Our commitment to quality continues as EU reaches regulatory milestone

To be certain, May 26, 2022, marked the beginning of a new era of regulation. But the transition leading up to that initial deadline of the EU's landmark In Vitro Diagnostic Medical Devices Regulation (IVDR) was no small climb.

In fact, the pandemic prompted the European Parliament to amend the IVDR's transitional provisions and deadline for systems already on the market — known as legacy devices. That amendment came in January 2022. And although the May 26 deadline went into effect for new products *and* for products that had *significantly* changed, the European Parliament extended the transition phase for others. That deadline now varies, depending on product class.

"Ensuring patient safety has been the most important driving force behind the IVDR from the very start," explained Noor Malki, Head of Regulatory & Quality Operations for Siemens Healthineers Laboratory Diagnostics. "And while we've always fully embraced the spirit of the regulation, our work towards full compliance continues — with our focus riveted on delivering quality in all that we do."

For most, if not all, IVD manufacturers, meeting the IVDR requirements will occur in stages — as this sweeping regulation increases the number of devices subject to regulatory oversight across the entire industry, and it broadens the breadth of compliance, with no grandfathering in of products already on the market.

For Siemens Healthineers, that means roughly 2,700 IVD products for sale in the EU are affected by the regulatory change — across the Laboratory Diagnostics, Molecular Diagnostics, and Point of Care businesses.

"By working to meet the requirements of the IVDR in as timely a fashion as we can — while also communicating our progress to customers and other stakeholders — our efforts have been directed at ensuring that the systems our tests run on remain available to laboratorians and clinicians," explained Kerstin Wagner, Head of Marketing and Sales Operations for Siemens Healthineers Laboratory Diagnostics. "We fully understand how critical these diagnostic solutions are to their ability to deliver the kind of high-quality care that leads to the best possible outcomes for patients."

Notably, as the five-year transition period for the new regulation neared its initial May 26 deadline, Siemens Healthineers was already one of the first companies to implement IVDR requirements within our comprehensive product portfolio, with our first IVDR certificate issued in July 2021.

"The intensity of our effort continues," Kerstin underscored. "Because when all is said and done, complying with the IVDR is about ensuring that our breakthroughs in healthcare continue to benefit *everyone, everywhere*."

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