Mitigations for the move to the UKCA mark from 01 July 2023

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The Birmingham Health Partners Centre for Regulatory Science & Innovation was established in 2020 to support the development and delivery of novel therapeutics and medical devices in the UK, through advanced regulatory standards and tools. A truly multidisciplinary initiative, the CRSI aims to bring together experts in medicinal science, health policy and management, clinical trial design, medical law, and patient-reported outcomes research, from across BHP member organisations. The mission of the CRSI is to drive innovation in regulatory science to promote efficient, safe, and cost-effective implementation of new therapies, for the benefit of patients and society. **www.birminghamhealthpartners.co.uk**

The Regulatory Horizons Council (RHC) is an independent expert committee that identifies the implications of technological innovation, and provides government with impartial, expert advice on the regulatory reform required to support its rapid and safe introduction.

March 2021

Executive Summary

The UKCA (United Kingdom Conformity Assessed) mark is the new UK product marking for medical devices being placed on the market in Great Britain. The EU CE mark will continue to be recognised in Great Britain until 30 June 2023, after which all medical devices on the market will require a UKCA mark. The Regulatory Horizons Council commissioned the Birmingham Health Partners Centre for Regulatory Science and Innovation (CRSI) to collate multi-stakeholder views on the 'implications of the end to the use of the EU CE mark for medical devices in Great Britain' and the 'mitigation work that could take place to facilitate the move to the UKCA mark'.

The CRSI team began by performing a literature review using PubMed and Google Scholar to search the published literature and Google Search Engine to search the grey literature. We then used three qualitative methods to comprehensively collate the views of stakeholders from across the medical device sector: i) one-on-one, semi-structured interviews with stakeholders were conducted; ii) a multidisciplinary stakeholder workshop was convened to review initial findings and discuss areas of agreement and disagreement; and iii) a post-workshop survey was distributed to attendees to further explore areas of contention discussed during the workshop. All data were subsequently analysed using a framework approach.

The evidence review and stakeholder engagement process identified that the end to the use of the EU CE mark for medical devices and the move to the UKCA mark pose unique implications for different stakeholder groups. We have categorised the implications and mitigations into three groups accordingly: those most relevant to regulators, those most relevant to medical device companies, and those most relevant to patients and the public.

Regulators The principal implication for regulators is a surge in demand for their services. All medical devices on the market in Great Britain will require a UKCA mark from 01 July 2023 which means that UK regulators have under two-and-a-half years to authorise all medical devices. Stakeholders are concerned that there are insufficient numbers of designated UK Conformity Assessment Bodies (UK-CABs) to meet the demand placed on them. Multiple strategies to increase the UK's regulatory capacity were suggested, including: i) increasing the number of UK-CABs; ii) prioritising the allocation of limited UK regulatory resources; iii) encouraging UK-CABs to expand their coverage of high-risk medical devices; iv) expanding the Medicines and Healthcare products Regulatory Agency's (MHRAs) role and responsibilities, and v) potentially enabling third-parties to perform UKCA and EU CE conformity assessment in parallel. Stakeholders also suggested that increasing coordination across regulatory authorities (MHRA), health technology assessors (NICE), procurers (NHS), and healthcare service inspectors (CQC) may make the regulatory process more efficient. More generally, stakeholders raised concerns that the UK's reputation and influence in global regulatory affairs may diminish, as the UKCA mark will only be applicable to Great Britain, a relatively small market.

Medical device companies Multiple interconnected implications for medical device companies, mostly driven by regulatory divergence, were identified during our research. Regulatory divergence generates additional cost for medical device companies; if the cost and complexity of complying with the new UK regulation are greater than the profits afforded by doing so, medical device companies – especially small and medium-sized enterprises (SMEs) which account for 80% of the businesses in the UK life sciences industry – are likely to prioritise other markets instead. Uncertainty around the impact of new UK regulation on businesses is likely to deter investors and a decline in levels of investment is, in turn, likely to inhibit innovation and research. The complexity has caused confusion and frustration among many people working in the medical device sector and, consequently, some have considered relocating their businesses from Great Britain to Northern Ireland to benefit from the parallel regulatory pathways available to them there. There was strong agreement amongst stakeholders that clear guidance that focuses on the practical implementation of new regulations would reassure medical device companies, and their potential investors, thereby mitigating against most of the above issues. Other mitigation strategies were suggested to encourage companies to continue developing and selling devices in the UK and to promote innovation, investment, and research, including i) financial incentives; ii) state-of-the-art regulation for complex medical devices; and iii) mutual recognition of clinical evidence. Extending the transition period for all or some medical devices was another mitigation strategy suggested by stakeholders, though further work is required to determine the most effective way to approach extension.

Patients and public If medical device companies prioritise other markets over the UK market, this is likely to lead to a reduction in the availability and choice of medical devices for patients and the public. Any reduction in the availability and choice of medical devices on the UK market may impact patients with rarer conditions more than patients with common conditions and could exacerbate existing disparities in care provision between these patient groups. Additionally, an inadequate understanding of the relevant implications of the new UKCA mark – for example, uncertainty around whether access to medical devices will be affected – may cause stress and anxiety amongst patients. To mitigate against this, stakeholders have highlighted the importance of openly and honestly communicating with patients and the public about relevant risks and opportunities and effectively involving and engaging them as key stakeholders moving forward.

Key Findings

Implications of the end to the use of EU CE marked medical devices in Great Britain on 30 June 2023

Implications for regulators

Surge in demand for the services of UK Conformity Assessment Bodies in excess of current regulatory capacity. A surge in demand for the services of UK-CABs is anticipated in advance of the hard stop to the use of EU CE marked medical devices on 30 June 2023. However, there are only three legacy UK Notified Bodies (NBs) which have been automatically designated as the UK-CABs. This is felt to be insufficient number of UK-CABs to meet that demand at present. This creates risks for medical device companies seeking UKCA marking for their medical devices, as they will end up overly reliant on a small number of third-party commercial entities to perform conformity assessment. For example, there may end up being bottlenecks in device certification, which delay devices getting to market. This problem is compounded by the fact designations for non-UK-based notified bodies (NBs), which have, up until now, performed a significant amount of conformity assessment for medical devices entering the UK market, are expiring and overstretched. The MHRA will need to designate additional UK-CABs to overcome this issue, a process which itself takes time and may not be achievable prior to the hard stop on 30 June 2023.If the MHRA is unable to attract/appoint existing EU NBs to formally become UK-CAB in time, it may, by default, have to undertake the role of CAB itself. This option is not felt to be feasible, as the MHRA does not have sufficient in-house capacity or powers to do so at present.

Decrease in the UK's international regulatory influence. Medical device companies are likely to prioritise selling their products in larger markets over smaller ones and, by extension, they are going to prioritise conforming to the regulatory standards of larger markets over those of smaller ones. If medical device companies are prioritising non-UK markets and regulatory standards, such as the US and EU, it may lose international regulatory influence.

Implications for medical device companies

Increase in costs to medical device companies due to dual regulatory burden. Regulatory divergence will result in medical device companies seeking to sell their products in the UK and internationally having to go through two separate regulatory processes. This may, for example, necessitate them having to generate additional clinical evidence or produce additional versions of a product or its packaging. GB-based medical device companies will need to appoint an EU-based Authorised Representatives (ARs) to sell their devices in the EU, while EU-based companies must designate a UK Responsible Person (RP) to place the device in the UK market. These implications generate additional work, complexity, and, ultimately, cost for medical device companies.

Unequal impact on small vs. large medical device companies. There is a difference of opinion with regards to whether the end to the use of the EU CE mark for medical devices in the UK on 01 July 2023 will impact smaller medical device companies more or less than larger ones. Some stakeholders believed that it would impact start-ups and SMEs more, as regulatory processes constitute approximately one-third of their outgoings and they tend to have less financial reserve; other stakeholders felt that it would impact larger medical device companies with large product portfolios more, as they would face complex logistical challenges when re-labelling, re-packaging, and re-marketing their products.

Reduction in number of medical device companies prioritising UK market authorisation. Medical device companies, especially SMEs, would prioritise markets based on size, ease of access, and likelihood of generating revenue. Taking a divergent and unpredictable regulatory course without any clear guidance, may result in significant withdrawal of companies from the UK market, especially those companies that predominantly sell products outside of the UK at present.

Decrease in the amount of UK-based medical device research. Divergent regulatory processes are likely to make coordinating clinical trials with other countries more challenging. While the UK has secured its participation in Horizon Europe, the largest transnational research funding scheme in the world with a budget of €95 billion, the UK, like other associate countries, will only have 'observer status' in programme committees. This, coupled with the exclusion of the UK from a selection of funds, raised concerns in UK-based SMEs.

Inhibition of UK-based innovation in the medical device area. In today's era of fast-evolving technology, innovation is the cornerstone of the medical device industry. If the new UK regulatory process is too cumbersome, it will stifle innovation and increase the time it takes for new devices to reach the market.

Decrease in the level of investment in the UK medical device sector. A strong business investment environment lays the foundation for a thriving sector. Uncertainty around future UK regulation is likely to lead to decline in investment in the short term.

Lack of clear guidance prevents medical device companies from planning and preparing for the move to the UKCA mark. Medical device companies do not feel confident to plan and prepare for the move to the UKCA mark because of a perceived lack of clarity regarding the new 'rules of the game'. The uncertainty around new regulations and lack of clear guidance may lead to delays in decision making and have negative health and economic consequences.

Incentive for businesses to relocate from Great Britain to Northern Ireland to benefit from parallel regulatory pathways. A separate regulatory regime for NI, which continues to require EU CE marking alongside the new UKNI mark may incentivise medical device businesses and personnel to relocate to NI, to benefit from the parallel regulatory pathways available there.

Implications for patients and the public

Reduction in availability and choice of medical devices. Medical device companies will weigh up the cost of complying with new UK regulations against the benefits of doing so. If the former outweighs the latter, it is highly possible that there will be delays in the time it takes for medical devices to receive UK market authorisation and a decline in the overall number of medical devices that receive UK market authorisation. This, coupled with supply chain instability and uncertainty resulting from regulatory changes, may mean that there is less availability and choice of medical devices on the UK market.

Unequal impact on patients with rare vs. common conditions. The rigorous market authorisation process costs device companies much time and money. These costs have historically encouraged companies to concentrate their development efforts on devices whose profits exceed the substantial costs of approval – typically devices that treat common conditions. Consequently, patients with rare conditions are likely to face unequal difficulties in accessing new and existing medical devices.

Confusion and anxiety amongst medical device users. Uncertainty amongst patients and the public around potential implications of the end to the use of the EU CE mark for medical devices in the UK and the move to the UKCA mark may cause confusion and anxiety.

Key Findings

Mitigation work that could take place to facilitate the move to the UKCA mark from 01 July 2023

Mitigations for regulators

Increase the number of UK Conformity Assessment Bodies. One way to increase capacity to perform UKCA conformity assessment is to increase the number of UK-CABs. This involves encouraging the formation of new ABs, incentivising existing NBs to become ABs, and training and retaining regulatory experts. As training can be a lengthy process and the deadline is fast approaching, it is important to start now.

Prioritise allocation of limited UK regulatory resources. Given the limited capacity of ABs within the UK, there is a risk of many devices not being certified before the deadline. One approach would be to allocate UK regulatory resources to those devices based on medical need rather than date of application or commercial relationships. This would, for example, avoid authorisation of multiple generic "me-too" devices. There are, however, a myriad of ethical, legal, and practical issues associated with prioritisation that would be challenging to overcome.

Encourage UK Conformity Assessment Bodies to expand their coverage of high-risk medical devices.
At present, there are only a limited number of EU NBs with required capabilities and competences to assess high-risk (high-class) medical devices. Limited numbers of UK-CAB designations may cause a regulatory bottleneck for such devices. It is important that the available UK-CABs expand their coverage to include high-risk medical devices, so as to ensure that companies producing these types of devices are able to have them assessed and authorised for the UK market.

Expand the MHRA's role and responsibilities.
If the UK is too small a market on its own to support third-party conformity assessment, the UK Government may be required to expand the MHRA's role and coverage to perform conformity assessment and issue the UKCA mark for medical devices.

Enable designated third-parties to perform UKCA and EU CE conformity assessment in parallel. There is likely to be a significant degree of overlap in what is required from UK-CABs performing conformity assessment for UKCA marking and EU NBs performing conformity assessment for EU CE marking. If third-parties were able to perform UKCA and EU CE conformity assessment in parallel it would avoid duplication of efforts and make the process more efficient, with time and cost savings for all involved. However, there are challenges, such as ensuring sufficient harmonisation in audit processes and technical documentation. In addition, risks such as accepting designations from non-UK organisations must be borne in mind.

Increase coordination across regulators, health technology assessors, and procurers. A more streamlined medical device pipeline with greater coordination across regulators, health technology assessors (HTAs), and procurers may make the process more efficient. Aligning evidence requirements, for example, would bridge the gap between regulatory and HTA agencies; however, more onerous evidence requirements from an early stage of the pipeline would potentially create challenges for medical device companies.

Mitigations for medical device companies

Provide medical device companies with clear, transparent, and unified guidance.
Medical device companies need to know what the new 'rules of the game' are as soon as possible so that they can properly plan and prepare for the move to the UKCA mark. This requires UK regulatory authorities to provide medical device companies with clear and transparent guidance. Companies would benefit from guidance that focuses on the practical implementation of new regulations, rather than the legislation, and having access to a single, central hub where they can go for advice and information.

Encourage mutual recognition of clinical evidence across UK, EU, and US regulatory systems. Harmonisation of clinical evidence requirements across regulatory jurisdictions including the UK, EU, and US would avoid medical device companies having to duplicate or triplicate their research efforts, thereby increasing efficiency in medical device research and development (R&D).

Incentivise medical device companies to develop and sell devices in the UK. The UK government could encourage medical device companies, especially SMEs, to develop and sell devices in the UK using financial incentives such as tax reliefs and R&D tax credits.

Develop state-of-the-art regulation for complex and innovative medical devices to attract innovators and investors. Developing UK-specific regulations for categories of medical devices for which regulations already exist would be an inefficient use of UK regulatory resources and expertise. Where possible, the UK should focus on shaping standards for complex and innovative categories of medical devices, such as artificial intelligence as a medical device (AIaMD) and novel technologies, and developing technical specifications for novel technologies, as it has done during the COVID-19 pandemic. This would address the UK's innovation agenda and naturally, lead to a greater attraction for innovators and investors.

Extend the transition period for all or some medical devices. An extension to the transition period beyond 30 June 2023 may help ensure effective implementation of the new UK medical device regulation and availability of devices to the UK public. A pragmatic approach may be to align the extended deadline with the end of the grace period for devices with certificates issued under the MDD (25 May 2024), which would smooth the introduction of new legislation.

Mitigations for patients and the public

Provide patients and the public with clear, transparent, and understandable information.
Patients and the public need to know what the relevant implications are to them of the end to the use of the EU CE mark and the move to the UKCA mark for medical devices. This requires a communication campaign to clearly and transparently answer people's questions in a way that they can understand. Patients and the public should also be involved as key stakeholders in future debate and decision-making regarding regulatory reform of medical devices.

Abbreviations

BHP	Birmingham Health Partners
CRSI	Centre for Regulatory Science and Innovation
EU	European Union
EU CE	European Union Conformity Assessed
EU MDD	European Union Medical Device Directive (93/42/EEC)
EU MDR	European Union Medical Device Regulation 2017/745
GB	Great Britain
HTA	Health Technology Assessment
MHRA	Medicines and Healthcare products Regulatory Agency
NB	Notified Body
NI	Northern Ireland
NICE	National Institute for Health and Care Excellence
NHS	National Health Service
R&D	Research and development
RHC	Regulatory Horizons Council
RP	Responsible Person
SME	Small and medium-sized enterprise
UK	United Kingdom of Great Britain and Northern Ireland
UKCA	United Kingdom Conformity Assessed
UK CAB	United Kingdom Conformity Assessment Body
UKNI	Northern Ireland Conformity Assessed
US	United States

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This report reflects the views of a range of stakeholders and should not be attributed to specific individuals or organisations unless explicitly stated.

Drs Han and Ibrahim contributed equally to this report and are recognised as joint first authors.

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*Advisory board members

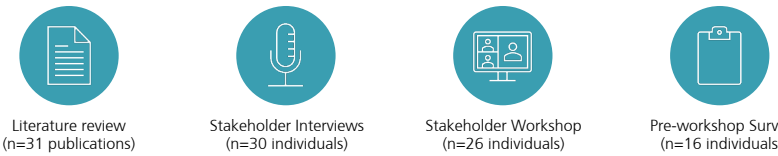
APPENDIX 1: Methods

Qualitative methods were used to collate the views of stakeholders from across the medical device sector.

1. Data Collection

Data were collected from four sources:

Figure 1. Data Sources.



1.1. Literature Review

A literature review was conducted on 08 January 2021. PubMed and Google Scholar were used to search published literature and Google Search Engine was used to search grey literature. Only the first 100 citations from Google Scholar and Google Search Engine were screened due to time constraints. Citations were independently screened by two co-investigators (DH and HI) according to predefined inclusion and exclusion criteria. Disagreements were resolved via consensus. A total of 31 citations were included in the literature review.

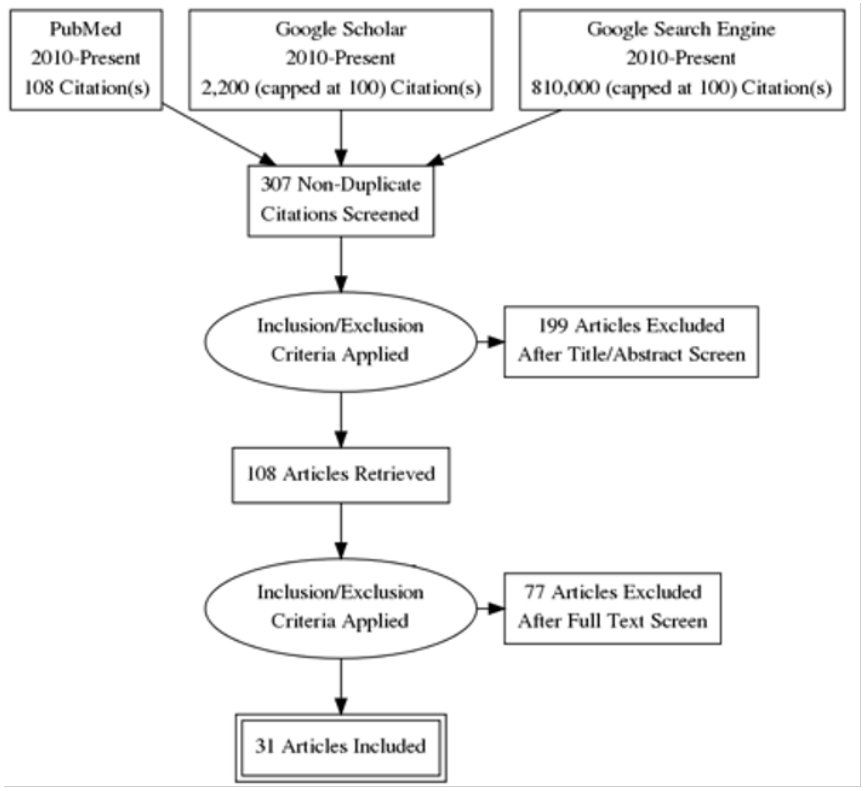
Table 1. Search Terms

PubMed			Google Scholar	Google Search Engine
	Search Terms	Record no.	EU CE marked Medical device Brexit UK impact OR impacts OR implication OR implications	EU CE marked Medical device Brexit UK impact OR impacts OR implication OR implications
1	medical device			
2	medical devices			
3	OR (1-2)	1,561,268		
4	CE mark			
5	CE marked			
6	CE marks			
7	CE marking			
8	conformity europeenee			
9	european conformity			
10	declaration of conformity			
11	UKCA			
12	UK CA			
13	OR (4-12)	1,576		
14	legislation			
15	legislations			
16	conformity			
17	regulation			
18	regulations			
19	OR (14-18)	3,384,232		
20	3 AND 13 AND 19	108		

Table 2. Inclusion and Exclusion Criteria for Literature Review.

Inclusion criteria	Exclusion criteria
English language	Non-English language
Published on or after 01 January 2010	Published on or before 31 December 2009
Medical devices and/or in vitro diagnostic medical devices	Drugs
Debates, discussions, opinions, reflections, and views about potential implications of an end to the use of EU CE marked medical devices in Great Britain on 01 July 2023 and mitigation work that could take place to support industry in the change to the regulatory framework and move to the UKCA mark from 01 July 2023	Factual information about potential implications of an end to the use of EU CE marked medical devices in Great Britain on 01 July 2023 and mitigation work that could take place to support industry in the change to the regulatory framework and move to the UKCA mark from 01 July 2023

Figure 2. Flow Diagram for Literature Review.



1.2. Stakeholder Interviews

Stakeholder interviews were conducted online via MS Teams between 04 January 2021 and 02 February 2021. A total of 30 one-on-one, semi-structured interviews were conducted with stakeholders from across the medical device sector: medical device companies (n=7), regulatory consultancies (n=6), UK Government agencies (n=5), product testing or certifying bodies (n=4), academics and clinicians (n=4), trade associations (n=2), and patient and public partners (n=2).

1.3. Stakeholder Workshop

A workshop was conducted online via MS Teams on 09 February 2021. The aim of the workshop was to discuss areas of agreement and disagreement identified after analysis of data from the literature review and stakeholder interviews. A total of 26 stakeholders attended the workshop.

1.4. Post-Workshop Survey

A post-workshop survey was conducted online via Qualtrics Survey Software between 19 February 2021 and 05 March 2021. The survey was designed to further explore areas of contention discussed during the workshop. A total of 16 stakeholders completed the survey.

2. Data Analysis

Data were managed and analysed thematically using the framework approach. This method allows a comprehensive review of collected narratives, that is driven by stakeholders' original accounts and literature review. Raw data from the four sources were analysed by two co-investigators (DH and HI). The interviews were reviewed and coded independently using the stakeholder interview questions as an initial thematic framework. Textual codes were grouped into clusters around similar and interrelated concepts and a matrix of themes were created and analysed within Google Sheets.

APPENDIX 2: Evidence

Implications of the end to the use of the EU CE mark for medical devices in Great Britain

Key themes	Interview	Workshop	Literature review
Implications on regulators			
Surge in demand for the services of UK Approved Bodies in excess of current regulatory capacity.	• The insufficient number of UK ABs and expiration of existing EU NBs designation under the new UKCA marking creates bottleneck concerns. • There are only a few UK ABs which may pose a risk as medical device companies would be reliant on a small number of commercial entities. • There may not be enough business incentive for EU NBs to set up UK ABs. • There are insufficient regulatory resources within the MHRA to re-approve existing EU CE mark medical devices whilst continuing to approve new and innovative medical devices.	• The lack of capacity within conformity assessment processes is likely to be the biggest headache as we run up to 30 June 2023. It is difficult for conformity assessment bodies to become designated, which is a particular issue. • There isn't a single country that is working on its own anywhere that has sufficient regulatory capacity to do everything on its own. Even the FDA, the largest, does not have sufficient capacity to perform all of its own tasks. The UK will never have sufficient capacity to do everything on its own. • There isn't the capacity in the EU NB market to meet the new EU MDR for medical devices seeking EU CE mark coming into force. This exacerbates the UK's problem as the existing resources available, even the UK NB/ABs, are currently diverted towards processing EU CE marking assessments under EU MDR. • If UK AB capacity were insufficient, the MHRA, by default, could be required to conformity assess medical devices. This would not be feasible at present as there are not enough staff and resources within the MHRA. If the FDA, which is the largest regulatory authority in the world, cannot meet their commitments to regulate/audit all the devices going into the USA, then to think UK ABs and the MHRA have the necessary capacity to do is ludicrous.	•
Implications on medical device companies			
Increase in costs to medical device companies due to dual regulatory burden.	• A new regulatory system in the UK would create additional cost and complexity that would be borne on medical device manufacturers. • At best, if regulations diverge, it means there are two sets of regulatory processes to go through; at worst, it means there are two versions of the product which need to be made. In both circumstances, additional work and complexity, and therefore costs, are generated. • If clinical evidence from the UK is not accepted in Europe it will lead to duplication of research efforts and therefore increased costs for medical device developers and innovators.	• Many SMEs are worried about the costs of adapting to a new regulatory system.	• If the UK's NBs were removed from the European network – and vice versa – it would require duplication of the process for every manufacturer, which would be time-consuming and costly. • The practical effect of a dual regulatory burden (on UK business) will be a likely increase in production costs. • Financial implications … changes to a product's packaging, labelling or design • There have been reports that a number of manufacturers are maintaining their CE Certificates with UK based Notified bodies as they largely sell their products in the UK market and do not export a significant amount. While this is a legitimate reason for not moving their CE certificate, it does mean that they will have to go back to the start of the application process if they do decide to sell in the EU or possibly the rest of the world (E.g. Australia has a mutual recognition agreement to accept EU CE certificates) at a later date. With this, further investment will be required to re-approve in the future. • The UK is a sizable life sciences market within the EU and applicants will be likely to want to have market authorisations (MAs) in both the EU and the UK. Adopting a system in which completely separate applications are needed will increase the costs for applicants as well as the workload of the MHRA and EU regulators. • A more complex and urgent step is for manufacturers from outside of GB (not the whole UK, just GB) to appoint a UK Responsible Person (UKRP), as well as, or instead of, their EU Authorized Representatives (ARs) depending on whether or not they are deploying products to the EU. The most complex step is that if a manufacturer is using an EU, not UK, based Notified Body then they will need to additionally engage a UK Approved Body. • UK manufacturers would have to appoint an Authorised representative (similar to the MHRA) outside the UK to approve their products, so that they could be marketed back into the UK. A costly process with little benefit to the manufacturer. • If UK manufacturers want to export their medical devices to the EU-27 market, they will need an importer and a "Responsible Person" appointed within the EU-27.

Key themes	Interview	Workshop	Literature review
Implications on medical device companies (continued)			
Unequal impact on small vs. large medical device companies.	• The end to the use of EU CE marked medical devices in the UK on 01 July 2023 will disproportionately impact start-ups and SMEs compared to larger companies, as they do not have the resource reserve to go through an additional regulatory process, especially considering regulatory processes currently constitute about a third of their outgoings. • The end to the use of EU CE marked medical devices in the UK on 01 July 2023 will impact large companies in unique ways as those with large product portfolios would face complex logistical challenges associated with marketing, labelling, and packaging.		
Reduction in number of medical device companies prioritising UK market authorisation.	• All companies, especially non-UK manufacturers, will move products to meet the requirements of the EU MDR/IVDR in order to be able to continue selling products in the EU. THey will prioritise this over the UK, which is a relatively small market. • Already a large number of SMEs are choosing to go to the US, which is valued as the largest medical device market in the world. The opportunity of generating revenue on the US market outweighs the costs of going through a separate regulatory approval process (i.e. via FDA). • When Canada went through a similar process, medical device companies that predominantly sold their products elsewhere, and only sold a limited number of products in Canada, stopped selling products in Canada. The same thing is almost certainly going to happen in the UK.	• Medical device companies are choosing the US market over the UK to do innovation for two reasons: predictability and guidance.	• Kromek currently manufactures almost 50% of its products at its UK headquarters – which, like Stream Bio, is located in County Durham, where a majority (57.7%) voted to leave the EU in the referendum of June 2016. Most of Kromek's other manufacturing takes place in the US, and Basu says that Brexit may influence the company's next investment decisions. "We are currently looking at a capital investment programme of £6–10m over the next 6–9 months, and depending on what happens in March, we have the flexibility to alter where that capital investment programme happens," Basu says. "If it's complete chaos, the board will have a duty to go to where we have a better visibility of market conditions, he adds. • As in medicines, the medical technology companies that work with the NHS and employ 94,000 people in the UK would also face an incentive to leave the UK unless there is also some scope for UK bodies to clear products to be exported across the EU.
Decrease in the UK's international regulatory influence.	• Companies will primarily work towards and seek regulatory approval from the EU and US and see the UK as a third country. Therefore, the UKCA mark will become a "rubber stamp" and the UK will actually have less control over the regulatory standards. • Leaving the EU will mean the UK loses its place on the EU Regulatory Committee.		• Leaving the EU means that the UK will no longer be able to shape the directives that set the standards: we will be rule-takers, not rule-makers.
Decrease in the amount of UK-based medical device research.	• "The UK is not an island when it comes to the evidence ecosystem" • Medical device companies are deciding against conducting clinical trials in the UK due to changes to regulatory standards and questions over what is expected in terms of clinical performance data as it does not make sense for them to have to conduct separate clinical trials to comply with two different regulatory jurisdictions. • There are Inadequate resources to run effective clinical trials for medical devices in the UK alone.		• UK institutions find it more difficult to take part in cross-Europe clinical trials due to divergent processes, and possibly ineligibility for the flagship Horizon Europe funding programme. • The UK is a substantial net beneficiary of EU research funding from the Framework and Horizon 2020 programs, with both academic and industry participation. If there is no successful negotiation, the UK will lose membership access to EU research grants, which is a very significant source of economic funding to academic research including industry–academia collaborations, It would be a huge loss to the academic ecosystem if the UK is relegated to third-country status in those collaborations.
Inhibition of UK-based innovation in the medical device area.	• If the new UK regulatory process is too cumbersome, it will stifle innovation. • A delay in re-approval process of existing EU CE-marked medical devices will reduce the number of innovative medical devices getting to the UK market.	• Companies are choosing the US rather than the UK to do innovation for two reasons: predictability and guidance.	
Decrease in the level of investment in the UK medical device sector.	• Without data harmonisation and compatibility, expected loss of potential investment from big multinational companies. • UK-based investors may prioritise the local/home market, hence the UKCA mark, but there is no guarantee that International investors will do so also. •		• The lack of clarity, expressed even before it was clear how late in 2020 any UK–EU agreement would be finalised, was a source of serious concern among our research participants. Industry and researchers will face diminished global competitiveness due to trade barriers … incentivising less investment. One interviewee said it was likely that "you'll just see investment decline fairly sharply, at least for two years", with the possible "death of certain sub-sectors". • Suppliers may need to obtain new UK-specific certifications or even rebuild the software to adhere to new regulations. Some market analysts believe that this uncertainty may defer new investments.
Confusion and frustration amongst people working in the medical device sector.	• The transition process has created confusion for businesses, especially those wishing to sell products in Northern Ireland. • The potential for delays in medical devices getting UKCA mark approval may lead to anger at the level of businesses.		• Specific changes to tariffs or regulations are less of a headache than the uncertainty surrounding what will happen.

Key themes	Interview	Workshop	Literature review
Implications on medical device companies (continued)			
Incentive for businesses to relocate from Great Britain to Northern Ireland to benefit from parallel regulatory pathways.	• Northern Ireland finds itself in a "special situation" where medical devices may require different markings or combinations of markings depending on where the device is produced and where it is planning on being sold. As a "middle ground" between the UK and the EU, it is possible that NI will be seen as an ideal place for regulatory consultancies and regulatory testing centres to relocate. Without embracing regulatory activity that brings Northern Ireland in with the rest of the UK, there is potential risk of GB-based and international companies choosing to leave GB and relocate to NI, resulting in a "brain-drain" and loss of significant industry players.	• Northern Ireland is in a unique regulatory position. This could be a good thing or a bad thing depending on how you look at it.	
Implications on patients and the public			
Reduction in availability and choice of medical devices.	• If acquiring the UKCA mark created additional work, complexity, and cost for medical device companies, it may mean that there are fewer medical devices available on the UK market, meaning less choice for the UK population. The devices that are lost are likely to be the ones that do not generate sufficient profit for medical device companies. • Delays to the UK regulatory approval process may mean that there are delays in access to essential and state-of-the-art innovative medical devices. • Changes to the regulatory process for medical devices in the UK may disrupt the supply chain of medical device parts and products coming into the UK from overseas. Supply chain instability may have a negative downstream impact on availability of medical devices for clinical services and ultimately patients in the UK.	• Medical device manufacturers will weigh up the cost of complying with new regulations against the potential profits afforded from business opportunities by doing so. If they find that the former outweighs the latter, products will likely disappear from the market. • There is an expectation that we'll lose 20-30% of products from the market as the cost of compliance will outweigh business opportunity.	• A separate UK authorization process may be unappealing for the industry owing to additional costs precluding companies from accessing the British market. This, in turn, could delay the availability of the newest technologies in the UK. • Many companies are already struggling with the demands of the MDR/IVDR such as the increased costs. This coupled with the additional authorisation process required to reach the UK market may lead to delays or deter companies from selling their products in the UK altogether. • There is a huge risk of a regulatory logjam with devices being potentially rendered unusable until they are authorised through the new GB system. • According to GlobalData's pipeline products database, there are over 17,000 active medical devices currently in the pipeline with approximately 42% of these devices in the early stages of development. The high proportion of products being developed in the EU and UK indicates that a vast majority of devices will be caught in transitioning approval processes, which may lead to a temporary decline in the volume of approved devices. • One greater concern that is less resolved is the supply chain. What happens when a product is manufactured in a number of different countries? Both in terms of taxation and the regulation of import and export of partially constructed devices, the future is less clear. For example, if a device was to have an initial build in Germany, followed by transit to Britain for component addition and then return to France for final assembly and sterilisation then the situation is complex. It is not clear how often regulation – or taxation, for that matter – will be imposed on that product, especially if a trade deal is not achieved and we fall back on World Trade Organization rules.
Unequal impact on patients with rare vs. common conditions.	• Patients, especially those who suffer from rare conditions, will lose out. For instance, medical devices for managing prevalent conditions like heart disease will continue to be sold as the patient populations are sufficient to warrant seeking regulatory approval; but medical devices for managing rare diseases may stop being sold on the UK market. The end to the use of EU CE marked medical devices in the UK on 1 July 2023 will therefore impact patients with rarer conditions more than it will impact patients with common conditions.		
Confusion and anxiety amongst medical device users.	• There are lots of questions that may be going through a medical device users' mind: Has the medical device changed? Will the cost of the device change? Will access to the medical device change? Do you need to return the EU CE mark medical device? Do you get a new UKCA mark medical device? If so, how? Not answering these questions and the prospect of delays in medical devices receiving UK market authorisation may cause anxiety.		

Mitigation work that could take place to facilitate the move to the UKCA mark

Key themes	Interview	Workshop	Literature review
Mitigations for regulators			
Increase the number of UK Approved Bodies.	• We need more UK ABs. Currently there are only a few designated third parties to process all medical devices and IVDs; those requiring re-certification as well as new products entering the UK market. • Providing financial incentives from the government may encourage more third parties to seek UK AB designation.	• Increasing UK AB capacity requires training someone to understand the new regulation. If it takes longer than 2 years to train a reviewer, it wouldn't be possible to increase capacity via this strategy in time for the deadline in 2023.	
Prioritise allocation of limited UK regulatory resources.	• We should be smart and focus our limited regulatory resources towards innovative devices rather than ones where, for example, there are already 6 other "me-too" devices.	• Prioritisation would need to be driven by the DHSC and NHS but that would require them to have a granular understanding of the risks associated with device supply and impacts of service provision. • There are significant practical/legal/ethical challenges associated with selecting which types of devices to prioritise. If done based on the numbers used it may discriminate against newer (and potentially better) devices that have not yet achieved a large market presence. Companies whose devices are not prioritised will be more than irritated.	
Encourage UK Approved Bodies to expand their coverage of high-risk medical devices.	• It is important to encourage UK ABs to increase their capacity to assess high-risk devices such as implantables. This may require grants and financial investment.		
Expand the MHRA's role and responsibilities.	• The MHRA has to be able to oversee UK ABs that perform conformity assessment. This is an essential part of MHRA's public health responsibility to the UK population.	• If the UK is potentially too small a market to support ABs, should the UK be considering a complete change in the regulatory process - potentially with the MHRA providing conformity assessment and issuing the UKCA mark on the products?	
Enable designated third parties to perform UKCA and EU CE conformity assessment in parallel.	• There will be a lot of overlap in the UKCA and EU CE medical device assessment process. It would be quicker and cheaper to perform the assessment processes in parallel. One way to do this is to encourage third party organisations to perform UKCA and EU CE assessments simultaneously. The BSI has a UK and Netherlands branch and would be able to do this quite easily. One of the ways to achieve this would be for the medical device companies themselves to put pressure on the third-party organisations to do so.	• There is a risk with accepting designations of EU NBs who may not appropriately prioritise the UK requirements when performing UKCA assessments. • It would be necessary to incentivise harmonisation in audit processes and technical documentation across UK ABs and EU NBs to make this happen. • It may be difficult to incentivise EU NBs to set up additional mechanisms to assess products for UKCA. • The UK needs to consider an smart/efficient utilisation of international regulatory infrastructures and resources that already exist to maximise the UK's regulatory capacity.	
Increase coordination across regulators, health technology assessors, and procurers.	• Bring the regulatory and HTA processes closer together to streamline the pipeline for medical devices in the UK. • Adopt a "virtual work bench" where the device is in the centre and all the relevant organisations such as MHRA/NICE/CQC work around the device. This would make things easier for industry by making all aspects of the system visible to them and make things easier for MHRA/NICE/CQC as all the relevant information would be available to them therefore making the process more efficient.	• Linking regulation and HTA can create very high hurdles even if it is sensible for manufacturers to build evidence to clear both. This minds me of Martin Buxton's well-recognised quote: "It is always too early to assess a technology until suddenly it is too late". • There is a good case for innovators to develop their strategy taking account of Regulation and HTA so the evidence becomes additive and they have a faster and more cost-effective journey to market.	

Key themes	Interview	Workshop	Literature review
Mitigations for medical device companies			
Provide medical device companies with clear, transparent, and unified guidance.	• There should be a 'central hub' where manufacturers can go for advice which provides clear guidance potentially via a roadmap or toolkit to help companies navigate the new UK regulatory pathway. If this was to be delivered by a single organisation, this should probably be the MHRA, but if the remit of the advice hub were to be the whole medical device development pipeline, it could also include bodies like NICE and CQC. • Training to enable medical device manufacturers and regulatory consultants to better understand the new rules and regulations i.e. webinars by MHRA. • It is important to engage with medical device companies to raise awareness of the potential implications of the move to the UKCA mark. • Transparency around UK AB service fees would help manufacturers, especially SMEs, mitigate against price hikes.	• It is really important that the UKCA requirements are clear, pragmatic, and predictable. • Medical device companies need to know with certainty what the 'rules of the game' are going to be. Clear guidance on implementation and not just legislation is necessary to allow them to properly plan what they need to do and begin to action that plan. • Certainty is essential. Otherwise companies will continue to wait, convinced the rules will keep changing. • Increasing regulatory capacity does not address the issue of clarity: "Clarity is just as important as capacity". •	• "If we knew what we were planning for, we could plan for it," he argues. "But we can't plan for five different scenarios." "When asked what the government could do to help his business do even better, his answer is immediate. "Give us clarity," he says. "Give us clarity of what's going to happen, give us clarity over what time scale it will happen. As businesses we are slightly less bothered about the politics. What we are really bothered about is, give us enough time to plan so that we can cope."
Encourage mutual recognition of clinical evidence across UK, EU, and US regulatory systems.	• Harmonising clinical evidence standards so that companies seeking UKCA regulatory approval just need to re-submit the same information that they submitted to get EU CE or US FDA regulatory approval would be helpful. It would reduce the burden of obtaining clinical data and allow data generated from a single clinical study support application for UKCA, EU CU and FDA approval.	• We should be looking at data compatibility rather than regulatory compatibility to ensure that data is transferable between jurisdictions.	
Incentivise medical device companies to develop and sell devices in the UK.		• The government could try to incentivise SMEs, who may be considering dropping out of the UK market, to seek UKCA marking as well as EU CE marking, through means such as tax relief and R&D tax credits.	
Develop state-of-the-art regulation for complex and innovative medical devices to attract innovators and investors.	• It is important not to try to reinvent the wheel but rather to make the UK a good place to introduce innovative medical devices such as those involving AI/ML technology..	• The innovation agenda is best served by investing in shaping regulation for new innovative technologies. This would benefit UK innovators and attract international innovators and their investors to the UK too. • What should the UK outsource and what should the UK develop internally? The UK has been a leader in creating technical files as demonstrated during COVID-19. The UK has the right people to create the necessary technical guidance. • A number of companies working in novel areas (AI/ML in particular) are frustrated by the lack of guidance for regulatory approval. We cannot wait another 15 years to be able to adequately utilise new and groundbreaking technology.	
Extend the transition period for all or some medical devices.	• In light of the COVID-19 pandemic's impact on medical device industry players and late-stage finalisation of UK-EU Trade and Cooperation Agreement in December 2020, extension of transition period would help medical device companies and regulatory consultants to adapt to the new regulations and train the relevant workforce accordingly. • All certificates issued under the EU MDD designation will be void after 27 May 2024. Aligning this end date for devices under MDD designation with the end date for recognition of EU CE mark in the UK would reduce complexity.	• Patients in the UK are going to demand the same number of products to be available in the UK as are available in Europe. To meet this demand, there needs to be an equivalent capacity to perform conformity assessment in the UK as there is in the rest of Europe. There may have to be discussion around an extension to the mutual recognition of conformity assessment beyond June 2023 to ensure availability to UK patients. • There are challenges/risks associated with delaying deadlines constantly. • We should simply be pragmatic and continue to accept the CE (MDD) until it is due to be re-licensed under a new EU MDR. This would smooth the introduction of new legislation.	
Implications on patients and the public			
Provide patients and the public with clear, transparent, and understandable information.	• The change from CE mark to UKCA mark will need to be explained to members of the public so that they understand what it means when their medical device (e.g. asthma inhaler) no longer has a CE mark on it and all of a sudden has a UKCA mark on it. Communication is essential; people, as the end-users of these medical devices, need to know what is happening ahead of time and what it means. • There needs to be a properly organised communications strategy delivered ahead of time. This might involve patient organisations and social media. It is important that the complex scientific or political language is translated into something readable and understandable.	• "If we knew what we were planning for, we could plan for it," he argues. "But we can't plan for five different scenarios." "When asked what the government could do to help his business do even better, his answer is immediate. "Give us clarity," he says. "Give us clarity of what's going to happen, give us clarity over what time scale it will happen. As businesses we are slightly less bothered about the politics. What we are really bothered about is, give us enough time to plan so that we can cope."	

APPENDIX 3: References

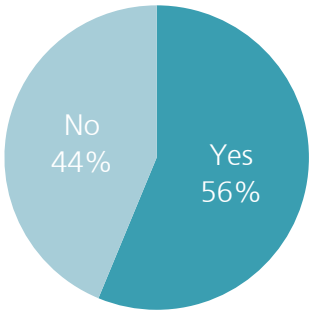
3.1. Literature Review

1. Stanley A. A new era for the dental industry. BDJ Pract. 2020;33(4):18-19. doi:10/ghzh9m
2. Blog: UKCA – What does it mean for medical device companies? Hardian Health. Accessed February 5, 2021. https://hardianhealth.com/blog/2020/9/3/blogukca
3. Brexit and the CE Mark - implications for European regulation of medical devices. Brandwood CKC. Published June 26, 2016. Accessed February 5, 2021. https://brandwoodckc.com/brexit-and-the-ce-mark-implications-for-european-regulation-of-medical-devices/
4. Brexit and the Medical Devices Regulation – Opportunities and Risks. Accessed February 5, 2021. https://www.criticalsoftware.com/news/brexit-and-the-medical-devices-regulation
5. Denissen T. BREXIT impact. Accessed February 5, 2021. https://www.medical-risk.com/regulatory-insights/item/83-brexit-and-the-impact-on-your-business-in-the-eu
6. Brexit Medical Device Implications. Acorn Regulatory. Published August 25, 2016. Accessed February 5, 2021. https://acornregulatory.com/brexit-medical-device/
7. Brexit, medical devices and transfer of notified bodies. What will be the procedure? Accessed February 5, 2021. https://www.engage.hoganlovells.com/knowledgeservices/news/brexit-medical-devices-and-transfer-of-notified-bodies-what-will-be-the-procedure
8. Mitchell P. "Brexit" stuns UK biotech into waiting game, but not all signals are red. Nat Biotechnol. 2016;34(8):787-788. doi:10/ghzh9n
9. Cygan A. De-Europeanisation of UK regulatory governance and the future UK–EU trade relationship. ERA Forum. 2020;20(4):509-529. doi:10/ghzh9s
10. Hervey T, Antova I, Flear ML, McHale JV, Speakman E, Wood M. Health "Brexternalities": The Brexit Effect on Health and Health Care outside the United Kingdom. J Health Polit Policy Law. Published online October 14, 2020. doi:10/ghzh9q
11. McHale JV. Health law, Brexit and medical devices: A question of legal regulation and patient safety. Med Law Int. 2018;18(2-3):195-215. doi:10.1177/0968533218807255
12. Harris M. Hi-tech firms seek clarity amid Brexit confusion. Phys World. 2019;32(3):10-11. doi:10/ghzh9r
13. Matters B. How leaving the EU might impact the UK medical device industry. Business Matters. Published March 2, 2020. Accessed February 5, 2021. https://bmmagazine.co.uk/in-business/how-leaving-the-eu-might-impact-the-uk-medical-device-industry/
14. Dayan M, Trust N. How will our future relationship with the EU shape the NHS? :36.
15. How will the UK regulate medical device market after Brexit? Accessed February 5, 2021. https://www.medicaldevice-network.com/comment/uk-medical-devices-brexit/
16. Impact of Brexit on UK and EU based Medical Device Manufacturers. Med-Di-Dia: Medical, Digital Health, Diagnostics. Accessed February 5, 2021. https://med-di-dia.com/news/impact-of-brexit-on-uk-and-eu-based-medical-device
17. Impact of Brexit: Medical Devices and CE Marking. Accessed February 5, 2021. https://www.imeche.org/policy-and-press/reports/detail/impact-of-brexit-medical-devices-and-ce-marking
18. Medical Device - Poll # 11 – Implementation of the new EU Medical Device Regulation. Accessed February 5, 2021. https://survey.alchemer.eu/s3/90298955/Medical-Device-Poll-11-Implementation-of-the-new-EU-Medical-Device-Regulation
19. Keogh K, McConaghie G. Medical device use post Brexit: should we be concerned? Bull R Coll Surg Engl. 2017;99(7):250-251. doi:10/ghzh88
20. Medicines and medical devices regulation post-Brexit. Accessed February 5, 2021. https://www.taylorwessing.com/synapse/september16.html
21. MedTech Europe Position Paper on Article 50 Negotiations between the European Union and the United Kingdom (Brexit). Accessed February 5, 2021. https://www.abhi.org.uk/media/1701/mte-brexit-position-paper.pdf
22. Parvizi N, Parvizi S. New Health Technologies: A UK Perspective; Comment on "Providing Value to New Health Technology: The Early Contribution of Entrepreneurs, Investors, and Regulatory Agencies." Int J Health Policy Manag. 2017;6(12):721-722. doi:10/ghzh9p
23. Position on the implications of the UK exit from the European Union. AESGP. Published March 21, 2019. Accessed February 5, 2021. https://aesgp.eu/articles/aesgp-position-on-the-implications-of-the-uk-exit-from-the-european-union
24. Piorkowska M, Goh V, Booth TC. Post Brexit: challenges and opportunities for radiology beyond the European Union. Br J Radiol. 2017;90(1072):20160852. doi:10/f9tbjm
25. Product safety assessment marks after Brexit – out with the old, in with the new. Accessed February 5, 2021. https://www.penningtonslaw.com/news-publications/latest-news/2020/product-safety-assessment-marks-after-brexit-out-with-the-old-in-with-the-new
26. The European Union Medical Device Regulations: lost in the wash? | Bone & Joint 360. Accessed February 5, 2021. https://online.boneandjoint.org.uk/doi/abs/10.1302/2048-0105.85.360727
27. The immediate futures of health law after Brexit: Law, 'a-legality' and uncertainty - Tamara Hervey, Elizabeth M Speakman, 2018. Accessed February 5, 2021. https://journals.sagepub.com/doi/abs/10.1177/0968533218810746
28. Lewis M, Shah BL-O, Ranson P, Manoussakis S. The Impact of Brexit on Medical Devices Regulation in the United Kingdom | Lexology. Accessed February 5, 2021. https://www.lexology.com/library/detail.aspx?g=9483d187-2e01-4df4-ba49-c978f89d16d1
29. The ripple effect of Brexit on medical device regulation. ARC Regulatory. Published September 11, 2020. Accessed February 5, 2021. https://www.arc-regulatory.co.uk/the-ripple-effect-of-brexit-on-medical-device-regulation/
30. UK Medical Device Manufacturers Prepare for Post-Brexit Regulations. Accessed February 5, 2021. https://www.assemblymag.com/articles/96011-uk-medical-device-manufacturers-prepare-for-post-brexit-regulations?v=preview
31. Dayan M, Fahy N, Hervey T, McCarey M, Jarman H, Greer S. Understanding the impact of Brexit on health in the UK. :58.

3.2. Others

1. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. BMJ. 2000;320(7227):114-116. doi:10.1136/bmj.320.7227.114
2. Ritchie J, Lewis J. Qualitative research practice: a guide for social science students and researchers. 2003, London: Sage.

With regard to the move to UKCA mark, do you think the medical devices industry is able to meet the requirements by the deadline of 1st July 2023?



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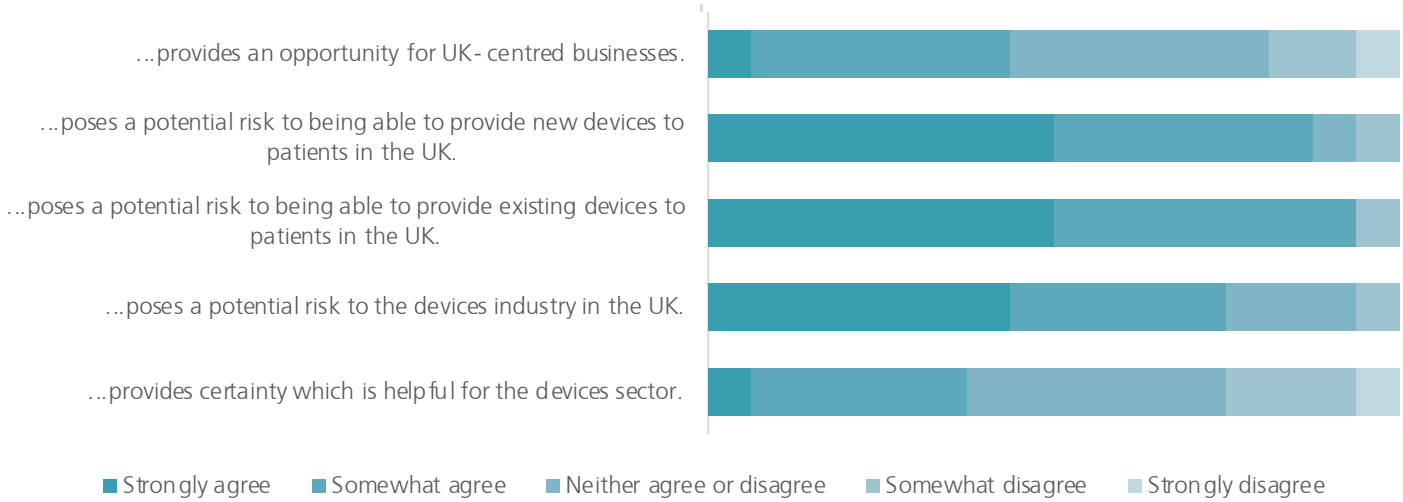

In terms of timing, the UKCA should be…