Consultation questions	ResMed Feedback
Consultation question 1 ***Is there any additional information that the TGA could publish about the new application audit framework that would help with improving the quality of applications* to support more timely inclusion of devices?**	Alongside TGA proposal of publishing the risk factors and their categorization on the TGA website, some suggestions for improving guidance on the risk criteria for selecting medical devices for non-compulsory audits: • Categorize devices into risk tiers (e.g., high, medium, low) based on a combination of factors. Clearly define what factors contribute to each risk category and provide examples to illustrate the categorization process. • Scoring System: Consider implementing a scoring system that assigns numerical values to different risk factors. Manufacturers/Sponsors can use this system to self-assess the risk level of their devices, making it easier to understand how likely they are to be selected for a non-compulsory audit. • Risk Assessment Tool: Provide an online (or offline checklist) risk assessment tool or questionnaire that manufacturers can use to evaluate the risk level of their devices. The tool can calculate a risk score based on the provided information and indicate whether an audit is recommended. • Transparency: Be transparent about the weight given to each risk factor in the assessment process. This helps manufacturers understand the rationale behind audit selections. • Case Studies: Publish anonymized case studies that highlight real-world examples of devices selected for non-compulsory audits. This can provide practical insights into the risk assessment process.
Consultation question 2 ***Are there any concerns with limiting mandatory audits to high-risk devices only, noting that the TGA may select any device for a non-mandatory audit if required?***	No Concerns.
Consultation question 3 ***Are there any concerns with not subjecting high risk medical devices (including IVDs) supported by US FDA PMA certification to mandatory audits, noting that the TGA could select any such device for a non-mandatory audit if required?***	No Concerns.
Consultation question 4 ***What are the merits or risks of establishing a pathway for Class III medical devices based***	When Class III medical device are subjected to mandatory Level 2 audits the Sponsor is required to provide clinical evidence and risk management report. These documents are required as part of a US FDA 510(k) submission package.

on MDSAP certification and US FDA 510(k) approval?	Furthermore, the additional documents that TGA may require by exception (e.g. mechanical safety data, software design V^V, biocompatibility data, sterility etc.) are also part of the US FDA 510(k) submission package, where applicable. Hence, TGA would review same document s already reviewed by FDA. Based on the consideration above, establishing a pathway for Class III medical devices based on MDSAP certification and US FDA 510(k) should result in less burden and cost for both Sponsor and Regulator and support more timely inclusion of Class III devices. Note: please note that ResMed is not Manufacturer/Sponsor of Class III medical device therefore might not be aware of foreseeable/unforeseeable challenges of it implementation.
Consultation proposal 5 ***Are there any concerns with formalising the requirement for the submission of:*** ***(a) IFU and CER for all Class III devices supported by EU MDR certification?*** ***(b) IFU and Performance evaluation (clinical and analytical) reports for all Class 4 IVDs supported by EU IVDR certification?***	No Concerns and/or observations. However, please note that ResMed is not Manufacturer/Sponsor of Class III MD and/or Class 4 IVDs, therefore might not be aware of foreseeable/unforeseeable challenges of it implementation.
Consultation question 6 ***Do you have feedback about further measures to improve assessment timeframes?***	Provided that Sponsor are allowed to request for extension to supply information when deemed necessary and as the TGA is will give the opportunity to discuss issues via a phone or video call before responding, no further comments.
Consultation question 7 ***What information could the TGA provide that would be useful for sponsors to have greater visibility of application timeframes?***	ResMed appreciated that the interim system to provide timeframe visibility will need to be weighed against the TGA digital transformation project, where further improvement can be implemented don this matter; however, there are improvement that TGA should implement in the interim: • Publish: ○ clear and realistic standard processing timeframes for different types of applications, helping sponsors set expectations for the review process;

	○ historical data on average review times for different types of applications and categories of medical devices. This data can help sponsors understand how long similar applications have taken in the past. • Estimated Review Milestones: Break down the review process into key milestones, such as application validation, assessment, and decision-making. Provide estimated timeframes for each milestone; • Status Updates: Update the status of applications and provide notifications to sponsors when their applications move to the next stage or if any delays are expected. This can be done through automated emails or messages; • Estimated Queue Position: If applicable, inform sponsors of their estimated position in the queue of pending applications and/or Audit review. Knowing their place in line can help sponsors plan accordingly. • As part of the TGA digital transformation: • Online Application Tracking: Develop an online portal or system that allows sponsors to track the status of their applications in real-time. This portal should include information on which stage of the review process the application is currently in, including notifications to sponsors when their applications move to the next stage or if any delays are expected. • Develop interactive tools or calculators that allow sponsors to estimate the likely timeframe for their specific application based on its characteristics and complexity at a specific time (considering TGA backlog)