TÜV Rheinland Applies for Medical CAB Approval Under UKAS-MHRA Authorities

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TÜV Rheinland, a global leader in independent technical services, today announced it has applied for the new medical Conformity Assessment Body (CAB) approval under UKAS-MHRA Authorities. The United Kingdom Accreditation Service (UKAS) is the United Kingdom's sole National Accreditation Body (NAB) for undertaking mandatory and voluntary accreditation in the UK. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating the UK medical devices market. In the UK, medical devices and in vitro diagnostic medical devices must conform to the Medical Devices Regulations 2002 in order to be registered with the MHRA and placed on the market.

Contact:

Jen Picardo
Director of Communications - TUV Rheinland of North America, Inc.
978 506 7073

As of now, the MHRA will accept CE marking and associated EU conformity assessment certifications based on the Medical Device Directives 93/42/EEC, 90/385/EEC, and 98/79/EC as basis to place the medical devices on the market in Great Britain until June 30, 2023. However, after this date, it will be required to switch from CE marking to UKCA. Very recently, the MHRA started a public consultation on the future regulation of medical devices in the UK, so that currently defined requirements to use the UKCA mark might change after the transition period.

In order for medical devices to be registered with the MHRA after June 30, 2023, the device must first comply with a conformity assessment from a MHRA-designated UK Approved Body. A UK Approved Body ensures manufacturers comply with the regulations, including reviewing clinical and scientific data, manufacturing processes, and the quality management system. If they comply, the UK Approved Body will issue a UKCA certificate, which manufacturers use as the basis for placing the UKCA mark on their device to show that it has passed the conformity assessment. As of January 1st, 2021, the UKCA mark is voluntary. However, starting July 1st, 2023, the UKCA mark will become mandatory for medical devices and in vitro diagnostic medical devices. As of today, the UKCA mark will be based on the conformity assessment to the requirements of the UK Medical Devices Regulation 2002.

Kimberly McCoy, Global Vice President of Medical Products at TÜV Rheinland says, “We are looking forward to a successful approval and accreditation from UKAS-MHRA Authorities on becoming a UK Conformity Assessment Body (CAB). Once approved, we aim to support our customers with conformity assessments of their medical devices to ensure they meet the requirements of the UK Medical Devices Regulation 2002, allowing them to sell their products in the UK.”

TÜV Rheinland stands for safety and quality in virtually all areas of business and life. Founded almost 150 years ago, the company is one of the world's leading testing service providers with more than 20,000 employees and annual revenues of 2 billion euros. TÜV Rheinland's highly qualified experts test technical systems and products around the world, support innovations in technology and business, train people in numerous professions and certify management systems according to international standards. In doing so, the independent experts generate trust in products as well as processes across global value-adding chains and the flow of commodities. Since 2006, TÜV Rheinland has been a member of the United Nations Global Compact to promote sustainability and combat corruption.
Website: www.tuv.com