[redacted]

[redacted]

[redacted]

30 August 2023

Tel [redacted]
Fax [redacted]
[redacted]

Device Reforms
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

Dear Device Reforms

[redacted] Comments on TGA Consultation: Proposed application audit framework for medical devices

[redacted] welcomes the opportunity to comment on Therapeutic Goods Administration (TGA) consultation seeking feedback on the proposed application audit framework for medical devices (July 2023).

[redacted] responses to specific questions on the consultation paper are provided below and are preceded by the consultation proposal and question.

Consultation proposal 6: We will limit the number of substantial review rounds to two, with any additional (substantial) rounds to be by exception only.

Consultation question 6:
Do you have any feedback about further measures to improve assessment timeframes?

[redacted] appreciates that restricting medical device and IVD application audits to two substantial review rounds will assist the TGA in reducing application queues and assessment timeframes. However, limiting the number of review rounds also increases the potential for the withdrawal and resubmission of an application, delaying patient access to medical devices and IVDs, as well as therapies with diagnostic selected indications.

We thank the TGA for providing the opportunity to participate in this consultation process and we look forward to receiving the outcomes of the consultation.

Kind regards,

[redacted]

[redacted]

[redacted]