When the UK left the European Union on 31 January 2020, the Withdrawal Agreement and the resulting 12-month transitional period came into play. The EU-UK negotiations began to focus on reaching an agreement on the future trade relations between both parties. Trade negotiations have continued and intensified over the months of October and November, and although some progress has been made in recent discussions, significant differences remain in a number of areas, with just a few weeks remaining before the end of the transition period.

During this 12-month transition period, not much has changed for the EU’s Medtech sector. The UK has remained within the single market and customs union, and all EU rules, policies and legislation continue to apply until 31 December 2020. However, relations with the UK are set to change at the end of the transition period regardless of whether there is a deal on trade or not as the UK will be recognised as a third country and EU legislation will cease to apply. A summary of the key changes for economic operators can be found below.

In the absence of a deal on trade, the UK would fall back on basic World Trade Organisation (WTO) terms, which would mean that tariffs on goods and border checks would be introduced from 1 January 2021.
### Key Changes for EU Economic Operators

<table>
<thead>
<tr>
<th><strong>Importers</strong></th>
<th>Any natural or legal entity placing devices on the market from a third country (e.g. the UK) for the first time would be considered an importer.(^1)</th>
</tr>
</thead>
</table>
| **UK Manufacturers** | Need to relocate to an EU-27 Member State or establish an authorised representative within an EU-27 Member State. An authorised representative must accept to undertake this role and act on behalf of the manufacturer, for example, when liaising with competent authorities.  
Continue to register with their own competent authority (i.e. the MHRA) and refer to their guidance in order to place products on the UK market.  
All products placed on the EU-27 market must continue to meet the requirements of EU device legislation. |
| **Authorised Representatives (AR)** | If located in the UK will be required to relocate to an EU-27 Member State.  
ARs relocating to Republic of Ireland as a result of Brexit should register their organisation and device details with the HPRA. |
| **Device Labels/ Packaging & Documentation** | Device labels/packaging and documentation must be compliant with EU legislation.  
EU-27 notified body must be identified on the labelling as appropriate.  
EU-27 authorised representative must be identified on the labelling as appropriate.  
Manufacturers and authorised representatives should ensure documentation (e.g. declaration of conformity and device certificates) reflects the EU-27 notified body and/or authorised representative.  
Where this will not be in place by the 31 December 2020, the HPRA are requesting that label transition plans are submitted to devices@hpra.ie. This will assist the HPRA with device traceability and market surveillance.  
Transition plans should outline devices requiring label updates, a prioritisation plan and justification and expected date for completion. |

\(^1\) From 26 May 2021, such entities will have to fulfil the obligations of an importer under the MDR.

### Northern Ireland

As part of the Withdrawal Agreement the Northern Ireland Protocol was introduced and will become applicable from 1 January 2021 when the transition period ends. Under this Protocol certain provisions of EU law, including EU device legislation, will continue to apply in Northern Ireland. This means in practice that:

- Manufacturers based in Northern Ireland can freely place devices compliant with the Directives/ Regulations on the EU-27 market without the need for an EU authorised representative;
- Devices manufactured in Northern Ireland and shipped to the EU will not be considered imported products for the purpose of labelling and identification of economic operators;
- EU importers and authorised representatives can be established in Northern Ireland;
- Certificates issued by a notified body in Great Britain are not valid in Northern Ireland.

Further information on the application of the Northern Ireland Protocol can be found in the European Commission’s Notice to Stakeholder (March 2020).

### Guidance Documents

The HPRA would encourage all stakeholders to be aware of the regulatory steps to remain in compliance with the EU medical device legislation; in particular, all Irish distributors should review their supply chain to assess if they now have additional regulatory responsibilities as they may take on the role and responsibilities of an importer. To assist stakeholders with their planning, the HPRA has developed a Brexit Transition Period Checklist.

The Department of Business, Enterprise and Innovation also has a Brexit Preparedness checklist, which you can find here. We encourage all stakeholders to once again prepare for the possibility of a no-deal on trade and plan accordingly.

The European Commission has issued a number of stakeholder notices on how to prepare for the end of the transition period. This includes recently published notices on Trademarks and Design & Good Laboratory Practices. Both documents are available on the Commission website here. In addition to the publication of new guidance documents for stakeholders, the Commission has revised and consolidated the 2018 stakeholder notice and the 2019 FAQ document. The consolidated notice was published on 13 March and is available here. The Commission has also published a specific Communication on readiness at the end of the transition period. The HPRA encourages all stakeholders to become familiar with this Communication.
**Brexit FAQs**

We have received a number of queries from stakeholders relating to Brexit and how best to plan for the end of the transition period. Below are some common questions from recent weeks. Further queries on the impact of Brexit can be sent to devices@hpра.ie.

- **What is meant by ‘first placed on the EU market’?**
  
  Placing a device on the market means the first time a device is supplied for distribution, consumption or use on the market in the course of a commercial activity, whether in return for payment or free of charge. This definition applies to each time an individual product is placed on the market. In order for a device to be placed on the market, there must be a transfer of ownership, via a financial or legal transaction, from the manufacturer; this would not, however, require a physical transfer of the goods. In the context of Brexit, this provision will apply only to those individual devices which have been manufactured and placed on the market in the EU or the UK before the end of the transition period.

- **Would a sales office based in the UK responsible for the shipment of product within the EU be considered acceptable?**
  
  A sales office location in the UK is outside the scope of the MDR. All economic operators within the EU must be compliant with the application Directive(s) or Regulation(s).

- **In the absence of a trade deal can an EU product be shipped through the UK before re-entering the EU?**
  
  Importers and distributors operating in this scenario should review the transit provisions for goods crossing the UK. Further information on when the transit provision would apply is available on the Revenue & Customs website. The European Commission's document outlining Brexit transit scenarios may also be of assistance.

- **Is it acceptable to place a device on the EU market with both the EU and UK labels, e.g. CE mark and UK CA?**

  In order to place a medical device on the EU market it must meet the requirements for labelling, packaging and accompanying documentation set out in the current medical devices Directives. From May 2021, the requirements of the new Medical Devices Regulation will apply. While there may be additional information on the device label, this must not obscure the required EU details.

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**In Vitro Diagnostic Tests for COVID-19**

Tests for COVID-19 are currently regulated under Directive 98/79/EC on In-Vitro Diagnostic Medical Devices (IVDs) and must be CE-marked in accordance with the requirements of the Directive before placing on the EU market.

Testing for COVID-19 has evolved as the pandemic progresses and as more information becomes available, it helps inform “state of the art”. Over time, the numbers of tests CE marked for professional use has increased with a broadening of the variety of technologies used in testing.

The HPRA has not prohibited the sale or purchase of legitimately CE-marked COVID-19 test kits on the market in Ireland to date, but is highlighting the importance of understanding the various characteristics of these test kits; information on IVD tests for COVID-19 is available on our website. It is recommended that individuals eligible for testing, access testing through the national testing strategy to ensure the results are quality assured and can be identified for use in contact tracing efforts.
While importers of medical devices have always existed, the MDR/IVDR calls out new regulatory responsibilities for these economic operators. If operating within the medical devices supply chain, it is important to identify your legal obligations and maintain documentation to demonstrate your compliance with the new EU Regulations. Any natural or legal person established within the Union that places a device from a third country (i.e. outside the EU) on the union market is an importer. Unlike the movement of other goods, there is no requirement for importers or distributors of medical devices to hold a licence issued by a competent authority. Importers should fulfil the requirements set out in Article 13 of the MDR or IVDR, whereas distributors should fulfil obligations set out under Article 14 of both Regulations. Both economic operators should also pay attention to Article 16 (MDR/IVDR), and the situations under which they may take on the roles and responsibilities of a manufacturer when placing a device on the EU market.

Distributors will take on the role and responsibilities of an importer if they are placing a device on the EU market for the first time, regardless of whether or not the manufacturer already has an importer in place. In accordance with The Commission’s Interpretative Guide to Placing on the Market, placing on the market refers to each individual physical device. At each point of entry to the EU market, each economic operator placing the device on the EU market for the first time will take on the roles and responsibilities of an importer. It is therefore possible to have more than one importer, as devices may enter the EU market via more than one channel. All importers must fulfil their obligations, to ensure traceability and oversight of the supply chain throughout Europe. Although some activities may be subcontracted outside the importer’s organisation, it is not possible for one importer to delegate their legal responsibilities to another legal entity. Importers/distributors must complete their checks as per Article 13 and 14 (MDR/IVDR), and they cannot rely on upstream economic operators (i.e. manufacturers or authorised representatives) to complete these checks on their behalf.

Some companies are contracted to provide third-party shipping or storage services. However, as they are not considered to be a legal entity placing the device on the market, they would not be considered an importer. In order to be placed on the market, there must be a physical or legal/financial transfer of ownership. Although transportation or storage activities may be subcontracted outside of the importer’s organisation, the importer retains responsibility for storage and transport conditions and, as such, must ensure the subcontractor’s conditions do not jeopardise compliance with the general safety and performance requirement of Annex I.

Ahead of May 2021, when the MDR becomes fully applicable, we are strongly encouraging distributors to ensure they are meeting the requirements of Article 13, Article 25 (and Article 16 if applicable). While national distributor registration is currently being explored as a national policy by the Department of Health, we are asking distributors to engage with the HPRA and notify us of your distributor status and to be included on the HPRA’s economic operator database. Importers should adhere to the relevant Eudamed registration requirements, details of which are laid out on hpra.ie and elsewhere in this newsletter. Queries on these obligations can be sent to devices@hpra.ie, and a member of the Medical Devices department will endeavour to assist you in understanding these requirements.
With rapidly improving healthcare IT infrastructure and a rising demand for remote patient monitoring services, the global digital health market is expected to grow and reach a total value of almost $640 billion by 2026 (full report). Within the field of digital health is medical device software (MDSW).

The HPRA recognises the essential role MDSW developers play in protecting and promoting public health. We also recognise the challenges new MDSW developers face in navigating through the regulatory landscape. In response to the growing number of queries we receive from MDSW developers, the HPRA has outlined three important considerations to help guide such stakeholders through their product development process.

**Have a clear design and development strategy from the start**

From an early stage, you should clearly define your product’s intended purpose and mechanism of action (i.e. its action on data, and how it achieves its intended purpose). These are key considerations in the qualification and classification of MDSW and will better enable you to identify the regulatory requirements applicable to your product. For example, if your product is not intended to carry out any of the medical purposes set out in the MDR or IVDR definition of a medical device or IVD respectively, or if it does not carry out an action on data, it is unlikely to be regulated as MDSW. Guidance has been developed at an EU level by member states to facilitate stakeholders in qualifying and classifying their software.

The HPRA would also advise you to generate and appropriately evaluate clinical data where necessary to demonstrate the efficacy and safety of your product. If your product is intended to be operated with another product, you must demonstrate their compatibility and safety. An awareness of relevant standards and international guidance can be useful. As an example, the europa.eu and imdrf.org websites are both useful resources.

**Anticipate the impact of the new Medical Devices Regulation (EU) 2017/745**

The new Medical Device Regulation will have a significant impact on current and future MDSW developers from May 2021. Upon the application of stricter classification rules, the majority of MDSW will be up-classified from Class 1 devices and will require notified body assessment prior to CE-marking. Developers should duly anticipate this change and prepare the necessary documentation in advance of a conformity assessment procedure. Other changes will include new requirements for web-based services, cybersecurity and data protection.

In accordance with Article 120 of the MDR and the second corrigendum, MDSW certified under the Directives or ‘up-classified’ under the MDR can avail of the associate transition periods for their products. Further details on these transition provisions can be found in the CAMD FAQ document.

**Engage with regulators early**

Competent authorities such as the HPRA are always willing to engage with and support our stakeholders through the regulatory process. We recognise that some stakeholders will be encountering regulation for the first time. If you are seeking guidance, you can contact us directly at devices@hpra.ie or through the HPRA’s Innovation Office.
National Registration Requirements: HPRA Medical Device Portal

The HPRA is currently in the process of developing a new HPRA medical device portal, which will facilitate the national registration of economic operators and medical devices. The new system will accommodate the registration of both economic operators and medical devices under the Directives and the Regulations.

**Economic operators that can register on the HPRA’s medical devices portal**

- Manufacturers (as defined in the legislation)
- Authorised representatives
- Importers (located in Ireland)
- Distributors (located in Ireland)
- System and procedure pack producer
- Healthcare institutions (involved in the manufacture of custom made devices or IVDs)
- Information society service / service provider (providing a service to Ireland)
- Manufacturing facilities (not acting as the manufacturer as defined in the legislation)

For economic operators that are currently registered with the HPRA, we will contact you via email in advance of the launch of the new system with details of how you can log into the new system. All existing registration details that we hold regarding your organisation and devices will be transferred to the new medical device portal.

In advance of going live with the new system, we will conduct a training webinar. Details of the training webinar will be communicated via email and detailed on our website. Following the webinar, a training video will be available on the HPRA website and medical device portal.

The HPRA envisages that this new system will provide better oversight of the medical device economic operators operating in Ireland and the medical devices that are manufactured here. This will greatly assist with our national surveillance activities regarding both economic operators and medical devices. The new system will also facilitate a more streamlined process for validation of applications, processing of fees, the introduction of a credit card payment for initial registration and on-screen information regarding annual maintenance fees.

**Registration on Eudamed**

In accordance with Article 31 of the Medical Device Regulation 2017/745 (MDR) and Article 28 of the In vitro Diagnostic Medical Device Regulation 2017/746 (IVDR), manufacturers, authorised representatives and importers placing devices on the EU market will be required to register on the electronic system for registration of economic operator, Eudamed. The actor module of Eudamed, that facilitates the registration of economic operators, will be available, on a voluntary basis, from 1 December 2020.

The registration on Eudamed has to be completed by the economic operator himself, (manufacturer (EU and non EU), authorised representative and importer). The information cannot be uploaded from national registration systems. For Irish-based entities, once the details relating to an economic operator located in Ireland are submitted to Eudamed, this information will be validated by the HPRA and once validated a single registration number (SRN) will be provided via Eudamed.

For the registration of MDR-compliant devices, it is envisaged that the device module of Eudamed will be available, on a voluntary basis, in May 2021. Manufacturers or authorised representatives wishing to register MDR compliant devices in advance of that date can register these device with the HPRA. Details on the interim registration process are available on our website.

Until Eudamed is fully functional (the anticipated date is May 2022), the HPRA recommends that, to ensure compliance with Article 123 of the MDR and Article 113 of the IVDR, any economic operators established in Ireland registering on Eudamed should also register with the HPRA.

When our new national registration portal is operational, and the Eudamed registration machine-to-machine interface for Competent Authorities is available, the HPRA intends to periodically download the registration details of economic operators and medical devices to the national register to avoid the need for economic operators to update / maintain two registration systems. We will advise stakeholders when this option is available.
The HPRA’s Medical Devices department has developed an introductory reference list for Class I medical device manufacturers. From 26 May 2021, Regulation (EU) 2017/745 on Medical Devices (MDR) will become fully applicable and manufacturers will be required to comply with the regulations in their entirety.

Although not an exhaustive list, this introductory list aims to help Class I manufacturers plan and co-ordinate their regulatory activities, helping ensure compliance in advance of May 2021.

The Medical Devices section of the HPRA website contains further guidance and helpful resources.

From 9 to 13 November, the HPRA ran a series of online information sessions. This webinar series was designed to provide insights into some of the practical applications of the Medical Device Regulation and the In-Vitro Diagnostic Regulation requirements in the areas of economic operator obligations, remote inspections, EUDAMED and registration, clinical data and IVDs.

We received great engagement from stakeholders through the webinar Q&A function and we tried to respond to as many questions as possible throughout each session. Due to the high volume of questions received, we were not able to respond to each question. However, we are currently reviewing all questions received and hope to address these in guidance, newsletter articles or website updates in the short term.

The HPRA received very positive feedback from our stakeholders. Each of our live sessions has been recorded and will be free to access on the HPRA’s medical devices webpage shortly.

Eudamed is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

On 30 October 2019, the Commission published a notice where they outlined that the full functionality of Eudamed required the availability of:

<table>
<thead>
<tr>
<th>Six Interconnected Modules</th>
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<tr>
<td>• Actor registration, including a single registration number (SRN)</td>
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<tr>
<td>• Clinical investigations and performance studies</td>
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<tr>
<td>• UDI/device registration</td>
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<tr>
<td>• Vigilance and post-market surveillance</td>
</tr>
<tr>
<td>• Notified bodies and certificates</td>
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<tr>
<td>• Market surveillance</td>
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EU CO-OPERATION
and full operation of all six modules in accordance with the technical specifications and confirmed by an audit as referred to in Article 34. The notice foresaw the launch of a fully functional Eudamed in May 2022. However, at its meeting of 12 March 2020, the MDCG agreed that the Commission will make the different modules of Eudamed available on a gradual basis as soon as they are functional. Further details from the European Commission on Eudamed can be found here.

It is envisaged that all of the EUDAMED modules and the audit of the system will be completed before May 2022.

**Actor Registration Module**

In line with the MDCG decision referred to above, the Commission has confirmed its readiness to deploy the actor registration module as of the 1st December 2020. Actors that register on Eudamed will be able to obtain a SRN. Further details regarding the actor registration module can be found on the European Commission’s website.

**Interim Procedures for Modules that are not available by May 2021**

As some of the modules of the Eudamed system will not be ready for the date of application of the MDR in May 2021, the Commission is currently preparing a document that will outline the interim processes that will need to be followed in the absence of Eudamed.

**Preparing Your Organisation’s Systems for Eudamed**

Eudamed will provide actors with a user interface, where they will be able to access all six modules as they become available. The user interface will facilitate manual input of data and for some information the option of a machine-to-machine interface will also be available, e.g. manufacture incident reports. It is therefore very important for actors to keep a close eye on the Commission website to obtain the relevant details as they become available. This will ensure that actors can prepare their own local systems to ensure that they are compatible with Eudamed. In advance of each module going live the Commission website will be updated with the relevant technical specifications and documentation to assist with this process.

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**Timelines**

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<th>The timelines for the availability of the different modules of Eudamed are:</th>
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<tr>
<td>1. Actor registration</td>
<td>December 2020</td>
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<tr>
<td>2. UDI/device registration</td>
<td>May 2021</td>
</tr>
<tr>
<td>3. Notified bodies and certificates</td>
<td>May 2021</td>
</tr>
<tr>
<td>4. Clinical investigations and performance studies</td>
<td>May 2022</td>
</tr>
<tr>
<td>5. Vigilance and post-market surveillance</td>
<td>May 2022</td>
</tr>
<tr>
<td>6. Market surveillance</td>
<td>May 2022</td>
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The Medical Devices Coordination Group (MDCG) met on 20 and 21 October to discuss the implementation of both the MDR and the IVDR. During this session particular focus was placed on planning and progressing the IVDR implementation. The Commission and Member States discussed key priorities for IVDR implementation, including availability of notified bodies, performance evaluation, EU reference laboratories designation and common specification development. The need to have quantifiable information on the readiness of the market specifically for IVDR implementation was also discussed and it is expected that the EU Commission will launch a survey shortly to gather information in this regard.

Implementation updates on the work of the MDCG working groups was also provided including the activities of the NBO working group, Annex XVI products (products without an intended medical purpose), standards, vigilance and nomenclature working groups.

An overview of the progress of designation of notified bodies was also provided with the Commission reporting that 48 applications for the MDR and 15 for the IVDR have been received. The EU Commission also presented the ongoing work in the area of expert panels. Experts have been formally appointed and webinar trainings have been scheduled and are in progress. The Commission is finalising a series of guidance documents, templates and operational procedures for the expert panel members.

The MDCG also endorsed a number of guidance documents during the October meeting which were recently published and listed in the table below.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Title</th>
<th>Publication Date</th>
<th>Reference and Link</th>
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<tr>
<td>Notified Bodies</td>
<td>Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR).</td>
<td>August 2020</td>
<td>MDCG 2020-14</td>
</tr>
<tr>
<td>Notified Bodies</td>
<td>Guidance on transitional provisions for consultations of authorities on devices incorporating a substance which may be considered a medicinal product and which has action ancillary to that of the device, as well as on devices manufactured using TSE susceptible animal tissues.</td>
<td>June 2020</td>
<td>MDCG 2020-12</td>
</tr>
<tr>
<td>UDI</td>
<td>Guidance on UDI for systems and procedure packs.</td>
<td>June 2020</td>
<td>MDCG 2018-3 Rev 1</td>
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