EUROPEAN IN-VITRO DIAGNOSTIC DEVICES DIRECTIVE (IVDR 98/79/EC) - UK NEQAS RESPONSE

The European Union In Vitro Diagnostics Regulation [Regulation (EU) 2017/746 (EU IVDR)] was implemented on 26th May 2022. This is an important regulation and applies to manufacturers, importers, and distributors of IVDs within the European Union.

UK NEQAS, as the leading supplier of external quality assessment (EQA) schemes worldwide, feels it important to clarify the position of EQA materials within the IVDR regulations [https://euivdr.com/].

Within the IVDR regulation, Chapter 1, Section 1, Article 1 'Subject matter and scope', point 3 states:

> *3. This Regulation does not apply to:*
> *(a) products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;*
> *(b) invasive sampling products or products which are directly applied to the human body for the purpose of obtaining a specimen;*
> *(c) internationally certified reference materials;*
> ***(d) materials used for external quality assessment schemes.***

This statement clearly shows that EQA materials are not required to meet IVDR regulations. As such no action is required by **UK NEQAS** or any of our European Union participants with regards to the continued provision and participation in **UK NEQAS** EQA schemes with regards to the IVDR regulation.

As always, we are proud to continue to support you and thank you for your continuing participation with **UK NEQAS**.

Source: UK NEQAS Board. Posted: 19th January 2023.