# British Standards after Brexit

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# Brexit?

- BSI after the date, for the future

- Two of the Key Business's
  - Standards
  - Medical Devices *Notified Body

*Bsi is a Notified Body for other EU Directives/Regulations

# What is Brexit?

- Brexit –the date the UK quits membership in the European Union
- When will Brexit occur?
  - Original date 29 March 2019
  - Delayed until 12 April 2019 when UK Parliament intervened to prevent No Deal Brexit
  - No Deal exit date now pushed back to 31 October 2019 per "agreement" with EU
  - Exit can occur sooner if UK Parliament agrees exit plan & EU agrees with separation terms
  - Brexit could be cancelled altogether if new UK referendum held and citizens voted to revoke Article 50

# What type of Brexit?

- May occur or do we want!
  - Hard
  - Soft
  - And various descriptions in between

# Standards

- BSI will remain the UK National Standards Body
- Retain key role in CEN/CENELEC
- Retain key role in ISO/IEC
- Committee Structure will remain as is, subject as usual to periodic review
- Continue working with UK Government Departments

# What are the Latest Regulatory Implications of Brexit

# 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

https://www.gov.uk/guidance/rules-of-origin

* only of concern for dutiable products

bsi. ...making excellence a habit.

# April/May 2019 Assumptions/Currently likely outcomes

- UK will take an active part in the EU Elections 23-26th may 2019
- UK Government will continue to try to find a deal to exit (Time limit 31st October 2019)
- A negotiated deal will trigger the original transition period i.e. December 31st 2020
- The likelihood of a no deal BREXIT is **significantly** diminished
- The MHRA will continue within the EU system until 31/12/2020
- UK Notified Bodies will continue within the EU system until 31/12/2020

Medicines & Healthcare products Regulatory Agency

# Guidance: Technical information on what the implementation (transition) period means for the life science sector (likely 31/12/2020)

**Market access for medical devices during the implementation period**

CE marking will continue to be used and recognised for both the UK and EU markets, and UK-based manufacturers will not require an authorised representative established in the EU.

UK notified bodies will continue to conduct third-party conformity assessment in the UK and the results of these tests will continue to be used and recognised for both the UK and EU markets…

**MHRA and VMD access to EU systems during the implementation period**

During the implementation period industry would be able to continue to submit information to the MHRA and the VMD using the existing submission routes. The UK will continue to access all EU databases and systems that we currently have today.

**UK 'not acting as leading authority'**

Article 123 of the draft Withdrawal Agreement states that "During the transition period, the United Kingdom shall not act as leading authority for risk assessments, examinations, approvals and authorisations at the level of the Union or of Member States acting jointly referred to in the acts/provisions…

Medicines & Healthcare products Regulatory Agency

# Status of UK Notified Bodies and certificates issued by these Notified Bodies after the UK's left the EU

After the UK leaves the EU UK-based Notified Bodies will no longer be recognised by the EU. Devices they have certified will no longer be in conformity with the applicable EU Directive. The lack of CE certification means that these devices may not legally placed on the EU market.

To support the continuity of supply of devices to the UK market, we will give UK based Notified Bodies an ongoing legal status and continue to recognise the validity of certificates that they issued prior to the UK's departure from the EU. This will allow devices covered by certificates issued by UK-based Notified Bodies to continue to be placed on the UK market after the UK leaves the EU.

These UK-based Notified Bodies will continue to oversee these devices and their manufacturers, to ensure continued compliance with the applicable standards of safety and performance.

# BSI Notified Body Clients – Migration Contingency Outcome

- Designated MDD / AIMD & IVD Directives 9th November 2018
- Uniquely amongst UK NB covered the cost of moving clients to a 27 Member State NB
- Completed approx. 95% of Client Migrations prior to the 29th Match Article 50 deadline
- >4000 Certificates now issued in NL BSI Group Netherlands BV 2797
- Undertaking new Conformity Assessments in the NL and issuing de novo certificates

- Remain Designated MDD / AIMD & IVD Directives CA
- Uniquely BSI (0086) are the only EU NB Designated under MDR (21st January 2019)
- Now accepting new MDR Conformity Assessments in the UK
- Continuing to service UK only focussed manufacturers for the existing medical devices directives

# Notified Bodies (NBs) –
## A Key Pillar of the Medical Technology Regulatory System

Notified Bodies are responsible for assessing medical devices (MDs) and *in vitro* diagnostics (IVDs). They are an indispensable part of the regulatory system since they grant a CE mark to each device before it can be placed in the EU market.

Notified Bodies are undergoing a significant revamp in order to comply with their greater obligations according to the new Medical Device and In Vitro Diagnostic Regulations.

### Key facts about Notified Bodies


### How many Notified Bodies (re-)certify MDs and IVDs?*


Countries can have a different amount of NBs: none, one or several

*EC NANDO database

MedTech Europe
from diagnosis to cure

# Some others considerations

- NB Workload & Capacity over recent years – need to close gap
- Impact on Supply Chain
- Importance of maintaining compliance
- What planning did your company undertake to cope with Brexit
  - Does your company use a UK NB
  - Did you consider an EU 27 NB
  - Extent of your planning
  - UK Medical Device Regulations
- Lots of debate, answer limited, monitor the on-going debates

# Thank you for your time and attention

# Questions ?

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