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## R-Biopharm is IVDR certified



Darmstadt (ots) -

The quality management system of the biotechnology company complies with the European in-vitro Diagnostic Regulation (IVDR)

Quality orientation is an integral part of the culture and processes at R-Biopharm AG. The biotechnology company from southern Hesse thus ensures that quality is integrated throughout the entire company and continually improved in order to deliver reliable products for the health of patients in the long term. The family owned company has regular audits conducted to check the suitability and functionality of all quality-related elements. In fall 2021, R-Biopharm was one of the first companies to undergo the comprehensive audit for the new IVDR certification by TÜV SÜD and has now received the certificate.

What has become mandatory for manufacturers of *in vitro* diagnostics throughout Europe after a five-year transitional phase at the end of May 2022 in accordance with the European regulation for *in vitro* diagnostics has already been proven by the biotechnology company in fall 2021. The IVDR certification will ensure that R-Biopharm can continue to offer its clinical *in vitro* diagnostics in Europe and worldwide according to the stricter legal requirements. The simultaneous recertification according to MDSAP (Medical Device Single Audit Program), ISO 9001:2015, and DIN EN ISO 13485:2016 as well as the Directive for *in-vitro* diagnostics 98/79/EC makes R-Biopharm one of only few companies worldwide that are currently certified according to these four standards.

With its holistic quality management system, R-Biopharm ensures that normative and regulatory requirements are fulfilled from the development to the application of products and that correspondingly high-quality standards apply. "In our company, quality is not the action of a few but rather the attitude of all our employees", says board member Dr Hans Frickel. "Our focus on quality is also highly relevant internally. By applying quality-oriented standards, we can detect risks and errors, efficiently design working methods, identify our strengths and potentials, and derive needs for action that will help us to continually improve".

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#### Medieninhalte



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