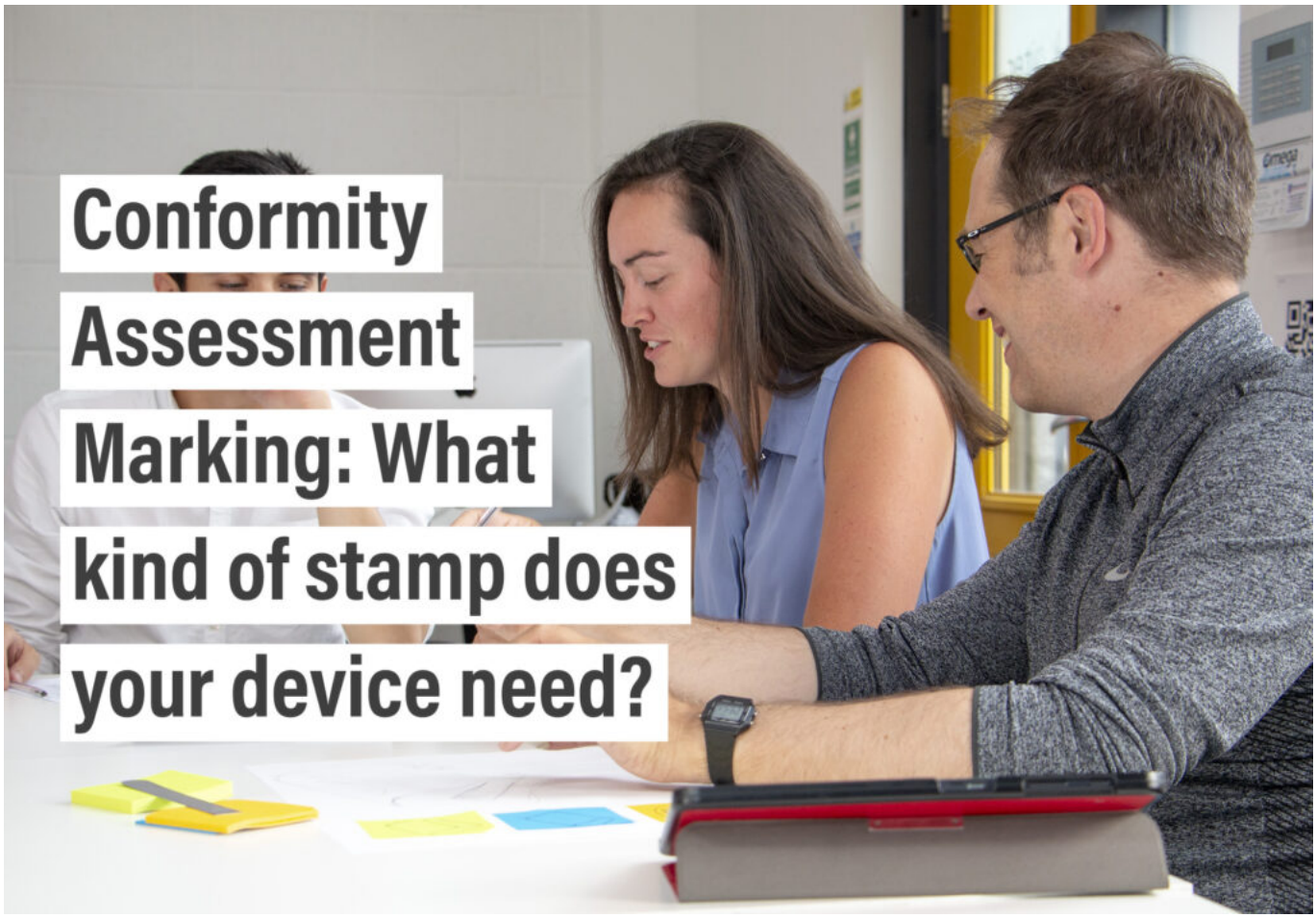
# Conformity Assessment Marking: What kind of stamp does your device need?




# Conformity Assessment Marking: What kind of stamp does your device need?

Reading time 9 mins

## Key Points

- The UK leaving the EU led to changes in conformity assessment marking requirements. Changes and transitionary periods come into effect from July 2023
- Manufacturers placing products on the Great Britain market (England, Scotland, and Wales) must register their product with the Medicines and Healthcare products Regulatory Agency (MHRA) and affix a UK Conformity Assessed (UK CA) stamp on their product
- Manufacturers placing products on the EU market must register their product with a European Competent Authority (i.e. the European Medicines Agency) and affix a Conformité Européenne (CE) stamp on their product
- Manufacturers of low-risk devices in both GB and the EU can self-declare conformity and affix the UKCA and/or CE marking on their product once any additional technical documentation has been completed
- GB manufacturers intending to place their products on the EU market must appoint a European Authorised Representative to act on their behalf
- EU manufacturers intending to place their products on the GB market must appoint a UK Responsible Person to act on their behalf



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In a previous post, we looked at how UK medical device regulations differ from the EU requirements and the impact that the UK leaving the European Union had (and continues to have) on the healthcare industry. Most of these differences involve conformity assessments, nomenclature (i.e. terminology that one region uses that another does not), and device classification (e.g. how software as a medical device is classified). It can be a confusing landscape to navigate – especially regarding conformity assessment marking – but a systematic approach will help you get off to a good start [1]:

1. From 1 July 2023, all medical devices placed on the Great Britain (GB) market (England, Scotland, and Wales) must have the UK Conformity Assessed (UKCA) marking
2. The UKCA marking cannot be used for products/devices that will be placed on the EU or Northern Ireland market. For this, the Conformité Européenne (CE) mark must also be placed on your device/product
3. Manufacturers of medical devices can use either the UKCA marking or the CE marking on devices they place (or have already placed) on the GB market until 30 June 2023
4. In most cases, manufacturers of Class I (low-risk) medical devices in both GB and EU can self-declare conformity and affix the UKCA and/or CE marking on their product once any additional technical documentation (e.g. General Safety and Performance Requirements) has been completed
5. Manufacturers based outside GB must appoint a UK-based Responsible Person to carry out specific tasks (e.g. Declaration of Conformity) on their behalf
6. Manufacturers based outside the EU must appoint a European Authorised Representative to act on their behalf
7. UK manufacturers can follow designated standards to claim a ‘presumption of conformity’ with the corresponding essential requirements that relate to their product
8. EU manufacturers can follow harmonized standards to claim a ‘presumption of conformity’
9. GB manufacturers that cannot self-declare will need a third party to assess the conformity of their product. This is conducted by a UK Approved Body – which can be found in the UK Market Conformity Assessment Bodies (UKCAB) database

10. EU Notified Bodies conduct third-party conformity assessments for products placed on the EU market that don't qualify for self-declared conformity
11. Manufacturers must register their devices with the relevant regulatory authorities. In the UK, this is the Medicines and Healthcare products Regulatory Agency (MHRA). In the EU, this will be with a European Competent Authority (e.g. the European Medicines Agency)
12. The rules on affixing the UKCA marking are currently the same as for affixing the CE marking, i.e. visible, legible, indelible

# Classifying devices for their intended purpose and target market

Before any of the steps outlined above can be carried out, you'll have to ensure that your device has, in fact, been classified correctly. This, too, can be tricky – especially for borderline products, and those with no intended medical purpose (e.g. non-prescription coloured contact lenses) that have risks similar to medical classified devices (e.g. infection, injury).

According to the UK Medical Devices Regulation 2002 (UK MDR 2002), a medical device is: any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of [2]:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or a physiological process, or
- control of conception

How these devices are classified and the compliance required will depend on the level of risk it presents to the user or patient. Both the UK and EU follow the same risk-based classification system, and while the latter applies a more stringent rules-based system to classify medical devices, both correspond to the classification rules established by the International Medical Device Regulators Forum (IMDRF)

- Class I: Low-risk devices, e.g. stethoscopes and bandages
- Class IIa: Medium-risk devices, e.g. hearing aids, contact lenses
- Class IIb: Complex medium-risk devices, e.g. ventilators, diagnostic x-ray
- Class III: High-risk devices, e.g. pacemakers, breast implants, a joint replacement

system

# Technical documentation needed for conformity assessment marking

Regardless of your device classification and ability to self-declare conformity, keeping your documentation in order will help to ensure your conformity process is as hassle-free as possible. Essential documentation that you – or your authorised representative – must keep demonstrating conformity includes [3]:

- How the product is designed and manufactured. This will include your quality management system – which is also mandatory for compliance
- How the product has been shown to conform to the relevant requirements. This can include your risk management processes, e.g. Failure Modes and Effects Analysis
- Your business and/or storage facility address
- Your UK Declaration of Conformity. If you plan on putting your product or device on the EU market, you must have a separate EU Declaration of Conformity
- The legislation, as well as designated standards (UK) or harmonised standards (EU), which were adhered to

## A final thought on UKCA and CE marking

While conformity assessment marking might sound time-consuming, the good news is that both the UK and EU conformity processes are similar, and an effort has been made to keep them harmonised. This means that manufacturers and developers don't necessarily have to duplicate their efforts to place their products in different markets, as most of the technical documentation required would be the same.

That said, these conformity and classification rules are relatively straightforward when it comes to 'conventional' devices. However, technology can transform a conventional low-risk medical device (e.g. a stethoscope) into a robust digital healthcare tool (e.g. interactive stethoscope for remote patient monitoring) that has multiple uses.

Does this change the regulatory scope?
If the risk to the patient is electronic (e.g. cyber security), is this regulated in the same way as if the risk could cause physical harm?
Can regulators anticipate innovation and future-proof legislation?

As we saw in a previous post on the key regulatory challenges of software as a medical device, these

emerging technologies (including AI) have caused a lack of harmonisation between different regulatory bodies. This has made conformity assessments trickier, but further reforms planned by the EU and UK should smooth these out.

Have you had much experience with conformity assessment marking? Did you find the process easefull or stressful? Please share your thoughts in the comments below – or feel free to get in touch if you have a regulatory issue that we might be able to help with!


1. Using the UKCA marking. (2022, November 14). GOV.UK. https://www.gov.uk/guidance/using-the-ukca-marking
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## Comments


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2. Quality Management Systems in the MDR. (2022, December 6). Mantra Systems. https://www.mantrasystems.co.uk/eu-mdr-compliance/quality-management-system-qms
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4. Opportunities and risks around future UK regulatory reform of medical devices. (2021, April). Birmingham Health Partners Centre for Regulatory Science & Innovation. https://www.birminghamhealthpartners.co.uk/wp-content/uploads/2021/08/Opportunities-and-risks-around-future-UK-regulatory-reform-of-medical-devices.pdf

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