Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/tuev-sued-gets-uk-approved-body-designation

TÜV SÜD gets UK Approved Body designation

TÜV SÜD has received approval as a UK Approved Body (UKAB) for medical devices. With this approval, medical device manufacturers can implement UKCA certification for the UK market and CE certification for the European market in a time- and cost-efficient manner with TÜV SÜD.

UKABs are responsible for carrying out conformity assessments of medical devices under the UKCA scheme. UKCA conformity assessments are necessary, analogous to the European CE conformity assessment procedure, in order to bring to market medical devices in the UK. The capacity to carry out UKCA conformity assessments for medical devices within the deadlines set by the government is scarce. The designation of TÜV SÜD as a UKAB helps to create new capacity. In addition, by obtaining both UKCA and CE certification through TÜV SÜD at the same time, medical device manufacturers can minimise costs and time to market for new products across Europe.

Monisha Phillips, Head of Medical and Health Services (MHS) Certification Body at TÜV SÜD UK, said: "Our designation with an almost full scope for general medical devices mirrors TÜV SÜD Germany's EU Notified Body scope. This will allow our medical devices clients to be fully supported for EU and UK market access, so they can optimise efficiencies. As the UK's Medical Device Regulations will only accept CE marked general medical devices on the Great Britain market until 30 June 2028 and 2030 (dependent on device type), the medical device market is under pressure to get medical devices transitioned to UKCA certification in just five years."

TÜV SÜD is designated as a UKAB for Part II of the UK Medical Devices Regulations 2002 (SI 618, as amended) for general medical devices. Full details of the scope of the designation can be found in the sidebar.

Press release

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Source: TÜV SÜD AG

Further information

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- TÜV Sued
- Document of Approval