What are the Regulatory Implications of BREXIT?

Does this impact the

"Seismic"

concurrent EU regulatory changes?

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Key Facts Expectations & Assumptions

- Consensus data indicates that circa 45% of all Medical Devices CE marked in Europe utilise UK NB for their conformity assessment requirements
- It is estimated that 70% on Non EU Based Manufacturers USE UK Notified Body Services
- There is an acute need to maintain Patient Access to life saving and life enhancing technologies
- Well recognised mechanism exist for non EU Member states to be part of the EU regulatory system either as part of EFTE /EEA or through MRA (e.g. Norway/ Switzerland and Australia)
- BSI is in frequent contact with HM Government (BEIS/DEXEU and DIT) and kept well informed. This reinforces **our expectation which remains** that suitable mechanisms will be found to provide continuity of access to the wider European Union trade area after the transition period

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Treaty on the Functioning of the European Union ("TFEU")

Key Aspects ….

- This is not signed it's a draft …
- The "TFEU" extends current regulatory arrangements until December 2020
- The "TFEU" is unclear *(in that it does not state)* as to what the Status of CE certification would be post 2020
- However, our discussions with HM Government indicate that there is no desire to disrupt access to vital goods and services (both by HMG and the EU Commission /Parliament) quite the converse there is a consensus on the importance of maintaining functioning markets.
- Expectation remains of an ongoing participation within the existing EU MDR & IVDR regulatory system for Medical Device's

90/385/EEC
93/42/EEC
98/79/EC

Initial Designation

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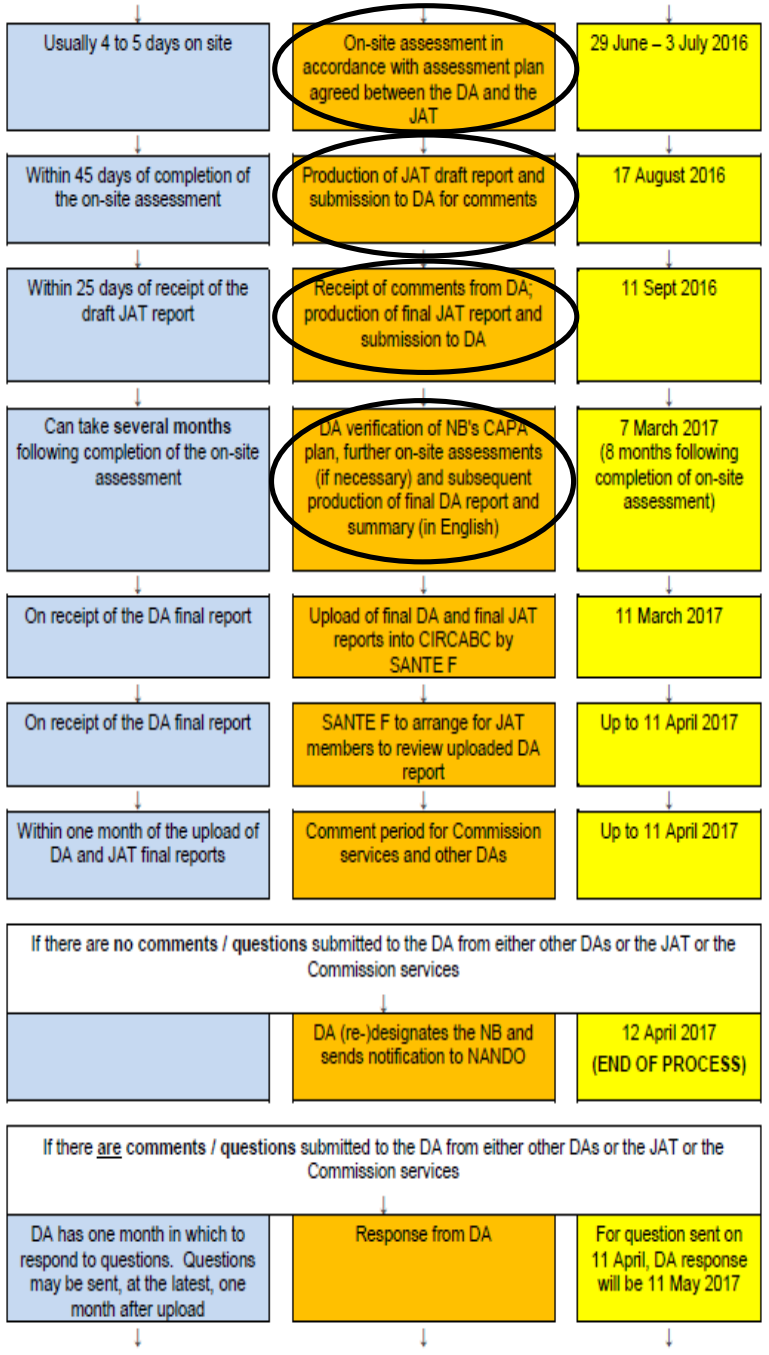
MDD & AIMDD

MD & AIMD:

- Submitted App. 07 Feb 2017
- 16 June 2017 + IVD Application
- Joint Audit 11-15 September 2017
- 25 February 2018 (Last responses)
- March 1st Responded
- **Next Steps**
- Follow up Audit **May 2018** (confirmed)
- Designation **anticipated** August
- **Offer Migration to NL NB in Q3/Q4 2018**



EU/2017/745 MD Regulation
EU/2017/746 IVD Regulation

Initial Designation
Maintaining Designation

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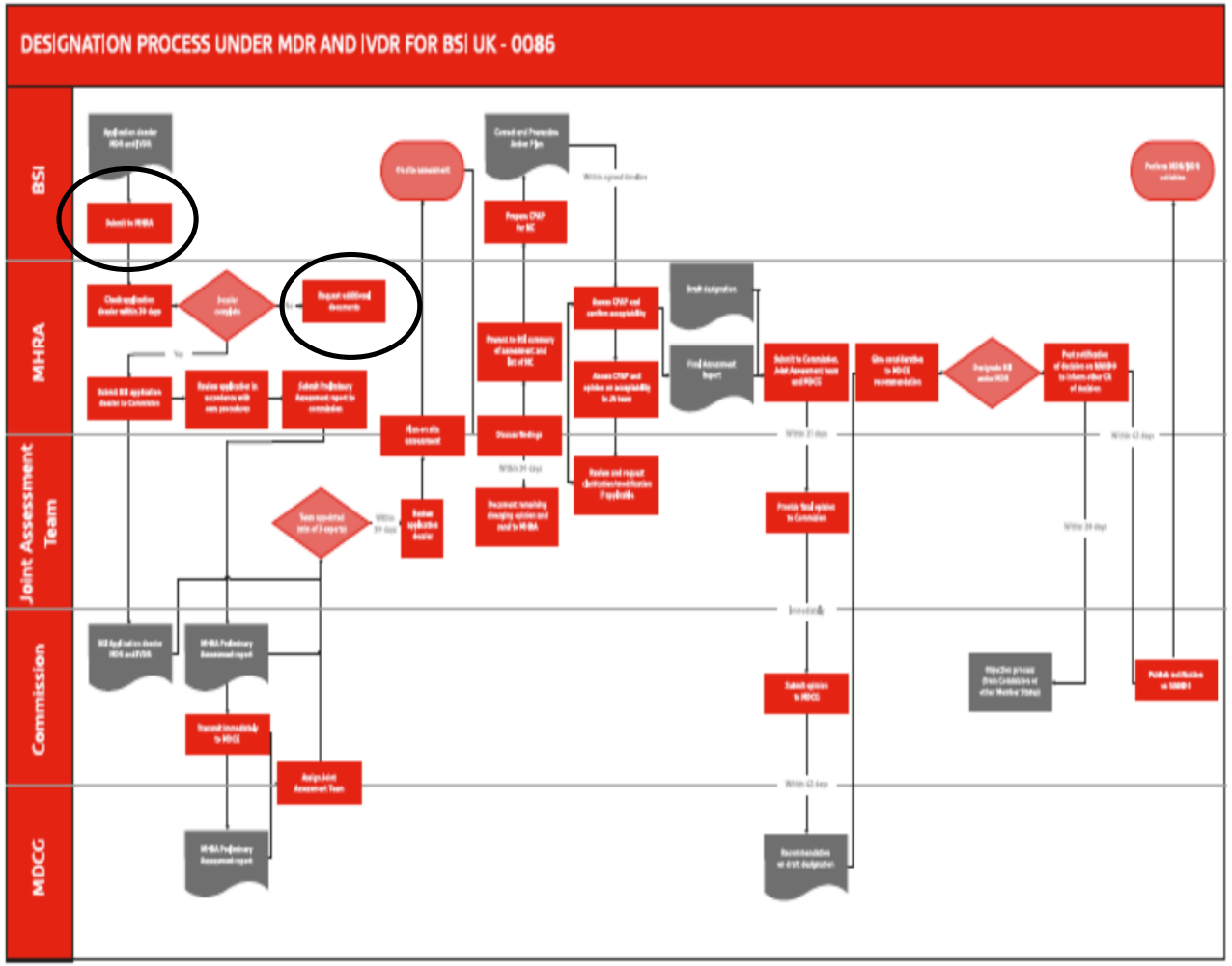
EU MDR / IVDR – Designation – Article 38-40 / 38-40

MDR & IVDR:

- 27 & 28 Nov
- 28 Dec
- JA Expected 09/18
- Aiming for Designation H1 2019



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MDR Transition (Article 120)

Entry into Force (OJEC + 20days)
(25 May 2017)

Date of Application
(26 May 2020)

27 May 2025
No more « placing on the market » of devices covered by MDD/AIMD certificates

05 May 2017
Adoption of MDR

Transition period
3 years

MDD/AIMD certificate validity
(4 years)

Annex IV certificates expire (27 May 2022)

MDD/AIMD certificates (max 5-year expiry from issue/renewal date)

Last MDD/AIMD certificates expire
(27 May 2024)

MDR certificates

NBs designation under MDR

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Do Not Leave Your Regulatory Transition Plan to Late

(Irrespective of BREXIT)

- Deadlines & Timelines are Pressing
- The system Lack's Capacity
- Less than 50% MD NB have indicated publically they are going to apply for the MDR
- Less for the IVDR

If you align expectations with reality, you will never be disappointed. Terrell Owens (US athlete and NFL Player)

bsi.

...making excellence a habit.™

Brexit: Impact on Movement of Goods

Jennifer Revis, Partner (London), Customs & Trade

Impact of Models on Movement of Goods

Single market

- Goods in free circulation move freely within single market

Customs Union

- Goods in free circulation are not subject to customs duties when moving within customs union, but:
- **Customs declarations required (?) and import VAT payable**
- Possible simplifications?
- UK imports benefit from EU FTAs but UK exports do not

FTA

- Preferential duty rates* only available for goods which meet **origin rules**
- **Customs declarations required and import VAT payable**
- Possible simplifications?
- UK trade does not benefit from EU FTAs

Fallback (WTO)

- No preferential treatment*
- **Customs declarations required and import VAT payable**
- UK trade does not benefit from EU FTAs

* only of concern for dutiable products

Medical Devices: Pre-Brexit

Manufacture in UK

Suppy of materials/ components from the UK

NO DUTY; NO IMPORT VAT; NO BORDER CONTROL

Manufacture in EU

Suppy of materials/ components from the EU

Medical Devices: Post-Brexit – FTA Model

Manufacture in UK

Export from EU and import into free circulation in UK

UK CUSTOMS BORDER

NO DUTY IF: (i) PRODUCT IS DUTY FREE; OR (ii) ROO IS MET

BUT IMPORT VAT

EU CUSTOMS BORDER

Export from UK and import into free circulation in EU

Manufacture in EU

Medical Devices: Post-Brexit – WTO Model

Manufacture in UK

Export from EU and import into free circulation in UK

UK CUSTOMS BORDER

duty* and import VAT

duty* and import VAT

EU CUSTOMS BORDER

Export from UK and import into free circulation in EU

Manufacture in EU

* unless product is duty free

fieldfisher

Brexit and Medical Devices

Resolving the EU and UK regulatory positions

26 April 2018

- Will the EU Withdrawal Bill be enacted essentially in current form?
- Will there be mutual recognition with the EU?
- Will the Transition Agreement be agreed, or will the UK “crash out of the EU”: the ultimate hard Brexit?
- Will the UK Government introduce laws bringing MDR/ IVDR into UK law?
- ……or will there be something different?!

UK LAW from 30 March 2019

EU law enacted as UK law (Directives):
Become "stand-alone" UK law:
MDD/ AIMD/ IVDMDD

EU law with direct effect (Regulations):
Become part of "stand-alone" UK law ONLY if both in force AND "applicable" at **29 March 2019**:

Most provisions of MDR and IVDR will not be part of UK Law on 30 March 2019

Transition
EU law will apply in UK until 31 December 2020

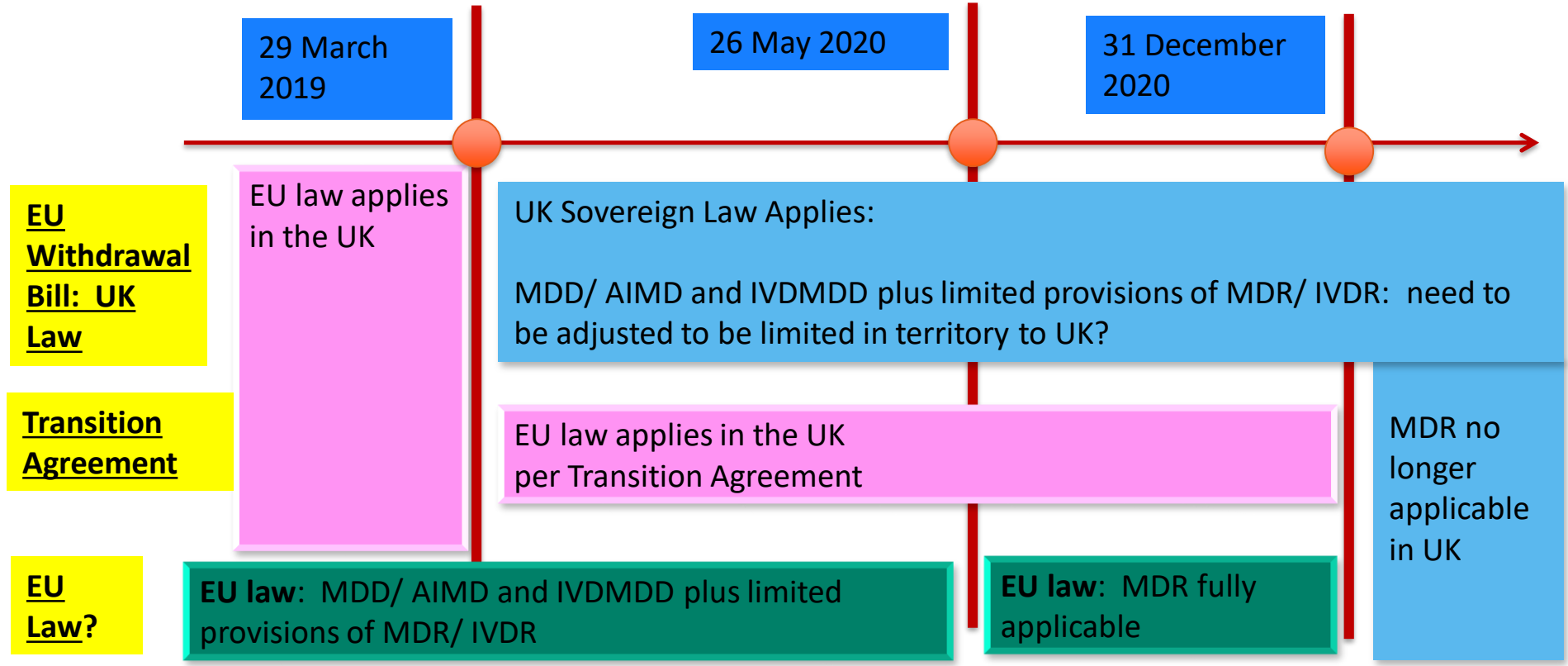
EU LAW

Gradual applicability of MDR and IVDR:

26 May 2020: MDR fully applicable

26 May 2022: IVDR fully applicable

Current Flow of Legislation in UK: Per Current Documents



For

1. "Close, warm relationship"

Mutual Recognition

2. MHRA instrumental in drafting
3. MDR/ IVDR represent the latest thinking on best practice
4. Access to other markets that recognise the CE mark

Against

1. Need to follow ECJ decisions?
2. c.60 sets of secondary legislation (UK no input to these)
3. Desire to be seen to have "sovereignty"

FIRST: UK must enact MDR and IVDR equivalents as part of UK law

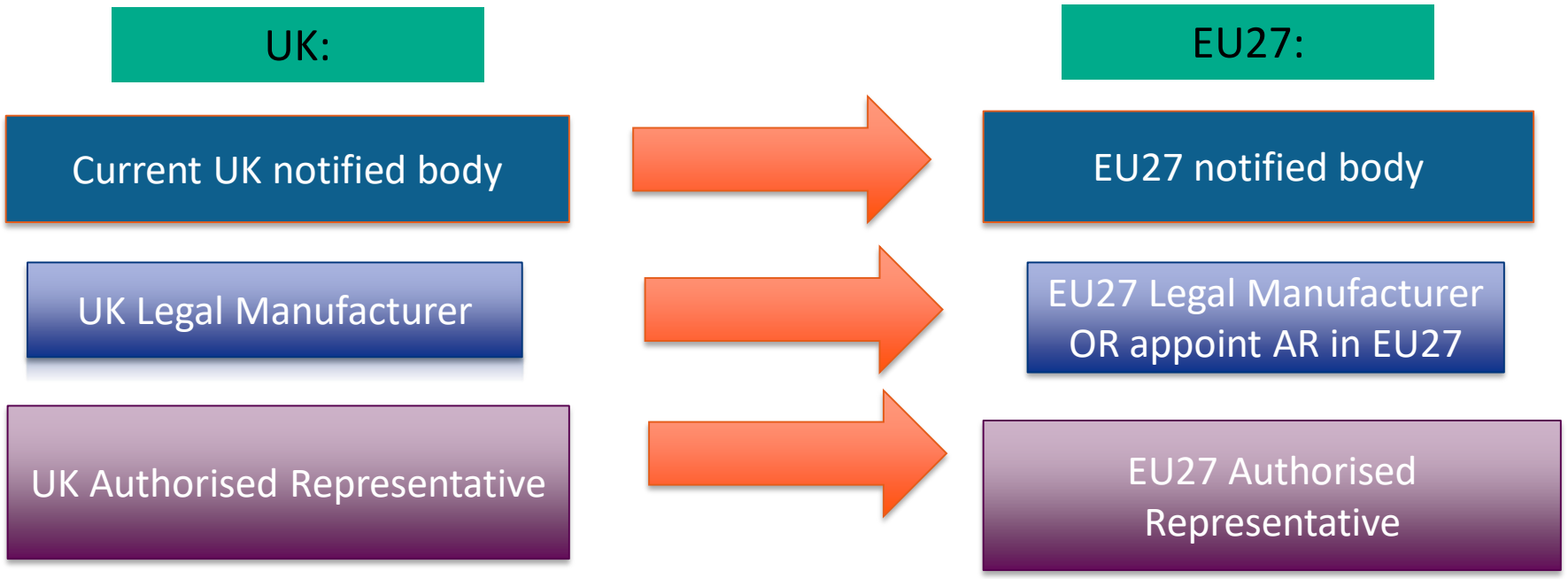
BUT: No "cherry picking":

The European Council recalls that the four freedoms are indivisible and that there can be no "cherry picking" through participation in the Single Market based on a sector-by-sector approach, which would undermine the integrity and proper functioning of the Single Market.

Medical Device Manufacturers: What to do, and when?

Regulations: Making Sales in EU after 31 December 2020

29 March 2019



Interesting NB Dilemma: What about the UK?

Interesting NB Dilemma: What about the UK?

- Under EU law, cannot apply to two notified bodies under EU law at the same time
- Until either 29 March 2019 or 31 December 2020: EU law will apply

Solutions for the UK Government

EITHER:

1. UK to have concurrent UK law allowing application to UK NBs during transition period for UK certification only (with EU agreement); OR
2. UK government will need to recognise EU27 NB certificates for the period until separate UK laws start to apply and with a second transition period, giving time to obtain UK NB certificates

R&D/ manufacturing/ regulatory functions/ European HQ in UK?

- EU law does not prevent these being outside the EU27
- Medtronic European HQ is in Switzerland!
- Just need other another entity inside EU to be holder of the regulatory functions: legal manufacturer/ holder of CE certificates for EU27
- MDR, Article 15: "Person responsible for regulatory compliance": <u>no requirement to be in the EU27</u>

Any Questions?

Alison Dennis
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Brexit and Ireland – What you need to know

ABHI – Are you ready for Brexit? 26 April 2018

Michael Finn

Number One Ranked Irish Funds Law Practice acting for 29% of Irish Domiciled Investment Funds by AUM
Monterey Insight Ireland Fund Survey 2017

Ireland M&A Legal Adviser of the Year
Mergermarket European M&A Awards 2017

Ranked Ireland's Most Innovative Law Firm
Financial Times Innovative Lawyers Report 2017

International Firm in the Americas
International Tax Review 2017

Introduction

- Brexit – Ireland's unique position
- The medical device sector in Ireland
- What our clients are doing
- Uncertain? You are not alone…
- Implications for the medical device sector
- Regulatory problems - Irish solutions
- Some useful information

Brexit – Ireland's unique position

The Medical Device Sector in Ireland

- 350+ companies in Ireland employing 27,000 people
- 18 of the world's 25 largest medtech companies
- €12.6 billion worth of exports annually
- Second largest exporter of medtech products in Europe
- 33% of the world's contact lenses are made in Ireland
- 50% of the world's acute hospital ventilators
- **Notified Body:** National Standards Authority of Ireland
- **Competent Authority:** Health Products Regulatory Authority

What our clients are doing…

- Avoiding disruption - securing long-term ability to access European markets
- Contingency planning for a hard Brexit
- Assessing all options
- Clearing up misinformation:
  - Brexit does not mean all operations have to move!
  - Structure depends on what is necessary for passporting
- Looking for some certainty in an uncertain world…

Uncertain? You are not alone

- *"Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the UK from the EU will have."* – **J&J**
- *"[Brexit] will have numerous consequences in all areas of business including economic, regulatory, operational; the actual impact depends on the ultimate deal reached and is very difficult to assess at this time."* – **Boston Scientific**
- *"Although it is unclear what the terms will be, it is possible that there will be greater restrictions on imports and exports … and increased regulatory complexities."* - **Medtronic**

Implications for the medical device sector

- European Commission Guidance, February 2018 - here
  - UK will become a third country
  - UK manufacturer or importer will no longer be established in the EU – must appoint a European Authorised Representative
  - EU distributors of UK devices will become importers
  - Responsible persons – guidance contradicts the law
  - Non-recognition of UK Notified Bodies – erased from Nando
    - *Option 1:* seek a CE certificate from an EU Notified Body
    - *Option 2:* transfer technical file, etc. to an EU Notified Body under a contract between UK Notified Body, EU Notified Body and Manufacturer

Regulatory problems – Irish solutions

Some useful information

- HPRA survey open until 8 May – 'potential impact of Brexit on the Medtech sector in Ireland'
- HPRA Medical Devices Information Day, Galway 23 May 2018
- IDA Ireland - https://www.idaireland.com/
- HPRA - http://www.hpra.ie/
- NSAI - https://www.nsai.ie/

If at first you don't succeed …

Thank you

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