UKCA-marking of Medical Devices under the UK Medical Devices Regulation 2002 No 618

Great Britain Market Access Medical Devices

Prior to launching a product on the market in Great Britain, a manufacturer must demonstrate that the product complies with all applicable requirements in UK legislation. The requirements are based on the Active Implantable Medical Devices Directive 90/385/EEC, Medical Device Directive 93/42/EEC and the In-Vitro Diagnostic Medical Devices Directive IVDD 98/79/EC. Each Directive was written into UK law through the UK Medical Devices Regulation 2002 No 618, which has since been updated.

The UKCA (UK Conformity Assessed) marking is a new UK product marking that will be used for goods being placed on the market in Great Britain (England, Wales and Scotland).

UKCA marking is the manufacturer's declaration that a product fulfils relevant regulations and standards, including safety, health and environmental protection requirements. All medical devices marketed within the borders of Great Britain must fulfil the UKCA marking requirements including:

> the requirements set out in the UK Medical Devices Regulation 2002 No 618, proving safety and performance.
> specific requirements as set out by the Medicines and Healthcare products Regulatory Agency (MHRA), such as specific requirements for virtual manufacturers.

UKCA marking is not recognised in Northern Ireland. Products to be placed on the market in Northern Ireland must carry CE marking or CE marking with UK(NI)-marking.

For more information on CE marking for products being place on the Northern Ireland market and within the borders of the European Economic Area, please contact one of DEKRA's EU Notified Bodies at medical.global@dekra.com.

Applying for UKCA with DEKRA Certification UK Ltd

DEKRA Certification UK Ltd is a UK Approved Body (8505) designated by the UK Competent Authority, MHRA. This allows us to issue certification for manufacturers to use UKCA marking under the UK Medical Devices Regulation 2002 No 618. To view our scope, please click here.

DEKRA Certification UK Ltd is also an ISO 13485 accredited Certification Body.

Step 1: Pre-Application

Should you be interested in having devices certified for UKCA marking by DEKRA, the first step is to submit a pre-application. The same process applies whether pursuing a standalone UKCA route or an abridged application route. For existing DEKRA clients, please see page 5 for more information.

The following documents should be submitted for the pre-application:
> A completed Company Information Form (CIF)
> A copy of any relevant certificate(s)
> Brochure material, instructions for use, photographs, animations, and any other relevant (device) information.

Based on a review of the above documents, DEKRA will determine whether it is able to provide the requested certification services. Once it has been determined that DEKRA can offer the required services, a quotation will be compiled and provided.

Please note that the Technical Documentation, QMS documents and related correspondence can only be accepted by DEKRA in English.

Step 2: Application

After acceptance of the quotation by a customer, the UKCA application process can start. The Medical Device Application Submission Form, along with any additional supporting documentation identified in the pre-application review, is submitted to DEKRA.

The assigned DEKRA Project Manager will begin the formal application review, after which the Certification Agreement is established.

At the end of the application phase the technical documentation review activities and audit activities will be planned.

Step 3: Service Delivery

After receipt of the technical documentation, DEKRA shall perform a brief completeness check of the file. When approved, the technical documentation review will begin at an agreed date. After the review DEKRA delivers the first report containing, if applicable, a list of questions and findings.

The on-site audit will result in a report where non-conformities, if applicable, are identified. The manufacturer provides a corrective action plan to address non-conformities identified during the on-site audit and submits evidence of correction of the findings.

Step 4: Certification

When both the technical documentation review and audit have satisfactory results, the relevant certificates under the applicable Directive can be issued by DEKRA Certification UK Ltd for UKCA marking of the identified device(s).

Summary of Steps Towards UKCA marking

Step 1: Pre-Application Process

Obtain a quotation for certification.

> Submit Company Information Form and accompanying documents.

> Response from DEKRA following pre-application review.

> Indication of costs and timelines provided by DEKRA (quotation)

Required documents in this phase:

• A completed Company Information Form (CIF)

• A copy of any relevant certificate(s)

• Brochure material, instructions for use, photographs, animations, and other relevant (device) information

Step 2: Application Process

You have accepted the quotation of DEKRA

> Submit Medical Device Application Form with supporting documents

> Assignment of a Project Manager by DEKRA

> Application review by DEKRA of the provided form and related documents

> Establishment of a Certification Agreement between DEKRA and the manufacturer

> Scheduling of technical documentation* review and Audit activities

* technical documentation can only by accepted by DEKRA in English

Step 3: Service Delivery

Start and planning of the review and audits.

> Submit technical documentation*

> Off-site review of technical documentation by DEKRA

> On-site audit at the manufacturer

> On-site audit at critical suppliers (if deemed necessary)

Step 4: Certification

> Verification of compliance by DEKRA Certification Management

> Issuance of certificates under UK Medical Devices Regulation 2002 No 618



Validity of your UKCA certificate

After receiving the relevant UKCA certificate, all documentation and processes relating to product safety and performance must be maintained by the manufacturer. In principle, the certificates will be valid for five years after initial issuance by DEKRA Certification UK Ltd, after which time the certificates must be renewed.

Surveillance Audits

Once the UKCA certificates have been issued, the surveillance phase will commence and DEKRA will visit the location(s) of the manufacturer on an annual basis. The purpose of surveillance audits is to confirm that the UKCA -certified medical devices and the related quality processes continue to fulfil all regulatory requirements.

Renewal Audits

At the completion of the certification cycle, the DEKRA Project Manager will generate a plan to begin another five-year certification period. The renewal audit is typically scheduled to occur three (3) months before the certificate expiration date. During the renewal process, the effectiveness of the entire quality management system within the context of internal and external changes will be reviewed and audited with respect to its continued relevance and applicability to the scope of the certification. Where a technical documentation assessment certificate has been previously issued, DEKRA expects the client to lodge a formal Renewal Application in a timely manner; at least six (6) months prior to expiry of the certificate(s).

Subcontractor Audits

Depending on the type of activities outsourced by the manufacturer, additional time may be allocated for subcontractor audits. Whether an (additional) audit at a subcontractor's premises is deemed necessary depends on the type and extent of control the manufacturer has over the subcontractor's activities. Therefore, it is important that DEKRA is informed about all involved (critical) subcontractors and suppliers.

Unannounced Audit

DEKRA performs unannounced audits to manufacturers who hold a UKCA certificate in accordance with the requirements of certification. Following a risk evaluation of the UKCA-marked product lines, DEKRA may conduct unannounced audit(s) at the manufacturer's premises and/or critical production, subcontractor or supplier locations as listed on the DEKRA Certification Notice.

Vigilance

Vigilance reporting is required by DEKRA Certification UK Ltd, in line with the UKCA requirements. Therefore, in accordance with the Certification Agreement and DEKRA General Terms and Conditions, it is required that the manufacturer notify DEKRA, along with the relevant regulatory authorities, of all reportable incidents, field safety corrective actions (FSCAs), field safety notices (FSNs) and recalls related to medical devices covered by the certification.

Change notifications

Once certified, the manufacturer is obliged to notify DEKRA of changes to a certified device(s) and quality management system according to UKCA requirements.

This includes changes to:

- Approved quality management system(s) or product-range covered
- Approved design of device
- Intended use and claims made for the device
- Approved type of device
- Any substances incorporated in or utilized for manufacturing of a device

Existing DEKRA Clients with valid CE Certificates

Abridged Application

DEKRA Certification UK Ltd aims to deliver UKCA marking through the manufacturer's contacts at their DEKRA EU notified body. This means that wherever possible, the Project Manager assigned to the manufacturer for CE marking will also manage UKCA marking. The abridged application route allows DEKRA clients to leverage existing CE marking as evidence of meeting some of the requirements for UKCA marking.

Customers with existing CE certificates not issued by DEKRA

The abridged application route also allows clients with CE certificates not issued by DEKRA to leverage this as evidence of meeting some of the requirements for UKCA marking. The client can either request to transfer their CE certificates to DEKRA or to keep the certificates with the current Notified Body.

Transfers

The transfer process is open to manufacturers of products with existing UKCA or CE certificates that has been issued by a UK Approved or Notified body.

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