GEHC RESPONSE follows:

RE PROPOSAL 1
GEHC propose that the implementation of the EP checklist be delayed in the event that the EU MDR implementation is being delayed as well (i.e.Brexit impact)

RE PROPOSAL 4
The requirement to display the ARTG number on the electronic label: Adding the ARTG number to the dedicated version number screen of the software will require significant technical implementation, especially for SaMDs that contain multiple software options which each have their own ARTG license number. In addition, depending on customer preferences, an SaMD may be supplied with different selection of software options. This will mean the list of ARTG numbers displayed on screen will need to vary dynamically, depending on the software options that are purchased by individual customers. Building this dynamic into the software would be complex.

Please call if we need to discuss.

Regards,

Eddy McFadden
QARA Leader ANZ
GE Healthcare