

## TÜV Rheinland Announces the Issuance of its First IVDR 2017/746 Certificate



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TÜV Rheinland LGA Products GmbH, a global leader in independent technical services is pleased to announce the issuance of TÜV Rheinland's first IVDR certificate under the [EU In Vitro Diagnostic Medical Device Regulation 2017/746](#). The conformity assessment including the evaluation of general safety and performance requirements set out in Annex I and relevant Annexes are conducted through technical documentation review and audit to determine if devices meet the requirements. A certificate was issued to Siemens Healthcare Diagnostics Products GmbH. It marks the first IVDR CE certificate for Siemens Healthineers that has been issued by TÜV Rheinland under the IVDR regulation (EU) 2017/746.

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First IVDR certificate for Siemens Healthineers includes the following products:

- Hemostasis reagents
- Plasma protein reagents
- Quality controls and calibrators for hemostasis and nephelometry analyzers

Stable access to quality equipment through the transition period is very important, and Siemens Healthineers' commitment to begin updating their IVDR certifications early is commendable.

Global operator, TÜV Rheinland, offers customers an extensive list of services which includes Regulatory Compliance, Product Performance, Engineering Analysis and Reliability Services for various active and non-active medical devices, and In Vitro Diagnostic devices. TÜV Rheinland LGA Products GmbH is a Notified Body of the EU In Vitro Medical Device Regulation (IVDR) 2017/746. The IVDR came into effect on May 25, 2017 and will replace Directives 98/79 (IVDD) on May 26, 2022.

TÜV Rheinland stands for safety and quality in virtually all areas of business and life. Founded almost 150 years ago, the company is one of the world's leading testing service providers with more than 20,000 employees and annual revenues of 2 billion euros. TÜV Rheinland's highly qualified experts test technical systems and products around the world, support innovations in technology and business, train people in numerous professions and certify management systems according to international standards. In doing so, the independent experts generate trust in products as well as processes across global value-adding chains and the flow of commodities. Since 2006, TÜV Rheinland has been a member of the United Nations Global Compact to promote sustainability and combat corruption.  
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