UKCA marking for medical devices

Your roadmap to compliance at a glance

Understanding and complying with the UKCA marking requirements is not just about maintaining access to the British market after the withdrawal from European Union. It's also about ensuring the safety and effectiveness of your medical devices for the patients who rely on them. Navigating the UKCA marking process can be complex, but with the right knowledge and resources, you can master it.

The first step in the UKCA marking process is to understand the requirements outlined in the UK Medical Devices Regulations 2002 (UK MDR 2002/ SI 2002 No 618, as amended). These regulations specify the essential requirements for the design and manufacture of medical devices, covering aspects such as safety, performance, and labeling.

THE CONFORMITY ASSESSMENT PROCEDURE

The next step is to carry out the conformity assessment procedure. This procedure varies depending on the classification of your device. For lower-risk devices, manufacturers can typically conduct the assessment themselves. However, for higher-risk devices, an assessment by a UK Approved Body, such as TÜV Rheinland, is required.

The role of the UK Approved Body is to independently verify that the medical device complies with the requirements of the UK MDR 2002. This involves reviewing the manufacturer's technical documentation, inspecting their manufacturing facilities, and potentially conducting tests on the device.

Here is a helpful checklist to guide you through the process:

- Understand the specific conformity assessment procedure for your device classification
- Implement a quality management system
- Manufacturers located outside the UK need to appoint a UK Responsible Person and establish a written mandate outlining their specific tasks
- Compile a technical file demonstrating compliance with the relevant requirements
- For higher-risk devices apply and prepare for an assessment by a UK Approved Body
- Ensure that post-market surveillance and vigilance systems are in place

YOU WANT MORE DETAILS? *Click here!*

www.tuv.com

TÜVRheinland®
Precisely Right.

AFFIXING THE UKCA MARKING

Once the conformity assessment has been successfully completed, you can affix the UKCA marking to your device. The marking must be visible, legible, and indelible. If the device is too small to bear the marking, it must be included on the packaging and in the accompanying documentation.

It's important to note that the UKCA marking is not recognized in the European Union, EEA, or Northern Ireland. Devices intended for these markets require the CE marking.

TRANSITIONAL ARRANGEMENTS FOR UKCA TRANSITION

The government is now aiming for core aspects of the future regime for medical devices to apply from 1 July 2025[1]. In the spring of 2023, the UK government decided to extend the period of acceptance of CE marked medical devices on the Great Britain market. This is to avoid a short-age of the important goods.

However, manufactures need to pay attention because different timelines apply to the individual product types!

CHANGES AROUND THE CORNER

For the future, the UK government announced plans to implement regulations that will significantly reform the current regulatory framework for medical devices in the UK. A guidance has been updated to indicate that core aspects of the future medical device regime are now scheduled to apply beginning July 1, 2025. Furthermore, there are post-market surveillance requirements planned, that are expected to come into effect starting mid-2024.

FURTHER QUESTIONS?

You have further questions about the UKCA marking process and compliance with UK Medical Device Regulations? On our website we provide you with detailed information. Get in touch with one of our experts for medical devices and the UK MDR. We are happy to support you through the entire process.

[1] Source: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period/implementation-of-the-future-regulations

CONTACT US!

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nuremberg, Germany
Telefon +49 911 655-5225
service@de.tuv.com

www.tuv.com

TÜVRheinland®
Precisely Right.