

June 2023

To Whom It May Concern:

I would like to confirm that all products which are manufactured by Reagecon, are not In-Vitro Diagnostic Devices. These products are not intended for parenteral or in-vivo use of any type. It is imperative that our products are not to be used in vitro.

However, our products can be used for general laboratory use or for external quality assessment as per the exemptions in the IVDR Regulations.

Yours sincerely,



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Dean Meagher

Regulatory Compliance Manager