**UK Medical Devices Regulations: TÜV Rheinland is now a UK Approved Body according to UK MDR**

MDR: Stricter requirements for medical devices / TÜV Rheinland receives MHRA designation for UKCA certification according to UK MDR / Approved body number: 2571 / [www.tuv.com](http://www.tuv.com)

**Cologne, Germany, 21 Nov 2023.** TÜV Rheinland, one of the world's leading providers of testing and certification services, has been designated by the United Kingdom competent authority “Medicines and Healthcare products Regulatory Agency” (MHRA) to carry out UKCA certification in accordance with the Medical Devices Regulations in the United Kingdom (UK MDR).

"As a result of Brexit and with the switch from the CE mark to the UK CA mark, Notified Bodies accredited within the European Union are no longer empowered to certify medical devices on their compliance with UK regulations, explains Agnieszka Tabanska-Bira from TÜV Rheinland UK. “As a result, EU Notified Bodies wishing to operate within the United Kingdom long term must seek recognition from the competent authority MHRA”, Tabanska-Bira continues. UK Approved Bodies are appointed by the MHRA to determine whether manufacturers and their medical devices meet the requirements set out in the Medical Devices Regulations 2002.

TÜV Rheinland recognizes the British (UK) medical device market and medical device manufacturers located within the UK to be of major significance under a global perspective. As to be present locally and to be able to provide national certifications services to all manufacturers and distributors that intend to serve the market with medical devices and in-vitro diagnostics, TÜV Rheinland UK has founded a medical section last year. This part of TUV Rheinland UK has been added to the MHRA’s list of designated UK Approved Bodies just recently and is now able to help support patients access to safe and effective medical devices and in-vitro diagnostics needed to support general healthcare within the United Kingdom by verifying the quality and design of a device as it is defined to be suitable for each unit or batch. This reflects the core competency of TÜV Rheinland’s medical branch and is based on more than 25 years of experience.

*Safety and quality in almost all areas of business and life: That’s what TÜV Rheinland stands for. The company has been active for more than 150 years and is one of the world’s leading testing service providers. TÜV Rheinland has more than 20,000 employees in over 50 countries and generates annual sales of around 2.3 billion euros. TÜV Rheinland’s highly qualified experts test technical systems and products around the globe, accompany innovations in technology and business, train people in numerous professions and certify management systems according to international standards. In this way, the independent experts ensure trust along global flows of goods and value chains. Since 2006, TÜV Rheinland has been a member of the United Nations Global Compact for more sustainability and against corruption. Website:* [*www.tuv.com*](http://www.tuv.com)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Media contact:

TÜV Rheinland, Press Office, Tel.: +49 221 806-21 48

Press releases as well as photo and video footage are available on request by email to contact@press.tuv.com or on www.tuv.com/press.