



MDCG EUDAMED Subgroup

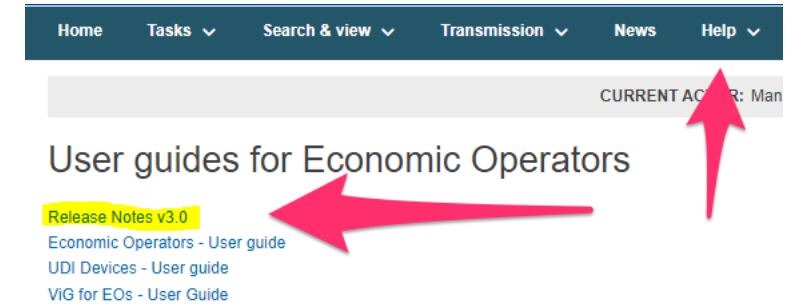
Software release 2.7.0 and 3.0.0 overview



28-04-2022

Release notes

- Important to check releases notes!
- Release notes available under help menu
- For each module check is there a pre-requisites section
- For each feature check is there a “Known issues” section



1) *Manufacturer Incident Report (MIR)* ;



Known issues :



1) Vigilance Module

pre-requisites



Production Release 2.7.0

- New functionality in Actors and Certificates modules
- Changes implemented in Actors, Devices and Certificates modules
- Issues fixed in Actors, Devices and Certificates modules

Playground Release 3.0.0

- Vigilance
 - Important Pre-requisite / Known issue – A user can only be a member of one Actor to use Vigilance
 - LAA must grant vigilance profiles
 - Forms Available: MIR, FSCA, PSUR, NCAR
- Market surveillance
 - LAA must grant Market Surveillance profiles
 - Register and Manage an MSU procedure
- Certificates Module

Questions ?

Thank you



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