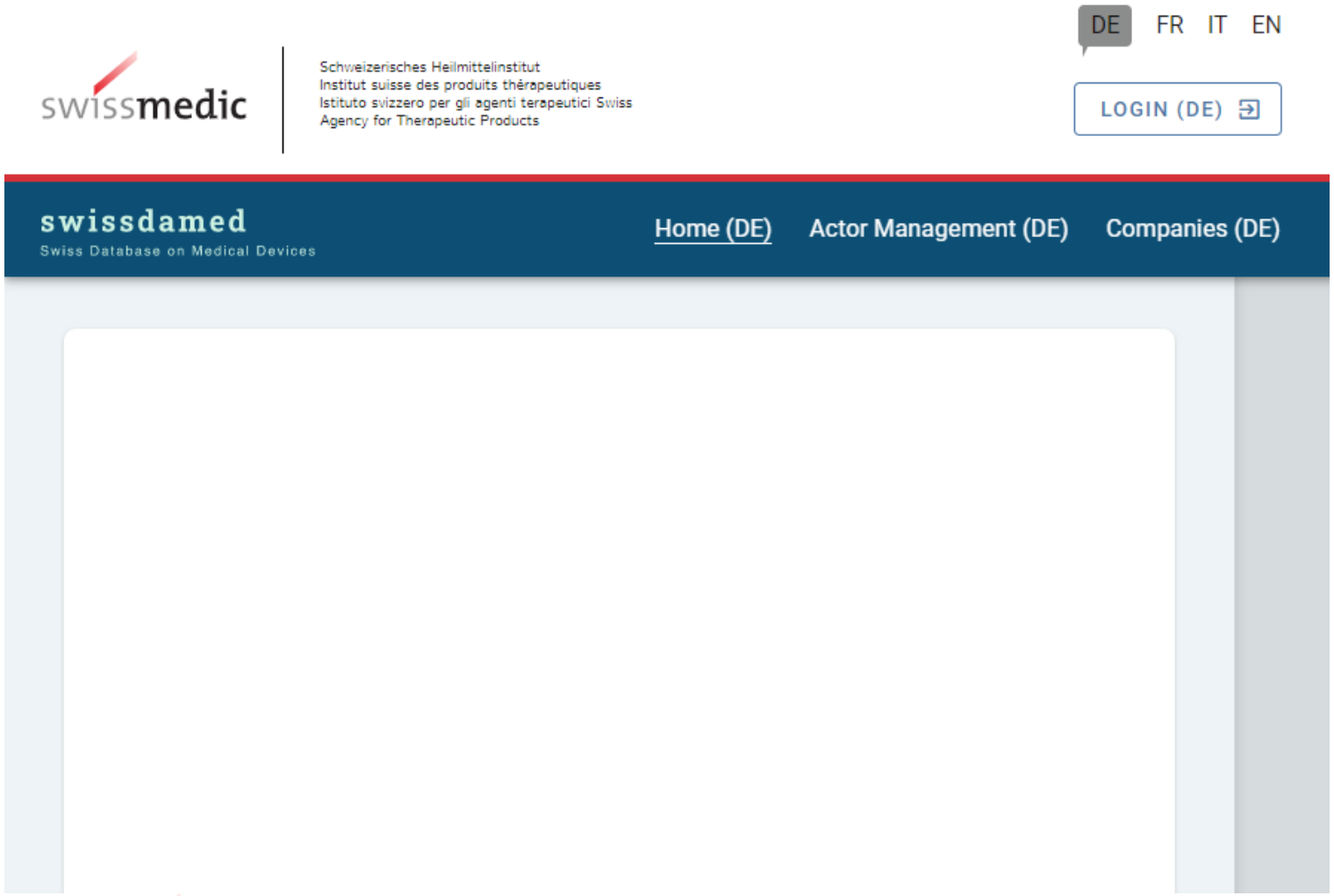
swissdamed restricted

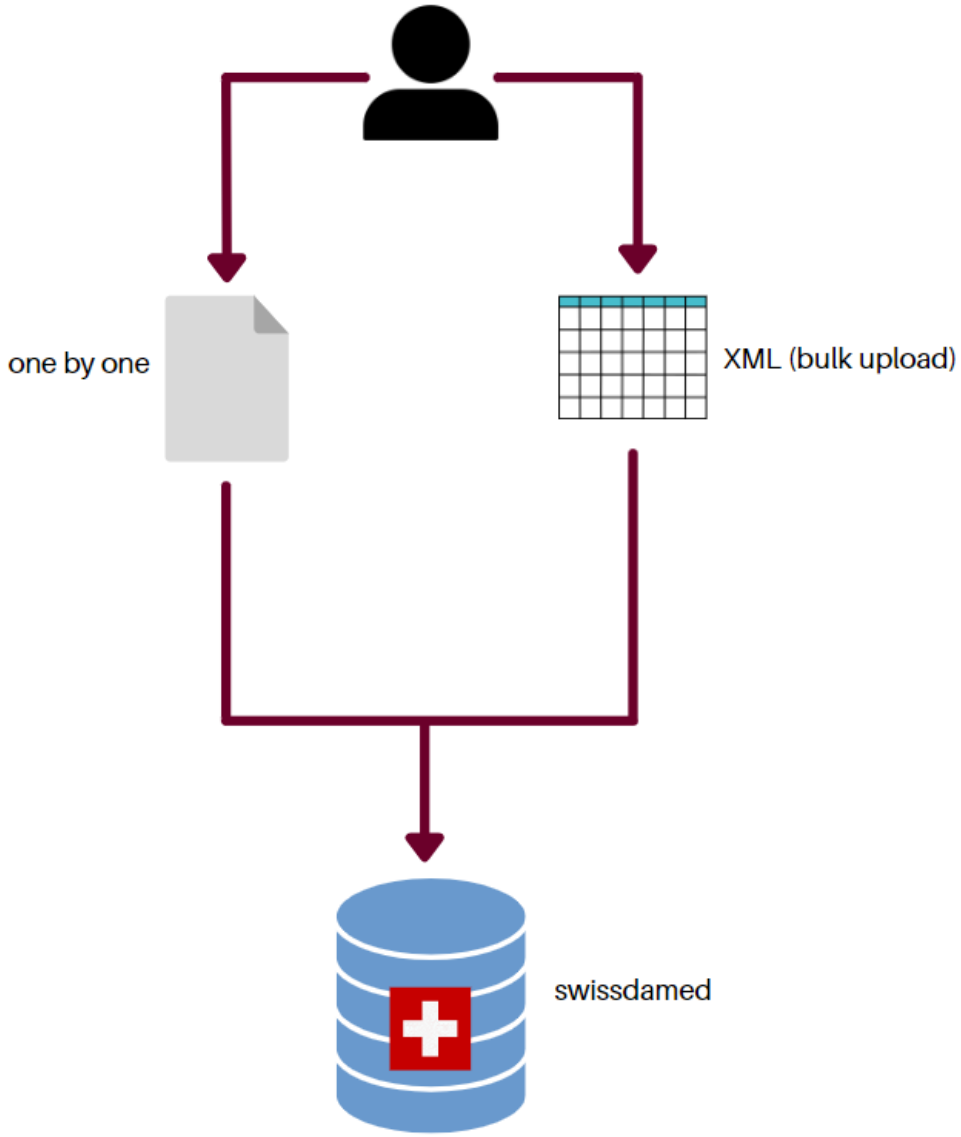
All information accessible for economic operators and Swissmedic

Legislation

Art. 17 MedDO and Art. 16 IvDO

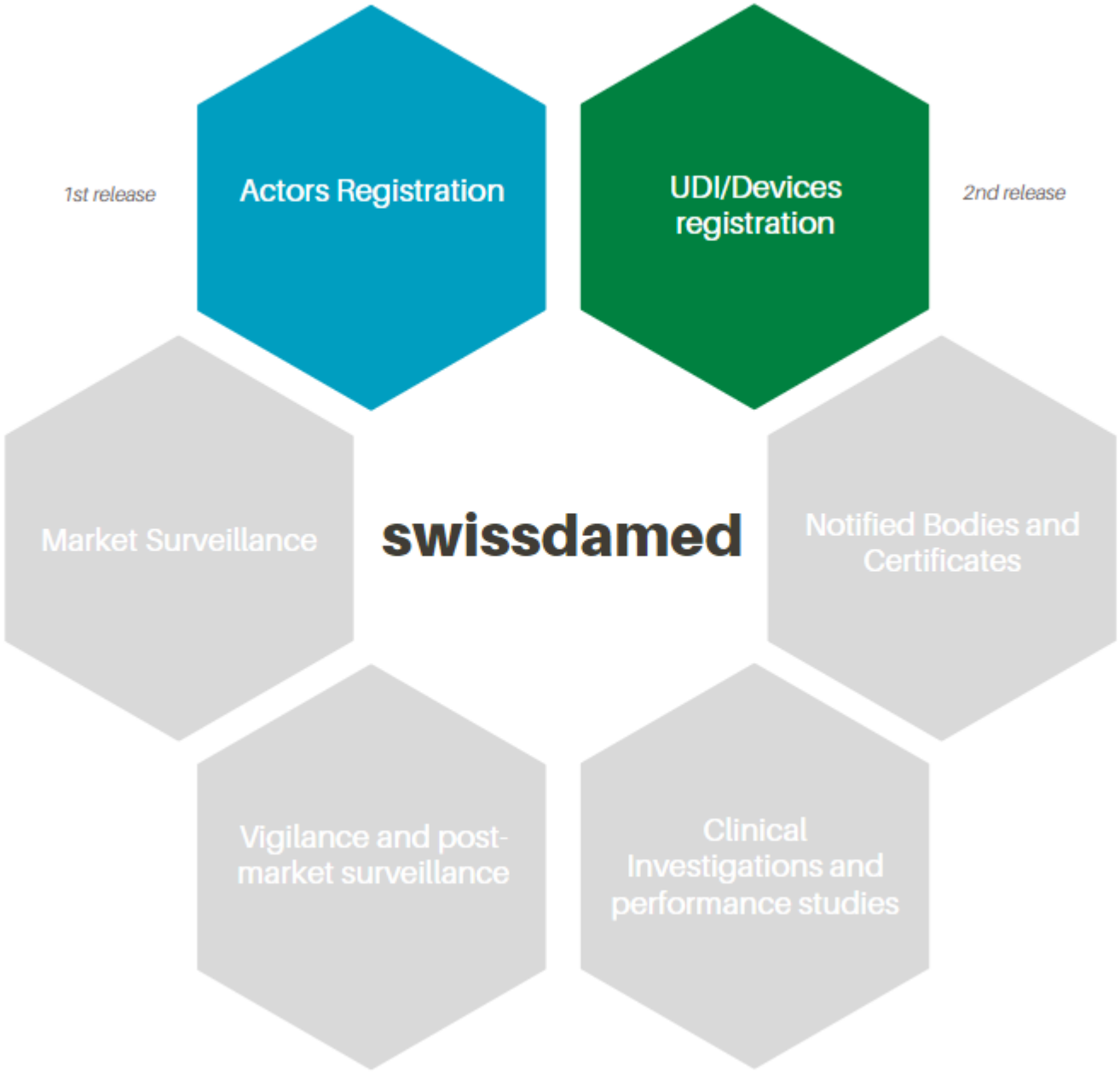
How do I register my device?





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.