

Sent: jeudi 18 juillet 2019 10:32

Subject: RE: Follow up from agenda item 11: European Database on Medical Devices (Eudamed) at MDCG 20. June 2019

Attachments: MDR Eudamed - Functional Specs\_v5.docx; Eudamed high level roadmap 20190715.docx

Categories: AZ

Please find in attachment a new high level roadmap for Eudamed. After further internal reflexion, in light also of discussions during the last MDCG, we have now a new plan with only 4 releases of Eudamed (instead of 5) for reaching full functionality that would be achieved by May 2022 (by date of application of IVDR) instead of end of 2022 (6 months earlier than what was presented in the MDCG).

After long discussion with our colleagues of the IT team, this is the best realistic timing we can have for the Eudamed implementation. Of course convergent efforts from all public and private stakeholders will be key to achieve this objective and these deadlines.

hope that with this document you have enough to share internally in your organisation, with the Ministry of Health or with your stakeholders.

It is only at the next MDCG meeting (end of September) that everyone (else) will be informed.

Best regards,



**European Commission**

DG for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)  
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