

# 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](http://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.

## 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 (MHRA's) 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



## Acknowledgements

### Authors

Dr Diana Han\*, Dr Hussein Ibrahim\*, Dr Xiao Liu, Dr Olalekan Lee Aiyegbusi, Matthew John Taylor, Prof Alastair Denniston, Dr Eliot Marston, and Prof Melanie Calvert of Birmingham Health Partners Centre for Regulatory Science and Innovation.

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### Disclaimers

While this report was commissioned by the Regulatory Horizons Council, Birmingham Health Partners Centre for Regulatory Science and Innovation retained full editorial control of the report's content.

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.

Professor Melanie Calvert (MC) receives funding from the NIHR Birmingham Biomedical Research Centre, the NIHR Surgical Reconstruction and Microbiology Research Centre, NIHR ARC West Midlands at the University of Birmingham and University Hospitals Birmingham NHS Foundation Trust, Health Data Research UK, Innovate UK, Macmillan Cancer Support, and UCB Pharma. MC has received personal fees from Astellas, Takeda, Merck, Daiichi Sankyo, Glaukos, GSK, and the Patient-Centered Outcomes Research Institute.

### Funding

This report was supported by a Quality-related Research grant from Research England.

# Stakeholders

We extend our thanks to the following people who kindly agreed to participate in the preparation of this report:

Adrian Jonas	National Institute for Health and Care Excellence
Alan Fraser	University Hospital of Wales
Anne Vanhoestenbergh	University College London
Antoine Valterio	ResMed
Carolyn Ruston	National Physical Laboratory
Charles de Rohan	The Binding Site
Charlie Winkworth-Smith	Knowledge Transfer Network Neurotechnology Special Interest Group
Chris Pomfrett	National Institute for Health and Care Excellence
Christina Silcox	Duke-Margolis Center for Health Policy
David Grant	Enesi Pharma Ltd
Doris-Ann Williams*	British In Vitro Diagnostics Association
Eamonn Hoxey	E V Hoxey Ltd
Gary Price	Centre for Patient Reported Outcomes Research Patient Partner
Hugh Harvey	Hardian Health
Ian Newington	National Institute for Health Research
Ivan Perez Chamorro	MedBoard
Ivor Gillbe	Bioinduction Ltd
James Carpenter	SurePulse Medical Ltd
James Pink	NSF International
Jane Wilson	Intuitive Surgical
Johannes Starlinger	Starlinger+ Digital Health Architects
John Wilkinson	Global Medical Device Nomenclature
Kathy Oliver	International Brain Tumour Alliance
Kevin Butcher	North American Science Associates
Martin Levermore	Medical Devices Technology International Ltd
Michael Kipping*	Innovate UK
Omar Moreea	National Institute for Health and Care Excellence
Phil Brown*	Association of British HealthTech Industries
Rob Turpin	British Standards Institution
Tim Constandinou	Imperial College London
Tim Denison	University of Oxford
Tom Beale	Centre for Process Innovation
Tom Campbell	The Magstim Company Ltd
Tom Clutton-Brock	University of Birmingham
Warren Jameson	North American Science Associates

\*Advisory board members

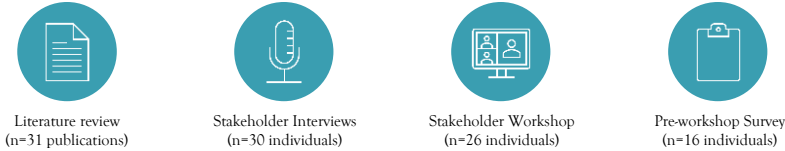


Qualitative methods were used to collate the views of stakeholders from across the medical device sector.

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.

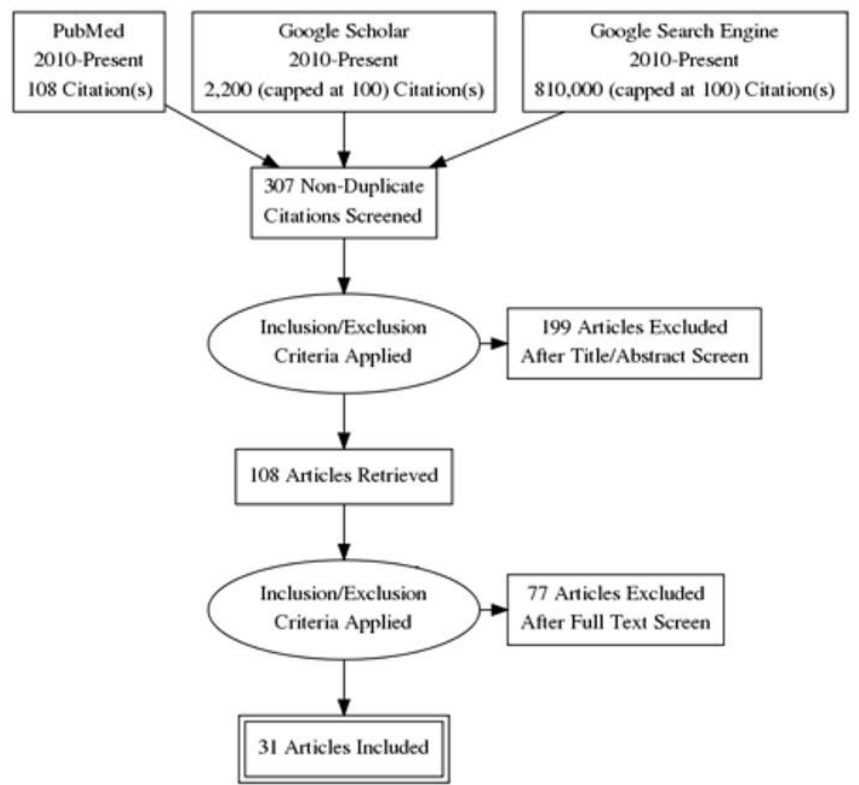
Table 1. Search Terms

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.

## 3.1. Literature Review

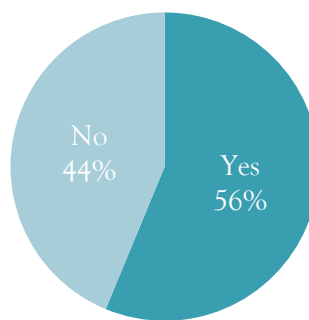
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## 3.2. Others

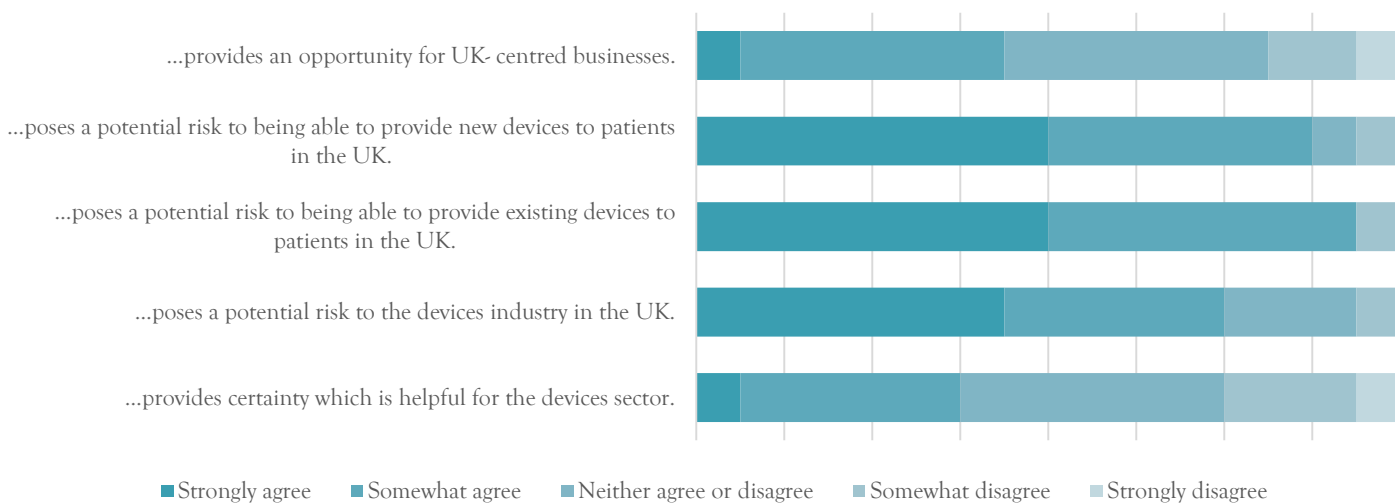
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## APPENDIX 4: Post-Workshop Survey Results

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?



The UKCA deadline of 1st July 2023...



In terms of timing, the UKCA should be...

