

# Press Release



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Active Implantable Medical Devices

22 December 2023

## Seamless UKCA and CE certification for manufacturers with the extension of the Approved Body designation from TÜV SÜD

Munich. TÜV SÜD BAPT Unlimited is now a designated UK Approved Body (UKAB) for Part III of the UK Medical Devices Regulations 2002 (SI 618, as amended) for Active Implantable Medical Devices. It is the first UKAB to achieve a designation scope for active implantable medical devices after progressing through the full initial designation application process.

UKABs carry out medical device conformity assessments under the UKCA scheme. The scheme allows manufacturers to market their products in the UK. TÜV SÜD's UKAB designation will help ease market pressure, at a time when industry is concerned by the limited capacity to conduct UKCA medical device conformity assessments within specified government deadlines. TÜV SÜD's UKAB accreditation also offers medical device manufacturers the chance to gain UKCA and CE certification simultaneously which can reduce costs and time to market across Europe for new products.

Monisha Phillips, Head of UK Medical and Health Services (MHS) Certification Body at TÜV SÜD, said: "Extending our designation scope to include active implantable medical devices mirrors TÜV SÜD Germany's EU Notified Body scope and will allow our active implantable medical devices clients to benefit from our full support for EU and UK market access, so they can optimise efficiencies."

Full details of the scope of designation can be accessed here:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1178444/TUV\\_SUD\\_BAPT\\_Unlimited\\_Medical\\_Devices\\_Scope.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1178444/TUV_SUD_BAPT_Unlimited_Medical_Devices_Scope.pdf)

Further information:

- [www.tuvsud.com/uk](http://www.tuvsud.com/uk)
- [www.tuvsud.com/en-gb/industries/healthcare-and-medical-devices](http://www.tuvsud.com/en-gb/industries/healthcare-and-medical-devices)

## Media Relations:

TÜV SÜD AG Corporate Communications Westendstr. 199 80686 Munich, Germany	Dirk Moser-Delarami Phone +49 89 5791-1592 E-Mail <a href="mailto:dirk.moser-delarami@tuvsud.com">dirk.moser-delarami@tuvsud.com</a> Internet <a href="http://tuvsud.com/newsroom">tuvsud.com/newsroom</a>
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Founded in 1866 as a steam boiler inspection association, the TÜV SÜD Group has evolved into a global enterprise. More than 26,000 employees work at over 1,000 locations in about 50 countries to continually improve technology, systems and expertise. They contribute significantly to making technical innovations such as Industry 4.0, autonomous driving and renewable energy safe and reliable. [tuvsud.com](http://tuvsud.com)