SIEMENS Healthineers

Press

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Siemens Healthineers has received first IVDR certifications to keep in-vitro diagnostics available throughout the EU

- **The TÜV Rheinland certification agency has granted Siemens Healthineers' first IVDR certifications for in-vitro diagnostics.**
- **Certifications comply with Europe's new In-vitro Diagnostic Regulation (IVDR), and will be required for products sold within the EU from May 2022 onward. A transitional regulation allows established, non-IVDR-certified products to be sold and used if they entered the EU before May 2022.**

Siemens Healthineers has announced that its first products have been certified by the TÜV Rheinland certification agency as complying with the European In-vitro Diagnostic Regulation (IVDR), EU 2017/746. These certifications granted by notified bodies like TÜV Rheinland are required for in-vitro diagnostics to continue being sold in the EU. The IVDR's extensive requirements were adopted by the European Parliament in 2017 and must now be implemented by May 26, 2022. Siemens Healthineers has steadily implemented the EU's regulatory requirements and made all the necessary preparations to get more than 4000 products for laboratory, molecular and point-of-care diagnostics certified.

"It's an extraordinary team achievement for us to enable a successful transition to the new regulation in spite of the COVID-19 pandemic," said Kerstin Wagner, Head of Marketing for Laboratory Diagnostics at Siemens Healthineers. "The entire industry had to set new priorities, such as bringing COVID-19 tests to market in record time and overcoming constraints in the global supply chain. These challenges have made the implementation of the IVDR more difficult, but have not delayed it so far."

TÜV Rheinland has now certified the first 129 in-vitro diagnostic products from Siemens Healthineers for hemostasis and nephelometry. These were prioritized in accordance with IVDR classifications because they serve to diagnose and monitor treatment of critical

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diseases. These certifications confirm that the products meet the IVDR's high quality standards, which focus on protecting the health of patients and users. To safeguard those standards now and in the future, the IVDR calls for additional performance assessments over and above its predecessor directive, based on scientific, clinical and analytical data. It also improves traceability in the supply chain and establishes a proactive monitoring system for the early detection of issues in products already in circulation. Along with further changes, the new regulation also expands the responsibility of the notified bodies. Previously, they were involved in less than 20 percent of the regulatory procedures for all aspects of in-vitro diagnostics; now they need to be included in around 80 percent.

The IVDR becomes mandatory as of May 26, 2022. There are also transitional rules that will allow well-established instruments that have not been IVDR-certified, but have entered the EU previously, to still be sold until 2025. Depending on their shelf lives, these can also be used after 2025. Siemens Healthineers has been investing in IVDR compliance since 2017, and chose TÜV Rheinland, a notified body that was able to begin certifying the entire relevant portfolio. Siemens Healthineers expects more than 4000 products to be certified in good time by May 2022, and thus, continuous, extensive patient care can be maintained.

This press release is available at
https://www.siemens-healthineers.com/press/releases/ivdr.
For further information, please see
https://www.siemens-healthineers.com/laboratory-diagnostics/ivdr.

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continuously developing its product and service portfolio, with AI-supported applications and digital offerings that play an increasingly important role in the next generation of medical technology. These new applications will enhance the company's foundation in in-vitro diagnostics, image-guided therapy, in-vivo diagnostics, and innovative cancer care. Siemens Healthineers also provides a range of services and solutions to enhance healthcare providers' ability to provide high-quality, efficient care to patients. In fiscal 2020, which ended on September 30, 2020, Siemens Healthineers generated revenue of €14.5 billion and adjusted EBIT of €2.2 billion. Following the acquisition of Varian Medical Systems, Inc. the company has approximately 66,000 employees worldwide. Further information is available at www.siemens-healthineers.com.