



Agilent Technologies, Inc.
5301 Stevens Creek Boulevard
Santa Clara, California 95010

September 2023

Agilent In-Vitro Diagnostics Regulation Position Statement

The EU's In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746 is a new, harmonized regulatory framework established to ensure the present and future safety and performance of in vitro diagnostic (IVD) medical devices in the EU. It replaces the previous IVD Directive (IVDD) 78/79/EC, under which many Agilent products have been CE-IVD marked, certifying compliance. Given the timelines and complexities of developing IVD medical devices and receiving regulatory approval, the European Commission adopted a progressive rollout of the Regulation, establishing new transitional periods according to device risk classes.

At Agilent, we are fully committed to compliance with regulatory requirements. We also recognized that this new IVDR framework would not only affect us as a manufacturer of in vitro diagnostics, but it would have significant impact on our customers who use our portfolio of products in their diagnostic laboratories. Our multi-disciplinary team with deep experience in European regulatory requirements for IVDs came together to make this a seamless transition for our customers as we endeavored to fulfill IVDR requirements within the established timelines.

In June 2022, we announced that our previously CE-IVD marked Class A instruments, kits, and reagents were released under IVDR in compliance with the new Regulation. This ensured that EU laboratories reliant on Agilent IVD products for their diagnostic workflows were able to continue to use these products without disruption. Since then, we have been working diligently to prepare for and meet the remaining IVDR requirements and timelines for Class B and Class C products. Agilent's Quality Management System has been initially certified for compliance with IVDR, and assessments of conformity and technical documentation for representative devices have also been successfully completed. As new products are introduced into the European marketplace, Agilent is partnering with its Notified Body to ensure products meet IVDR requirements.

Should there be any impact to our customers as we continue this transition journey, we will provide additional communication at that time.

Thank you. We look forward to continuing to serve you.

Sincerely,

A handwritten signature in black ink that reads "Jenipher E. Dalton". The signature is fluid and cursive, with a large initial "J".

Jenipher Dalton
Senior Vice President
Global Quality & Regulatory Affairs