Press release

altona Diagnostics receives the IVDR QMS certificate

Hamburg, Germany, December 12, 2024

In the fall of 2024, altona Diagnostics received the certificate for compliance with all applicable requirements of the *In Vitro* Diagnostic Medical Devices Regulation (IVDR; EU 2017/746) for their PCR testing products. altona can now launch CE-IVD marked products under the IVDR. The first assay to be launched will be the AltoStar® Parvovirus B19 PCR Kit 1.5 in January 2025, followed by a large set of AltoStar® assay products in spring of 2025.

The IVDR
Regulation (EU) 2017/746, also known as the *In Vitro Diagnostic Medical Devices Regulation* (IVDR), is a European Union regulation aimed at ensuring the safety, quality, and performance of *in vitro* diagnostic (IVD) medical devices used within the EU. It was adopted in 2017 and came into effect on May 26, 2022, replacing the previous *In Vitro Diagnostic Medical Devices Directive* (IVDD 98/79/EC). The IVDR introduced stricter requirements for the approval, performance, and post-market surveillance of IVD devices in the EU. To allow manufacturers and notified bodies to meet the new requirements, there are transitional periods for different device classes, with deadlines extending up to 2029 for certain legacy devices.

The altona path to IVDR certification
altona Diagnostics has been working for years on the development of products that meet the new requirements under the IVDR. With the granting of the IVDR QMS certificate, altona has reached the milestone of being able to continue the availability of their PCR testing products under the IVDR.

After these years of preparatory work towards altona's IVDR compliance – first with the designation of altona's notified body in 2023 and in 2024 with the passing of the first QMS audit under IVDR – altona has been awarded with the EU Certificate for Quality Management Systems under the new Regulation (EU) 2017/746 IVDR.

Dr. Sven Cramer, Head of Regulatory Affairs at altona, points out: "IVDR compliance is in line with altona's commitment to providing products that can be used safely, show a consistently high performance and deliver robust and reliable results."

Launch of altona IVDR cleared products in 2025
Thanks to their anticipatory efforts to prepare their products for the IVDR, altona will be able to make both their AltoStar® and FlexStar® PCR testing assay product lines available to healthcare professionals in laboratories long before the new transition periods for legacy devices expire. The first wave of products of the automated workflow product line, AltoStar®, will be IVDR cleared as early as in spring of 2025 starting with the AltoStar® Parvovirus B19 PCR Kit 1.5 in January 2025. This *in vitro* diagnostic test is based on real-time PCR technology and is intended to detect and quantify parvovirus B19 specific DNA in human plasma. Parvovirus B19 causes childhood rash called fifth fever, and is a virus frequently tested for monitoring of transplant and immunocompromised patients.

Then in quick succession thirteen AltoStar® kits will be launched, among them our products of the transplant and immunocompromised panel.

About altona Diagnostics
altona Diagnostics is a medical diagnostic company that develops and manufactures *in vitro* diagnostic tests for the PCR based detection of pathogens such as viruses, bacteria, or parasites. Headquartered in Hamburg-Altona, Germany, altona Diagnostics is privately owned and employs more than 350 people worldwide, thereof 300 in Hamburg, Germany. The company has been in the molecular diagnostics business for over 25 years and is ISO 13485 certified. altona Diagnostics sells its registered products to medical laboratories globally through subsidiaries and more than 40 distribution partners.

Molecular diagnostic tests from altona Diagnostics are based on real-time PCR technology. altona Diagnostics offers the AltoStar® Molecular Diagnostic Workflow, an automated solution that is complete with instrumentation, reagents, consumables, and software. Furthermore, the company's product catalog contains over 50 CE marked PCR tests that are also compatible with open real-time PCR platforms.

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Resources

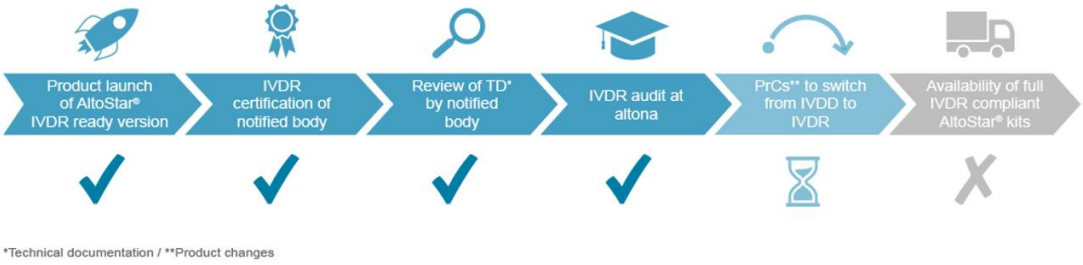
altona Diagnostics website area about IVDR
https://altona-diagnostics.com/ivdr-and-altona-diagnostics/

Official European Union website about IVDR
https://eur-lex.europa.eu/eli/reg/2017/746/oj

Explanatory graphics

IVDR transition periods

The altona IVDR path



Remark: The graphics provided are only to be used in the context of this press release.