

Cerca Biotech Announces ISO 13485:2016 Certification

BERLIN, GERMANY, September 21, 2023 /EINPresswire.com/ -- [Cerca Biotech](#) GmbH ("Cerca"), a Germany-based diagnostic company in oncology and women's health, today announced that its quality management system (QMS) has achieved ISO 13485:2016 certification for the design and development, production and distribution of in vitro diagnostics and software for molecular testing.

ISO 13485 is a globally recognized standard, published by the International Standards Organization, setting out the requirements for quality management systems for diagnostics and medical devices. "Compliance with the ISO 13485 standard ensures that we offer our customers quality products and services. We strive to provide better solutions in oncology and women's health through our innovative diagnostic products such as [MammaTyper®](#)," said Jay Z. Zhang, CEO of Cerca Biotech.

About MammaTyper®

MammaTyper® is a standardised multiplex real-time PCR test that quantifies mRNA levels of four essential breast cancer biomarkers (ER, PgR, HER2, and Ki-67) in surgical or biopsy tissue to stratify breast cancer into subtypes according to the St Gallen Guideline. Compared to the traditional immunohistochemistry (IHC) subtyping, MammaTyper® is a qPCR assay that provides objective and reproducible test results in a shorter turnaround time and obviates subjective IHC scoring by pathologists. Moreover, a large body of published clinical studies have demonstrated that MammaTyper® offers more accurate breast classification and can guide more effective treatment leading to improved patient outcome.

About Cerca Biotech:

Cerca Biotech is a Germany-based diagnostic company focused on bringing novel and innovative diagnostic products to the oncology and women's health market. We strive to introduce the best tests to meet the unmet clinical needs at an affordable cost, with clinical accuracy and rapid results to the fore. Utilising a mixture of experienced distributors and some direct sales Cerca has a commercial reach from Germany, the UK through the Nordics and Eastern Europe to the Middle East, India and beyond. Our team comprises of highly experienced commercial, technical and clinical experts in the field of IVD, allowing rapid deployment of novel technologies with a 'get it right first time' strategy. Cerca Biotech is an affiliated subsidiary of Shuwen Biotech. For more information, please visit: www.cercabiotech.com.

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