FAQ

DEKRA
On the safe side.

Changes for medical device manufacturers relating to Brexit

1. What is UKCA-marking?

The UKCA (UK Conformity Assessed) mark is a new UK product marking that has been introduced as a result of Brexit.
UK Government information on UKCA marking can be found here.

2. Will I need UKCA-marking for my medical device product(s)?

The requirements for UKCA-marking depend on where you market your products.
You will not need UKCA marking if you do not place products on the market in Great Britain (England, Scotland and Wales). You will need-UKCA marking if you place your medical device product on the market in Great Britain. In Great Britain, UKCA mark will replace CE-marking and CE-marking will no longer be required. For completion, if you only place your product on the market in Northern Ireland, you will not need UKCA-marking, but you will need CE-marking.
The UKCA mark will not be recognised in the EU, EEA or Northern Ireland markets, and products currently requiring a CE marking will still need a CE marking for sale in these markets. UK Government information can be found here.

3. When will UKCA-marking be required?

UKCA-marking has been introduced on 1 January 2021, currently manufacturers can use the UKCA on a voluntary basis. Great Britain will continue to recognise CE-marking during a transition period, until 31 December 2027 for high-risk devices and 31 December 2028 for medium and low risk devices. After this date, UKCA marking will be mandatory and CE-marking will no longer be recognised. UK Government information can be found here.

4. What is a UK Approved Body?

From 1 January 2021, UK Approved Bodies (UKAB) will be responsible for the UKCA marking of manufacturers. This means conformity assessment processes required for UKCA marking will be performed by UK Approved Bodies. UK Approved Bodies need to be located in the UK. DEKRA Certification UK was designated an approved body in September 2022 with approval number 8505.
UKABs will not be able to perform CE-marking certification.
EU Notified Bodies will not be able to perform UKCA-marking.
DEKRA UKAB works together with our two existing EU notified bodies DEKRA Certification BV (0344) and DEKRA Certification GmbH (0124) to enable the UKCA and the CE marking of manufacturers.
UK Government information can be found here.

5. I am new to medical device certification, what certificates do I need?

The certificates you need depend on where you want to place your device on the market. UK Approved Bodies can issue UKCA marking certificates; but will not be able to issue CE-certificates. EU notified bodies can issue CE-marking certificates; but will not be able to issue UKCA-certificates.
Since DEKRA has two EU notified bodies for medical device conformity assessment [DEKRA Certification BV (0344) and DEKRA Certification GmbH (0124)] and now a UK Approved Body [DEKRA Certification UK Ltd. (8505)] it can now issue both UKCA and CE certificates.

6. I have CE-marking for my medical device products with DEKRA Certification BV and DEKRA Certification GmbH or another an EU notified body, what happens now?

Your certificate remains valid in the European Economic Area.

You will not need to make any changes if:

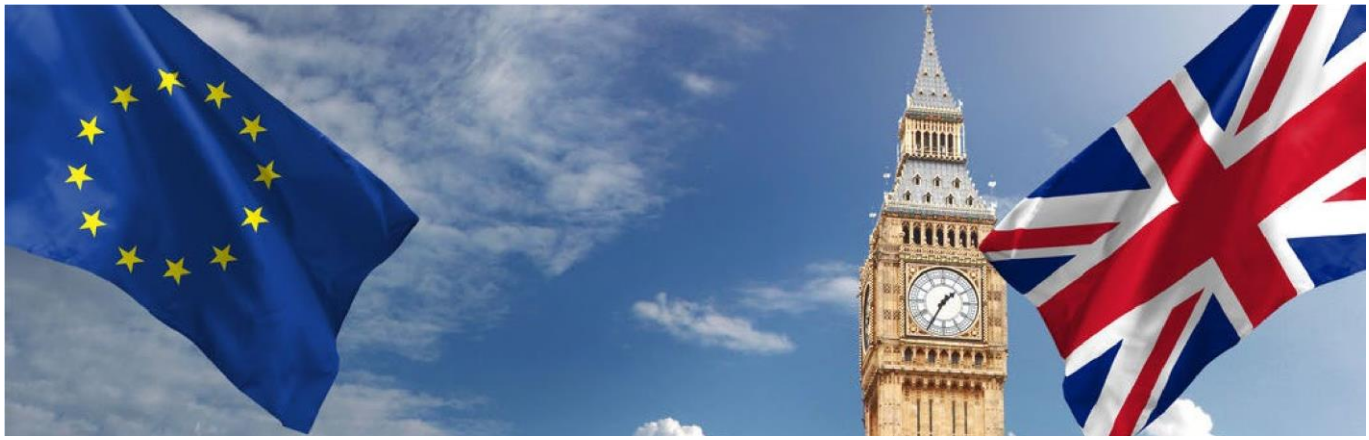
a) you are not located in Great Britain, and

b) you do not wish to place products on the market in Great Britain.

If you are located in Great Britain, you will need an authorised representative based in the EU to register your products in the EU. European Commission's information on the requirements can be found here.

If you wish to place your products on the market in the United Kingdom, you will need to register with the MHRA. A UK Responsible Person is required to register the device for manufacturers not in the UK.

Labelling changes are also required. Learn more here.



7. If I have CE-marking with DEKRA, will I need to go through the whole certification process to obtain UKCA-marking for the same products?

At DEKRA, our UKAB has an established and cooperative relationship with our two EU notified bodies for medical device conformity assessment. We work cooperatively together to minimise the additional activities required for UKCA-marking where our customer already have CE-marking. In these situations, the UKAB will use the audit reports and technical documentation review reports as much as possible. However, there are additional requirements for UKCA-marking compared to CE-marking. Where possible, we will combine the UKCA assessment with your existing CE-marking schedule. In some cases, for example, where your timeline for UKCA-marking does not match the CE-marking schedule, we will need to perform additional activities; your DEKRA contact will be able to provide you with a revised quote.

8. If I have CE-marking with another EU notified body, will DEKRA be able to provide UKCA-marking for the same products?

EEU notified bodies are required to share information with UKABs when requested by the certificate holder (and UKABs should do the same with EU notified bodies). This information exchange will help UKABs to issue UKCA certificates without the need to repeat the entire certification process. However, in order to use the audit reports and technical documentation reviews from other EU notified bodies, they will need to meet the DEKRA requirements and therefore we review the possibility on a case-by-case basis.

It is important to remember that conformity assessment involves an audit of the manufacturer's quality management system and a review of the technical documentation related to the products to be certified for specific criteria and, therefore, if your EU notified body is not working cooperatively with a UKAB, additional on-site audit activities and technical documentation review activities will be required.

9. Is anything else required for placing products on the market in Great Britain?

Yes. All medical devices manufacturers, including manufacturers of in vitro diagnostic medical devices, wishing to place products on the market in Great Britain will first need to register with MHRA. More information on the registration process is available on the MHRA website.

10. What about Northern Ireland?

The Northern Ireland Protocol describes the rules for placing goods on the market in Northern Ireland. It has come into force from 1 January 2021.

In most cases, devices will need to be registered with the MHRA and have a UK Responsible Person if the manufacturer is based outside the UK.

Great Britain-based manufacturers will need to appoint an EU or Northern Ireland-based Authorised Representative.

CE marking will continue to be required and the EU MDR will apply in Northern Ireland from 1 January 2028 for high risk devices and 1 January 2029 for low and medium risk devices.

UK Government information can be found here.

11. Can the UK DEKRA office act as a Responsible Person for my product?

No, DEKRA only offers certification services. There are a growing number of organisations offering the service as a Responsible Person.

Contact details

DEKRA Certification B.V.
Phone: +31 88 96 83009
E-mail: medical.global@dekra.com

DEKRA Certification GmbH
Tel: +49 711 7861 3771
Email: med.certification.de@dekra.com

DEKRA Certification UK Ltd.
Phone: +44 330 9120 368
E-mail: certification.uk@dekra.com

DEKRA
On the safe side.