BSI issues its first certificate to the In Vitro Diagnostic Devices Regulation

BD earns certificate under Annex IX Chapter I & III

British Standards Institution (BSI), the national standards body for the United Kingdom and a designated European Notified Body, today announces it has certified its first group of products to the In Vitro Diagnostic Devices Regulation (IVDR) EU 2017/746 via its Netherlands Notified Body (2797).

The Annex IX Chapter I & III certificate covers two Class C Generic device groups for Monoclonal Antibodies/Flow Cytometry. Prior to the new, more stringent, legislation coming into force, these were classified as self-declared devices and did not need to be reviewed by a notified body under the IVD Directive.

The certificate has been granted to BD (Becton, Dickinson and Company), a leading global medical technology company based in Franklin Lakes, NJ.

Manuela Gazzard, Group Director for Regulatory Services at BSI, said: “We are delighted to be issuing our first conformity certificate under the new IVDR to BD Biosciences. This is a testament to their commitment to ensuring innovation remains at the forefront of their product development. These high-risk products will support patient safety at a critical time and are a sign of the resilience of our industry.”

Erica Conway, Global Head of IVD Medical Devices at BSI, added: “Approving our first IVDR devices is an honour. Achieving our IVDR designations and now delivering a conformity assessment under the new Regulation is evidence of the hard work, dedication, skills and expertise of our people. The Regulation is a significant challenge to the in vitro diagnostic device industry, and it brings greater regulatory requirements on all Economic Operators in the system from manufacturers and notified bodies to importers and distributors. We are proud to have expanded our expertise internally and met the stringent requirements. We continue to work towards certifying more devices under the IVDR, including those that are currently self-certified, to what are becoming tighter timelines as we approach the May 2022 deadline.

Puneet Sarin, Worldwide President for BD Biosciences shares, “Being the first medical technology company to receive the new IVDR Annex IX Chapter I & III, Class C certificate from BSI reinforces our commitment to quality and regulatory compliance. The new IVDR also reflects the European Union’s steadfast commitment to quality for all in vitro diagnostic devices and ensuring all such products meet the highest quality and regulatory compliance. I would like to thank both BSI for the timely and high-quality review of this first group of devices and the BD Biosciences cross-functional IVDR project team members who were instrumental in reaching this significant milestone.”

Ken Gelhaus, VP/GM Clinical Solutions for BD Biosciences adds, “BD Biosciences is pleased to be among the first medical technology companies to receive IVDR certification from BSI. Along with BSI, we recognize the utmost importance of the new requirements in IVDR and its positive impact on both customers and patients. This important event reflects our commitment, and we look forward to bringing additional products to IVDR compliance by May 2022.”

About BSI
BSI is the business improvement company that enables organizations to turn standards of best practice into habits of excellence. For over a century BSI has championed what good looks like and driven best practice in organizations around the world. Working with 84,000 clients across 195 countries, it is a truly international business with skills and experience across a number of sectors including aerospace, automotive, built environment, food, and healthcare. Through its expertise in Standards Development and Knowledge Solutions, Assurance, Regulatory Services and Consulting Services, BSI improves business performance to help clients grow sustainably, manage risk and ultimately be more resilient and trusted.

To learn more, please visit: www.bsigroup.com

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health™ by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance

researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit www.bd.com.

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