The Royal College of Pathologists of Australasia
ABN 52 000 173 231

Durham Hall 207 Albion Street Surry Hills NSW 2010 Australia
Telephone 61 2 8356 5858 Facsimile 61 2 8356 5828

RCPA
The Royal College of Pathologists of Australasia

29 May 2020

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden act 2606

E: devicereforms@health.gov.au

Re: Consultation – Scope of regulated software-based products

Thank you for your email of 23 April 2020 asking the Royal College of Pathologists of Australasia (the College) to give their view on the above important issue.

The College is generally supportive of the summary classification rules for software-based medical devices.

The College is also supportive of the proposal that certain medical software based products should be exempted when there is an alternative mechanism for oversight in place.

In the case of Laboratory Information Systems; Pathology related Clinical Decision Support Systems and Digital Pathology, the College would support these items being exempted as there is an alternative mechanism that could be accessed via the National Pathology Accreditation Advisory Council (NPAAC), the National Association of Testing Authorities (NATA)/RCPA accreditation process.

There may need to be development of further NPAAC Requirements to deal with these issues similar to the NPAAC Requirement for In House IVD's, particularly in relation to Pathology related Clinical Decision Support Systems.

The College will be very happy to work with the TGA and NPAAC to work through this issue.

[redacted]

Yours faithfully

[redacted]

President
Royal College of Pathologists of Australasia