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A Comprehensive Study on Impact of Brexit on Medical Device Application for Europe & United Kingdom

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Dhopare Mahesh R.
M. Pharm (Drug Regulatory Affairs) Sanjivani College of Pharmaceutical Education and Research, Kopargaon.

Bornare Vaishnavi D.
M. Pharm (QAT) Alard College of Pharmacy, Marunji. Pune.

Khedkar Kanchan V.
M. Pharm (QAT) Alard College of Pharmacy, Marunji. Pune.

Kurumkar Sanket
M. Pharm (Drug Regulatory Affairs) Smt. Kishoritai Bhoyar College of Pharmacy, Kamptee, Nagpur

Miss. Jyoti Kadam
Assistant Prof. Department of Quality Assurance Alard College of Pharmacy, Marunji. Pune.

Dr. Madhuri U. Shelar
Assistant Prof. Department of Quality Assurance Alard College of Pharmacy, Marunji. Pune.Corresponding authors: Deepali A Vidhate

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Abstract
On 29 March 2017, the UK notified the EU of its intention to withdraw from the EU, an event that became known as Brexit. the UK formally left the EU on 31 January 2020. A transition period began on 1 February 2020 and was due to end on 31 December 2020. During this period, the UK withdrew from participating in EU institutions, including the European Medicines Agency (EMA), but the EU pharmaceutical law remained in effect in the UK. Since 1 January 2021, EU pharmaceutical law is no longer in effect in the UK, except for Northern Ireland, based on the Protocol on Ireland/Northern Ireland. The Protocol is part of the withdrawal agreement between the EU and UK that established the terms of the UK's withdrawal from the EU. The Protocol is a part of the EU-UK separation agreement, which outlined the conditions of the UK & exit from the EU. The UK-EU is in the II scenario, as the first scenario requires applicants to send their dossier to the EU Competent Authority rather than the UK Competent Authority because Northern Ireland is part of the EU Union.

1. Introduction

Medical Device in EU

Technical File:- A CE Technical File is a detailed description of one's device that demonstrates compliance with the applicable European Union Directive, such as the Medical Devices Directive 93/42/EEC (MDD), the In Vitro Diagnostic Medical Devices Directive 98/79/EC (IVDD), or the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD).

Process for CE Marking Devices under the MDD:

- Identify if your product is a medical device and, if so, which EU Directive applies to it: the Medical Devices Directive (MDD), the In Vitro Diagnostic Device Directive (IVDD), or the Active Implantable Medical Device Directive (AIMDD)
- Determine your device's classification: Class I (non-sterile, non-measuring), Class I (sterile, measuring), Class IIa, IIb, or Class III.

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- Set up a quality-control system (QMS). Class I (non-sterile, non-measuring) devices are an exception.
- Create a Technical File (Class I, IIa, IIb) or Design Dossier for your device (Class III).
- If you don't have a physical presence in Europe, choose an Authorized Representative (EC REP).
- Unless your equipment is Class I non-sterile and non-measuring, have your QMS and Technical File/Design Dossier inspected by a Notified Body.
- You will obtain a European CE marking certificate after your Notified Body audit is completed successfully (and an ISO 13485 certificate depending on the route to conformity assessment selected). Additional registration procedures may apply, however this is dependent on the Competent Authority where your Authorized Representative is based, as well as the device's classification.
- Make a Declaration of Conformity (DoC) stating that your equipment complies with the relevant Directive.

Essential Requirements, Classification, and Conformity Assessment

Before you start working on your technical file, you must first choose the suitable device categorization. Depending on the risk level of your device, you may need to submit thorough clinical data and test reports. Your technical file will have fewer requirements if you have a low-risk device.

Because the type of equipment influences what information is contained in the document, no two technical files will appear precisely same. What is necessary for your technical file depends on three main variables.

1. **Essential Requirements:** The Essential Requirements define essential qualities that must be satisfied in order to reduce danger to the user/patient, provide information and documentation with your device, and identify your device. These can be found in the MDD's Annex I. The Essential Requirements, Sections 1-6 of Chapter 1, apply to all medical devices. Certain standards, such as those for measuring devices or those that use radiation or electricity, are only applicable to certain device types. Manufacturers frequently employ standards to ensure conformity, notably European Norm harmonised standards published in the European Union's Official Journal (OJEU).

2. **Device classification:** Classification of Devices The contents of a technical file or design dossier are also dictated by device categorization. The European device classification methodology follows a risk continuum, with Class I (non-sterile, non- measuring) devices having the lowest risk and Class III devices having the highest danger. The criteria that define risk level, on the other hand, are complicated. The MDD shows extra compliance criteria based on your device's categorization, which in part defines your device's "path" to conformity evaluation. You can precisely determine the regulations that apply to your equipment once it has been appropriately categorised. The MDD's Annex IX contains the classification criteria.

3. **Conformity Assessment:** Conformity Assessment The technical file's goal is to examine conformity: the information in the file should show that your device complies with the MDD's regulations for your device type and class. These guidelines apply to all aspects of your device's lifespan, from design and functionality through quality assurance and production. Conformity assessment refers to the Notified Body audit in Step 6 of the registration procedure in technical terms. Some low-risk gadgets, on the other hand, are not needed to complete the audit. In this scenario, a detailed technical documentation should enough to demonstrate your compliance, and you should be comfortable signing a DoC. Article 11 of the MDD discusses conformity assessment processes.

The "notified entity may request, if fully justified, any information or data essential for establishing and maintaining the attestation of compliance in view of the selected process," according to paragraph 10 of Article 11 of the MDD. To put it another way, you should supply the NB with whatever information it requests to demonstrate that your equipment meets the Essential

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Requirements. If you feel that some standards do not apply to your equipment, you must back up your claim with enough evidence to ensure that the device complies with the Directive.

2. Methodology

Common Elements of a Technical File/Design Dossier

Consider a technical file to be a sectioned narrative document. The reports or papers that support the sections' and the ER's content should be included to the technical file. These supplementary files may be referred to in specific circumstances. Although this list is neither complete nor prescriptive, the following elements are recommended:

The Device's description:

Design, characteristics, performances, representative images, intended purpose, patient population, medical condition, accessories, brief market history, classification (see Annex IX, Classification Criteria), and rationale, as well as the chosen conformity assessment route, may all be included in this section. You can also provide information on the materials used in the item.

Checklist of Essential Requirements (ER):

The ER checklist should be copied word for word from the Directive and provided as a table with identified columns such as ER, relevant applied standard, evidence of compliance, and documentation location. Make a note of each ER and whether or not it applies. Refer to the standard or practise employed if the ER is appropriate. Name and locate the explicit document that meets the criterion — the reviewer should be able to identify the document. If the ER isn't appropriate, give a rationale to back up your claim. The ER checklist serves as a guide to the identification and placement of supporting paperwork.

Assessment of the risk:

Discuss the findings and outcomes of the risk assessment activities in this section. As an attachment, the risk assessment paper should be supplied. (NBs would demand a manufacturer to conform with EN ISO 14971:2012, hence it is strongly recommended.)

Manufacturing: To illustrate inspection and preventative monitoring processes, conditions of manufacture, quality system certifications possessed by the manufacturer or important subcontractors, labelling control, and traceability, provide a manufacturing flow chart and rudimentary explanation of the technique of manufacturing. When contractors execute various activities or the manufacturer depends extensively on outsourcing, a flow chart is helpful.

Evaluation of the clinical situation:

This section contains a summary of the Clinical Evaluation Report (CER), as well as the entire CER. When Directive 2007/47/EC was translated into national legislation in December 2008 and implemented in March 2010, all medical devices seeking CE Marking, regardless of classification, were obliged to provide a CER. The topic of CERs will be covered in greater depth later in this work.

Labelling:

Include a rough draught of the labelling for your gadget. If applicable, you may also provide the CE marking together with the four-digit NB identification number. The use of symbols, especially those defined in EN 980, is recommended.

Conformity Declaration:

Issue this document as a draught; nevertheless, each NB and reviewer may have different expectations for what should be included in the document. After the manufacturer has completed all of the directive's requirements, the DoC draught is signed and issued, which may include a reference to the NB- issued CE marking certificate number. The topic of DoCs will be covered in greater depth later in this article.

All medical device makers are obligated to publish a compliant Clinical Evaluation Report, as previously stated (CER). The CER is a report that summarises the findings of your device's clinical evaluation. A compliant CER verifies that the clinical assessment procedure follows the MDD's guidelines. The review approach should back up convincing clinical data that your product accomplishes its goal without endangering users or patients.

Even though it will be an attachment to your technical file or design dossier, treat the CER as a separate

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document. As recommended in the Guidelines on Medical Device rev. 3, Appendix E, below is a list of possible components to include in your report:

General information: device and manufacturer name

- Concise physical and technical device description and intended application
- Outline of intended therapeutic or diagnostic claims
- Clinical evaluation and data types
- Summary of clinical data and review
- Describe analyses used to assess performance, safety, and relevance/accuracy of product literature
- Conclusions about safety, performance, and conformity

The Declaration of Conformity (DoC) is a legally binding document that certifies that your product complies with all applicable laws and regulations in order to be sold in the European Union. It specifies that your device complies with the MDD and the Essential Requirements. Regardless of their product's categorization, all medical device makers must complete a DoC.

Although the DoC is a short document, it should clearly convey that your company and device conform to the necessary requirements. Most DoCs include the following elements:

Device trade name and model number

- Device classification (Class and Rule)
- Your company name and address
- Name of quality management representative
- Notified Body name and ID number (if applicable)
- CE certificate number (if applicable)
- Date CE Marking was first applied
- Authorized Representative contact information
- Route to compliance (example: Annex II, V, VII)
- Standards applied (optional)
- Name and signature of company officer

Medical Device UK: Regulating medical devices in the UK

What you need to do to place a medical device on the Great Britain, Northern Ireland and European Union (EU) markets.

Contents

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Overview

The Medicines and Healthcare Products Regulatory Agency (MHRA) is in charge of overseeing the medical device industry in the United Kingdom.

This document contains information on the UK system, including:

1. Obtaining certification for your gadget
2. Branding your device for conformance
3. Register your gadget with the Medicines and Healthcare Products Regulatory Agency (MHRA)

This guide is separated into parts that cover the many rules that apply in the United Kingdom, Northern

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Ireland, and the European Union. England, Wales, and Scotland make up the United Kingdom.

Different restrictions apply in Northern Ireland than in the United Kingdom.

The following is a list of the most important conditions for placing a gadget on the market in the United Kingdom.

There have been a number of changes to how medical devices are placed on the market in the United Kingdom from January 1, 2021, as a result of secondary legislation (England, Wales and Scotland). These are the following:

- CE marking will be recognised in the United Kingdom until June 30, 2023.
- Certificates issued by EU-recognised Notified Bodies will remain valid for the UK market until June 30, 2023.
- Notified Bodies in the United Kingdom are no longer recognised by the European Union.
- UK Notified Bodies are no longer allowed to grant CE certifications (save for the "CE 5. UKNI" marking, which is only valid in Northern Ireland) and have evolved into UK Approved Bodies.
- For manufacturers intending to sell a device in the United Kingdom, a new path to market and product marking is now available.

Since January 1, 2021, all medical devices sold in the United Kingdom, including in vitro diagnostic medical devices (IVDs), must be registered with the Medicines and Healthcare Products Regulatory Agency (MHRA). There is a registration grace period:

1. All active implanted medical devices and IVD List A items, as well as Class III and Class IIb implantables, must be registered by May 1, 2021.
2. Beginning September 1, 2021, all Class IIb and Class IIa devices, IVD List B items, and Self-Test IVDs must be registered.
3. Beginning January 1, 2022, Class I devices, custom-made devices, and generic IVDs (that are not presently required to be registered) must be registered.
4. Manufacturers of Class I devices, custom-made devices, and general IVDs who were required to register their devices with the MHRA prior to January 1, 2021 (i.e. UK-based manufacturers or third-country manufacturers with Northern Ireland-based Authorised Representatives) must continue to register their devices on the same basisas they do now beginning January 1, 2021, rather than in accordance with the above dates.
5. If you are a manufacturer from outside of the United Kingdom and want to sell a device in the United Kingdom, you must designate a single UK Responsible Person who will be responsible for the product in the UK. Below is further information on the UK Responsible Person.

The MHRA's Function:

The MHRA is responsible for market monitoring of medical devices on the UK market and has the authority to make decisions about device marketing and supply.

The MHRA is in charge of appointing and overseeing UK Conformity Assessment Bodies.

Requirements for people who manufacture and provide gadgets in the United Kingdom:

1. Manufacturers that want to sell a device in the United Kingdom must first register with the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA's registrations advice has more information about registrations (including fees).
2. A manufacturer must nominate a UK Responsible Person to register and act on their behalf if they are not based in the UK.
3. Manufacturers of medical devices, including IVDs, shall adhere to appropriate product marking and conformity assessment regulations.

Registrations in Great Britain

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1. Before being sold in the United Kingdom, all medical devices, IVDs, and custom- made devices must be registered with the MHRA. This is true for all types of gadgets. To be registered with the MHRA in the United Kingdom (England, Wales, and Scotland), devices must comply with the UK MDR 2002, the EU MDR (until 30 June 2023), or the EU IVDR (until 30 June 2023).

2. The MHRA will only register devices if the maker or their UK Responsible Person has a registered business address in the United Kingdom. If the manufacturer is located outside of the United Kingdom, they must select a UK Responsible Person with a registered business address in the United Kingdom. This UK Responsible Person will then take over the manufacturer's responsibility for registering the device with the MHRA.

3. There is a grace period to give time for compliance with the new registration process, as this is an expansion of current registration obligations. Devices must be registered according to the schedule below.

If they are placed on the market in the United Kingdom after May 1, 2021, the following devices must be registered with the MHRA:

- active implantable medical devices
- Class III medical devices
- Class IIb implantable medical devices
- IVD List A products

If they are placed on the market in the United Kingdom after September 1, 2021, the following devices must be registered with the MHRA:

- Class IIb non-implantable medical devices
- Class IIa medical devices
- IVD List B products
- self-test IVDs

If placed on the market in the United Kingdom after January 1, 2022, the following devices must be registered with the MHRA:

- Class I medical devices
- general IVDs

- It is possible to register devices before the deadlines listed above, but there is no legal requirement to do so.

- Manufacturers of Class I devices, custom-made devices, and general IVDs who were required to register their devices with the MHRA prior to January 1, 2021 (i.e. where the manufacturer is based in the UK or the Authorised Representative is based in Northern Ireland) must continue to do so on the same basis as before, as the above registration timings will not apply to these devices.

- It is possible to register devices before the deadlines listed above, but there is no legal requirement to do so.

- Manufacturers of Class I devices, custom-made devices, and general IVDs who were required to register their devices with the MHRA prior to January 1, 2021 (i.e. where the manufacturer is based in the UK or the Authorised Representative is based in Northern Ireland) must continue to do so on the same basis as before, as the above registration timings will not apply to these devices.

- Registration for custom-made devices is based on the device's risk class. If you fail to register devices placed on the market after these dates, you will no longer be able to legally sell them in the United Kingdom.

- If you are a Northern Ireland-based manufacturer who has previously registered your device with the MHRA for Northern Ireland, you can place it on the Great Britain market without having to go through any further registration.

UK Responsible Person:

- As previously stated, manufacturers from outside the UK must designate a UK Responsible Person who is based in the UK in order to place a device on the Great Britain market (England, Wales, and Scotland). The requirements for selecting a UK Responsible Person to place devices on the

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market in Northern Ireland are discussed separately below. It is not necessary for importers and distributors to appoint a UK Responsible Person.

- Wherever feasible, manufacturers should select their UK Responsible Persons as soon as practicable. Following that, the UK Responsible Person must register relevant devices with the MHRA in accordance with the aforementioned grace periods, which vary by device class.

- The UK Responsible Person performs certain activities on behalf of the outside- UK manufacturer in regard to the manufacturer's obligations. This involves registering the manufacturer's gadgets with the Medicines and Healthcare Products Regulatory Agency (MHRA) before they may be sold in the United Kingdom.

- The UK MDR 2002 outlines the obligations of the UK Responsible Person (as amended). In summary, the UK Responsible Person must, in addition to the foregoing registration requirements:

1. Verify that the declaration of conformity and technical documents has been prepared, and that the manufacturer has conducted an appropriate conformity assessment procedure, if applicable.

2. For inspection by the MHRA, preserve a copy of the technical documentation, a copy of the declaration of compliance, and, if appropriate, a copy of the relevant certificate, including any revisions and additions.

3. Provide the MHRA with all information and documentation necessary to show a device's compliance in response to a request from the MHRA.

4. If they have samples of the devices or access to the devices, they must cooperate with any request from the MHRA for such samples or access.

5. Inform the manufacturer of any request from the MHRA for samples or access to the device, and inform the MHRA if the manufacturer intends to comply with that request, if they do not have samples or access to the device.

6. Work with the MHRA on any preventative or corrective action taken to remove or, if that is not practicable, reduce the risks presented by devices.

7. Notify the manufacturer right away if they receive complaints or reports from healthcare professionals, patients, or users regarding suspected occurrences using a device for which they are responsible.

8. If the manufacturer violates these Regulations, end the legal connection with the manufacturer and notify the MHRA and, if necessary, the relevant Approved Body.

- An importer or distributor might take on the role of UK Responsible Person.

- Where the UKCA mark has been applied, the name and address of the UK Responsible Person must be disclosed on product labelling. For CE approved equipment, the information of the UK Responsible Person does not need to be disclosed on the labelling.

Importers and distributors

- The importer must notify the appropriate UK Responsible Person of their plan to import a device if the Great Britain importer is not the UK Responsible Person. In such circumstances, the UK Responsible Person must disclose a list of device importers to the MHRA.

- Other than the aforementioned criteria, medical device distributors and suppliers have no other requirements. Previous storage, transit, and device label inspection obligations for CE or UKCA marking remain in effect. Unless the importer or distributor is functioning as the UK Responsible Person for the purposes of the UKCA mark, the importer's name and address do not need to be on the label. Any future adjustments will be subject to consultation.

UKCA mark and Conformity Assessment Bodies

UKCA mark:

- **The UKCA** (UK Conformity Assessed) mark is a product marking used in the United Kingdom for certain items, particularly medical devices, that

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are being sold in the country (England, Wales and Scotland). Because the UKCA mark is not recognised in the EU, EEA, or Northern Ireland, related items must have the CE mark in order to be sold there.

- Manufacturers can use the UKCA mark until June 30, 2023, on a voluntary basis. A UKCA mark will be required to sell a gadget in the United Kingdom from July 1, 2023.
- A UK Approved Body is necessary when third-party conformity evaluation is required. Manufacturers of Class I devices and generic IVDs, on the other hand, can self-certify against the UKCA mark.

From 1 July 2023, a UKCA mark will be required in order to place a device on the Great Britain market.

UK Approved Bodies:

For the purposes of the UKCA mark, the MHRA can designate UK Approved Bodies to conduct assessments against the relevant requirements.

Existing UK Notified Bodies holding designations under the EU MDD, EU IVDD, or EU AIMDD have their designations immediately carried over, eliminating the need to go through the designation procedure again.

Under Parts II, III, and IV of the UK MDR 2002 (as amended), UK Approved Bodies can undertake conformity assessments for medical devices, active implantable medical devices, and in vitro diagnostic medical devices for the purposes of the Great Britain market. Other than for the purposes of the "CE UKNI" marking, which is valid in Northern Ireland, UK Approved Bodies are unable to undertake conformity evaluations in regard to the CE marking.

Class I device manufacturers

Manufacturers of Class I medical devices and general IVDs can self-certify their compliance with the EU MDD or EU IVDD as transferred by the UK MDR 2002 (asamended) before applying the UKCA mark and putting the device on the market in the United Kingdom.

To be affixed with the UKCA mark and placed on the Great Britain market, Class I medical devices that are sterile or have a measurement function require clearance from a UK Approved Body.

CE marking and Notified Bodies CE marking:

On the British market, they will continue to accept CE-marked products until June 30, 2023. This applies to devices that have received the CE mark and are fully compliant with the following EU legislation:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC) on in vitro diagnostic medical devices (EU IVDD)
- Regulation 2017/745 on medical devices (EU MDR)
- Regulation 2017/746 on in vitro diagnostic medical devices (EU IVDR)

New devices sold in the United Kingdom must comply with UKCA marking regulations from July 1, 2023.

If you are presently CE marking your medical device on the basis of self-certification, you will be permitted to do so and sell it in the United Kingdom until June 30, 2023.

Notified Bodies:

- Certificates issued by EU-recognised Notified Bodies will be valid for the UK market until June 30, 2023.
- An EU-recognised Notified Body must conduct any obligatory third-party conformity evaluation for the CE marking. This comprises Notified Bodies based in the EU as well as Notified Bodies from countries registered on the EU's NANDO Information System.

Recognition of existing CE certificates for the Great Britain market

- A CE marked device with a valid declaration of conformity or certificate is regarded as satisfying the UKCA mark standards under the UK MDR 2002 (as amended), and the CE marking will be recognised in Great Britain until June 30, 2023.

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This contains gadgets that have been put on the market and are:

1. CE marked in conformance with the EU MDD, EU IVDD or EU AIMDD

2. CE marked in conformance with the EU MDR or EU IVDR.

- As a result, any enforcement or market surveillance authorities available in relation to the UKCA mark also apply to CE-marked equipment sold in the United Kingdom.

- Where a UK Notified Body granted certifications, the Notified Body has been renamed a UK Approved Body, and will continue to monitor these devices and their makers to guarantee continuous compliance with the applicable safety and performance criteria under the UKCA mark.

Labelling requirements:

- Medical equipment sold in the United Kingdom must bear either a UKCA or a CE mark, depending on whose law they were approved under.

- The number of the Notified Body or Approved Body must also appear on the label, if applicable.

- If your item already has a valid CE mark, you do not need to re-label it with a UKCA mark until July 1, 2023, in order to sell it in the United Kingdom. Prior to July 1, 2023, devices can have both markings on the labelling, and dual marking will be permitted on the Great Britain market after that date. However, when the UKCA mark has been applied, the name and address of the UK Responsible Person must be disclosed on product labelling (including when devices have been dual marked).

Regulation of medical devices in Northern Ireland:

Overview:

1. The Northern Ireland Protocol stipulates that the rules for placing medical devices on the market in Northern Ireland differ from those in the United Kingdom (England, Wales and Scotland).

2. If the manufacturer is situated outside the UK, it is usually necessary to register devices with the MHRA and have a UK Responsible Person, as detailed below.

3. Summary of key requirements for placing a device on the Northern Ireland market

4. Manufacturers intending to place medical devices on the Northern Ireland market must meet the following requirements:

- The EU MDR and EU IVDR will apply in Northern Ireland from May 26th, 2021 and May 26th, 2022, respectively.

- CE certification is necessary. In addition, if a UK Notified Body conducts necessary third-party conformity assessment, the UKNI marking is needed.

- Certain medical devices, including in vitro diagnostic medical devices (IVDs), must be registered with the MHRA before being sold in Northern Ireland. Class I devices and general IVDs placed on the market in Northern Ireland by Northern Ireland manufacturers and Authorised Representatives must be registered as they were prior to January 1, 2021, since the registration deadlines will not apply to these devices. Devices in other device classes must be registered by the following dates:

1. All active implanted medical devices and IVD List A items, as well as Class III and Class IIb implantables, must be registered by May 1, 2021.

2. Beginning September 1, 2021, all Class IIb and Class IIa devices, IVD List B items, and Self-Test IVDs must be registered.

3. When placing devices on the Northern Ireland market, manufacturers headquartered in the United Kingdom must establish an Authorised Representative domiciled in the EU or Northern Ireland.

4. Most manufacturers situated outside the UK must appoint a UK Responsible Person to operate as a regulatory point of contact within the UK and to comply with registration requirements once they are implemented.

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The EU MDR and EU IVDR in Northern Ireland:

Unlike the United Kingdom, Northern Ireland's Medical Device Regulations (2017/745) and in vitro Diagnostic Medical Device Regulations (2017/746) will take effect on May 26, 2021 and 2022, respectively, in accordance with the EU's implementation timeframe

CE marking for the Northern Ireland market and implications for UK Approved Bodies:

- Although the UKCA mark is valid in the United Kingdom, CE certification is required for products sold in Northern Ireland, and EU regulations must be followed.
- For the purposes of the Northern Ireland market, you can CE mark your equipment on the basis of self-certification when authorised by the relevant law.
- You must engage an EU-recognised Notified Body to conduct any obligatory third-party conformity assessment in order to affix a CE marking on your device for distribution in both Northern Ireland and the EU. The findings of conformity assessments conducted by UK Notified Bodies are not recognised by the European Union.

UKNI marking:

- For the purposes of the Northern Ireland market, UK Notified Bodies can perform conformity evaluations.
- If a device maker chooses to utilise a UK Notified Body for necessary third-party conformity assessment, they must additionally apply the UKNI marking in addition to the CE marking. The UKNI designation must always be used in conjunction with a CE marking by device makers. Manufacturers must use the CE marking alone, without the UKNI designation, to sell goods in the EU. The "CE & UKNI" label on goods will not be recognised on the EU market.
- In summary, you need to use the UKNI marking if:

1. You're putting certain medical devices on the market in Northern Ireland;
2. Your products require required third-party conformity assessment; and
3. You're using a UK Notified Body to conduct the conformity assessments.

Registration and UK Responsible Person requirements for Northern Ireland

- The MHRA requires that most medical devices, IVDs, and custom-made devices sold in Northern Ireland be registered.
- If you are an EU or EEA-based producer, you must nominate a single UK Responsible Person for devices put on the Northern Ireland market. You must select a single UK Responsible Person if you are a third-country manufacturer with an Authorised Representative situated in the EU.
- For the purposes of the Northern Ireland market, the obligation to designate a UK Responsible Person does not apply where:

1. You work as a manufacturer in the United Kingdom.
2. You are a Northern Ireland-based manufacturer.
3. You have a Northern Ireland-based Authorised Representative.
4. You only propose to market in Northern Ireland a Class I medical device, a custom-made medical device, or a generic IVD that has been registered with an EU Competent Authority.

- To place a device on the Northern Ireland market, Great Britain manufacturers must designate an Authorised Representative domiciled in the EU or Northern Ireland. When an Authorised Representative is appointed in Northern Ireland, the Authorised Representative must register all device classes with the MHRA. When an Authorised Representative is appointed in the EU, the manufacturer must register all device classes with the MHRA, with the exception of Class I devices, custom-made devices, and generic IVDs.

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- It is conceivable for a single entity to serve as both a Northern Ireland Authorised Representative and a UK Responsible Person.

- The following are the deadlines for registering medical devices with the MHRA. Class I devices, custom-made devices, and generic IVDs must all be registered by January 1, 2021, if appropriate. The following are the timings for different device classes:

1. All active implanted medical devices and IVD List A items, as well as Class III and Class IIb implantables, must be registered by May 1, 2021.

2. Beginning September 1, 2021, all Class IIb and Class IIa devices, IVD List B items, and Self-Test IVDs must be registered.

Importer requirements:

If the importer is not the Northern Ireland-based Authorised Representative or the UK Responsible Person, the importer must notify the appropriate Northern Ireland-based Authorised Representative or UK Responsible Person of their plan to import a device.

In such situations, the Authorised Representative or UK Responsible Person headquartered in Northern Ireland must furnish a list of device importers to the MHRA.

3. Conclusion:

The success of your technical file depends on the quality of your preparation. Establish a solid basis for the project by determining the applicable directive, correctly categorising your equipment, and determining the best path to compliance. Choose your Notified Body with care, and then follow the instructions in the guidance materials. To avoid any surprises or costly revisions, look to compliance and regulatory requirements early in your project.

Conflict of Interest:

The author declares that there is no conflict of interest regarding the publication of this article.

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