Thank you for the opportunity to provide comments on the regulation of software-based products.

The regulation is well thought out and provides many clarifications compared with other regulations. It is simple and easy to understand. The Australian classification rules for software-based medical devices are broadly aligned with the EU classification described but provide clearer and simpler classification for ease of understanding and protecting patient well-being.

In accordance with the request for consultation I would like to provide comments on:

1. Questions detailed within the consultation paper.
2. Suggested improvements
3. State that I support the proposal
4. An assessment of how the proposal will impact on my profession.

1. Questions detailed within the consultation paper.

- **What kinds of software-based products should be exempted from inclusion in the ARTG? What are they and why should they be exempted?**

The proposed regulation has correctly identified software that, while meeting the definition of medical device, is not considered to be posing potential for significant harm to a patient, user, or others.

The proposed list of **Exempted products** that do not have to be included in the Australian Register of Therapeutic Goods (and thus an application relating to the product does not have to be submitted to TGA for review) should be kept.

- **What kinds of software-based products should be excluded from regulation by the TGA? What are they and why should they be excluded?**

As stated in the proposed regulation, devices that are designed ***primarily with a medical purpose*** should be regulated. The proposed regulation has correctly identified the types of software-based products that should be excluded from the regulation.

- **Which approaches from international jurisdictions, if any, should be used to inform the Australian approach to this issue?**

The proposed regulation has correctly identified the appropriate approaches and regulations.

2. Suggested Improvements

The definition of Medical purpose may need to be more explicit with regard to a medical purpose for the patient exposed to the medical device. E.g. monitoring without a medical purpose will not make the software a medical device.

3. Support of Proposal

As previously highlighted, this is a well written regulation which has been thoroughly researched and the recommendations are appropriate. Suggested exemptions and exclusions have been correctly identified. I would fully support the implementation of this regulation.

4. An assessment of how the proposal will impact on my profession

I have been working in clinical research within the pharmaceutical industry for over 25 years. In that time huge advances have been made with respect to technology in the format of devices such as smartphones and watches as well as in the ability of software to better capture data and support patients. Unfortunately, the regulations have not kept up. There is a huge demand from patients in the health care industry but lack of appropriate guidance in current regulation has limited advances in the health care field. Appropriate regulation that accurately ensures the safety and wellbeing of patients is required to enable further advancement in this field. As technology moves forward at an increased rate with Artificial intelligence and customer demand it is imperative to have clear guidance on what must be regulated and what can be consumer driven.

In my current role we are looking at alternative, smarter technology ways to manage patient data in clinical trials. This regulation will give needed guidelines as to how we can use the new technology.

Thanks again for the opportunity to contribute to this review.