MHRA appoints first new UK Approved Body to certify medical devices since Brexit

Press release

DEKRA Certification UK Ltd has now joined the three current UK Approved Bodies

The Medicines and Healthcare products Regulatory Agency (MHRA) has confirmed that DEKRA Certification UK Ltd has now joined the three current UK Approved Bodies, increasing the UK's capacity to process conformity assessments for medical devices to ensure safe and effective devices reach the UK public.

DEKRA has become the first organisation to complete the new designation process that any potential organisation must now go through in order to become approved to certify medical devices in the UK. They are now designated as a UK approved body to undertake assessments for general medical devices (known as Part II designation).

An approved body is an organisation that has been designated by the MHRA to assess whether manufacturers and their medical devices meet the requirements set out in the UK Medical Devices Regulations 2002.

With the exception of the very lowest risk devices, manufacturers must apply to a UK approved body. Only after they have UKCA certification can their products be placed on the market in England, Wales and Scotland.

Following an appropriate assessment, the approved body will issue relevant certification allowing manufacturers to place a UKCA marking on their products before putting them on the market.

Dr Laura Squire, MHRA Chief Healthcare Quality and Access Officer said:

> This is a major milestone in our mission to ensure patients across the UK have access to the high-quality medical devices they need to

> protect their health.
>
> Approved Bodies play a critical role in the supply of medical devices and expanding capacity is vital to the successful development of the UK's medical device regulatory regime. This has been a significant piece of work and our teams have worked extremely hard to get to this stage.

The MHRA's detailed assessment process is designed to ensure that any organisations that wish to certify medical devices are stable, are able to undertake impartial and objective assessments, have an appropriate quality management system in place to support them, have the resources to undertake the assessments, and the processes and ongoing certification in place to meet the relevant regulatory requirements.

There are a further six organisations who are currently in the assessment process and there is active engagement with several further organisations who are preparing to submit their initial submission.

Find out more

Medical Devices: UK approved bodies

Notes to editors

- DEKRA Certification UK Ltd has joined the current three Approved Bodies: BSI Assurance UK Ltd, SGS United Kingdom Ltd and UL International Ltd.
- Between September and November 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) consulted on proposed changes to the regulatory framework for medical devices in the United Kingdom (UK). The proposals, alongside the consultation response and Government response have been published.

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