Regulatory Procedure of Importing and Registering Medical Devices, Medical and Laboratory Equipment and In vitro Diagnostics that are marketed in Great Britain (England - Wales - Scotland) and aren't Required to be Marketed in the European Union

Code: EDREX:GL.CAMD.011
Version number: 2
Issue date: 27/07/2023
Effective date: 27/07/2023

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1- Introduction

1. Since 1 January 2021, there have been a number of changes, introduced through **secondary legislation**, to how medical devices are placed on the Great Britain market (England, Wales and Scotland) following the United Kingdom departure from the European Union. The most notable are as follows:

Aspect	Before Brexit	After Brexit
Marking on the label	CE marking 	UKCA marking 
Notified body	All EU Notified Bodies are recognized in GB and all British notified bodies are recognized in Europe	British notified bodies are not recognized in Europe **UK Approved Bodies** https://www.gov.uk/government/publications/medical-devices-uk-approved-bodies/uk-approved-bodies-for-medical-devices
The authorized representative	One authorized representative (CE REP) is recognized in EU including GB	UK Responsible Person (UKRP) For manufacturers based outside the UK regardless of having authorized representative in EU
Regulations applied	EU Directives either: Directive 93/42/EEC (EU MDD) Directive 90/385/EEC (EU AIMDD) Directive 98/79/EC (EU IVDD) -MDR 2017/745 -IVDR 2017/746	UK MDR 2002

2. The Medicines and Healthcare Products Regulatory Agency (MHRA) announced on April 27th, 2023 the extension of validity of the certificates issued by EU-recognized Notified Bodies holding CE mark in the Great Britain market till June 30th, 2025 instead of June 30th, 2023(as announced by the British government earlier).
3. Transitional periods have been granted as of July 1st, 2025, for readjusting the conditions in order to implement the new regulations prior to obtaining the UKCA marking so that products can be marketed in Great Britain, as follows:

Type	Transitional period
CE marked medical devices according to MDR/IVDR/IVDD	Five years (to 30 June 2030) or when the certificate expires, **whichever is sooner**
CE marked medical devices according to MDD/AIMDD	Three years (to 30 June 2028) or when the certificate expires, **whichever is sooner**

- To access the information related to the transitional periods according to the classification of medical device, or in-vitro diagnostic, please follow the following link:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1166483/Infographic_-Devices_transition_timeline.pdf

4. Upon expiry of these transitional periods, medical devices will not be allowed to be marketed in Great Britain without obtaining the UKCA marking.
5. Manufacturers willing to market medical devices and equipment in Great Britain must label their products with the UKCA marking.
6. Companies and factories shall be obliged to register all medical devices, including in vitro diagnostics (IVDs), custom-made devices and systems or procedure packs, with the MHRA before being placed on the Great Britain market.
7. If a medical device manufacturer is based outside the UK and wishes to place a device on the Great Britain market, he needs to appoint a single UK Responsible Person for all of his devices, who will act on his behalf to carry out specified tasks, such as registration.
8. The European Union no longer recognizes UK Notified Bodies and therefore the UK Approved Bodies are not able to issue CE certificates.

9. The manufacturer that fulfills both of the CE requirements issued by EU Notified Bodies and the UKCA requirements issued by UK Approved Bodies, can include both the CE and UKCA markings on the labelling.

- **On May 11th, 2022, the Central Administration of Medical Devices has agreed upon the continuity of recognizing the United Kingdom as a reference country after Brexit.**

2- Scope of Implementation

Medical devices, equipment, laboratory equipment and in vitro diagnostics marketed in Great Britain (England, Wales, Scotland) and are not required to be marketed in the European Union.

3- The mechanism for registration and obtaining import approvals within the Arab Republic of Egypt:

The mechanism, through which the import and registration of medical devices and equipment that are marketed in Great Britain and are not required to be marketed in the European Union after expiry of the transitional periods includes the following:

- Registration Procedures:

Regarding quality and free sale certificates, the (ISO 13485:2016+UKCA) certificates shall be submitted in accordance with the updated rules in Great Britain according to the classification in addition to the requirements of the registration file contained in the regulatory guideline for registering medical devices published on the Egyptian Drug Authority website.

- Procedures of obtaining an import approval:

Regarding quality and free sale certificates, the (ISO 13485:2016+UKCA) certificates shall be submitted in accordance with the updated rules in Great Britain according to classification in addition to the requirements for the import approval file contained in the regulatory guidelines published on the Egyptian Drug Authority website.

- In case of importing registered medical devices, it is not necessary to apply to the Variation Department at the General Administration of Registration to make a change to the medical device registration license.

4- List of Abbreviations:

AIMDD	Active Implantable Medical Device Directive
CE	Conformité Européene
EU	European Union
GB	Great Britain
IVDD	In Vitro Diagnostics Directive
MDD	Medical Device Directive
MDR	Medical Device Regulation
MHRA	Medicines and Health Regulatory Authority
UK	United Kingdom
UKCA	United Kingdom Conformity Assessment
UKRP	United Kingdom Responsible Person

5- Versions:

Version	Issue Date	Places of Amendments
Version No. (1)	15/03/2022	---------
Version No. (2)	27/07/2023	Enrolling the transitional deadlines published by (MHRA)