

OGT first to achieve IVDR-certification for FISH probes

Norderstedt, Germany, 29 March 2023 – OGT, a Sysmex Group company, announces that IVDR-certification has been granted for eight CytoCell® fluorescence in situ hybridisation (FISH) probes important for patient management in haematological cancers and prenatal conditions. This award places OGT as the first manufacturer of FISH probes to obtain the new IVDR certification on its products – demonstrating continued safety, reliability and effectiveness under this substantially more stringent regulation.

Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) replaced Directive 98/79/EC on in vitro diagnostic medical devices (IVDD) on 26 May 2022. From this date, any new IVD products placed on the EU market must comply with the IVDR.

To avoid the anticipated backlog of IVDR conformity assessments, OGT committed early to IVDR and began discussions with a notified body, BSI, back in 2019. Since then, OGT has been working tirelessly to be 100% IVDR-ready and to meet conformity requirements under the regulation. This encompasses not just the safety and performance of its products but also facilities, manufacturing systems, supply chain, quality management system (QMS) and more. The culmination of this work has led to the certification of its first tranche of eight existing FISH probes as Class C devices under the IVDR, with further products to follow.

The IVDR certification means that customers can be confident in the continued quality, safety and performance of OGT's products and manufacturing processes. Being IVDR-compliant and already having products certified will also help to future-proof customer supply chains – adoption of OGT's products will avoid the need to change suppliers and revalidate if IVDR products are not available from other companies.

For further information or to receive notification when the IVDR-certified probes are available, please register on the OGT website: www.ogt.com.

Steve Chatters, Executive Vice President of Regulatory, Medical and Quality Affairs, OGT: “IVDR is all about patient safety and effectiveness, and at OGT, we're really committed to compliance with changing worldwide regulations and providing products that meet these needs, for clinicians and patients alike. We have a great team that got us ahead of the game and in a rare position of not only being 100% IVDR-ready but gaining certification for our first set of CytoCell FISH probes. This demonstrates that OGT means what it says and that our products live up to the claims. Our IVDR FISH probes are still the same trusted products that we've always had – the certification has further validated our quality, safety and effectiveness. These are products and a company you can depend on.”

Adrian Smith, CEO of OGT: “I'm incredibly proud that OGT is the first FISH probe manufacturer to bring its probes to market under the new IVD Regulation. Gaining IVDR certification is a challenging process. This achievement is a testament to the clinical efficacy and safety of our products, the dedication of our people and our unwavering commitment to quality.”

Samantha Giangregorio, Head of Life Science, Vice President at Sysmex Europe: “It's exciting to have another pioneer product line getting IVDR certification in our portfolio. This is another step in the right direction following our patient-centric approach and playing our part in shaping the future of personalised diagnostics for supporting treatment decisions. Patients,

cytogeneticists and pathologists will be safer and have peace of mind when opting for IVDR-certified medical devices.”

About Oxford Gene Technology

OGT, a Sysmex Group company, is a leading global provider of clinical and diagnostic genomic solutions that are created for scientists by scientists – including CytoCell[®], CytoSure[®] and SureSeq[™] ranges of FISH, microarray and NGS products. The company is dedicated to creating products that enable researchers and clinical decision makers to reach the right care decisions for each patient, every time. OGT strives to unlock the future of genetic clinical care with a commitment to working in partnership with its customers – not only by sharing its expertise of 25 years at the forefront of genetic endeavour, but also by working closely with scientists to understand their unique challenges and to customise its approach to meet their exact needs. Dedicated to improving clinical care, OGT believes that through partnership – together – we’ll achieve more. For more information, please visit www.oqt.com.

CytoSure[®], SureSeq[™] and myProbes[®]: For Research Use Only, not for use in diagnostic procedures. CytoCell[®]: Some products may not be available in your region.

About Sysmex Europe SE

Sysmex supports healthcare professionals around the world in lighting the way with diagnostics by providing a broad range of medical diagnostics products and solutions. In the fields of haematology, urinalysis, haemostasis, life science, flow cytometry, essential healthcare and now immunochemistry, we combine highly dependable, multi-functional and easy-to-operate instruments, a variety of reagents and software, plus reliable service and support.

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