Production Release 2.0 - Known issues

The new release updates some functionalities for the users of the UDI/Device and Certificates modules of EUDAMED. The following are known issues that have been reported that will be prioritised and addressed in the coming period:

Actor/User Module

- Only notifications requiring an action to be taken (labeled "Action") are included in the Notifications Inbox within EUDAMED. Informational notifications are currently sent via email only.
- VAT, EORI and national trade registry number cannot be added if initially empty.

UDI/Device Module

- Device Certificate Information is required for all Legacy Devices irrespective of the Applicable legislation and Risk Class (still in internal analysis);
- Consistency checks performed when submitting Devices (Regulation and Legacy) having the same UDI-DI require the devices to have the same attributes values in both the regulation and Legacy Device. Not having the same attribute values will impede the submission of the latter Device submitted in EUDAMED;

Previous issue reported from Playground solved :

- The linking of a Regulation Device to a Legacy Device (or vice versa) but having a different Manufacturer associated;
- Direct Marking DI is updatable for Devices only in case initially the value of the Direct Marking DI was not provided;
- Allow the registration of Regulation Device without providing Device Certificate Information (discrepancies between the EUDAMED UI and DTX)

Notified Bodies & Certificates

- When amending a certificate the system will not allow to remove languages from the preceding certificate;
- When re-issuing a certificate (including merging several certificates) the system will not allow to remove languages from the preceding certificate (s)
- When restricting/re-issuing one of the following certificate type:
    - (MDR) EU Quality Management System certificate (Annex IX Chapter I)
    - (MDR) EU Quality Assurance certificate (Annex XI Part A)
        - which scope is defined with Device(s) and System or Procedure Pack(s) the system will not allow to remove all System or Procedure Pack(s) or all device(s) from its scope
        - System allows to cancel a certificate (status becomes CANCEL by MF) when its current status is SUSPENDED.