February 17, 2019

Australian Government
Department of Health
Therapeutic Goods Administration
Submitted online and to devicereforms@tga.gov.au

Re: Comments on January 2019 Consultation: Potential reclassification of active medical devices for diagnosis and patient therapy[1]

ResMed is a global leader in connected care, delivering innovative technology to improve quality of care, promote therapy adherence and decrease health care costs. ResMed manufactures cloud-connected medical devices used to treat obstructive sleep apnoea (OSA), chronic obstructive pulmonary disease (COPD), and other respiratory conditions. Our Australian-based operations are among the few medical device companies that continue to utilise Australia as a manufacturing base. From our facility in Bella Vista (NSW), ResMed exports Australian made products to more than one hundred and twenty (120) countries around the world and employs approximately fourteen hundred (1,400) Australians.

ResMed appreciates the opportunity to provide comments to the Therapeutic Goods Administration (TGA) on the-captioned consultation. It appreciates that the TGA intends to safeguard and enhance the health of the Australian community through strengthening the regulation of therapeutic goods in Australia, as well as bringing Australian regulations into alignment with the European Union (EU) Medical Devices Regulations (MDR).

ResMed's comments are focused on the proposal to up-classify continuous positive airway pressure (CPAP) devices to Class III. ResMed does not believe that the EU MDR Rule 22 is applicable to any ResMed product that measures and responds to breathing system pressure, and therefore this proposed up-classification is not appropriate. This position is aligned with discussions between ResMed and our EU Notified Body, and with *IEC 60601-1-10:2007 Medical electrical equipment – Part 1- 10: General requirements for basic safety and essential performance – Collateral standard: requirements for the development of physiological closed-loop controller,* which clarifies that any device that measures and responds to breathing pressure systems are not considered a closed-loop system.

Supporting Information

As described below, we recommend the TGA not include CPAP devices in any interpretation of the applicability of EU MDR Rule 22. ResMed does not agree that a Class III medical device classification is appropriate for CPAP devices since these devices do not present the same high risk profile as an automated external defibrillator (proposed for reclassification under Rule 22), or an existing Class III device like an implant. Based on discussions with our EU Notified Body, ResMed expects CPAP devices will be classified under EU MDR Rule 9 as Class IIa, therefore, if the TGA reclassifies CPAP devices as Class III, the TGA's intention to align with the EU will not occur.

[1] https://www tga gov au/sites/default/files/consultation-potential-reclassification-active-medical-devices-diagnosis-and-patient-therapy pdf

ResMed recommends the TGA delays publishing any TGA specific guidance on device classification until after the European Commission updates MEDDEV 2.4/1 or issues new guidance on the classification of medical devices as per the MDR rules.

I. A Class III designation for CPAP devices is not appropriate and does not provide any added clinical or safety benefits.

CPAP devices with automatic algorithms have been in the market for over ten (10) years . Positive airway pressure modes on CPAP devices are designed to improve therapy delivery comfort by adjusting the pressure delivered to the patient within physician set limits. This function is not a diagnostic function as it does not identify the disease or condition which is associated with the patients' health condition, nor does the automatically adjusting mode significantly determine the patient management.

In the Australian context, CPAP devices are now predominantly used for the treatment of OSA. Given that the classification of medical devices is risk-based, the use of CPAP devices for OSA does not represent essential performance and the CPAP therapy is not delivered in a hazardous fashion.

Pivotal safety and performance data in state-of-the-art and device-specific literature for CPAP devices does not identify any safety concerns from the use of these devices.

Additionally, based on discussions with our Notified Body and European National Competent Authorities regarding the applicability of Rule 22, ResMed believes they share the opinion that CPAP devices remain classified as Class IIa. If the TGA reclassifies these devices as Class III, it will no longer be aligned with the EU.

There is no scientific evidence, or information from vigilance or post-market surveillance activities that support the reclassification of CPAP devices from Class IIa (low-medium risk) to Class III (high risk), i.e., the same risk classification as an automated external defibrillator (proposed reclassification under Rule 22), or implants (currently classified as Class III).
It is also worth noting that the primary international standard that governs the performance and essential safety requirements for CPAP devices is *ISO 80601-2-70 Medical electrical equipment -- Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment*. This standard is currently under review by ISO committee subject matter experts (physicians, industry, regulators and other interested parties).

The current expert consensus is that an algorithm function within a CPAP device that automatically adjusts gas pressure would not classify the CPAP device as having an integrated or

incorporated closed loop diagnostic function which significantly determines patient management. This also supports not reclassifying CPAP devices as Class III.

In addition to this, the TGA's justification for the reclassification of closed loop systems is the following (taken from the TGA's consultation document): *"Given the patient cohort who relies on closed loop systems, tight controls over the design and production of these devices is crucial to ensure that they are safe and perform as intended."* As stated above, CPAP devices in Australia are predominantly used for the treatment of OSA. Patients with OSA do not rely on these devices and are not exposed to significant and potentially fatal hazards.

II. Including CPAP devices under MDR Rule 22 as Class III devices will create confusion and additional administrative work that does not improve patient safety.

The additional requirements for clinical investigation data for Class III devices will lead to unnecessary medical research for technology which is very well established and has a long history of safe and effective use. It is important to also note that the Declaration of Helsinki states: *"Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects."* Conducting further clinical investigations for well-established, safe technology would be at odds to this principle from the Declaration of Helsinki.

The need for additional evidence and expert review of documentation (Class III conformity assessment route) will also result in higher costs and a disproportionate burden for manufacturers of these devices. This will reduce innovation and competition, and significantly lengthen time to market or even potentially prevent current devices being made available, restricting patient access products.

***

ResMed appreciates the opportunity to comment on the proposed reclassification. We look forward to working with the TGA to ensure the sustainability of the Australian regulatory system for medical devices, appropriateness and robustness of assessments, and timeliness of patient access to medical devices.

Sincerely,

[redacted]

Carlos M. Nunez, M.D.
Chief Medical Officer