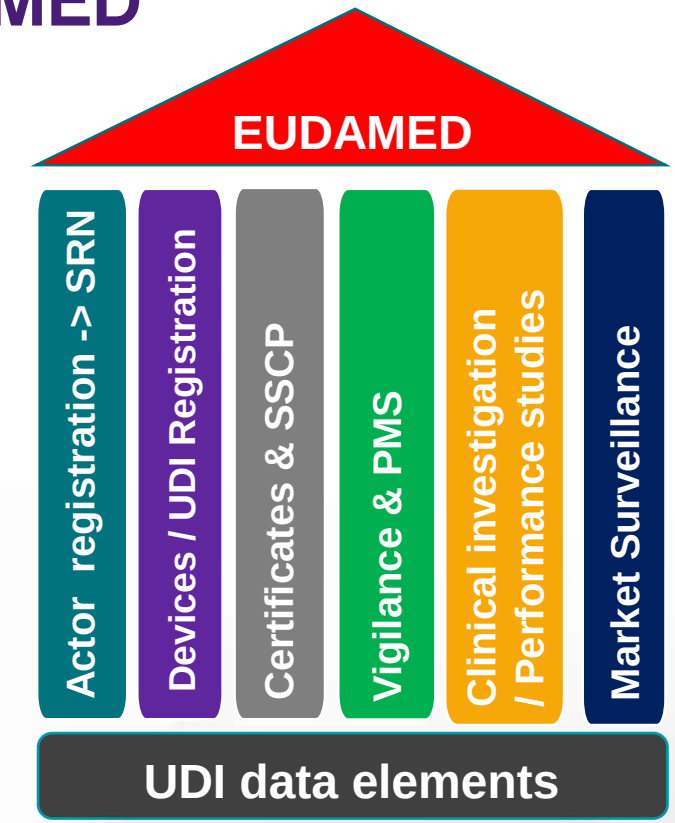
MedTech Europe
from diagnosis to cure

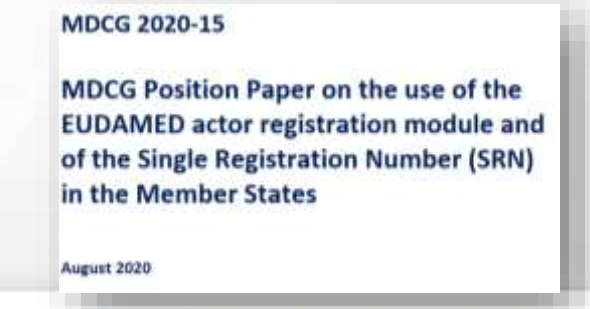
Actor registration in EUDAMED

1 December 2020

Registration of Economic Operators in EUDAMED

- **Available from 1 December 2020 onwards in various EU Member States, on a *voluntary* basis**
  - Mandatory use of EUDAMED cannot be enforced by MDR/IVDR before database is fully functional → forecast for May 2022
  - Member States may accept to fulfill the MDR/IVDR actor registration obligation in EUDAMED in lieu of national registration (France, Belgium already confirmed)
- **Advantage of registering manufacturers, importers and authorised representatives, system/procedure pack producers in EUDAMED *before* May 2022**
  - Gain a Single Registration Number (SRN) = include in relevant MDR/IVDR documentation now *(no need to update regulatory documents at a later stage such as Declaration of Conformity, Technical Documentation, Certificates issued by a Notified Body, Certificate of Free Sale)*




MDCG 2020-15

MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States

August 2020

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Registration of economic operators in EUDAMED - process

1. BEFORE START REGISTRATION IN THE ACTOR MODULE

- Clarify roles of different economic operators (MF, AR, IMP, SPPP)
- Assign Person Responsible for Regulatory Compliance
- Arrange contract with Authorised Representative
- Identify Local Actor Admin (LAA) and Local User Admin (LUA)
- Fill documents / agreements necessary to upload to EUDAMED
- Gather your contact emails for EUDAMED feedback (UDI, VIG)

START REGISTRATION

2. REGISTRATION

- LAA creates an EU login
- LAA accesses EUDAMED
- LAA enters appropriate contact data for economic operator and uploads required documentation
- SUBMIT REGISTRATION TO RESPONSIBLE COMPETENT AUTHORITY

3. AFTER

- Data is being validated by responsible Competent Authority and SRN is assigned
- Disseminate SRN to relevant units within your organisation
- Include SRN in appropriate regulatory documents
- MAINTAIN DATA IN EUDAMED AND ON DOCUMENTS

Users in EUDAMED

Admins/Superusers:

- The **LAA (local actor administrator)** registers the company, manages the actor data (e.g. name, address, VAT, etc.) and notification email addresses. LAA is the highest profile and contains the rights of all lower profiles. E.g. LAA includes the LUA rights for managing new user access requests.

  The person who first enters the details of an actor automatically becomes the LAA for that actor once the registration has been accepted. It is good practice for each actor to have at least 2 LAAs (and at least one of them should not belong to a sub-contractor).

- The **LUA (local user administrator)** validates/updates/ deletes user access requests (manages the users and their roles and can permit users to add and confirm submissions)
- A single user can register/manage multiple actors – each to be validated by the responsible authority

Users:

- Anyone with an EU Login account can request access to a registered actor. These specific users can then add data to the various modules once they are released (such as UDI&Device / Vigilance&PMS / Clinical Investigation/Performance Evaluation).
- The same user can user belong to multiple Economic Operators.
- It is possible to have multiple users with the same profile for the same Actor (no limit).

Actor registration as of 1 December 2020

1. From 1 December 2020, economic operators on the field of medical devices and IVDs (**manufacturers, authorised representatives, importers, system/procedure pack producers)** can start voluntarily use the EUDAMED actor registration module. Member States authorities - where the actor has its registered place of business - may accept this registration to fulfill the MDR/IVDR actor registration obligation in lieu of registration in the national database / according to the national requirements.* (France and Belgium already confirmed to accept)
2. Please note that the **registration is required per role** e.g. if a legal entity acts as the authorized representative as well as the importer, the same legal entity will need to get registered two times: once as an EC REP and once as an importer.
3. **Distributor registration is out of the scope of MDR/IVDR and thus of EUDAMED:** they remain to be managed by the National Competent Authority and if the local law requires, in the national database. Distributors will not get an SRN. See MDR Art 31; IVDR Art 28 for the legal requirements.
4. **The Single Registration Number (SRN) required by the MDR and IVDR can only be obtained through the EUDAMED Actor registration module after the economic operator registration has been validated by the responsible National Competent Authority** (please note that there is no timeline indicated in the MDR/IVDR for Competent Authorities to complete the validation of the submitted registration).
5. R**egistration in EUDAMED Actor registration module is not legally binding as per MDR/IVDR until 6 months after the launch of a fully functional EUDAMED completed with ALL modules which is planned in May 2022** - unless national law obliges the use of EUDAMED.

* The related MDCG position paper includes a **commitment of National Competent Authorities accepting the registration done through the EUDAMED Actor module** as far as national law allows that. They are committed **to avoid double registration of the same actor for the same role** – one at the national level and another in EUDAMED – again, as far as national law allows that.

Commission's dedicated page for EUDAMED Actor registration

Commission's dedicated page for Actor registration in EUDAMED: https://ec.europa.eu/health/md_eudamed/actors_registration_en

Disclaimer: The documentation in this page is subject to changes and updates whenever new information becomes available.

Actor registration module

- On 1st December 2020 the European Commission has made available the Actor registration module.
- It is the first of six EUDAMED modules.

Access to EUDAMED restricted site
Access to EUDAMED public site

FAQs

- Actor module FAQs

Single Registration Number – SRN

- The Actor registration module enables economic operators to submit, by means of an actor registration request, the information necessary to obtain a single registration number (SRN).
- The SRN guarantees an EU-wide unique identification for economic operators (also outside of EUDAMED).
- Following the assessment and approval of the request by the concerned national competent authority, EUDAMED generates the SRN of the economic operator to the national competent authority and transfers it to the requesting economic operator.
  Infographic: Actor roles and SRN

Actor registration request process

- Economic operators (**EU and non-EU manufacturers, authorised representatives, system/procedure pack producers and importers**) have to register as an actor in EUDAMED and provide the required information.
- Infographic: Actor registration request process
- Video: Demo actor registration module

Documents to provide with the actor registration request

1. **Declaration on information security responsibilities**
   All actors must upload a signed Declaration on information security responsibilities (template in all EU languages)
2. **Mandate Summary document**
   To register in EUDAMED, the non-EU manufacturers must have an active authorised representative and submit with the registration a Mandate Summary document

EUDAMED registered users

- For an actor already registered in EUDAMED, all persons who intend to act on behalf of this actor need to enter an access request.
- Infographic: Users access requests

User guide for Economic Operators

- Guide to using EUDAMED – Actor registration module for Economic Operators

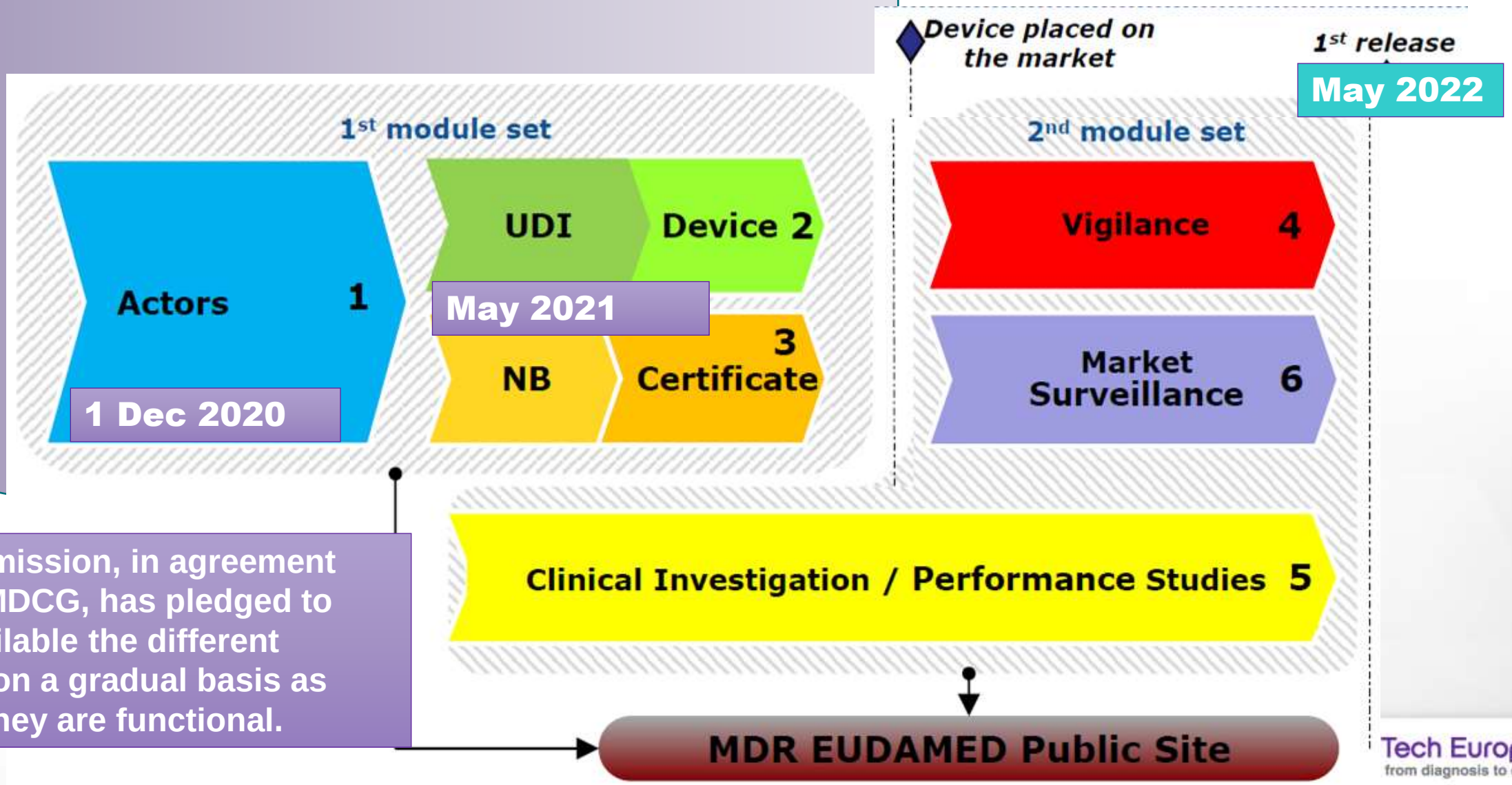
Technical documentation

- Actor Module Business Process - the M2M management will only be available when the UDI/Device module will be made available
- Actor Module Business Rules
- AIM-Business Process - the first NB LAA will only be available when the certificate module will be made available
- AIM-Business Rules

Other useful information

- MDCG 2020-15 MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
- Guidance documents to assist stakeholders in implementing the medical devices regulations.

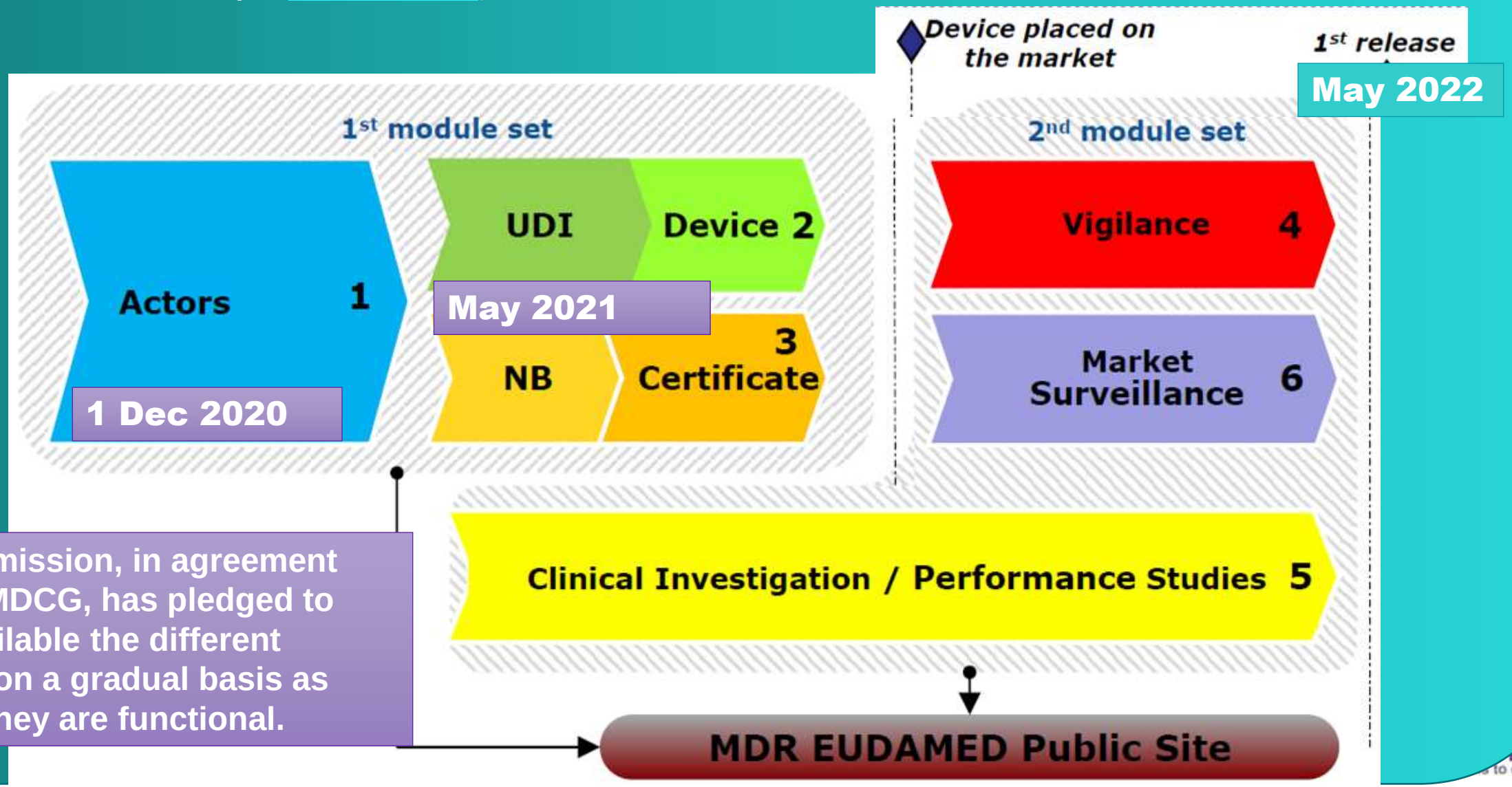
Voluntary use



The Commission, in agreement with the MDCG, has pledged to make available the different modules on a gradual basis as soon as they are functional.

Mandatory use after 1st launch of EUDAMED completed with all modules

(timeline: 18+6 months as per MDCG 2019-4)



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