TIDAL N+
Evidence Briefing

The impact of Brexit on Assistive Technologies

Commissioned by
TIDAL Network+

Researched and written by
Rapid Research Evaluation and Appraisal Lab (RREAL)

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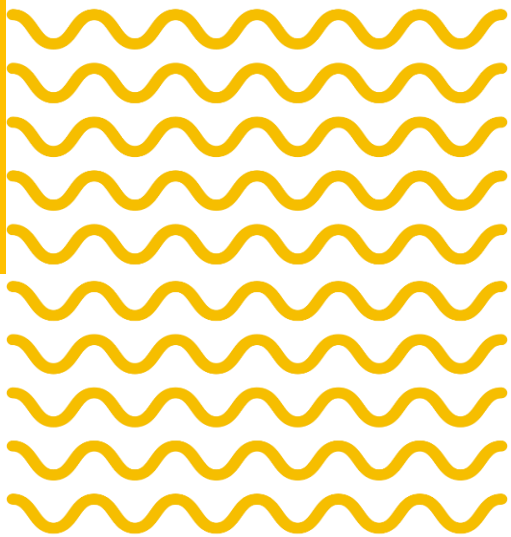

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TIDAL Network+

TIDAL Network+ is an EPSRC-funded collaboration between UCL, Strathclyde, Salford and Loughborough Universities. We are building an interdisciplinary network of researchers; users of assistive technologies, products and services (AT); entrepreneurs, and clinical practitioners, to identify and tackle new research challenges that will help us to transform AT. Together we will create novel, innovative solutions that will lead to improvements in the quality of AT, and enhance the lives of the people who use them, their families and carers. Our vision is for innovative, sustainable and equitable AT, both physical and digital.

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Introduction

The aim of this report is to provide an overview and understanding of the available evidence on the regulatory landscape for assistive technologies (AT) in the UK in the post-Brexit context. When it left the EU, the UK entered a transitional phase, seeking to dampen the impact on businesses and to allow the UK and EU to agree on a future trading relationship. That transition period ended on the 31 December 2020, and since the 1 January 2021 the regulatory landscape in the UK has changed and is characterised as complex and fragmented. The UK regulatory framework for medical devices stems from the following European Union (EU) directives:

- Medical Devices Regulations UK 2002, SI 2002/618
    - Directive 93/42/EEC on medical devices (MDD)
    - Directive 90/385/EEC on active implantable medical devices (AIMDD)
    - Directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

However, in the wake of Brexit certain aspects of that framework are changing, as the EU makes regulatory advances, and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) put in place transitional plans, including amendments, while establishing the UK's new regime which will come into force in 2024.

The UK MDR 2002 has been amended by:

- the Medical Devices (Amendment etc) (EU Exit) Regulations 2019 (UK MDR 2019), SI 2019/791 (see: LNB News 28/01/2019 69 and the explanatory memorandum)
- the Human Medicines and Medical Devices (Amendment etc) (EU Exit) Regulations 2019, SI 2019/1385 (see: LNB News 25/07/2019 9 and the explanatory memorandum)
- the Medical Devices (Amendment etc) (EU Exit) Regulations 2020, SI 2020/1478 (see: LNB News 20/11/2020 10 and the explanatory memorandum)
- the Medical Devices (Amendment) (EU Exit) Regulations 2021, SI 2021/873 (see: LNB News 21/07/2021 37 and the explanatory memorandum)
- the Medical Devices (Northern Ireland Protocol) Regulations 2021, SI 2021/905 (see: LNB News 17/06/2021 55 and the explanatory memorandum)

These amendments were made to ensure that the medical device regulatory landscape is fit for purpose on implementation period (IP) completion day, the Medicines and Healthcare products Regulatory Agency (MHRA) can act as a standalone national regulator and render the Protocol operative.

The products which are intended to assist people in performing certain functions that would normally be restricted due to health-related factors can be defined as Assistive technologies or as a medical device. The classification is dependent on the intended purpose according to the manufacturers' description and the way it is marketed, medical devices should also be mechanical or physical by nature. Assistive technologies (AT) consist of the products and services that enable people with disabilities or impairments to be more independent. Under the Equality Act 2010, AT is recognised as a 'reasonable adjustment' which should be made available to prevent discrimination across a wide variety of contexts. There are also "aids for daily

living" which help with day-to-day activities and do not necessarily have a specific health-related purpose. Medical devices are products that are mainly intended to be used for a medical purpose and with a direct link between its corrective functions and the individual using it. Medical devices play a key role in healthcare, and are vital for diagnosis, therapy, monitoring, rehabilitation, alleviation, and care. As such, the use of an aiding technology or device does not in itself constitute that the product is a medical device subject to regulation under the medical device framework.

The report starts by providing a brief legislative context regarding disability rights, assistance, and accessibility as well as trade and manufacturing in light of the UK leaving the EU's regulatory regime. This is followed by an overview of the regulations governing 'Digital Assistive Technologies'. The report finally examines the regulations governing the use of medical devices.

Post Brexit Regulation Timeline

June 2018	European Union (Withdrawal Act 2018).
April 2019	Medical Devices (Amendment) (EU Exit) Regulations 2019 No. 791.
Dec 2020	Medical Devices (Amendment) (EU Exit) Regulations 2020 No. 1478.
11pm 31/12/20	End of the Brexit Implementation Period.
1 Jan 2021	Northern Ireland Protocol comes into force. EU-UK TCA comes into provisional effect.
Feb 2021	Medicines and Medical Devices Act 2021.
1 May 2021	EU-UK TCA official enforcement date.
June 2021	EU approved adequacy decisions for EU GDPR. Law Enforcement Directive (LED) 28/6/21.
July 2021	The Medical Devices (Northern Ireland Protocol) Regulations 2021 No. 905.
Aug 2021	The Medical Devices (Amendment) (EU Exit) Regulations 2021 No. 873.
Sept – Nov 2021	MHRA consultation on proposed changes to regulatory framework for medical devices in UK.
Sept 2022	Retained EU Law (Revocation and Reform) Bill introduced to Parliament.
Oct 2022	Decision to extend the period of recognition of E marked medical devices on GB market
Nov 2022	Decision to extend period of recognition of CE mark products on GB market (excluding medical
Dec 2023	Retained EU Law Bill, if passed, will sunset the majority of retained EU law so it expires
Up to July 2024	CE marked medical devices accepted on GB market. New medical devices regulations to be brought in.
Up to 31/12/24	CE marked products are acceptable on the GB market (excluding medical devices).
June 2025	EU approved adequacy decisions for EU GDPR & LED expected to last until 27/6/2025.

Broad Legislative Context

Brexit-related Legislation

Legislative Background

- At the end of the Brexit Transition Period at 11pm on 31 December 2020, the UK officially withdrew from the EU Single Market/Customs Union, and is no longer bound by its laws and regulations.
- The *European Union (Withdrawal) Act 2018 (EUWA)* allowed for the retention of most EU law, as it applied in the UK legal system on 31 December 2020.
    - EUWA incorporated EU law that applied to the UK onto the statute book as *"retained EU law" (REUL)*
        - REUL is a new category of UK domestic law consisting of EU-derived legislation preserved in the UK legal framework by the EUWA.

EU-UK Trade and Cooperation Agreement

- The UK and EU signed a *Trade and Cooperation Agreement* on 30 December 2020 on the terms of their future relationship primarily focuses on ensuring free trade of goods, which includes assistive technologies and medical devices. This was implemented in the *European Union (Future Relationship) Act 2020*.
- Northern Ireland's relationship with the European Union is governed by the *Northern Ireland Protocol*
    - During negotiations the EU and UK agreed a Northern Ireland Protocol to ensure there would be no new checks on goods crossing the border between NI and the Republic of Ireland
- Under the TCA, goods originating in the EU or UK benefit from preferential treatment, meaning that goods can move between the EU and the UK (except for NI, for which there is a special protocol) without being subjected to tariffs, so long as the relevant rules of origin are met.
- **TCA impact on Medical Devices**
    - The TCA does not contain specific provisions around medical devices, which means that in order to place products on the EU or UK markets, manufacturers must navigate both regimes.

Future Impact

- Government asserts REUL was never intended to remain on UK statute book indefinitely
    - In January 2022 the *UK Government announced a bill revoking EU law* with the aim reclaiming Parliamentary sovereignty and restoring the legislative primacy of Parliamentary Acts.
- On 22nd September 2022 *the Retained EU Law (Revocation and Reform) Bill* was introduced to Parliament
    - This Bill facilitates planned reforms to over 2,400 pieces of REUL.
    - The Bill includes a 'sunset' date (31/12/2023) by which all remaining retained EU Law will either be repealed or assimilated into UK domestic law. The 'sunset' may be extended for specified pieces of retained EU Law until 2026.

Disability rights, assistance and accessibility

This table outlines the legislative context protecting disability rights and establishes the legal pretext for ensuring disabled accessibility and providing disabled people with assistance and equipment such as assistive technology. The EU Charter for Fundamental Rights provided the basis in the EU for such protections, and although the UK has left the EU these protections persist under UK legislation.

Table 1

Legislation	Implications for disability and Assistive Technology
Charter of Fundamental Rights of the EU 2012 (CFREU) No longer applies post-Brexit	• The CFREU no longer applies in the UK, non-discrimination and the right of integration of disabled people remain largely covered by the UK's Equality Act while the right to privacy is protected by the UK's *Data Protection Act 2018* (based on EU's GDPR). o Article 8: Protection of personal data (Remains covered by Data Protection Act 2018) o Article 21: Non-discrimination on basis of disability and Article 26: Right of Integration of persons with disabilities. (Remain protected under the Equality Act)
Chronically Sick and Disabled Persons Act 1970 Not impacted by Brexit	• Section 22 of this act establishes the obligation for the Government to conduct annual research and development work and report to Parliament on the progress made in relation to equipment that might increase the range of activities and independence or well-being of disabled persons, and in particular such equipment that might improve the indoor and outdoor mobility of such persons. Such equipment can generally be considered as Assistive Technology.
Equality Act 2010 Not impacted by Brexit	• The Equality Act provides a range of measures relating to discrimination and creates the obligation for reasonable adjustments to be made for disabled people, which includes increasing accessibility and providing assistance and/or providing equipment such as Assistive Technology and providing information in an accessible format such as Braille, Large Print, Easy Read or by using coloured paper. o The aim is to provide a service to disabled users that resembles, as closely as possible, the standard service that is provided to the public at large and provides the grounds for Web Accessibility.

Trade

Post-Brexit Trade Landscape

The aim of this table is to outline the key impacts of Brexit regarding the regulations governing commercial trade in the UK and with the EU, which covers most types of assistive technologies that are not considered medical devices (covered by their own specific regulations).

Table 2: Post-Brexit Trade Landscape

Placing manufactured products on the market in Great Britain	○ UKCA marking is the marking used for products being placed on the market in Great Britain post-Brexit (England, Scotland and Wales).
	  ○ Where mandatory third-party conformity assessment was required for CE marked products, it's also required for UKCA marked products.
	  ○ Conformity with these requirements can be achieved by using designated standards (which the UK introduced to replace EU harmonised standards).
	○ The deadline for when businesses need to use UKCA has been extended and the CE marking and reversed epsilon marking remain valid on the GB market until 31 December 2024.
	○ Under some product legislation an authorised representative is mandatory, but in most cases it is voluntary. For instance, the supply of medical devices for the GB market will require a UK-based responsible person.
	○ As the CE marking remains valid in the UK, there is currently less incentive to use the UKCA marking as it is not accepted in the EU and as such can be perceived as an additional layer of administrative burden.
	
	Further guidance can be found here:
	
	○ *UKCA marking: roles and responsibilities*
	○ *UKCA marking: conformity assessment and documentation*
	○ *Designated standards*
	○ *Import goods into the UK: step by step*
	○ *Export goods from the UK: step by step*

Placing medical devices on the market in Great Britain	○ As above UKCA and CE both recognised
	  ○ CE marking for medical devices will continue to be recognised in Great Britain until 30 June 2024.
	○ All medical devices, including In Vitro Diagnostics (IVDs), custom-made devices and systems or procedure packs must be registered with the MHRA before being placed on the Great Britain market.
	  ○ If the manufacturer is based outside the UK, they must appoint a *UK-based Responsible Person*.
	○ Manufacturers of non-sterile and non-measuring Class I devices and general IVDs can self-certify against the UKCA marking.

	○ Manufacturers of Class I medical devices that are sterile or have a measuring function must have a third part conformity assessment to affix the UKCA marking and place their devices on the GB market. ○ Where a third-party conformity assessment is required, a UK Approved Body (UKAB) is needed. The MHRA can designate a UKAB to conduct conformity assessments against the relevant UKCA requirements. Further guidance can be found here: ○ *Designated standards: medical devices* ○ *Export medical devices from the UK*
Placing manufactured goods on the market in Northern Ireland	○ The Northern Ireland Protocol came into force on 1 January 2021. While it remains in force, NI will align with relevant EU rules relating to placing manufactured goods on the market. ○ In Northern Ireland, EU CE conformity markings continue to be used to show that goods meet EU rules. ○ If you are using a UK body to carry out mandatory third-party conformity assessment, then you must also apply. a UKNI marking (UKCA marking cannot be used for products on the NI market) ○ UK manufacturers need to appoint an *Authorised Representative (AR)* in the EU or NI to place a product on its market. ○ Where a NI-based AR is appointed, the AR needs to register devices of all classes with the MHRA. ○ UKNI marking is never applied alone - must accompany EU conformity marking. Goods with both CE and UKNI marking cannot be placed on the EU market, goods with CE only can. Further guidance on *UKNI marking*.

Placing medical devices on the market in Northern Ireland	○ Under the terms of the *Northern Ireland Protocol*, the rules for placing medical devices on the NI market differ from those applicable to GB.
	  ○ *Since May 2021, the EU MDR has applied in Northern Ireland and the EU IVDR since May 2022*.
	○ MHRA will have to apply UK rules in GB and EU rules in NI, meaning manufacturers and companies operating across the UK will have to comply with both regulatory regimes. This will be burdensome and may become increasingly problematic if the UK and EU rules diverge.
	  ○ Like other goods, CE marking is required for devices on the NI market. In addition, the UKNI indication is required if a UK Notified Body undertakes mandatory third-party conformity assessment.
	○ Some medical devices, including IVD medical devices, placed on the NI market must be registered with the MHRA.
	○ All custom-made devices must be registered with the MHRA within 28 days of being available on the NI market

	○ If placing devices on the NI market, GB-based manufacturers must appoint an EU or NI-based Authorised Representative ○ IVD manufacturers based outside the UK may be required to have a UK Responsible Person in place to act as a regulatory point of contact within the UK and comply with the registration requirements

Moving goods from Northern Ireland to Great Britain	○ There are no changes to how qualifying Northern Ireland goods move directly from Northern Ireland to Great Britain. There are some changes for *qualifying goods* moved indirectly through Ireland.
	  ○ Nevertheless, you cannot move goods through NI to avoid the UK tariff or import processes.
	  ○ For goods originating in the EU and coming to GB through NI, you must comply with export requirements in the home member state.
	
	Further guidance on *Trading and moving goods in and out of Northern Ireland*

Placing manufactured goods and medical devices on the EU market, and using the CE marking	○ The 'CE' marking appears on many products that are traded on the single market in the European Economic Area (EEA), including various assistive technologies:
	  ○ Medical devices
	  ○ In vitro diagnostic medical devices
	  ○ Electrical equipment
	  ○ Electromagnetic compatibility
	  ○ Machinery
	○ Any mandatory conformity assessment for the EU market needs to be carried out by an EU-recognised conformity assessment body.
	  ○ Most medical devices require assessment by EU-recognised Notified Body
	  ○ Where allowed under the relevant legislation, you can CE mark your medical device based on self-certification for the purposes of the EU market
	  ○ In cases where you self-certify for the CE marking, you will be able to continue to do so and place your device on the GB market until 30 June 2024. You will need to meet EU MDR and IVDR requirements for CE marking Class I devices.
	○ UK conformity assessment bodies can no longer carry out mandatory conformity assessment for products being placed on the EU market and the EU does not recognise UKCA or UKNI markings.
	  ○ GB-established authorised representatives and responsible persons are not recognised in the EU and UK approved bodies are no longer recognised as EU notified bodies.
	○ If you're required to (e.g. if you sell online and ship directly to the end user) you need to appoint an authorised representative or responsible person based in the EU, EEA or Northern Ireland.
	
	Further guidance on *Placing a medical device on the EU market*

Certified conformity assessment markings

The table below illustrates the accepted conformity assessment markings on each relevant market.

Table 3: Guide to GB, NI and EU certified markings

	Type of good (see list of product areas below)	**Accepted marking or combination of markings***
Placing goods on the market in Great Britain N.B. Conformity with UKCA requirements can be achieved by using *designated standards* (introduced to replace EU harmonised standards).	Manufactured products being placed on the GB market until 11pm on 31 December 2024 **CE marking for medical devices will continue to be recognised in Great Britain until 30 June 2024. From 1 July 2024, a UKCA marking will be required in order to place a device on the Great Britain market in line with MHRA.*	UKCA or CE
	Manufactured products placed on the GB market from 11pm on 31 December 2024	UKCA
Placing good on the market in Northern Ireland	Manufactured goods being placed on the market in NI using an EU conformity assessment body	CE
	Manufactured goods being placed on the market in NI using a UK-based body	CE and UKNI
Placing qualifying Northern Ireland goods on the market in Great Britain (unfettered access)	Qualifying Northern Ireland goods being placed on the GB market under unfettered access	CE or CE and UKNI
Placing goods on the EU market	Manufactured goods being placed on the EU market	CE

NB: You may use combinations of the product markings listed in each box and your goods may be acceptable with more than one marking. For example, a product with both the CE and UKCA markings can be placed on the UK market so long as both are clearly visible and the legislative requirements for both GB and the EU are met. To be placed on the NI market by a UK body a product must have both CE and UKNI. However, for the EU market the CE mark must appear without the UKNI or UKCA indication as goods bearing multiple markings are not acceptable in the EU market. This means these goods must be manufactured to EU rules and cannot be assessed by a body based in the UK.

Other considerations

Here are listed some further considerations for manufacturers, distributors and vendors on operating in the UK or trading with other countries and the basics of UK product safety law. Finally, there is a brief outline on customs and VAT tax relief for equipment which helps disabled people in their day to day lives, including assistive technologies.

EORI

You may need an *Economic Operators Registration and Identification number* (EORI number) if you move goods:

- between Great Britain (England, Scotland and Wales) or the Isle of Man and any other country (including the EU)
- between Great Britain and Northern Ireland
- between Great Britain and the Channel Islands
- between Northern Ireland and countries outside the EU

Product Safety

- If you make, import, distribute or sell products in the UK, you need to understand the basics of *UK product safety law*.
- You must comply with the regulations for specific product types. If none apply, you must comply with the General Product Safety Regulations 2005.
- For guidance on regulations relating to:
    - Medical devices and medicines, visit the *Medicines and Healthcare products Regulatory Agency* (MHRA)
    - Electrical and electronic devices, visit the *Electrical Equipment (Safety) Regulations 2016, Electromagnetic Compatibility Regulations 2016* and *Radio Equipment Regulations 2017*
    - The safety of products intended for commercial use is enforced by the *Health and Safety Executive (HSE): https://www.hse.gov.uk/*

Customs Duty and VAT relief on goods for disabled people

- You can claim *relief to pay no Customs Duty or VAT* on goods specially designed or adapted to assist disabled people, including people who are blind or partially sighted, in carrying out everyday activities. You can bring goods into the UK from outside the UK (this now applies to goods coming from the EU as well) free from Customs Duty if:
    - you're an organisation *approved by HMRC* mainly concerned with the education of, or assistance to disabled people or those who are blind or partially sighted
    - you have a disability, are blind or partially sighted and are bringing in goods for your personal use because of your disability
    - you're a nominated carer - someone acting on behalf of a disabled, blind or partially sighted person and known to them, such as a parent, guardian, spouse or partner, or family member- importing goods to be used by the disabled person only

- Some goods are zero rated for VAT when imported for disabled or older people (60+ years old), imported by charities or purchased with donated funds (this now also applies to goods being imported from the EU).
- Products such as desktops, laptops, tablets, smartphones, e-readers can only be bought VAT free when they're sold as part of an assistive technology system.
    - To be considered 'Assistive technology' involves the pre-installation of specialist software which is specifically required by the disabled individual. Where such a purchase is made, the complete system will be defined as designed solely for use by that disabled person and will be eligible for the relief.
- *Find out about which goods and services for disabled people and people aged 60 or over that you should apply zero or reduced rate VAT*

Digital Assistive Technologies

Regulatory requirements

If you are developing or manufacturing digital AT, it is your responsibility to determine which regulations and legislations apply to your technology.

The criteria and requirements of the following regulatory bodies should be considered in the development and manufacture of digital AT:

- The Medicines and Healthcare products Regulatory Agency (MHRA) regulates software and data-driven technology that meets the definition of a medical device or in vitro diagnostic tool.
    - See guidance on medical devices for further information.
- The *Care Quality Commission (CQC)* regulates organisations using products that carry out certain clinical services.
    - There are *14 clinical service activities* regulated by the CQC.
- The *General Pharmaceutical Council (GPhC)* registers organisations using products that are involved in the delivery of pharmacy services.
    - *GphC's Brexit related guidance*

Further *guidance on the development and manufacture of digital AT*.

Public Sector Bodies Accessibility Regulations

The *Public Sector Bodies (Websites and Mobile Applications) (No. 2) Accessibility Regulations 2018* stems from the *EU Web Accessibility Directive (EU) 2016/2102* and applies to public sector entities (which includes NHS) and NGOs that specifically address the needs of, or are intended for, persons with disabilities.

- The accessibility regulations build on existing obligations to people who have a disability under the Equality Act 2010 (*Disability Discrimination Act 1995* in Northern Ireland) and aims to make websites and mobile applications of public sector bodies more accessible to users, particularly with disabilities.
    - Includes the requirement to work on the most commonly used assistive technologies (e.g. screen magnifiers, screen readers and speech recognition tools, among others)

These regulations were amended due to Brexit by the *Public Sector Bodies (Websites and Mobile Applications) Accessibility (Amendment) (EU Exit) Regulations 2022* which came into force on 26 October 2022.

- As a result of this amendment, the Minister for Cabinet Office will now be required to publish a report on the compliance of these regulations by December 2024 and every three years thereafter.

Implications of regulatory changes:

There is increasing divergence in EU and UK regulatory frameworks, since the EU has now adopted the *European Accessibility Act (Directive 2019/882)* which enhances the regulatory scope as it also applies to private companies that provide products or services sold or used within the EU regardless of where the companies are based.

- This divergence in regulations will place increased burdens on developers and manufacturers of AT, if you are UK based and wanting to place your AT on the market in the EU.

Developing digital AT for the public sector:

If you are developing or manufacturing digital AT that you intend to supply to the public sector, you may need to ensure you are meeting the relevant accessibility requirements including those outlined in the *Technology Code of Practice (TCoP).*

There have not been any major regulatory changes due to Brexit that would impact manufacturers or designers of AT, general guidance on meeting these regulations can be found here:

- *A guide to good practice for digital and data-driven health technologies*
    - Collated resources on *evaluating digital health products*
- Collated resources on *Guidance and tools for digital accessibility*
    - *Understanding accessibility requirements for public sector bodies*
        - *Make your website or app accessible and publish an accessibility statement*
- *Technology code of practice*
    - *Make things accessible and inclusive*
    - *Make privacy integral*
- *Making your service accessible*

Divergence in regulatory frameworks

Outside of the European Accessibility Act other legislative changes have been made to EU regulations that have not been transposed into UK law, which may impact digital AT.

Consumer law:

If you are UK manufacturers and developers that may place their AT on the market in the EU, you may want to consult the following EU consumer law directives:

- *The Digital Content and Digital Services Directive (DCSD) (EU) 2019/770*
- *The Sales of Goods Directive (SGD) (EU) 2019/771*
- *The Enforcement and Modernisation Directive (EMD) (EU) 2019/2161*

These directives cover areas governed by the *Consumer Rights Act 2015 (CRA)* in the UK.

- Further information on this regulatory divergence is provided by *Hill Dickinson* and *Field, Seymour, Parkes*.

Digital Regulations:

If you are UK manufacturers and developers that may place their AT on the market in the EU, you may want to consult the following regulations regarding digital markets and services:

- The Digital Services Act (DSA) – *Regulation (EU) 2022/2065*
    - Set up a framework for regulating digital services in the EU.
        - The UK government have proposed a comparative *Online Safety Bill (OSB)*.
    - Introduces a number of amendments to the *e-Commerce Directive 2000/31/EC*, increasing divergence from UK regulations.
- The Digital Markets Act (DMA) -- *Regulation 2022/1925*
    - Impacts how large digital platforms are permitted to operate in the EU.

        - The UK government has announced plans for the implementation of their own comparative regulatory framework, *a new pro-competition regime for digital markets*.
    - Amends *Directive (EU) 2019/1937* and *Directive (EU) 2020/1828*.

Further information on the divergence of UK and EU digital regulations is provided by *Clifford Chance* and the *Centre for European Reform*.

Data protection and exchange

This section provides a summary of the key legislation and regulations you need to be aware of if your AT uses personal data, and what changes have occurred due to Brexit.

The General Data Protection Regulation (GDPR)

The *EU General Data Protection Regulation (GDPR) (EU) 2016/679* no longer applies to the UK. However, the provisions of the EU GDPR have been retained in UK law as the *Data Protection Act (DPA) 2018*, which is the UK's implementation of the EU GDPR.

Due to Brexit two amendments were made to the DPA 2018 that are collectively known as the DPPEC Regulations, which established a new data protection regime for the UK known as the 'UK GDPR' to replace the EU GDPR.

The amendments made to the DPA 2018 known as the DPPEC regulations are:

- *The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (SI 2019/419)*
- *The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2020 (SI 2020/1586)*

It is important to consider which data protection regulations may apply to your AT, as post-Brexit there may be multiple regulations you have to take into account.

- If you are a UK entity that operates in, offers goods and/or services to, or monitors the behaviour of, individuals in the EEA you may need to follow both the UK and EU data protection regulations.
    - Further guidance on this is provided by the *Information Commissioner*
- The UK GDPR also applies to those based outside the UK if their data processing involves offering goods or services to individuals in the UK; or monitoring the behaviour of individuals taking place in the UK.

Implications of regulatory changes:

In practice there are minimal changes to the core data protection provisions of the DPA 2018 due to Brexit, with legislative changes mostly focused on ensuring the continued functioning of the legal framework for data protection in the UK post-Brexit.

The key amendments to consider are:

- The Information Commissioner (ICO) will become the lead supervisory body and enforcer of the Data Protection Act and the UK GDPR.
- There are no changes to sending personal data to the EAA/EU countries, or Gibraltar.
- EU adequacy decisions made prior to Brexit will be integrated, including the US Privacy Shield program.

For those using personal-data in their AT, the following may need to be updated or introduced to reflect the UK's independent jurisdiction and align with the requirements of the UK GDPR:

- *Article 30 records*
- *Privacy notices*
- *Data protection impact assessments (DPIAs)*
- *Data subject access requests (SAR or DSARs)*
- *Data Protection Officers (DPOs)*
- *Records of Processing Activities (ROPAs)*

The ICO has produced a *detailed guide to the UK GDPR*.

EU Adequacy Decisions

In June of 2021 the EU approved adequacy decisions for the UK GDPR and the Law Enforcement Directive (LED), meaning that in most circumstances data can continue to flow freely from the EU to the UK as it did prior to Brexit.

- 'Adequacy' in this context means the EU has deemed the UK GDPR and LED to have an equivalent level of data protection to the EU.
    - These EU adequacy decisions apply to the entire UK including Northern Ireland.
    - These adequacy decisions are expected to last until 27 June 2025.
- If you receive personal data from the EU or EEA, this data can continue to flow as it did pre-Brexit, unless the data falls within the scope of the immigration exemption of the DPA 2018.
    - Further guidance on the *DPA 2018 immigration exception*.

Implications of regulatory changes:

If your digital AT's processing of personal data is subject to the EU GDPR post-Brexit, there will be a change in how you interact with the EU data protection regulatory authorities.

Some key considerations are:

- Review documentation such as privacy notices and DPIAs and update any references to EU law, UK-EU transfers or EU representatives.
- Your Data Protection Officer (DPO) must be easily accessible from both UK and EEA establishments.

The ICO has produced detailed guidance on key areas related to data exchange that have been impacted by Brexit and how to meet the new regulatory requirements:

- *International data transfers*
- *European Representatives*
- *Cross-border processing of personal data*
- *Documentation and accountability measures*

Further information on data protection regulations in the EU post-Brexit can be found at: *Data Protection and the EU*

Certification with the UK GDPR

The European Data Protection Board (EDPB) guidance on certification and accreditation are no longer binding under the UK regime post-Brexit. Certification of compliance with the UK GDPR is now overseen by the ICO, who are also working on developing further certifications.

The ICO has provided the following guidance regarding certification:

- *"Certification is a way to demonstrate your compliance with the UK GDPR and enhance transparency.*
- *Certification criteria are approved by the ICO and certification issued by accredited certification bodies.*
- *Certification will be issued to data controllers and data processors in relation to specific processing activities.*
- *Applying for certification is voluntary. However, if there is an approved certification scheme that covers your processing activity, you may wish to consider having your processing activities certified as it can help you demonstrate compliance to the regulator, the public and in your business to business relationships."*
- Source for quote: *https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/certification/#whatarepractical*

Further information on *GDPR certification* and *certification schemes for the UK GDPR.*

Artificial Intelligence

The current regulatory framework for the use of Artificial Intelligence mostly exists in relation to the use of personal data.

- If you utilise AI in your AT, it may fall within the scope of the UK GDPR and DPA 2018 if you use personal data to train, test, or deploy an AI system.
- The Equality Act 2010 and some administrative legislation can also be relevant to the use of AI in AT.
- More *information on the legal framework relating to the use of AI*

The ICO has released the following guidance with further information about the use of AI:

- **AI and data protection**
- **Explaining decisions made with AI**
- **Using AI and personal data appropriately and lawfully**

Future changes to regulations:

Several strategies and plans have been published that describe the intent of the UK government to further develop the UKs legislative frameworks around digital technologies, the use of data, and artificial intelligence.

These developments are ongoing and do not currently impact the regulatory landscape for AT, and can be monitored to assess the potential future regulatory impact on AT:

- *Digital Regulation Plan*

    - *Digital regulation: overview of government activity*
- *National Data Strategy*
    - *Guidance: National Data Strategy*
- *National AI Strategy*
    - *AI Action Plan*

Assistive Technologies that are Medical Devices

There are some specific regulations that apply to medical devices but not to other product types. Some assistive technologies are medical devices, while some are not, so manufacturers must determine whether their product is a medical device to ensure they follow the correct regulations.

The legal definition of a medical device can be found in the 'key definitions' table. Guidance on whether your product is a medical device can be found in the UK Government's guidance on *Assistive technology: definition and safe use* and the *MHRA's guidance* on Medical device stand-alone software including apps (including IVDMDs).

The following sections provide guidance relevant only to AT that are medical devices.

Summary and flowchart of the regulatory requirements for AT that are medical devices:

Is your AT a medical advice?

If no, see separate guidance for AT that are not medical devices.

If yes, do you wish to place your product on the GB market (England, Wales, Scotland)?

If no, see separate guidance for placing medical devices on the market in NI, EU or elsewhere.

If yes, are you a manufacturer based in the UK?

If yes, you need to register directly with the MHRA.

If no, you need to appoint a UK Responsible Person to register with the MHRA and act on your behalf

In all cases, the regulations you must follow are in the process of changing at the moment.

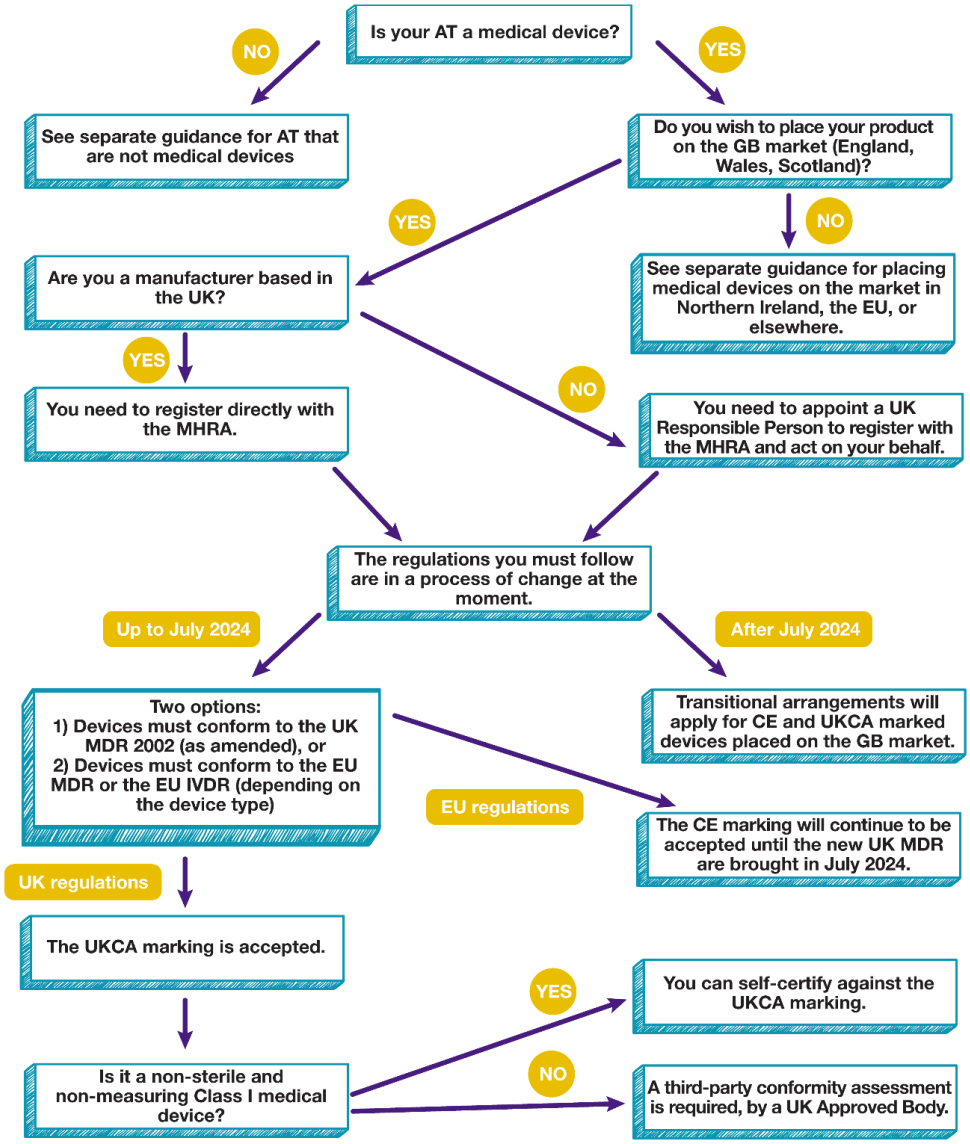
Up to July 2024:
You have two options:

1. Devices must conform to the UK MDR2022 (as amended), or
2. Devices must conform to the EU MDR or the EU IVDR (depending on the device type

If you are following UK regulations, the UKCA marking is accepted.
If it is a non-sterile and non-measuring Class 1 medical device, you can self-certify against the UKCA marking. If not, a third-party conformity assessment is required, by a UK Approved Body.

If you are following the EU regulations, the CE marking will continue to be accepted until the new UK MDR are brought in in July 2024.

After July 2024:
Transitional arrangements will apply for CE and UKCA marked devices placed on the GB market.



Medical devices: post-Brexit changes to legislation

This section provides a summary of the key legislation you need to be aware of if your AT is a medical device, and the Brexit-related amendments that have been written into law as of writing (November 2022).

Due to Brexit, the body of EU Directive-derived laws has been preserved and converted into UK domestic law with effect at the end of the Implementation Period (IP), which was 11 pm on 31 December 2020.

The UK Medical Devices Regulations 2002

The Medical Devices Regulations 2002 (No. 618) (from now on referred to as UK MDR 2002) is a UK Statutory Instrument (SI) that came into force on 13 June 2002. Prior to the end of the IP, this gave effect in UK law to the following EU directives:

- *Directive 93/42/EEC on medical devices*
- *Directive 90/385/EEC on active implantable medical devices*
- *Directive 98/79/EC on in vitro diagnostic medical devices*

The following Brexit-related amendments to the UK MDR 2002 have been written into law:

- *The Medical Devices (Amendment) (EU Exit) Regulations 2019, SI 2019/791*
- *The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, SI 2019/1385* *
- *The Medical Devices (Amendment) (EU Exit) Regulations 2020, SI 2020/1478*
- *The Medical Devices (Amendment) (EU Exit) Regulations 2021, SI 2021/873*

* This amendment included an amendment to the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 and an amendment to the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.

These amendments were made to ensure that the regulatory landscape for medical devices is fit for purpose from IP completion day, that the MHRA can act as a standalone regulator, and to give effect to the Northern Ireland Protocol (see later).

The full UK MDR 2002 (as amended) can be found on the UK Government Legislation website. Note that previous versions of each section of the legislation can be found by clicking the 'show timeline of changes' tab, and the extent of each regulation (e.g., UK vs GB vs NI) can be found by clicking the 'show geographical extent' tab.

Another amendment to the UK MDR 2002 is expected soon, to reflect the changes proposed in the MHRA consultation on the future regulation of medical devices in the UK that took place in towards the end of 2021, after the most recent legislation amendment. These proposed future changes are discussed later.

The Medical Devices (Northern Ireland Protocol) Regulations 2021

In addition to the amendments listed above, the UK MDR 2002 has also been amended to include a Northern Ireland Protocol. *Full protocol*. However, regulations specific to Northern Ireland (NI) can also be seen via the UK MDR 2002 (as amended) by using the 'show geographical extent' option mentioned earlier.

Broadly speaking, under the new regulations, NI is subject to EU requirements governing medical devices, although there are some changes to be aware of which are discussed later.

The EU framework for medical devices is being reformed:

- The *EU Regulation 2017/745 on medical devices* came into effect on 26 May 2021 and *repeals council directives 90/385/EEC and 93/42/EEC*
- The *EU Regulation 2017/746 on in vitro diagnostic medical devices* came into effect on 26 May 2022 and repeals council directive 98/79/EC

As these EU regulations did not take effect during the transition period, they were not EU law automatically retained by the EU (Withdrawal) Act 2018 and therefore do not and will not apply in GB, causing further divergence in EU and UK regulatory regimes. However, due to the NI Protocol, these two regulations apply in NI.

Medicines and Medical Devices Act 2021

Powers in the *Medicines and Medical Devices Act (2021)* allow the UK government / MHRA to amend the UK MDR 2002 which govern medical devices in Great Britain.

Medical devices: post-Brexit changes to regulations

The amendments to the legislation above mean that there are some key changes manufacturers need to be aware of, in order to conform to the new regulations. This section provides a summary of these key changes. For the full details on the Brexit-related amendments to the UK MDR 2002, refer to the table 'Changes to the MDR'.

General Medical Devices

Great Britain (England, Wales, Scotland)

1. **Language of instructions for use**
   Prior to Brexit, instructions had to be in English or another Community language, and if not in English, there had to be a statement in English stating which language the instructions were in. Under the new regulations, the instructions must be in English. For further details, refer to the *UK MDR 2002 (as amended), Part II Section 9*

2. **UK approved bodies vs EU notified bodies**
   The following applies to all medical devices except class I medical devices without sterile/measuring functions and general IVDs. Prior to Brexit, the conformity assessment procedure involved the intervention of a notified body. Under the new regulations, this will instead need to be conducted by a UK approved body. For further details, refer to the *UK MDR 2002 (as amended), Part V*.

3. **UK marking vs CE marking**
   Prior to Brexit, relevant devices could only be placed on the GB market if they had a CE marking. Under the new regulations, relevant devices will instead require a UK marking in order to be placed on the GB market. For further details, refer to the *UK MDR 2002 (as amended), Part II Sections 10-13*. However, the CE marking will continue to be recognised up to July 2024 (this date is different for products which are not medical devices) following a *recent extension*.

4. **UK responsible person vs EU authorised representative**
   Prior to Brexit, where a manufacturer was not based in the EU, they had to appoint an EU authorised representative to act on their behalf. Under the new regulations, where a manufacturer is based outside of the UK, they must appoint a sole UK responsible person to register with the MHRA and act on their behalf. For further details, refer to the *UK MDR 2002 (as amended), Part II Section 7A*.

5. **Registration of persons placing general devices on the market**
   Under the new regulations, a person (a manufacturer or their UK responsible person, based in Great Britain) who places general medical devices on the GB market must first register with the MHRA. For further details, refer to the *UK MDR 2002 (as amended), Part II, Section 7A*.

Northern Ireland

1. **CE marking + UK(NI) marking**
   Prior to Brexit, a CE marking was affixed on the basis of an assessment, or a certificate issued by a notified body. Under the new regulations, where a CE marking is affixed on the basis of an assessment or a certificate issued by a notified body established in the UK, it must be accompanied by a UK(NI) marking. For further details, refer to the *UK MDR 2002 (as amended), Part II, Section 10A*.

2. **Registration for placing devices on the market**
   The following is only relevant for Class I or custom-made general medical devices:
   Under the new regulations, a person (a manufacturer or their authorised representative, based in Northern Ireland) who places a relevant device on the NI market must first register with the MHRA. Where a manufacturer does not have a registered place of business in the UK, or an authorised representative who has a registered place of business in NI, the manufacturer must appoint a UK responsible person to register with the MHRA and act on their behalf. For further details, refer to the *UK MDR 2002 (as amended), Part II Sections 19* & *UK MDR 2002 (as amended), Part II Sections 19B*.

Medical devices: future changes to regulations

Since the most recent amendment to the UK MDR (published August 2021), the MHRA held a consultation on the future regulation of medical devices in the UK, which took place in September to November 2021. They proposed a number of changes to various aspects of the UK MDR 2002 (as amended), which have not yet been written into law. Therefore, manufacturers of medical devices who wish to place their products on the GB market should be aware of these potential future changes to the regulations. The proposed changes covered the areas listed below. *Full consultation, including proposed changes and outcomes*.

Scope of the regulations

- Medical device and IVD scope
- Products without an intended medical purpose
- Exclusion of products that contain viable biological substances
- Exclusion of food

Classification

- Classification of general medical devices

Economic operators

- Essential requirements for medical devices
- Manufacturer obligations – measures for recompense
- Health institutions
- Distance sales
- Claims
- Quality management systems
- UK responsible persons
- Obligations of importers and distributors
- Qualified persons
- Cases in which obligations of manufacturers apply to other economic operators

Registration and unique device identification (UDI)

- Identification within the supply chain
- Nomenclature
- Unique device identification
- Great Britain database on medical devices
- Registration of medical devices

Approved bodies

- Requirements of approved bodies
- Subsidiaries
- Approved body designation and monitoring

Conformity assessments

- Conformity assessment
- Mechanism for transparency and scrutiny of conformity assessments of certain medical devices
- Certificates of conformity
- Voluntary change of approved body
- Declaration of conformity

Clinical investigation and performance studies

- Clinical evaluation (general medical devices)
- Performance evaluations (IVDs)
- General requirements regarding clinical investigations (general medical devices)
- General requirements regarding performance studies (IVDs)
- Informed consent
- Specific requirements for clinical investigations / performance studies
- Clinical investigations / Performance studies in emergency situations
- Application for clinical investigations / performance studies
- Assessment of applications for clinical investigation/performance study by the MHRA
- Conduct of a clinical investigation / performance study
- Clinical investigations / performance studies regarding devices bearing the UKCA marking
- Modifications to clinical investigations / performance studies
- Corrective measures to be taken by the MHRA in relation to a clinical investigation / performance study

- Information from the sponsor at the end of a clinical investigation / performance study or in the event of a temporary halt or early termination
- Recording and reporting of adverse events that occur during clinical investigations / performance studies
- Types of clinical investigations / performance studies and exemptions / authorisations

In vitro diagnostic medical devices

- IVD classification rules
- Genetic testing
- Companion diagnostics
- Distance selling

Software as a medical device

- Scope and definitions
- Distance sales
- Classification: risk categorisation
- Classification: airlock classification rule
- Pre-market requirements
- Post-market requirements
- SaMD cyber security
- AI as a Medical Device

Implantable devices

- Implantable devices

Other product specific changes

- Re-manufacturing single-use devices
- Systems, kits and procedure packs
- Parts and components
- Custom-made devices

Environmental sustainability and public health impacts

- Environmental sustainability and public health impacts

Alternative routes to market

- MDSAP and domestic assurance
- Pathway for innovative MedTech

Transitional arrangements

- Transitional arrangements

Key documents & resources

Legislation

General

- *Disability Discrimination Act 1995*
- *Charter of Fundamental Rights of the EU 2012 (CFREU)*
- *Chronically Sick and Disabled Persons Act 1970*
- *Equality Act 2010*
- *European Union (Withdrawal) Act 2018 (EUWA)*
- *The Retained EU Law (Revocation and Reform) Bill*
- *Northern Ireland Protocol*

Trade

- *UK/EU and EAEC: Trade and Cooperation Agreement [TS No.8/2021]*
- *The Customs Tariff (Preferential Trade and Tariff Quotas) (EU Exit) (Amendment) Regulations 2022*
- *The Designs and International Trademarks (Amendment etc.) (EU Exit) Regulations 2019*
- *The Taxation (Cross-border Trade) (Miscellaneous Amendments) (EU Exit) (No. 2) Regulations 2021*
- *The Customs Importation (Miscellaneous Provisions and Amendment) (EU Exit) (Amendment) Regulations 2021*
- *The Trade Marks and International Trade Marks (Amendment) (EU Exit) Regulations 2021*

Digital AT

Accessibility Requirements

- *EU Web Accessibility Directive (EU) 2016/2102*
- *Public Sector Bodies (Websites and Mobile Applications) (No. 2) Accessibility Regulations 2018*
- *Public Sector Bodies (Websites and Mobile Applications) Accessibility (Amendment) (EU Exit) Regulations 2022*
- *European Accessibility Act (Directive 2019/882)*

Consumer law

- *Consumer Rights Act 2015 (CRA)*
- *The Digital Content and Digital Services Directive (DCSD) (EU) 2019/770*
- *The Sales of Goods Directive (SGD) (EU) 2019/771*
- *The Enforcement and Modernisation Directive (EMD) (EU) 2019/2161*

Digital services

- The Digital Services Act (DSA) – *Regulation (EU) 2022/2065*
- *Online Safety Bill (OSB)*
- *e-Commerce Directive 2000/31/EC*

- The Digital Markets Act (DMA) -- *Regulation 2022/1925*

Data protection

- *EU General Data Protection Regulation (GDPR) (EU) 2016/679*
- *Data Protection Act (DPA) 2018*
- *The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (SI 2019/419)*
- *The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2020 (SI 2020/1586)*

Medical devices

The UK MDR 2002 & amendments

- *The UK Medical Devices Regulations 2002*
- *The UK Medical Devices (Amendment) (EU Exit) Regulations 2019*
- *The UK Medical Devices (Amendment) (EU Exit) Regulations 2020*
- *The UK Medical Devices (Amendment) (EU Exit) Regulations 2021*
- *The UK Medical Devices (Northern Ireland Protocol) Regulations 2021*
- *The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019*
- *The Medicines and Medical Devices Act 2021*

EU regulations

- *Council Directive 93/42/EEC on medical devices*
- *Council Directive 90/385/EEC on active implantable medical devices*
- *Council Directive 98/79/EC on in vitro diagnostic medical devices*
- *The EU Regulation 2017/746 on in vitro diagnostic medical devices*
- *The EU Regulation 2017/745 on medical devices*

Guidance

General

- *Assistive Technology: definition and safe use*

Trade

- *Placing manufactured products on the market in Great Britain*
- *Placing manufactured goods on the market in Northern Ireland*
- *Placing manufactured goods on the EU market*
- *Using the UKCA marking*
- *UKCA marking: roles and responsibilities*
- *UKCA marking: conformity assessment and documentation*

- *Using the UKNI marking*
- *Using the CE marking*
- *Moving qualifying goods from Northern Ireland to the rest of the UK*
- *Trading and moving goods in and out of Northern Ireland*
- *Rules of origin for goods moving between the UK and EU*
- *Designated standards*
- *Import goods into the UK: step by step*
- *Export goods from the UK: step by step*
- *Product safety for businesses - A to Z of industry guidance*
- *Pay no Customs Duty or VAT on goods for disabled people*
- *Reliefs from VAT for disabled and older people (VAT Notice 701/7)*

Digital AT

- *A guide to good practice for digital and data-driven health technologies*
- *Guidance and tools for digital accessibility*
- *Understanding accessibility requirements for public sector bodies*
- *Technology code of practice*
- *Guide to the UK General Data Protection Regulation (UK GDPR)*
- *Guide to Data Protection and the EU*
- *Certification of compliance with the UK GDPR*
- *Legal frameworks for Artificial Intelligence*

Medical Devices

- *Factsheet: medical devices overview*
- *Regulating medical devices in the UK*
- *Designated standards: medical devices*
- *Medical device stand-alone software including apps (including IVDMDs)*
- *Export medical devices*

Other Information

- *Retained EU law dashboard*
- *Implementation of the future regulation of medical devices and extension of standstill period*
- *Consultation on the future regulation of medical devices in the United Kingdom*
- *Product marking extension*