



**Draft Minutes**  
**MDCG - EUDAMED Subgroup**  
**Plenary meeting**

**27 April 2021**

MDCG EUDAMED Subgroup meetings are not public and they are intended only for MDCG EUDAMED Subgroup members and selected observers. Due to the COVID-19 crisis the meeting is a virtual meeting with video-audio connection.

**1. Welcome & adoption of agenda**

COM welcomed the participants, thanking them for the feedback and support provided and reminded the housekeeping rules. This is the second meeting of the MDCG EUDAMED Stakeholders Subgroup. The EUDAMED is facing many challenges, including the Colvid-19 but significant progress has been done since the first meeting, particularly the actor module, in production since December 2020.

The COM presented the agenda. MedTech Europe sent some questions the day before. They will be addressed at the end if time allows.

The agenda was adopted.

**2. EUDAMED State of play**

COM presented the project state of play, particularly the Data Exchange mechanism and services implemented and the scope of the September production release.

MedTech Europe asked for an extension of the deadline for the playground feedback until mid-May. COM explained that whilst the playground is incremental and remains open all the time, after a certain time it is not possible to take the feedback into account for the next release, therefore late feedback will not be taken into account for Playground release 1.2. planned for July.

The COM informed that the planning is under review and will be communicated shortly.

### **3. Playground 1.1**

COM presented some general information about the 1.1 Playground, particularly, how to access it and the scope. UDID/Devices and NBs & certificates modules are visible in the search & view. The users will need to update their profiles to use the new modules.

COM explained that NBs information comes from NANDO and synchronises every night. The Playground mirrors production functionalities and has the same rules. NBs that are not designated under the MDRs cannot be in Playground but it is possible for them to participate via a test NBs created for this purpose.

COM reminded that as the notifications are not activated for any action triggering a workflow and a notification, the user should contact the support.

COM advises the users to make sure their access is correct. The Playground documentation is available in CIRCABC and in the Playground itself. The DTX 1.4 documentation is available for everybody.

Team NB said that NBs would like to have more devices registered in the system and more time to provide feedback as very few devices are registered because it took some time for manufacturers to play. So far more than 300 devices are registered.

COM answered that there are around 30 high risk classes requiring NB input. If NBs want to create fake manufacturers to enter devices and better check it could be possible. COM does not provide general test data.

Even if the timeline for the feedback is end of April, blocking bugs are always accepted and treated as priority. The next version of the Playground will be released end July with a feedback period and will contain more functionalities for the NBs.

Team NB asked for the possibility for NBs to access the other modules in the Playground and MedTech joined to this request. The COM has not considered this possibility.

COM clarified that NBs will have access to all modules following the MDRs extent, devices for which the NBs are responsible and also public info.

Team NB requested the COM feedback on a FAQ asked by all NBs during the different modules meetings. Team NB will send the document again.

### **4. AOB /Q&A**

There was no time to address MedTech questions. COM will come back bilaterally.

COM closed the meeting thanking the participants.

## **5. Participation**

**MDCG EUDAMED members:** AT, BE, DK, DE, ET, ES, FR, FI, GR, HR, HU, IE, IT, MT, NL, PT, PL, RO, SE,

**Observers:** TR, NO, Biomed Alliance, COCIR, AESGP, EAAR, EIGA, EFPIA, EUCOPE, EUROM I, EUROM VI, EUROMCONTACT, GIRP, GS1, HOPE, MedTech, NB-MED, Team-NB

**Commission:** SANTE B6, SANTE A4