The Director
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

16 October 2019

Dear Sir/Madam,

Re: Consultation: Proposed changes to medical device essential principles for safety and performance

Olympus Australia welcomes the opportunity to provide comment on the proposed changes to medical device essential principles for safety and performance and is supportive of the TGA's initiatives to wherever possible and appropriate, align with the European Union (EU) framework. We support most of the proposals given in the consultation, however Olympus Australia requests the following comments be taken into account before commencing with the proposed changes.

2. Do you agree with the proposal to provide additional clarity regarding expectations for compliance as specified under Proposal 2? In your answer, please provide reasons for your position.

We agree additional clarity regarding the points under Proposal 2 would assist the industry. Please provide guidance on how this clarity will be provided to the industry. Will these guidelines be incorporated into the Australian Regulatory Guidelines for Medical Devices (ARGMD) upon review? And will there be a separate consultation regarding these expectations?

4. Do you agree with the proposal that software medical devices without any physical packaging should include the ARTG number on the electronic label? Are there other devices where the ARTG number should be provided? In your answer, please provide reasons for your position.

We strongly disagree with this proposal, due to standard regulatory practice of obtaining European approval before TGA. We acknowledge under EU MDR these devices are required to include an "about" tab/electronic label that contains relevant information which would otherwise appear on a physical label label. However, all of the information included in this is added during the development phase and cannot be altered after registration in Europe without causing a software revision. As ARTG registration is obtained after European registration, this "about" tab cannot be modified unless the manufacturer initiates a software change after we register in Australia which will take time, have additional cost and delay entry of the software to the Australian market.

Should you have any queries regarding this submission please don't hesitate to contact on the phone number or email given below.

Thank you.

Kind regards,

[redacted]

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