

GSPR vs Essential Principles

Submission from Siemens Healthcare Pty Ltd

Remove Proposal 3 – Restructure for improved clarity –

Comment – Restructuring will not add additional clarity on certain requirements or align content with international requirements.

Remove proposal 4 – ARTG number

How does the ARTG number match with Essential requirements? The ARTG number is usually received after completed device approval. The EP are needed to be completed before regulatory approval.