# Response ID ANON-CBS3-RZA5-D

Submitted to Consultation: Proposed changes to the IVD medical device classifications and definitions
Submitted on 2025-03-18 16:55:31

## Introduction

What is your name?

Name:
[redacted]

What is your email address?

Email:
[redacted]

What is your organisation?

Organisation:
[redacted]

## Responding to this Consultation

Question 1(a): Do you agree with the proposals to change the Australian classification rules and principles that have an impact on approved products (as specified in the first Section of the paper), noting the changes are reflective of the regulatory scrutiny based on the associated health risks?

Respond to the question 1a:

Currently, much of this industry is self-regulated. In Europe, IVDR-registered kits are used, ensuring a high standard of validation. However, in Australia, laboratories can develop their own in-house assays and validate them through self-assessment, which is not as stringent as the requirements for kit manufacturers.

Therefore, I agree with the proposed changes, as they will not significantly alter the current status

Question 1(b): If no, which of the proposed changes do you not agree with? Please provide your reasons.

Respond to the question 1b:

as Above

Question 1(c): Are there any other classification rules and principles, relating to the IVD medical devices, that need to be considered as part of this proposal?

Respond to the question 1c:

In my opinion, the quality of reporting and diagnosis will significantly improve if facilities are required to switch to commercial kits rather than relying on their own in-house methods. This change will standardize results across different laboratories and ensure that all tests meet the stringent validation requirements of the IVDR. Currently, results can vary from lab to lab due to differences in self-assessment protocols, which are not as rigorous as those required for commercial kits

Question 2(a): Do you agree with the proposals to adopt certain terminology in the Australian classification rules that have no impact on approved products (as specified in Appendix A of the paper), noting the changes are to improve clarity?

Respond to the question 2a:

I have no opinion

Question 2(b): If no, which of the proposed changes do you not agree with? Please provide your reasons.

Respond to the question 2b:

Question 2(c): Do you agree the proposed changes in Appendix A of the paper, would not result in any impact on existing ARTG entries of IVD medical devices?

Respond to the question 2c:

No opinion

Question 2(d): Are there any other classification rules, relating to the IVD medical devices, that need to be considered as part of this proposal?

Respond to the question 2d:

the TGA registers the commercially available devices , kits etc that enter the country

After that , the industry regulates itself , and most of this becomes irrelevant

I don't believe any changes made will alter a thing ,

In the area of HPLC and LCMS diagnostics
Australia has the lowest rate of kits sold per head of capita in the modern world

Reason , because they are not required to use an IVDR validate method and can make up their own assay

Question 3(a): Do you agree with the proposal to amend the Australian definitions as specified in Appendix B of the paper?

Respond to the question 3a:

no opinion

Question 3(b): If no, which of the proposed changes do you not agree with? Please provide your reasons.

Respond to the question 3b:

Question 3(c): Are there any other definitions, relating to the IVD medical devices, that need to be considered as part of this proposal?

Respond to the question 3c:

Requirement to use commercially available IVDR products registered with TGA , and in house assay only if no ki are registered

Question 4(a): Do you agree with the proposal to apply a 6-month transition period after the EU IVDR transition timelines for the proposed Australian amendments to take effect?

Respond to the question 4a:

we lag the world, so it is always in transition

Question 4(b): Provide reasons for your position.

Respond to the question 4b:

I had a NATA calibration certification in thermocycler calibration
and more than 95% of the labs in Australia , did not calibrate their machines , because there is no government body forcing them to do so

It is the same with TGA registered medical devices , in this case our kits

Although they are proven IVDR , no authority is regulating to use commercial TGA registered kits

so in-house methods are commonplace

Question 5: Do you consent to your response being made publicly available on the TGA's Consultation Hub website? Please indicate your publishing preferences.

I consent to my submission being published anonymously (without my name or my organisation's name)

Question 6: If you consent to your submission being published, are there parts that you do not want published? Please specify which part(s). Please note – your contact email address and/or phone number will not be published with your submission.

Respond to the question 6: