TGA Device Reforms May 2020

Comments are as follows;

- The European class and risk framework appear to be appropriate for the Australian setting.

- It is not clear if apps/software that are excluded still require Class 1 registration.

- If all require Class 1 at minimum, the Class 1 ARTG process needs to be simplified and expedited as the existing process is not intuitive. To maximise ARTG additions, the process needs to be accessible to those without experience in navigating the TGA website.

- The consultation paper does not address artificial intelligence (AI). This should be part of the process as it is imminent and will be a significant component of SaMD.