ResMed

March 29, 2019

Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609
Australia

Submitted via the online consultation submission form

Re: Regulation of software, including Software as a Medical Device (SaMD)

To whom it may concern,

ResMed appreciates the Therapeutic Goods Administration's solicitation of stakeholder input on how software, including Software as a Medical Device (SaMD), is regulated in Australia.

ResMed is the world's leading manufacturer of medical devices for the treatment of sleep apnea. We trace our history to the invention of the continuous positive airway pressure (CPAP) device, first created by Professor Colin Sullivan and colleagues at the University of Sydney in 1981. CPAP was the first successful noninvasive treatment for obstructive sleep apnea (OSA), and remains the gold standard. In 1989, ResMed was founded to commercialize CPAP therapy and since that time, we have continued to revolutionize the sector by introducing highly innovative products and driving connectivity of home respiratory care including oxygen and ventilators.

Below are our comments:

Section	Comment/Proposed Change	Rationale
Changes to the essential principles – "that medical devices indicate when critical features and connections are or are not enabled, and provide appropriate alarms"	Modify to say ""…and provide alarms <u>where appropriate based on risk</u>"	This way, the alarm is a risk-based decision for the necessity of alarms.

Best Regards,
Christie Marquez
Associate, Regulatory Affairs
ResMed