Agilent

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Agilent In Vitro Diagnostics Regulation Position Statement

The European Union is making significant changes to its regulation of Medical Devices and *In Vitro* Diagnostics. These changes, termed "In Vitro Diagnostics Regulation" or "IVDR" are intended to ensure that medical products released in the European Union are safe, effective, and will perform as intended.

Agilent is fully committed to compliance with regulatory requirements, and our work is well underway to ensure that our products fully comply with IVDR. Agilent's Global Quality and Regulatory Affairs team, with deep experience in European regulatory requirements for in vitro diagnostics, is instrumental in evaluating Agilent's products and processes for compliance with IVDR. Areas of focus in this evaluation include:

- Product testing and validation
- Supplier controls
- Software validation
- Manufacturing processes
- Quality Assurance and Quality Control
- Clinical data
- Enhancement of processes and procedures to ensure compliance with IVDR reporting requirements.

While there has been much industry discussion regarding a possible delay in the implementation date for IVD products, Agilent plans to meet the requirements of the new Regulations by May of 2022. Should there be any impact to our customers as we continue this journey, we will provide additional communication at that time.

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

Jennifer M. Dalton

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