Press release

Molecular Health receives IVDR certification for MH Guide

Molecular pathology laboratories now benefit from the highest possible diagnostic reliability and quality in the automated interpretation of genetic tumor profiles

Heidelberg, Germany and Boston, USA – 13 July 2022 – Molecular Health, an international biotech IT company based in Heidelberg, Germany, has received European Union certification for its MH Guide *clinical decision support* software (SaaS) under the new In Vitro Diagnostics Regulation (EU) 2017/746 (IVDR). The MH Guide software, which is used in molecular pathology laboratories, is the first of its kind in Europe to receive this certification.

The new In Vitro Diagnostics Regulation (IVDR) differs from the previous Directive (IVDD) in several important aspects. Among important changes like a new risk-based classification system and a unique product numbering system to simplify the traceability of products within the supply chain is also a more in-depth involvement of notified bodies, such as TÜV SÜD Product Service GmbH, for the conformity assessment. Stricter requirements for technical documentation and clinical evaluation provide an even higher level of safety for users in the future. Finally, the IVDR also places increased obligations on the demonstration of analytical and clinical performance and requires evidence that safety of a device is adequate for its respective risk class. In addition, manufacturers must meet high data collection and assessment requirements as part of ongoing market surveillance on potential safety risks.

IVDR becomes the quality standard for molecular diagnostics

“Molecular pathology is now used to support many oncological therapy decisions,” explains Prof. Peter J. Wild, Director of the Dr. Senckenberg Institute of Pathology (SIP) at Frankfurt University Hospital. “It is therefore all the more important that all diagnostic examinations and analyses are subject to the highest quality requirements. This is guaranteed with the new IVDR regulation. It is important for us that we use the MH Guide software for the comprehensive clinical interpretation of genetic tumor profiles – which we have been doing for several years – as one of the first applications to meet this standard.”

Dr. Friedrich von Bohlen, CEO of Molecular Health, adds: “We are pleased to be one of the first companies to have initiated and completed on time the implementation of the new IVDR quality management and documentation requirements. When it comes to understanding serious diseases and supporting molecular pathologists in their clinical reporting, there can be no compromise on quality. This has been and remains our highest priority for our products and development services. We are certain that these regulations will gain importance against the backdrop of much needed digitalization in healthcare systems.”

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About Molecular Health:

Molecular Health is an international biotech IT company based in Heidelberg, Germany, that has been developing innovative software in the areas of *in silico* and precision medicine since 2004. Molecular Health's solutions make it possible to transform large amounts of data into evidence-based, medically relevant decision-making aids. They are used where precision medical care for patients and efficient drug development require increasingly complex data interpretations. At Molecular Health, specialists from the fields of medicine, data science, biology and bioinformatics, as well as software development, are working on making Big Data usable for healthcare. The result is intuitive analytical applications that are individually tailored to different healthcare requirements. Molecular Health is a portfolio company of dievini Hopp Biotech holding GmbH & Co KG.

For more information, visit www.molecularhealth.com.