Medical Device and IVD Registration in the UK

Placing medical devices and IVDs on the UK market

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Disclaimer:

This white paper is based on the EU-UK Trade and Cooperation Agreement as published in April 2021 and the associated available guidance documents.

Post-Brexit Medical Device Regulatory Requirements in the UK

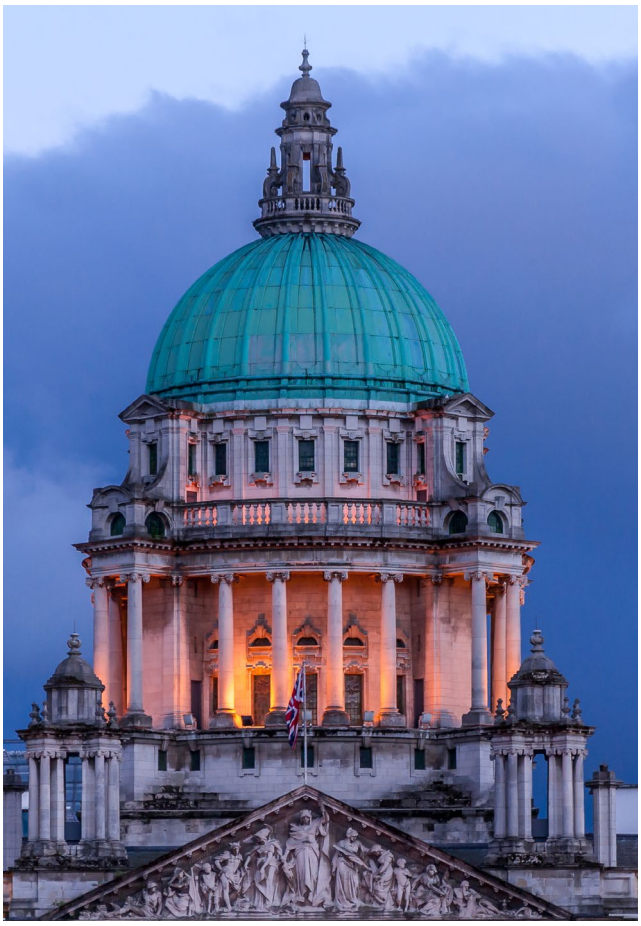
From January 1, 2021, the UK is a “third country” from the EU perspective, and the same applies to the EEA from the UK perspective. Within that context, medical devices can move between these markets.

This white paper will summarize 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.



Special status of Northern Ireland

Historical developments, spreading over more than eight centuries, have culminated in the island of Ireland being split into the Republic of Ireland (officially named Ireland), 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 breach the Belfast (Good Friday) 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 some form of customs control introduced, 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 2,530 pages long. It covers all sorts of subjects, from trade to fishery and cooperation in 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 2020 and the UK dropping out of the EU on January 1, 2021, there was no time for a careful democratic process. The agreement has since undergone a final process of legal revision and entered into force on May 1, 2021, without any substantial changes.

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 its own interpretation to these rules. There are arrangements in case of disputes.

The agreement also covers trade in services and investment, which 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 of up to 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 VNM by EXW 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 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 (AR) and an importer and apply labeling accordingly. For UK-based manufacturers, these requirements apply from January 1, 2021.

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 medical devices directives and regulations. They cannot issue CE certificates, and all CE certificates issued by these bodies have become void from January 1, 2021.

From January 1, 2021, UK-based sponsors of clinical investigations conducted in the EU 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 placing their devices on the Great Britain market, not much has changed. For Class I devices, custom-made devices and general IVDs that were already registered with the MHRA, this registration can be continued. For other devices, these must now also be registered with the MHRA (see below on Registration). They can keep using CE marking until June 30, 2030, at the latest, depending on device type and classification, 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, including 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 EU 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.

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

For non-UK manufacturers, especially EEA-based manufacturers, their devices will be considered by the UK as 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. Although no formal definition is provided in the UK MDR 2002, the importer is considered as the person established within the UK that places on the market a device from a country outside the UK.

Any UK-based (legal) person can become an importer, but it appears there must be some sort of agreement with the manufacturer. This is not specified in current requirements or guidance documents, but it has been communicated by the MHRA that 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 EU MDR/IVDR for the AR. 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 EU 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 applied from January 1, 2021.

Registration

In order to enable the MHRA to perform its market surveillance activities, it is necessary for the manufacturer, UKRP and importer to register themselves, their devices and the applicable certificates as well as clinical investigations or performance studies. Registration requirements apply for all devices before placement on the GB market, newly made or refurbished/re-labeled, including IVDs, custom-made devices and systems or procedure packs (SPPs) containing at least one device and also 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. The UKRP must register the manufacturer, the importer, and their devices. 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 is required to complete the registration. Most UKRPs will therefore reach out to their manufacturers to request the applicable details. 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.

Currently, a fee of 240 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 and registration status.

CE, UKCA, and CE UKNI marking

From January 2021 until, at the latest, June 30, 2030, the Great Britain market will remain open for CE-marked medical devices and IVDs, depending on device type and classification. 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. In addition, from January 1, 2021, UKCA marking has been available for medical devices that comply with the UK **Medical Devices Regulations 2002, as amended** and if necessary based on classification certified, received a certificate from a UK Approved Body (UKAB). The Regulations more or less follow AIMDD, MDD and IVDD requirements as applicable. It is anticipated that new UK medical device legislation will be published in 2025, and will closely align with the EU MDR and IVDR. Priority measures to protect patient safety will be put in place ahead of the new framework intended to be in place during 2025. The MHRA has confirmed that devices can have both the CE and UKCA markings present on the labeling; however, the name and address of the UKRP needs to be indicated on the product label, or the outer packaging, or the instructions for use only in cases where the UKCA marking has been affixed (including when devices have been dual marked). Note that the importer or distributor's name and address do not need to be present on the label unless the importer or distributor is acting as the UKRP for UKCA marking.

UK-based Notified Bodies were de-notified on January 1, 2021, but they are now designated by the MHRA as UK Approved Bodies (UKAB). UKABs can issue UKCA certificates for UKCA marking. Organizations designated as UKABs include:

- BSI Assurance UK Ltd (0086), designated active implantable medical devices (AIMDs), medical devices and IVDs
- DEKRA Certification UK Ltd (8505) designated for medical devices
- INTERTEK MEDICAL NOTIFIED BODY UK Ltd (8532) designated for medical devices
- LNE-GMED UK Limited (8521) designated for medical devices, AIMDs and IVDs
- Scarlet NB UK Ltd (8536) designated for medical devices
- SGS UK Ltd. (0120) designated for medical devices and IVDs (some limitations in their scope)
- TUV Rheinland UK Ltd (2571) designated for medical devices, AIMDs and IVDs
- TUV SUD BABT Unlimited (0168) designated for medical devices and AIMDs
- UL International Ltd. (0843) designated for medical devices and a single IVD scope code.

The situation in Northern Ireland is different: CE marking is required, and the MDR and IVDR have applied from May 26, 2021, and May 26, 2022, respectively. If the certification is performed by a UK Notified Body (UKNB), a UK-based conformity assessment body designated under the relevant EU legislation to conduct conformity assessments for the NI market, a CE UKNI marking is required. The CE UKNI mark is created as part of the Northern Ireland protocol and applies to 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. Note that there are currently no UKNBs designated to undertake such conformity assessments under the EU MDR or the EU IVDR.

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.

Certain medical devices, IVDs and custom-made devices that are placed on the Northern Ireland market need to be registered with the MHRA. The precise requirements depend on the location of the manufacturer, the location of the AR and the device class. Great Britain manufacturers are required to appoint an AR based in the EU or Northern Ireland to place a device on the market. Where a Northern Ireland-based AR is appointed, they need to register devices of all classes with the MHRA. Where an EU based AR is appointed, the Great Britain manufacturer needs to register all devices other than Class I devices and general IVDs (that are not for self-testing).

Additionally, the UK Government has guaranteed unfettered access for Northern Ireland's businesses to the rest of the UK internal market. For medical devices, this means that any CE marked device held by a Northern Ireland business is valid for the whole of the UK market. Therefore, CE and CE UKNI marked devices that can be placed on the Northern Ireland market and are qualifying Northern Ireland goods, can also be placed on the GB market and do not need to undergo any further registration in Great Britain.

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.

Distributors based in Northern Ireland face a special challenge. If devices come from Great Britain or another non-EEA country, the devices must be placed on the Northern Ireland market by an importer. This implies that a retailer selling, for example, bandages will have to meet the requirements related to the importer status. The precise requirements depend on which legislation the manufacturer has certified their device under.

The MHRA remains the competent authority for post-market surveillance activity for devices placed on the Northern Ireland market. Where incidents occur in Northern Ireland, these need to be reported to the MHRA.

From* \ to	Great Britain	Northern Ireland	EU
Great Britain	Register all devices with MHRA. Prepare for UKCA marking.	Apply CE (or UKNI) marking and appoint an EU or NI-based AR, as well as importer. Register certain medical devices with MHRA.	Apply CE marking and appoint EU based AR and importer. Register in EUDAMED (if applicable).
Northern Ireland	Unfettered access if CE- or UKNI- marked; certain medical devices, IVDs and custom-made devices need to be registered with MHRA. No importer or UKRP is required.	Apply CE (or UKNI) marking and register with MHRA.	Apply CE marking. Register in EUDAMED (if applicable).
EU	CE marking is acceptable until June 30, 2030 (at the latest), after which UKCA marking is applicable. Appoint UKRP and Great Britain-based importer. Register all devices with MHRA.	Apply CE marking 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 an 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.	Register in EUDAMED (if applicable).
Rest of World	CE marking is acceptable until June 30, 2030 (at the latest), after which UKCA marking is applicable. Appoint UKRP and Great Britain-based importer. Register all devices with MHRA.	Apply CE marking and appoint 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 marking, appoint EEA-based AR and importer. Register in EUDAMED (if applicable).

* "From" refers to the location of the manufacturer.

Incident reporting

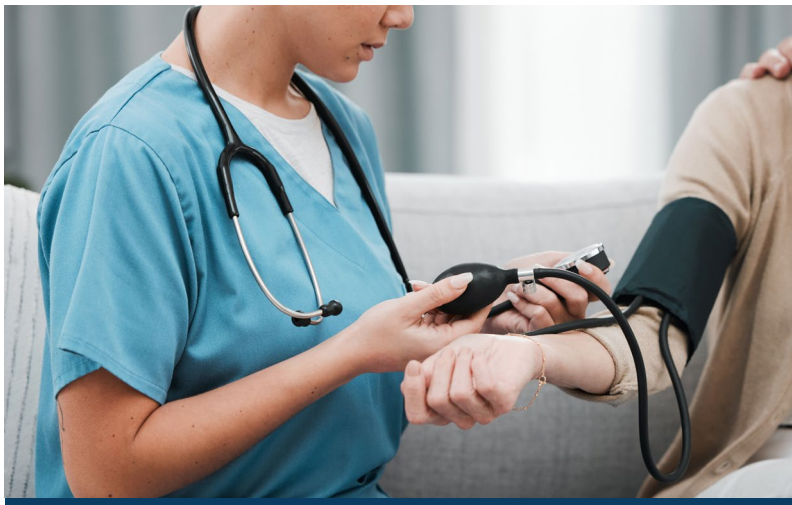
The MHRA refers to MEDDEV 2.12/1 rev. 8 for vigilance reporting, which implies that their system closely follows the former EU structure and procedures. Reporting requirements are placed upon the manufacturer, UKRP and the authorized representative based in Northern Ireland. In case a manufacturer is 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 portal.

Clinical investigations and performance evaluations

The procedures for registration of clinical investigations and performance studies being conducted in the UK must meet the requirements of the UK MDR 2002. If UK citizens are involved, you must notify the MHRA (templates are available on the MHRA website). The manufacturer of UKRP must give 60 days of prior notice and all notifications should be submitted using the application process on the IRAS portal. If no objection is received within 60 days of formal acceptance of the notice, the clinical investigation may proceed. The MHRA will collaborate with the Health Research Authority (HRA) on the coordinated assessment pathway which involves information sharing and benefits the applicant by ensuring the MHRA review and the Research Ethics Committee (REC) review are undertaken in parallel. 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 UK MDR 2002 requires manufacturers to record fully all adverse events and report all serious adverse events occurring in all participating centers to the MHRA.

As NI continues to align with EU rules, all clinical investigations involving a site in NI must be submitted to the MHRA in line with the requirements of the EU MDR.



Note: Where a clinical investigation includes sites in both Great Britain and Northern Ireland, submission to the MHRA must be made in line with the requirements of the EU MDR. By meeting the EU MDR, the requirements of the UK MDR 2002 for clinical investigations are deemed to be satisfied. Therefore, a single application made to MHRA under the EU MDR will cover any sites proposed in both Great Britain and Northern Ireland for the same clinical investigation.

Actions to take

Manufacturers of medical devices must adapt to the new status of the UK. We at Emergo by UL recommend 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 UKRP.
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. Confirm 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. Confirm 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.

Learn more

Need help navigating medical device compliance in Europe and/or UK? Emergo by UL helps medical device companies with regulatory compliance and market access in Europe and other markets worldwide. Here's how we can help:

- Brexit transition consulting and in-country representation (UKRP)
- Technical File and CER compilation and review
- European Authorized Representation
- MDR gap audits and transition consulting

Learn more about how we can help you with medical device compliance at **EmergobyUL.com**.

About the author

Karen Hill has over 20 years of medical device industry experience, primarily focused on high-risk, implantable devices and In Vitro Diagnostics (IVDs). Her background includes extensive experience in EU activities, such as Technical File/Design Dossier and Clinical Evaluation Report preparation. In addition, she is Emergo's leading consultant for support with UK medical device registrations and UKCA marking. On top of her European and UK regulatory expertise, she has also cleared multiple FDA 510(k)s and has several years of global regulatory research and strategy experience.

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