DCB0129

Clarification Statement

British In Vitro Diagnostics Association (BIVDA)

6 September 2023

BIVDA (British In Vitro Diagnostics Association) is the national industry association for manufacturers and distributors of in vitro (IVD) products in the UK, representing almost 250 organisations including multi-nationals, SME's and micro companies.

BIVDA members supply IVD products, equipment, tests, quality controls, pre-analytical consumables and services to the NHS and other health institution laboratories within a highly regulated environment.

This statement is to formally clarify that DCB0129 (often requested as part of DTAC) is not required for analysers and analytical platforms that are standalone, not embedded and are regulated in their own right as medical devices.

The scope of DCB0129 does not extend to equipment that is not implemented within a Health IT system in accordance with the guidance Applicability of DCB 0129 and DCB 0160 - NHS Digital.

If analytical platforms or analysers are connected to a Middleware or LIMS solution, the Middleware or LIMS in the context of the care pathway is in scope of DCB0129.

The integration and connection of an analytical platform, or analyser does not change the classification of a medical device or IVD that is regulated in its own right.

BIVDA has sought and gained confirmation from NHS England who maintain that this is clear in the interpretation and explanation guidance provided.