RQMIS

WHITE PAPER

Brexit: Understanding the New Requirements of a Transformed Landscape

After months of negotiations, the United Kingdom (UK) and the European Union (EU) finally reached an agreement that will define their future relationship, which came into effect at 23:00 GMT on December 31, 2020. As of this date, the UK is a "third country" from the EU perspective, and the same applies to the European Economic Area (EEA)from the UK perspective. This context has been one of great change for all businesses, in which medical devices have not been the exception. From that date, for medical devices to move between UK and EEA markets, new requirements must be met. But this not only affects England, it also affects Northern Ireland in a special way, where its situation also becomes "special".

The following situations are the most common for Manufacturers:

Situation 1

Manufacturer in UK wants to sell in EEA

The EU has a clear set of rules for countries that are not part of the single market, the so-called "third countries". In the case of medical devices, any manufacturer outside the EEA must designate an authorized representative, an importer and change their labeling accordingly.

As the UK is now considered a third country, you must comply with their requirements which went into effect on January 1, 2021, without a transition period. This requirement has been in place for four months and many UK manufacturers have already appointed an Authorized Representative ("AR"). Companies that have not designated an AR should make the necessary arrangements to do so immediately; otherwise, they will not be able to place devices on the EEA market.

In addition, as of January 1, 2021, UK-based sponsors of clinical research involving medical devices or IVDs must appoint an EEA-based legal representative to act on their behalf. If no legal representative is appointed, the study should be stopped, or at a minimum, enrollment should be stopped until this appointment is completed.

Situation 2

Manufacturer in EU wants to sell in UK

Manufacturers in the US, like any non-British manufacturer, and who do not have a mutual recognition agreement, must comply with the same rules. The manufacturer must designate a UK Responsible Person (RP) (UKRP) and their devices must be marketed by an importer located in the UK. It is important to understand that the requirements to designate an importer and a UKRP went into effect January 1, 2021, with no grace period.

Importer is defined as a person established in the UK who markets a device from a country outside the UK (definition from the 2019 Amendments to the Medical Device Regulations 2002). Any (legal) person based in the UK can become an importer, but the MHRA has verbally communicated that there must be some kind of an agreement with the manufacturer, although this is not specified in the current requirements or guidance documents. The importer must notify the relevant UKRP of their role, who must then register that importer with the MHRA after the manufacturer confirms that role. This information can be found in the MHRA registry as certain parts are publicly accessible.

The UKRP has a role similar to that of the Authorized Representative in the EU. UKRP requirements and activities are generally based on the MDR / IVDR Article 11 requirements for the Authorized Representative. This person acts on behalf of the manufacturer outside the UK and must register the devices on behalf of the manufacturer and importers involved (see Registration below). It appears that UKRP is not responsible for faulty devices as defined in section 11 (5) of the MDR. The manufacturer is required to report incidents but can request UKRP to do so on their behalf.

UKCA marking—the UK mark equivalent to CE mark

From January 1, 2021 to July 1, 2023, MHRA will allow the registration of medical devices and IVDs with the CE mark. At this time, there are devices in the EEA, certified in accordance with AIMDD, MDD, IVDD, MDR and IVDR; as these five sets of rules are still recognized in the UK.

Effective July 1, 2023, these requirements will be superseded by the UKCA rules, which for now are based on the 2002 Medical Device Regulations and has been amended both in 2019 and 2020. MHRA has not yet published a Consolidated version of UKCA requirements, although it appears to be based on Medical Device Regulation (EU) (MDR) 2017/745 and Invitro Diagnostic Regulation (EU) (IVDR) 2017/746

Situation 3

UK-based manufacturers placing devices on the Great Britain market

For UK manufacturers who continue to put their devices on the UK market, not much has changed, at least in the short term. The Medicines and Healthcare Products Regulatory Agency ("MHRA") is responsible for the designation and monitoring of UK conformity assessment bodies and is also the one who will continue to monitor the market for medical devices in the market. UK and can make decisions about the marketing and supply of devices in the UK.

For Class I devices, custom made devices, and general IVDs already registered with the MHRA, this registration may continue. For other devices, there are grace periods in parallel with devices from non-UK

manufacturers. Manufacturers can continue to use the CE marking until 1 July 2023, after which they must use the United Kingdom Conformity Assessment ("UKCA") marking (see below about the UKCA marking). Incident reporting requirements and procedures do not change significantly, and the requirements of Active Implantable Medical Devices Directive 90/385 / EC (AIMDD), Medical Device Directive 93/42 / EEC (MDD), Device Directives In Vitro Medical Devices 98/79 / EC (IVDD), Medical Device Regulation (EU) 2017/745 (MDR) and In Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR) can be used for the CE marking.

Situation 4

Mutual recognition agreements with the United Kingdom

UK manufacturers can place their devices in other markets outside the EEA, in accordance with the new mutual recognition agreements that have been signed, such as with Australia and New Zealand. These agreements cover the "United Kingdom of Great Britain and Northern Ireland".

Situation 5

Special status of Northern Ireland

Historical developments have resulted in Ireland being split into the Irish Republic, which is an EU member state, and Northern Ireland, which is part of the UK. The UK leaving the EU would ordinarily result in the EEA outer border being placed in Ireland. But this would be in breach of the Good Friday Peace Agreement of April 10, 1998. A major point of that agreement was an open border between both parts of Ireland. As long as the UK was part of the EU, it was possible to maintain this open border. As the UK leaving the EU would imply, now there must be an EEA outer border somewhere between Brussels and London, it was recognized that this border could not be placed in Ireland as it could jeopardize the Good Friday agreement. Therefore, Northern Ireland now has a special status within the UK, which complicates customs' requirements for moving goods in or out, especially between the UK and Northern Ireland. As such, CE-marked medical devices can be placed on the Northern Ireland market.

The situation in Northern Ireland is different: CE-marking is required, and the MDR and IVDR will apply from May 26, 2021 and May 26, 2022 respectively. If the certification is performed by a UKRP, a CE United Kingdom Northern Ireland (UKNI) marking is required. The CE UKNI mark is created as part of the Northern Ireland protocol and is applicable for other types of products as well. CE UKNI-marked devices can be placed on the Northern Ireland market but not on the EEA market. These devices can only be placed on the Great Britain market if the CE and UKNI mark is held by a manufacturer based in Northern Ireland.

CE UKNI marking

The UKNI marking is a new conformity marking for products placed on the market in Northern Ireland which have undergone mandatory third-party conformity assessment by a body based in the UK. This guidance explains how to use the UKNI marking (sometimes referred to as the UKNI mark or the UKNI indication). The UKNI marking is not recognized on the EU market. If you are placing goods on the EU market, you must use the CE marking on its own, without the UKNI marking.

A manufacturer needs to use the UKNI marking if all the following apply:

- **Are placing certain goods (mostly those goods subject to the CE marking) on the Northern Ireland market**
- **The goods require mandatory third-party conformity assessment**
- **It is planning to use a UK body to carry out those conformity assessments**
- **The manufacturer will not be able to use the UKNI marking if any of the following apply:**
- **Placing goods on the market in the EU**
- **Planning to use an EU body to carry out conformity assessments**
- **Manufacturer is based in Northern Ireland (or the manufacturer's authorized representative) and your goods are currently marked on the basis of a supplier's declaration of conformity, then you do not need to make any changes. Your goods will continue to be valid on the UK and EU markets using the relevant conformity markings.**

Situation 6

Notified Bodies

As the UK no longer follows the rules of the EU and the Court of Justice of the European Union, its notified bodies are no longer recognized in the EEA for the purposes of device directives and new regulations. They cannot issue CE certificates, and all CE certificates issued by these bodies were canceled effective January 1, 2021. This has also been anticipated for some time, RQMIS suspects that all but a few companies have made this change in your certification.

According to the MHRA publications, UK Notified Bodies stopped being notified as of January 1, 2021, but are now designated by the MHRA as UK Approval Bodies (UKAB). UKABs can issue UKCA certificates that can be used for UKCA marking. There are currently three UKABs:

- **BSI Assurance UK Ltd., designated for the full scope of active implantable medical devices, medical devices and IVD;**
- **SGS UK Ltd., designated for medical devices and IVD (some limitations in scope);**
- **UL International Ltd., designated for a single IVD scope code.**

Some EU notified bodies have indicated that they also intend to be designated for UKCA certification, at this time they have yet provide given assessment dates.

Great Britain registration process

For the MHRA to carry out its market surveillance activities, it is necessary for economic operators (Manufacturer or UKRP) to register themselves, their products, applicable certificates and clinical investigations or performance studies. The registration requirements apply to all devices marketed in the UK, whether newly manufactured or refurbished, this includes custom made devices and systems or procedure packages that contain at least one device and include IVDs for device evaluation performance.

UK based manufacturers can complete the registration themselves, but manufacturers outside of the UK must have a designated UKRP based in the UK to register for them. UKRP must register the manufacturer, importer, and their devices.

Furthermore, UK based manufacturers and Northern Ireland based authorized representatives are required to keep their current records of Class I devices, custom made devices and general IVDs. This implies that any new device must be registered before it can be marketed.

For non-UK manufacturers that were already supplying its devices to the UK market, the following deadlines for registration apply:

- **Active implantable devices, Class III devices, Class IIb implantable devices, and IVDs listed on List A must be registered before May 1, 2021;**
- **Class IIb non-implantable devices, Class IIa devices, IVDs listed on List B, and self-test IVDs must be registered before September 1, 2021;**
- **All other devices (Class I devices and general IVDs) must be registered before January 1, 2022.**

These are also deadlines for registration of the manufacturer and its UKRP. Deadlines are not specified for importers, but they must register as soon as possible, as importers must register before placing their devices on the market in the UK.

However, MDR 2017/745 and IVDR 2017/745 will be fully implemented in EU Member States from May 21, 2021 and May 21, 2022 respectively. As these regulations did not come into force during the transition period, their provisions will NOT be automatically implemented and enforced in Great Britain. The UK MDR 2002, on the other hand, will continue to have effect in Great Britain after the transition period.

When conformity assessment by a third party is required, it is necessary to apply to a UK Approved Notified Body. The MHRA designates the UK Approved Notified Bodies, so that the ability to conduct conformity assessments regarding the requirements for UKCA marking.

Compliance requirements

In Great Britain, devices must comply with UK MDR 2002 (implementing the EU AIMDD, MDD and IVDD Directives), MDR 2017/745 (until 30 June 2023), or IVDR 2017/745 (until 30 June 2023) to be registered with the MHRA. Manufacturers must therefore comply with the product marking and conformity assessment requirements of these directives.

Labelling of medical devices after Brexit

During the transition period, both medical devices and in vitro diagnostic devices can be traded freely between the UK and the EU. As of 1 January 2021, the rules for importing such products from third countries will apply to the UK. Just one rule concerns conformity with European regulations; to demonstrate conformity, manufacturers will have to obtain a CE certificate from a recognized notified body in one of the 27 remaining EU member states. After 1 January 2021 the product label must state the identification number of the new notified body.

Summary of General registrations processes

From/To		To Great Britain	To Northern Ireland	To EU
From Great Britain	**New Device**	Devices must conform to the UK MDR 2002. Manufacturers can use the UKCA mark on a voluntary basis until 30 June 2023. From 1 July 2023, a UKCA mark will be required to be able to place a device on the Great Britain market.	Apply CE or UKNI marking Appoint importer	Apply CE marking Appoint EU-based AR Appoint importer
	Existing Device	Maintain registration with MHRA and register higher risk devices before May or September 2021. Prepare for UKCA marking for 2023.		
From Northern Ireland	**New Device**	Unfettered access if CE- or UKNI-marked; if already registered, it is not necessary to register with MHRA. No importer or UKRP required.	Apply CE or UKNI marking Register with MHRA	Apply CE mark (MDR since May 21, 2021 and IVDR May 21, 2022)
	Existing Device	Unfettered access if CE- or UKNI-marked. No importer or UKRP required.		
From EU	**New Device**	CE marking is acceptable until July 1, 2023. Be ready for UKCA mark after that date. Appoint UK-based UKRP and Great Britain-based importer.	Apply CE mark and appoint UK- or NI-based UKRP or you are only placing Class I or custom-made devices or general IVDs on the NI market. Appoint a NI-based importer. Register devices with MHRA, with registration by UKRP, NI AR, or by the EU-based manufacturer for the above low -risk devices.	Apply CE mark (MDR since May 21, 2021 and IVDR May 21, 2022). No AR EU needed
	Existing Device			Apply CE mark (MDR since May 21, 2021 and IVDR May 21, 2022)

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