Brexit at work

Placing medical devices and IVDs on the UK market

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Disclaimer:

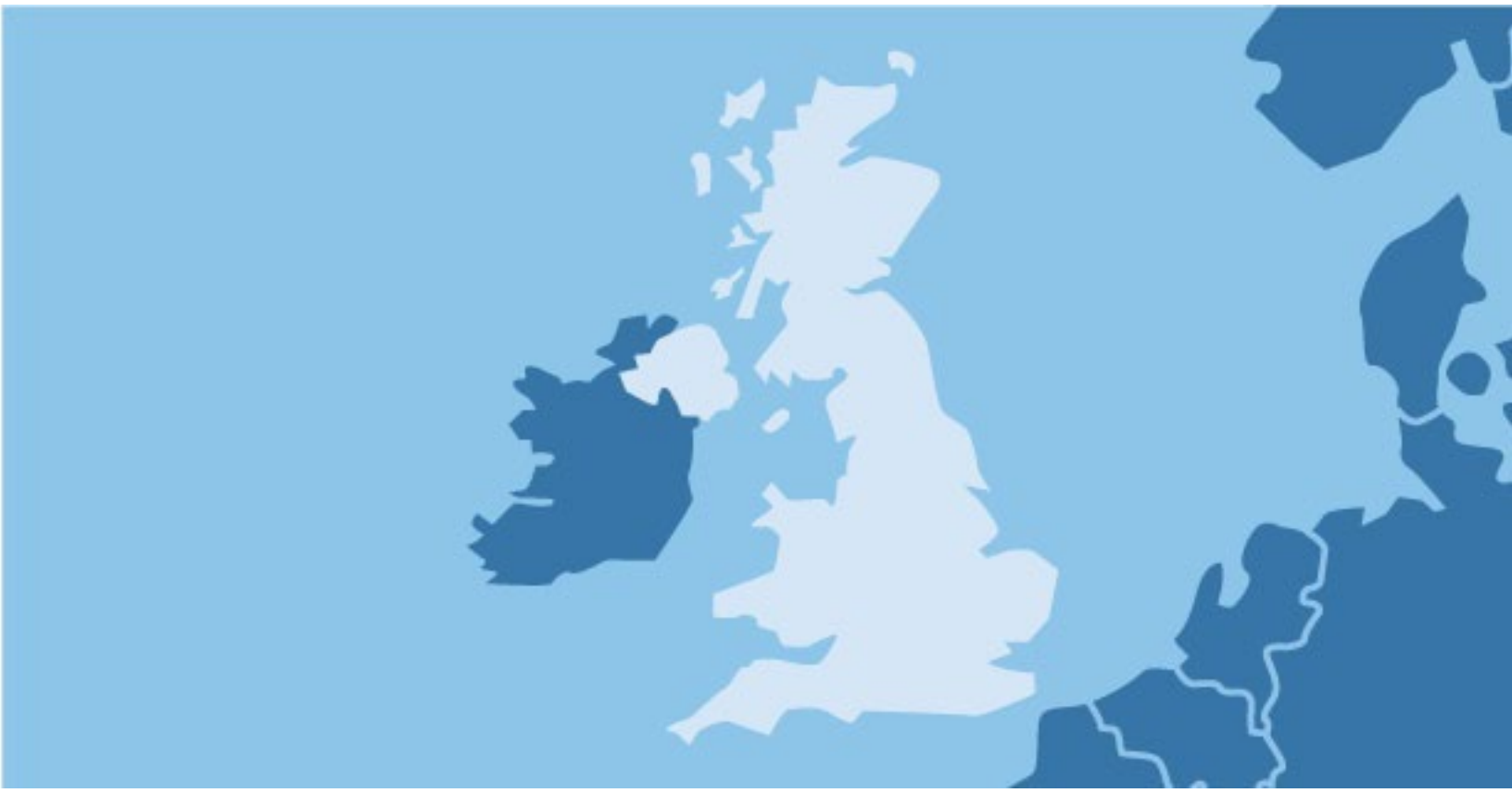
This white paper is based on the EU-UK Trade Agreement as signed in December 2020 and the available guidance documents. That trade agreement may not be in its final version, and some details in the guidance documents may be edited over the coming period.

Note: The UK market surveillance authority, the Medicines and Healthcare products Regulatory Agency or MHRA, has done an impressive job in issuing a wide range of guidance documents and online tools, as well as providing swift answers to direct questions. This has provided valuable support for the creation of this white paper.

The UK has left the EU

British voters have elected to leave the EU, a move that took effect on February 1, 2020. This date saw the beginning of a transitional period, allowing for the arrangement of a future relationship, during which the United Kingdom (UK) would remain in the customs union but not in the European Economic Area (EEA). After almost 11 months of intense EU-UK negotiations, an agreement was reached to allow for so-called “free trade” (no tariffs and no quotas). This means that from January 1, 2021, the UK is a “third country” from the EU perspective, and the same applies for the EEA from the UK perspective. Within that context it is possible for medical devices to move between these markets.

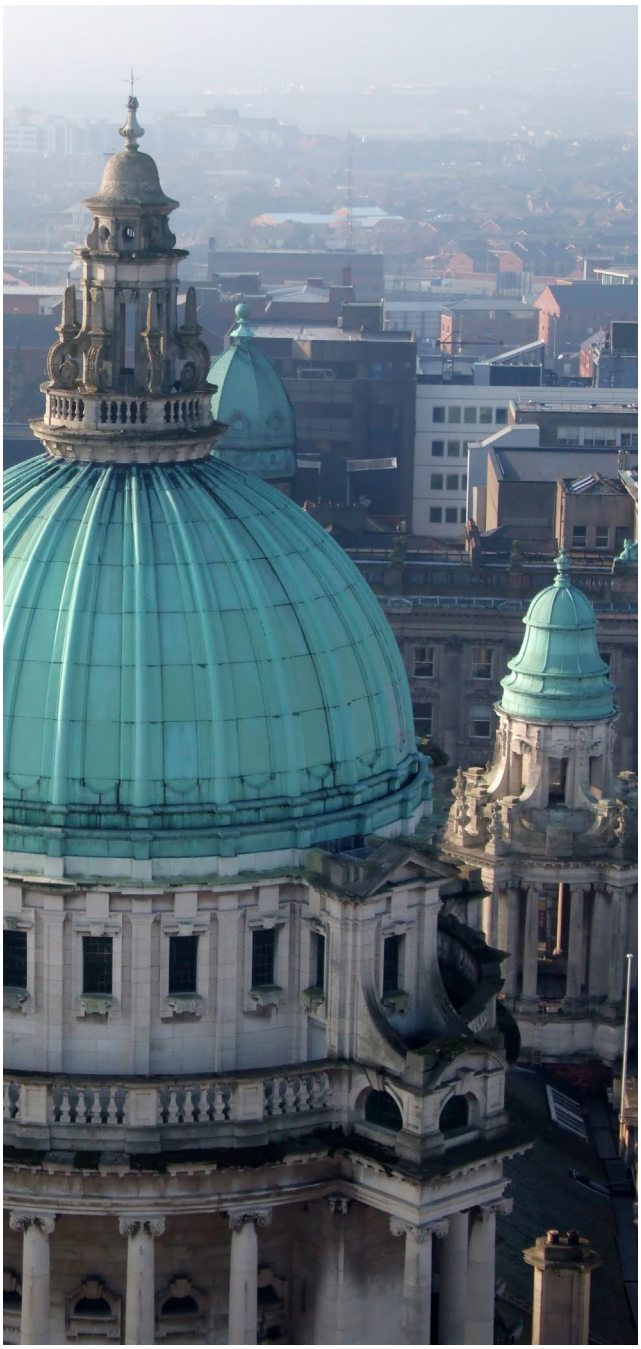
This white paper will provide a summary of the consequences of this trade agreement for medical devices and IVDs exported from the UK to the EEA and those imported into the UK market. It will also address the special situation in effect for Northern Ireland.



The UK, Great Britain, and Northern Ireland

Where the EEA forms a single market in which Member States work together in a single set of rules, the picture for the UK is a bit blurred. For the rest of this white paper it is recommended to understand the following:

- Great Britain consists of England, Wales, and Scotland.
- The UK is “the United Kingdom of Great Britain and Northern Ireland.”;
- The Crown Dependencies (the Isle of Man, the Bailiwick of Guernsey, and the Bailiwick of Jersey) fall under the British Crown and with some exceptions follow UK law, but they are not part of the UK.;
- The British Islands consist of the UK and the Crown Dependencies. The geography of the British Islands is relevant for defining fishing rights.
- The City of London is a ceremonial country within England. It is governed by the City of London Corporation. As it has at this moment not declared independence from England, it can for now be considered equivalent to any other part of Great Britain.



Special status of Northern Ireland

Historical developments, spreading over more than eight centuries, have culminated 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, which ended most of the violence that started in the 1960s. One 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 there has to 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 anybody moving goods in or out, especially between the UK and Northern Ireland. Within that context, CE-marked medical devices can be placed on the Northern Ireland market (see below on Northern Ireland).

The Trade Agreement has uncertainties and serious consequences

The agreement in the EU layout is 1,449 pages long. It covers all sorts of subjects, from trade to fishery and cooperation on international crime fighting. This wide scope has legal consequences. While the European Commission can prepare international trade agreements for the European Parliament to approve, agreements that cover other subjects must go past individual Member State parliaments. With this agreement struck on Christmas Eve and the UK dropping out of the EU on January 1, there was no time for a careful democratic process. As a result, this agreement will be applied before parliamentary scrutiny has taken place. This is at best "inelegant," and in the worst case could lead to a later rejection.

Focusing on the trade part of this agreement, it is clear that products meeting certain criteria can move between these markets without tariffs or quotas. These criteria mean that the UK will more or less have to follow EU requirements, but that is not stated as a hard rule, and the UK may add their own interpretation to these rules. There are arrangements in case of disputes.

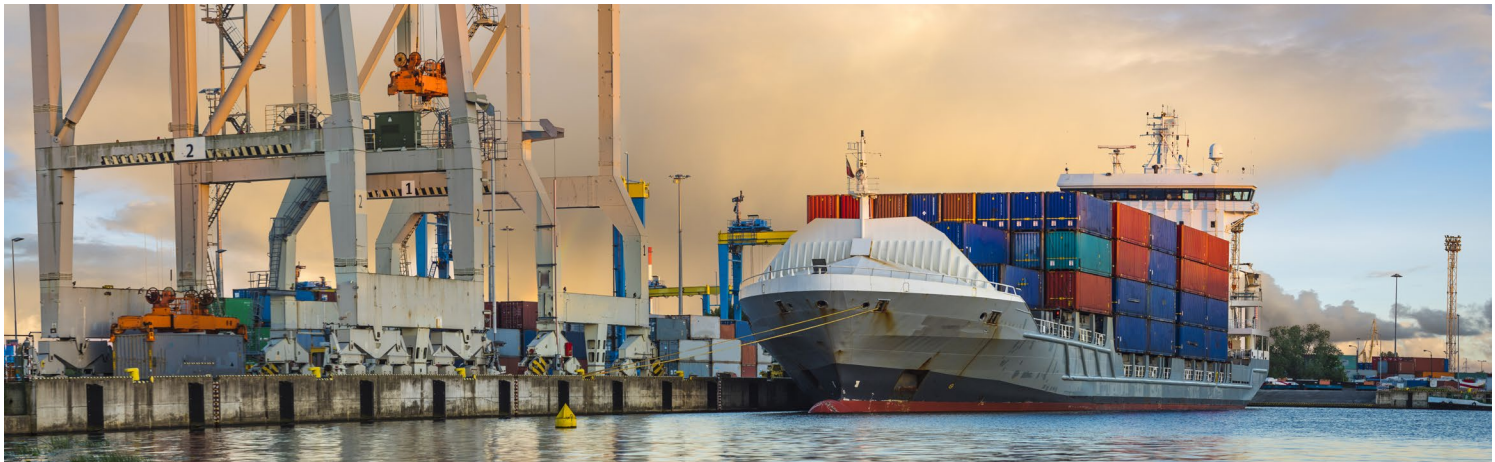
The agreement does not cover services. This may have consequences for suppliers of a medical service, rather than a device, such as home collection testing of IVDs. Within the EEA this service can be supplied without a problem, but that changes at the moment said service crosses the EEA border. This includes the personal data processing that will undoubtedly be part of said service. Companies involved in border-crossing services related to medical devices need to analyze their regulatory status carefully.

While there are no tariffs or quotas, customs duties must still be paid upon delivery, which means that online retail is faced with extra charges in the vicinity of 35% on top of the price paid to the supplier of the product. This may force a change in setting up distribution for some devices.

The agreement divides the population of traded goods into two main categories: goods that originate in the market from which they are intended to cross the outer EEA border, and goods that do not. For most products, at least 50% of the ex-works value must be created in the exporting market to qualify as originating in that market. In this context, the following terms used in the trade agreement are relevant:

- Value of non-originating materials (VNM): the materials used for manufacturing the product that are sourced from another market than that in which the product is made.
- Ex-works price (EXW): the value of the product as it leaves the factory in which it was produced.
- Maximum value of non-originating materials (MaxNOM): MaxNOM is calculated by dividing EXW by VNM and expressing this as a percentage.

Medical devices and IVDs are not specifically mentioned in the agreement (except for emergency relief in case of a disaster), and therefore the above requirement regarding the country of origin applies in full. This means that it is necessary to establish MaxNOM to determine whether the free trade agreement applies, or whether the World Trade Organization (WTO) arrangements must be applied. This is only relevant for customs and does not have regulatory consequences, but it may result in unforeseen changes in pricing. For example, an EEA-based manufacturer has a UK-based company packaging their devices. As the devices come from the EEA, the packaged product may be considered a product that does not originate from the UK. Another example: EEA manufacturers using supplies of raw materials and components from UK sources may have a similar problem when they want to export their devices to non-EEA markets. These issues are only related to customs requirements and additional taxation and tariffs; CE-marking or UKCA-marking have their own dynamics. Every company importing or exporting across an EEA or UK border, not limited to cross-Channel traffic, should calculate MaxNOM to see under which rules these goods can move.



The UK as a third country

The EU has a clear set of rules for countries that are not part of the Single Market. They are so-called “third countries.” In short, this status means that a non-EEA-based device manufacturer must appoint an authorized representative and an importer and change labeling accordingly. These requirements apply from January 1, 2021, without any further transitional arrangement. This has been foreseen for some time, and many UK-based manufacturers have already appointed an authorized representative. Companies that have not done this should arrange to do so urgently, because otherwise they will not be able to place their devices on the EEA market. UK-based importers that forwarded their devices to EEA-based distributors or users will have to set up a different arrangement with their suppliers or stop distribution.

As the UK no longer follows EU rules and the European Court of Justice, its Notified Bodies are no longer recognized within the EEA as notified for the purposes of the devices directives and new regulations. They cannot issue CE certificates, and all CE certificates issued by these bodies have become void from January 1, 2021. This too has been anticipated for some time, and Emergo by UL expects that all but a few companies have made this switch in their certification by now.

From January 1, 2021, UK-based sponsors of clinical investigations involving medical devices or IVDs must appoint an EEA-based Legal Representative to act on their behalf. If there is no Legal Representative appointed, the study must be halted – or at least the enrollment should be stopped – until this appointment has been performed.

Not all Directives or Regulations require an AR for non-EEA manufacturers.

UK-based manufacturers placing devices on the Great Britain market

For UK-based manufacturers that keep placing their devices on the Great Britain market, not much changes, at least in the short term. For Class I devices, custom-made devices, and general IVDs that were already registered with the MHRA, this registration can be continued. For the other devices, there are grace periods in parallel with devices from non-UK manufacturers (see below on Registration). They can keep using CE-marking until July 1, 2023, after which they must use UKCA-marking (see below on UKCA-marking). Incident reporting requirements and procedures do not significantly change, and the requirements from the **Active Implantable Medical Devices Directive 90/385/EC (AIMDD)**, the **Medical Devices Directive 93/42/EEC (MDD)**, the **In-Vitro Medical Devices Directives 98/79/EC (IVDD)**, the **Medical Devices Regulation (EU) 2017/745 (MDR)**, and the **In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR)** can be used for CE-marking.

UK-based manufacturers may place their devices on other markets outside the EEA. The UK has signed some mutual recognition agreements with other markets, like Australia and New Zealand. These agreements cover the "United Kingdom of Great Britain and Northern Ireland"; time will tell if this will have implications for CE-marked devices. Without these agreements, requirements depend on the markets to which these UK-based manufacturers are distributing. MHRA issues Certificates of Free Sales for devices placed on the UK market.

UK-based importers of non-EEA devices may in theory forward their devices to EEA-based distributors. They would have to appoint those same parties as importers. The MDR does not require the importer to receive the device directly from the manufacturer. However, this importer must have direct communication with the manufacturer for vigilance reporting, and if the physical flow of goods proceeds via the UK, those devices may be subjected to additional tariffs because they are not made in the UK. Therefore, it is quite likely most UK-based EEA importers will discontinue these activities.

Non-UK manufacturers placing their devices on the Great Britain market

Non-UK manufacturers, especially EEA-based companies, will see some major changes. From the UK perspective, their devices will be considered coming from a third country. Therefore, they need to appoint a UK Responsible Person (UKRP), and their devices have to be placed on the market by an importer. The importer is defined as the person established within the UK that places on the market a device from a country outside the UK (definition from the **2019 amendments to the 2002 Medical Devices Regulations**). Any UK-based (legal) person can become an importer, but it appears there must be some sort of an agreement with the manufacturer. This is not specified in current requirements or guidance documents, but it has been communicated verbally by the MHRA. The importer must notify the relevant UKRP about their role, who must then register that importer with the MHRA after confirmation of that role by the manufacturer. This information can be found in the MHRA register, of which parts are publicly accessible.

The UKRP has a role similar to that of the authorized representative in the EU, with some differences. The UKRP requirements and activities are loosely based on the requirements in Article 11 of the MDR/IVDR for the authorized representative. This person acts on behalf of the non-UK manufacturer and must register devices on behalf of the manufacturer and the importers involved (see below on Registration). It appears the UKRP will not be held liable for defective devices as defined in Article 11(5) of the MDR. The manufacturer must report incidents, but it can ask the UKRP to do this on its behalf (see below on Vigilance Reporting). It is important to understand that the requirements to appoint an importer and a UKRP apply from January 1, 2021.

Registration

In order to enable the MHRA to perform its market surveillance activities, it is necessary for economic operators to register themselves, their devices, and the applicable certificates and clinical investigations or performance studies. Registration requirements apply for all devices placed on the UK market, newly made or refurbished, including custom-made devices and systems or procedure packs (SPPs) containing at least one device and including IVDs for performance evaluation. Where UK-based manufacturers can take care of all their registrations by themselves, non-UK manufacturers must rely on an appointed UKRP based in the UK. The UKRP must register the manufacturer, the importer, and their devices. In order to do so, the manufacturer must supply the applicable details. Although a manufacturer can find the required details in the **MHRA guidance on registration** (also containing video tutorials), the UKRP should be in the lead for registration. Most UKRPs will therefore reach out to their manufacturers to request the applicable details. UK-based manufacturers and Northern Ireland-based authorized representatives must maintain their current registrations of Class I devices, custom-made devices, and general IVDs. This implies that any new device must be registered before it can be placed on the market.

For non-UK manufacturers that were already supplying their 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 deadlines are also the deadlines for registration of the manufacturer and their UKRP. For importers the deadlines are not specified, but it appears that they can be registered together with the UKRP and manufacturer at the earliest; they should register before they start placing their devices on the UK market. If the device portfolio covers devices from different risk classes, all devices can be registered within the strictest deadline (for example, a company manufacturing a Class III device and several Class I devices can register all devices before May 1, 2021). But a manufacturer may decide to register in multiple rounds.

Within the context of registrations, “devices” are understood as a device family with the same Global Medical Device Nomenclature (GMDN) code. Multiple products can be linked to that device. Note that the MHRA refers to GMDN and not to the European Medical Device Nomenclature (EMDN) codes needed for Eudamed.

A fee of 100 British pounds applies for each application. One application may cover up to 100 devices with a cumulative maximum of 20,000 products.

Note that part of the information will be made public via the public register. This register will publish name, address, and MHRA reference number, as well as all devices by their GMDN nomenclature code.[1]

CE, UKCA, and CE UKNI marking

From January 2021 until July 1, 2023, the UK market will remain open for CE-marked medical devices and IVDs. Note that other CE-marked products must be UKCA-marked by January 1, 2022. At this moment there are devices in the EEA certified in compliance with the AIMDD, MDD, IVDD, MDR, and IVDR; therefore, these five sets of rules are recognized in the UK. These requirements will be replaced by the UKCA rules, which are for now based on the Medical Devices Regulations 2002. The Regulations have been amended in 2019 and in 2020. At this moment there is no consolidated version of these requirements, which means that it is difficult to do a full analysis, but it appears that UKCA requirements more or less follow AIMDD, MDD, and IVDD requirements as applicable. It is expected that in the near future, a new set of UKCA requirements will be published. The MHRA has strong roots in EU tradition, and the UK has been involved in the EU switching to the new Regulations. It can be expected that UKCA requirements will look quite familiar for companies preparing for the MDR and/or IVDR. But only time will tell how this will turn out. The MHRA has indicated they will expect the UKRP and the importer to be indicated on the device, the label, or a document accompanying the device. For practical reasons this is not required for CE-marked devices, but it is required for UKCA-marked devices. This means that a manufacturer only needs to adapt their labels once.

UK-based Notified Bodies were denotified from January 1, 2021, but they are now designated by the MHRA as UK Approval Bodies (UKAB). UKABs can issue UKCA certificates that can be used for UKCA marking. Currently there are three UKABs:

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

Some EU-based Notified Bodies have indicated they have the intention to become designated for UKCA certification as well. Although BSI UK has announced that they expect to be able to certify devices currently certified by BSI NL as UKCA devices, it is likely that not all currently CE-marked devices can switch to be UKCA-marked by July 2023. Note that a manufacturer based in Northern Ireland placing CE-marked devices on the market can remain doing that in the UK as well.

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 UKAB, a CE 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. They can only be placed on the Great Britain market if the CE UKNI mark is held by a manufacturer based in Northern Ireland.

Northern Ireland

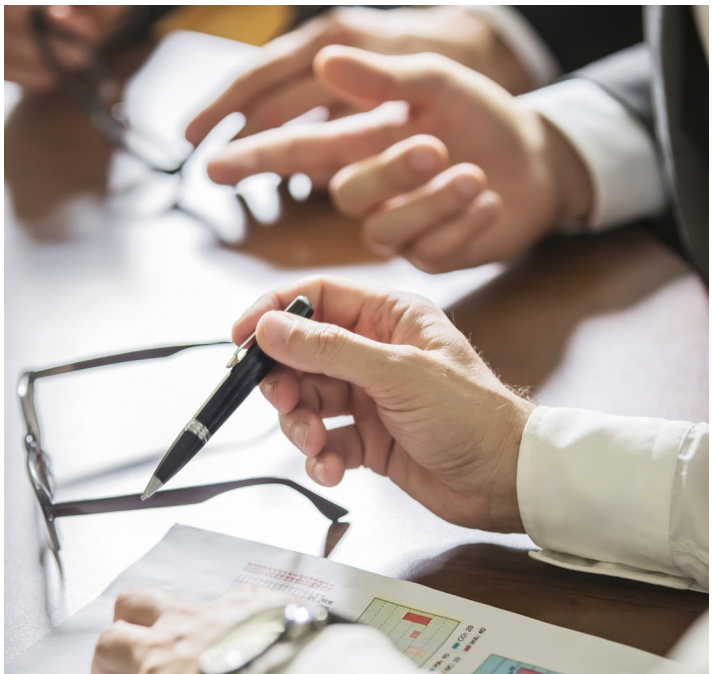
The situation for Northern Ireland is complicated by its dual position: this geographical area has characteristics of an EU Member State due to its open border with the Irish Republic, while it is part of a third country from an EU perspective. This has resulted in complicated customs requirements. Market access has its own dynamics, with the CE mark remaining applicable while the UKCA mark does not apply. Non-UK manufacturers can rely on their UKRP if they want to place their devices (CE-marked!) on the Northern Ireland market. If they only want to make their devices available on the Northern Ireland market, a Northern Ireland UKRP is also required. If they rely on an authorized representative based in Northern Ireland, it is not necessary to appoint a UKRP for Northern Ireland. But a non-EEA manufacturer with an EEA-based authorized representative must still appoint a UKRP.

Manufacturers based in Great Britain or Northern Ireland do not need to appoint a UKRP in Northern Ireland. Class I medical devices, custom-made devices, and general IVDs that are registered with an EEA Competent Authority also do not require a UKRP for the Northern Ireland market and need not be registered with the MHRA. If these devices were previously placed on the UK market, they must remain registered with the MHRA from January 1, 2021. Class III and Class IIb implantable devices, all active implantable devices, and IVD List A products must be registered from May 1, 2021. Other Class IIb and all Class IIa devices and IVD List B products must be registered from September 1, 2021. These timelines are the same as for devices placed on the Great Britain market.

Devices that have been placed on the EEA market can also be placed on the Northern Ireland market and rely on their EEA-based manufacturer or authorized representative. Manufacturers based in Great Britain must appoint an EEA- or Northern Ireland-based authorized representative if they want to make their devices available in Northern Ireland.

Distributors based in Northern Ireland face a special challenge. Regardless of whether devices come from Great Britain, the EEA, or the rest of the world, the devices must be placed on the Northern Ireland market by an importer. This implies that a retailer selling bandages will have to meet the requirements related to the importer status. Those requirements are related to the applicable legislation: as long as the MDD and AIMDD apply, the MHRA refers to the **Blue Guide** to specify their requirements. Section 3.3 of the Blue Guide basically puts the importer in the same position as the manufacturer with regards to responsibilities for compliance. This includes verification of the drawing up of technical documentation and ensuring these documents are available for the authorities. There are labelling requirements as well. These go further than the requirements for the importer as specified in the MDR, which will become applicable after the date of application of the MDR, May 26, 2021. It is likely distributors are not prepared to take up the role of importer, and manufacturers may not be prepared to share their data with all these companies. This may result in shortages of devices, especially self-help devices distributed via retailers, at least until May 2021. For IVDs, like pregnancy tests, these problems will persist at least until May 26, 2022. When questioned about this issue, the MHRA suggested additional guidance may be considered, allowing for an importer role that is more in line with those of the MDR/IVDR. Until said guidance is published, importers should apply these more complex requirements.

Another point of concern is that the MHRA must perform the market surveillance on CE-marked devices in Northern Ireland, while not being part of the EU market surveillance system. They will not have the same level of access to vigilance data as their EEA counterparts, although it appears there are ongoing negotiations about this. **Article 12 of the Northern Ireland Protocol** regulates that rulings of the European Court of Justice will also be recognized in Northern Ireland. This ensures that at least in Northern Ireland, the interpretation of the European legislation will be the same as in the EU.



From[2] \ to	Great Britain	Northern Ireland	EU
Great Britain	Maintain registration with MHRA and register higher-risk devices before May or September 2021. Prepare for UKCA marking.	Apply CE or UKNI marking and appoint importer.	Apply CE marking and appoint EU-based AR and importer. UK-based importers of non-EU devices can place their devices but they must facilitate the EU importers communicate and directly with the manufacturer.
Northern Ireland	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 and register with MHRA.	Apply CE marking and enjoy free access to Union market.
EU	CE marking is acceptable until July 1, 2023, after which UKCA marking is applicable. 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.	-
Rest of World	CE marking is acceptable until July 1, 2023, after which UKCA marking is applicable. Appoint UK-based UKRP and Great Britain-based importer.	Apply CE mark and appoint UK-based UKRP unless your AR is based in NI 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, appoint EEA based AR and importer. Register in Eudamed (if applicable).

Incident reporting

The MHRA refers to MEDDEV 2.12/1 rev. 8 for vigilance reporting, which implies that their system closely follows the EU structure and procedures. Reporting requirements are placed upon the manufacturer, UKRP, and the authorized representative based in Northern Ireland. In case a manufacturer is not based in the UK, reporting can be done by the UKRP or the authorized representative based in Northern Ireland. This should be agreed between the manufacturer and their UKRP or authorized representative. The manufacturer remains responsible. Reporting must be done in the MHRA **MORE** system or by sending an email with the necessary information.

Clinical investigations and performance evaluations

The procedures for registration of clinical investigations and performance studies are basically the same in the UK as in the EU, although there are some differences in the details. If UK citizens are involved, an application must be filed with the MHRA (templates are available on the MHRA website). The British Health Research Authority (HRA) will review the applications, and if Welsh healthcare providers are involved, so will Health and Care Research Wales (HCRW). The MHRA review can be conducted in parallel with the Research Ethics Committee (REC). Studies that have started before January 1, 2021 can proceed, and an EEA sponsor does not have to appoint a legal representative in the UK.

The guidance documents do not specify the requirements for reporting of adverse events, but it can be expected these will be similar to the European rules.

Actions to take

Manufacturers of medical devices must adapt to the new status of the UK. Emergo recommends the following steps:

1. Establish where the manufacturer is based. This can be in Great Britain, Northern Ireland, the EEA, or the rest of the world.
2. Establish where the device will be placed on the market. This can also be in Great Britain, Northern Ireland, the EEA, or the rest of the world.
3. Determine the need for an authorized representative and/or a UK Responsible Person.
4. Determine the need for an importer.
5. Ensure the sponsor or legal representative for clinical investigations or performance studies is still in line with the requirements.
6. Ensure the device is marked as required. Depending on the market and the timing, this can be CE, UKCA, or UKNI marking; make sure to engage with the correct Notified Body and/or UKAB.
7. Ensure correct registration, either with the MHRA or Eudamed.
8. Investigate any potential logistical issues regarding raw materials, components, assembly services, and finished products having to move across an EEA outer border.
9. Establish MaxNOM (%) to see if the device falls within the terms of the new EU-UK Trade Agreement.

End Notes

1 Guidance only mentions “manufacturers,” but it is expected that UKRP, and probably also importer, details will also be made public.

2 “From” refers to the location of the manufacturer.

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