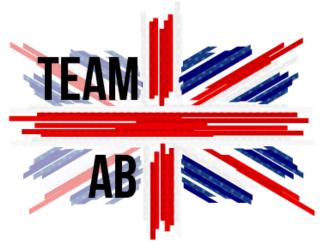
Approved Bodies for Medical Devices form Team AB

In recent years, the UK Regulatory landscape has been in a state of flux, presenting new challenges and opportunities for the entire medical device sector. Throughout this time, UK Approved Bodies (and those undergoing the designation process) have worked tirelessly to support this development.

In late 2023, a decision was made to bring this group of organisations together to officially form Team-AB (The UK Association for Medical Device Approved Bodies).

Team-AB represents UK Approved Bodies in their dealings with key stakeholders, including: the



Medicines and Healthcare products Regulatory Agency (MHRA), industry trade associations and other stakeholder groups where a combined effort is beneficial.

Team-AB will provide a forum for applicant and designated Approved Bodies to share experience, discuss pertinent topics and enable a united voice for medical device UK Approved Bodies. This is key to facilitate consistency in regulatory understanding and feedback to stakeholders in the coming years, given the anticipated evolution of the UK Medical Device Regulations.

Dr Monisha Phillips, Head of Approved Body at TÜV SÜD and Mr Vishal Thakker, Head of UK Approved Body at BSI, have been appointed co-Presidents of Team-AB for 2024 and will lead the organisation through its first year.

Founding members of Team-AB are:

- BSI Assurance UK Ltd
- DEKRA Certification UK Ltd
- DNV Business Assurance UK Limited
- DQS Medizinprodukte UK Ltd
- Intertek Medical Notified Body UK Ltd
- LNE-GMED UK Ltd
- Scarlet NB UK Ltd
- SGS United Kingdom Limited
- TUV Rheinland UK Ltd
- TÜV SÜD BABT Unlimited
- UL International (UK) Ltd

For contact and enquiries, please see the dedicated Team-AB LinkedIn page: https://www.linkedin.com/company/teamab/

Dr Monisha Phillips, Head of Approved Body at TÜV SÜD and Co-President of Team AB, said:

"At a time when the UK regulatory landscape is evolving and expecting to undergo significant changes, Team AB will offer an opportunity to bring consistency of interpretation of requirements across Approved Bodies that will benefit manufacturers and patients alike. I am excited and honoured to be involved in the creation of this group."

Mr Vishal Thakker, Head of Approved Body at BSI and Co-President of Team AB, said:

"With the everchanging UK regulatory landscape, we are at this moment to drive change by supporting the MHRA and the MedTech industry.

TEAM-AB provides an opportunity for us to work together by keeping all parties, including patients, in mind with the aim of bringing safe and effective medical devices to the UK market in a harmonised approach. It is great to see all the Approved Bodies get together and support the future of UK Medical Device Regulation. I am privileged to be one of the first Presidents of Team-AB"

Dr Laura Squire OBE, Chief Healthcare Quality & Access Officer at MHRA, said:

"The growth in Approved Body capacity is great news but it does make the job of ensuring consistency a little harder. I am delighted therefore, to see the formation of Team AB. We are at a point of real opportunity in the UK - we know that consistency and clarity of requirements matters to the medical device industry and is essential for ensuring the right products get to UK patients when they need them. I really look forward to working together with Team AB to achieve that goal."