What are the Regulatory Implications of BREXIT?
BSI Sept 2018

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 utilize UK NB for their conformity assessment requirements
- It is estimated that 70% of 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 mechanisms exist for non-EU Member states to be part of the EU regulatory system either as part of EFTA/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:

- Firstly this is a draft and could be rescinded in a non-negotiated outcome!
- 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 opposite, 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 Devices

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

Useful Reference Documents (Links)

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

TFEU March 2018

Guidance

Technical information on what the implementation period means for the life science sector 6th August 2018

BREXIT Guidance during Implementation

Guidance

How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal Published 23 August 2018

How to Regulate MD if No Deal BREXIT

Guidance

Technical information on what the implementation period means for the life science sector

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…

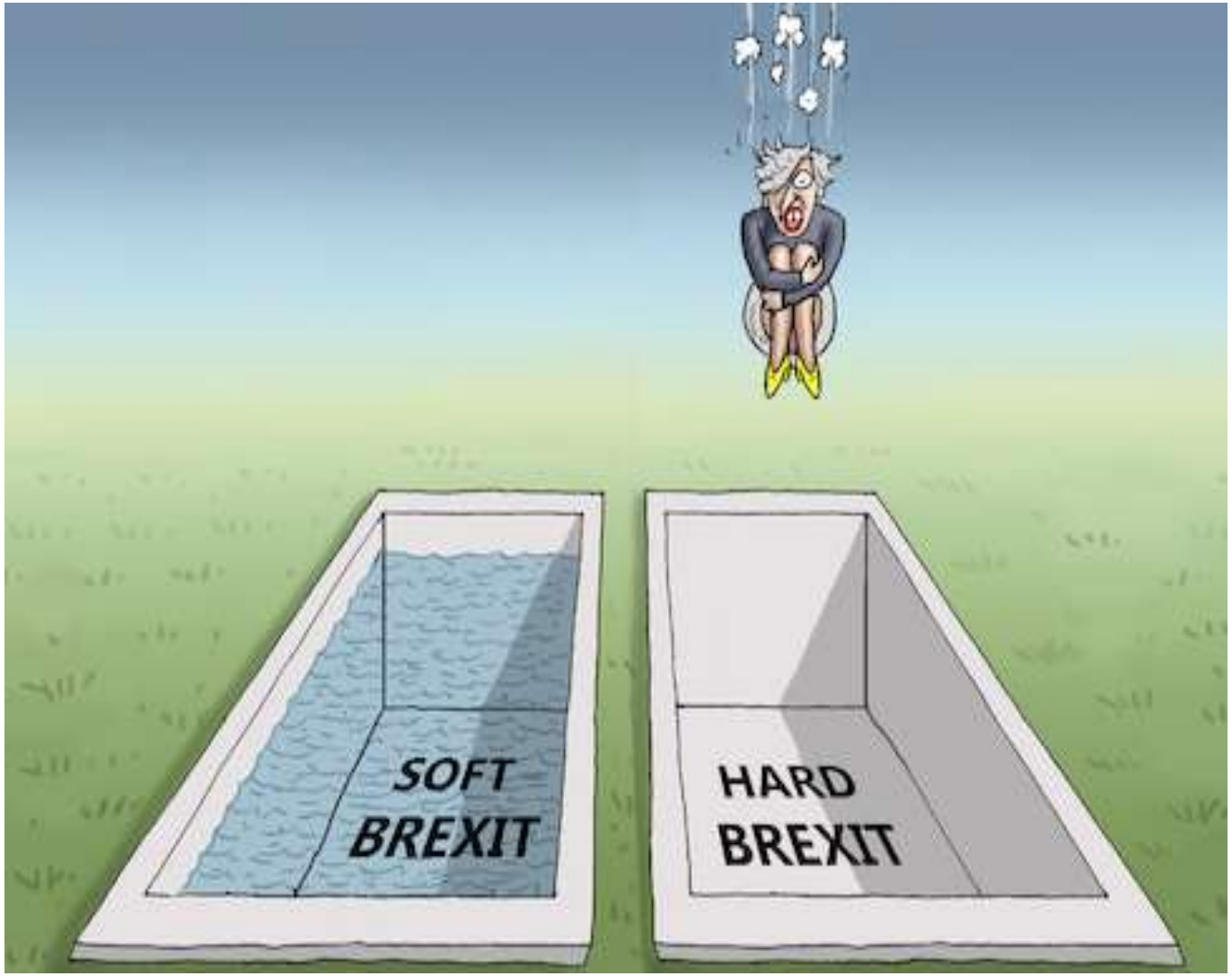
Chequers plan

A plan for Brexit which was agreed by the Cabinet at the Prime Minister's country residence, Chequers, on 6 July 2018. It includes: a "common rulebook" for all goods traded with the EU and a "facilitated customs arrangement" which aims to maintain frictionless trade in goods between the UK and the EU whilst allowing Britain to develop an independent trade policy with the rest of the world. The plan would end free movement of people.

Customs partnership

This proposal, also known as the hybrid model, would enable trade in goods between the UK and Europe without the need for customs checks. Proponents say it would help solve the Irish border question too, as the UK would collect the EU's tariffs on goods coming from other countries on the EU's behalf. If those goods stayed in the UK and UK tariffs were lower, companies could then claim back the difference.

Objective: To Undertake Full Migration to BSI's Netherlands NB Within Target Timelines If Required



Guidance

How medicines, medical devices and clinical trials would be regulated if there's no Brexit deal

Updated 14 September 2018

Medical devices on the UK market

For a time-limited period, we would continue to recognise the CE Mark on medical devices, which demonstrates their conformity with EU regulatory requirements. During this period, devices would be accepted on the UK market if they meet all EU requirements, which for all but the lowest-risk devices would include certification by EU Notified Bodies.

Further detail on the future process after this temporary situation of bringing a medical device onto the UK market will be subject to consultation in due course.

Notified Bodies

UK-based Notified Bodies would, in a 'no-deal' scenario, no longer be able to assess the conformity of medical devices for devices to receive the CE mark and enter the EU market.

Therefore, the MHRA will no longer be able to oversee Notified Bodies in the way that it does now.

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

Initial Designation

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Summit is in view!

Expected Designation Early Q4 2018

- Migrate MDD & AIMD Certificates to NL
- Notification by EC
- Number Issued NB 00NL
- Designation Confirmed by EC
- 4 week consultation period
- (ends 12/10)
- IGJ & NL MOH Recommend Designation
- NL MOH Submitted to BX 13/9
- Follow Up Audit & Close Out NC
- May & NC AP July 2018
- Initial Joint Audit
- September 2017
- Formal Application
- February 2017
- Initial Meeting agreed to move forward
- September 2016!

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RVA – Accreditation

Manufacturers can apply for a second certificate or

Move their certificate in future

Bijlage bij accreditatieverklaring (scope van accreditatie)
Normatief document: EN ISO/IEC 17021-1:2015
Registratienummer: **C 122**

RAAD VOOR ACCREDITATIE

van **BSI Group The Netherlands B.V.**

Deze bijlage is geldig van: **30-04-2018** tot **01-06-2021** Vervangt bijlage d.d.: **28-02-2018**

Locatie(s) waar activiteiten onder accreditatie worden uitgevoerd

Hoofdkantoor

John M. Keynesplein 9
1066 EP
Amsterdam
Nederland

Locatie	Certificatie Schema
ynesplein 9 Am am Ne am	ISO 9001:2008 ISO 9001:2015 VGM Checklist Aannemers (VCA) ISO 27001 ISO 13485:2003 en EN ISO 13485:2012 ISO 13485:2016 ISO 14001:2004 ISO 14001:2015 Handboek CO2-Prestatieladder
Kitemark Court Davy Avenue Knowlhill, Milton Keynes, 8PP Verenigd Koninkrijk	ISO 13485:2003 en EN ISO 13485:2012 ISO 13485:2016

Norm / Normatief document	Certificatieschema[1]
ISO 9001:2008 (tot 15-09-2018) ISO 9001:2015	Kwaliteitssysteem ifi bo erkterreinen (verwijzing naar IAF co E rev. n toepassing): 3 voedings- en genotmiddelen 4 textiel en textielprodu 9 drukkerijen 12 chemische industrie 14 rubber en kunststoffen

April 2017

Deze bijlage is goedgekeurd door het bestuur van de Raad voor Accreditatie, namens deze,

mr. J.A.W.M. de Haas
Operationeel Directeur

[1] indien niet wordt verwezen naar een codering en bij een normatief document of een schema geen datum of versie aanduiding wordt gegeven betreft de accreditatie de actuele versie van het document of schema
[2] indien wordt verwezen naar een codering beginnende met NAW, NAP, EA of IAF dan betreft het een schema waarvoor RvA-BR012 van toepassing is. De versie van het betreffende schema is vermeld op de lijst met schema's waarvoor de RvA accreditatie kan verlenen, zoals bedoeld in RvA-BR010.

Raad voor Accreditatie Pagina 1 van 4

UK to NL Migration

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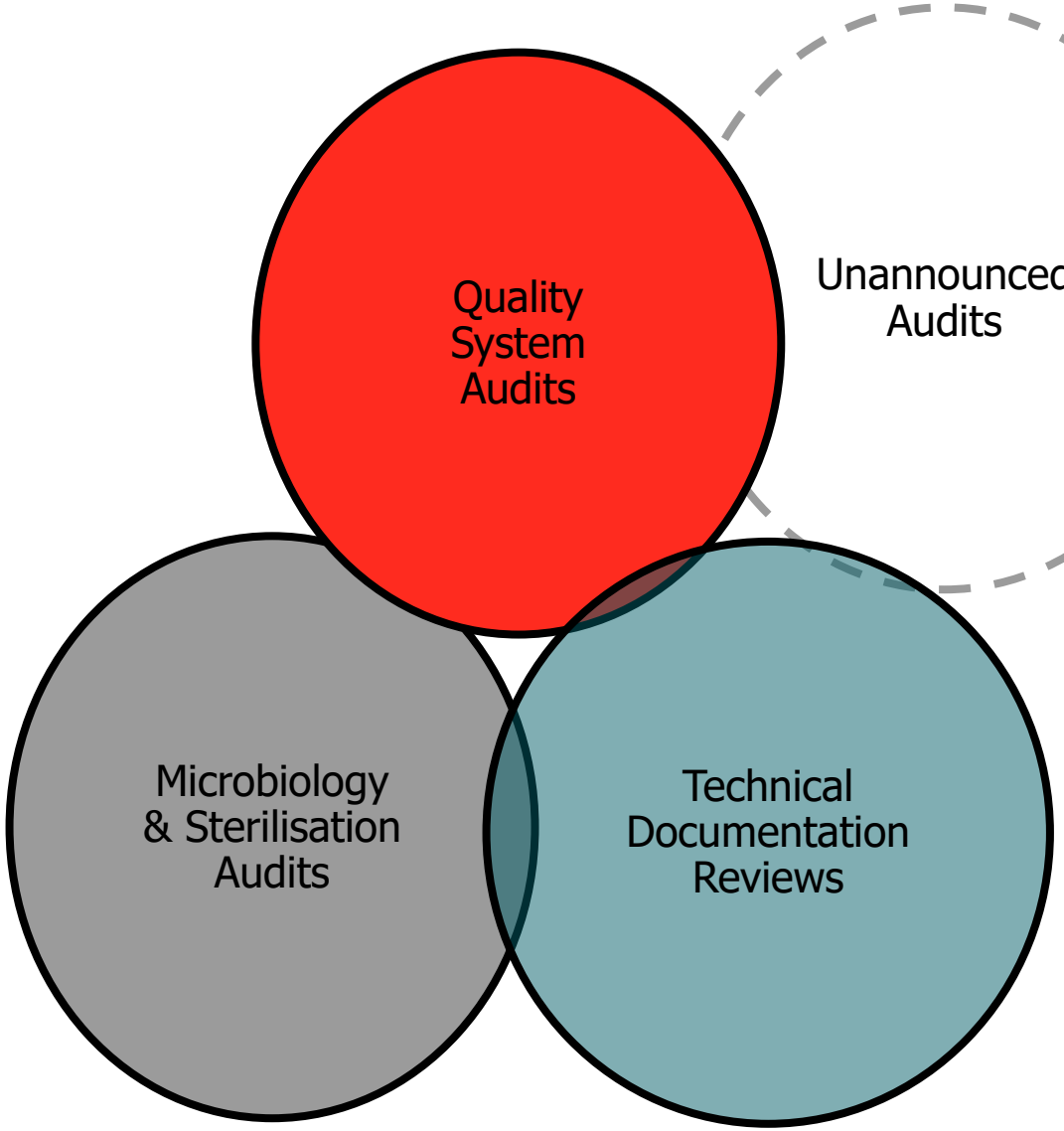
BSI Conformity Assessment



Identical Competence

Identical Processes

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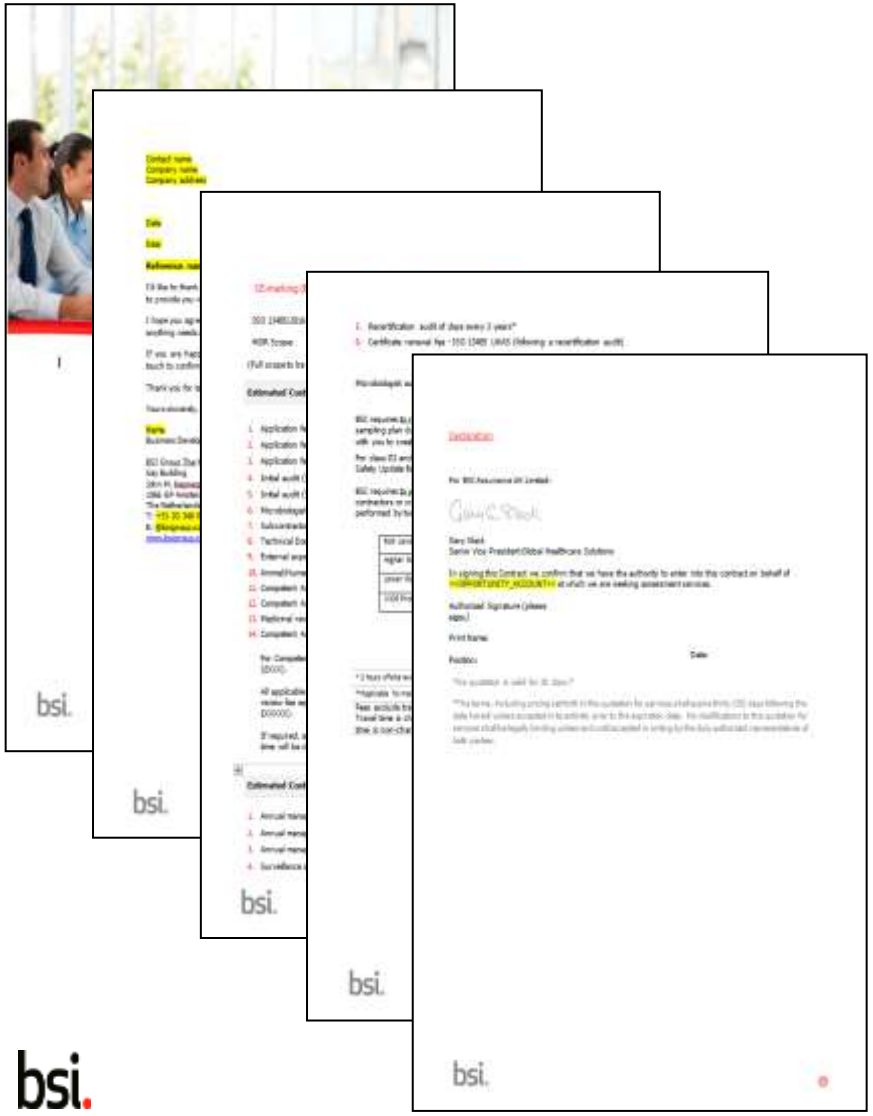
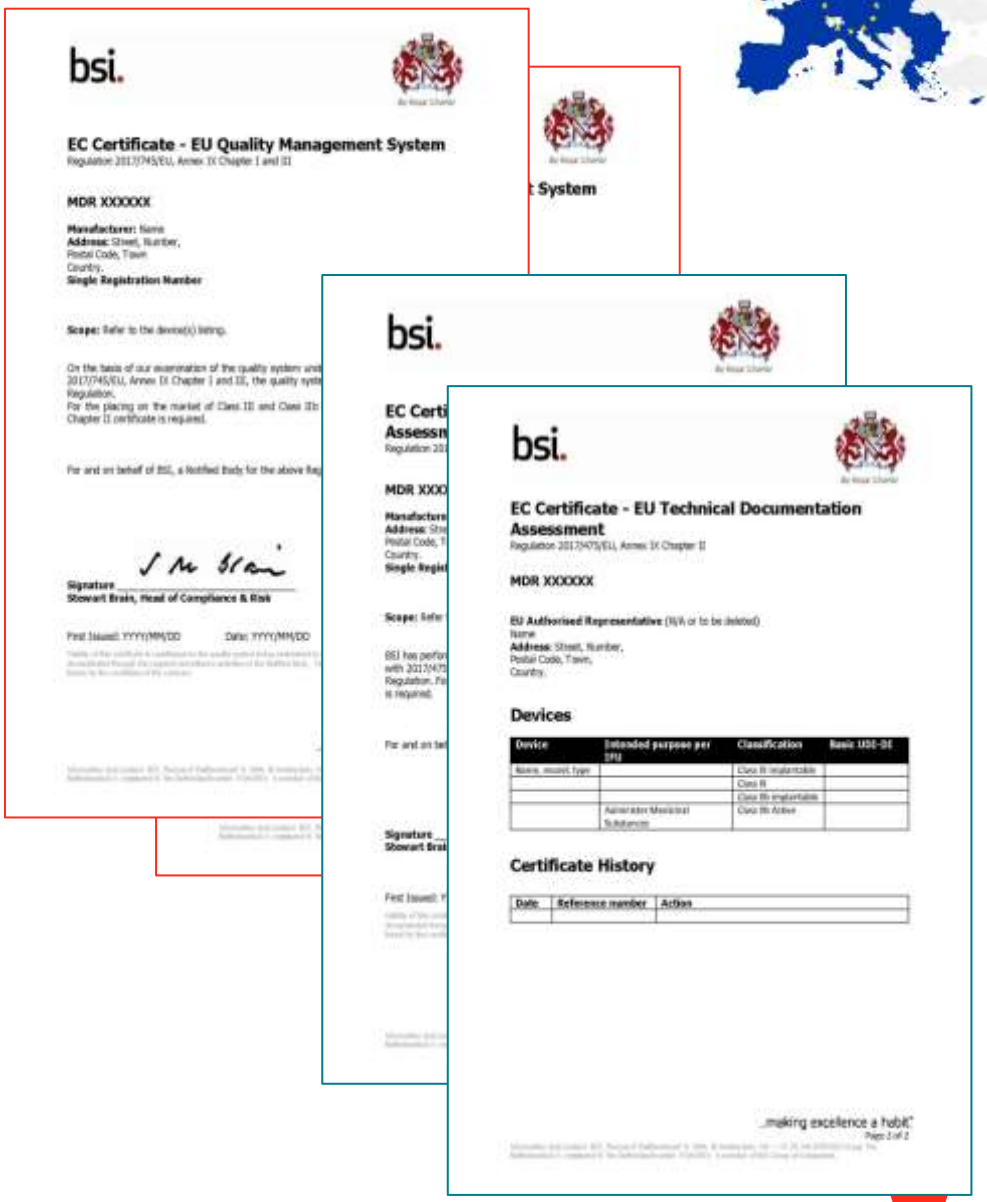
Contracts and Certificates





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Information for Users

SPR#23

(e) medicine, human, animal

(f) CMR + ED >0.1%

(j) 

(o) reprocessing cycles

(p) custom made

(q) clinical investigation

(r) quantity of constituents – achieving principal intended action

(a)

(g)

(c)

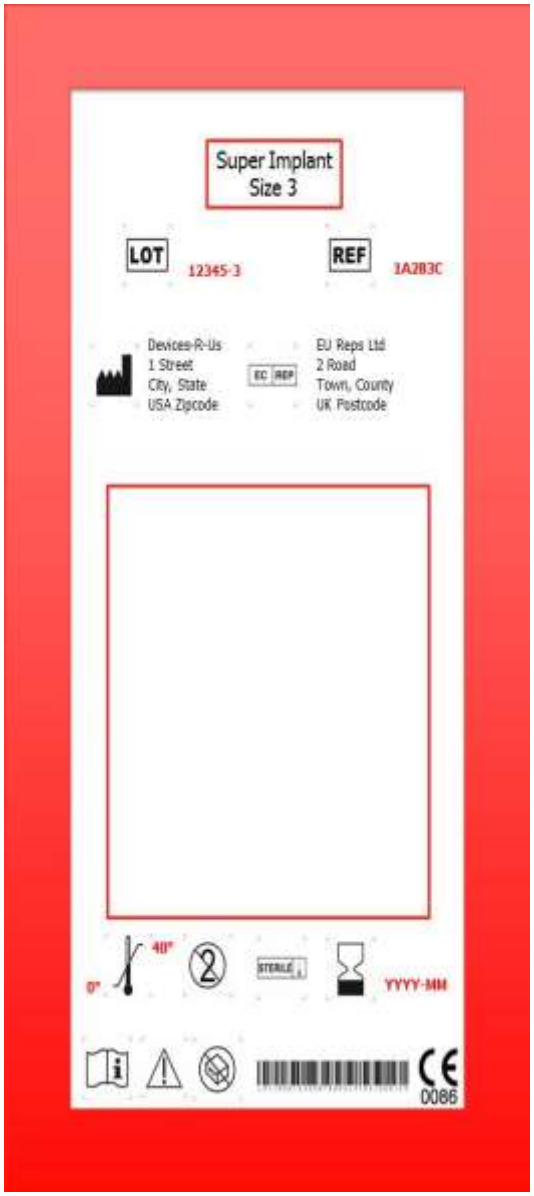
(b)

(l)

(k)

(n)

(m)



(s)

(d)

(i)

(h)

*Article 20

"In the event of a merger, it is for the newly-merged NB to decide on its identity/brand, and to choose which if the two NB numbers it will retain."

"This is why, to avoid excessive costs, we have suggested in the past that the listing in NANDO … as NBXXXX (also ex NB YYYY) so that the reference of the old NB can still be found."

"…manufacturers don't need to relabel products which have already been placed on the market to refer to the new NB number, since the old number can still be traced in NANDO."

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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

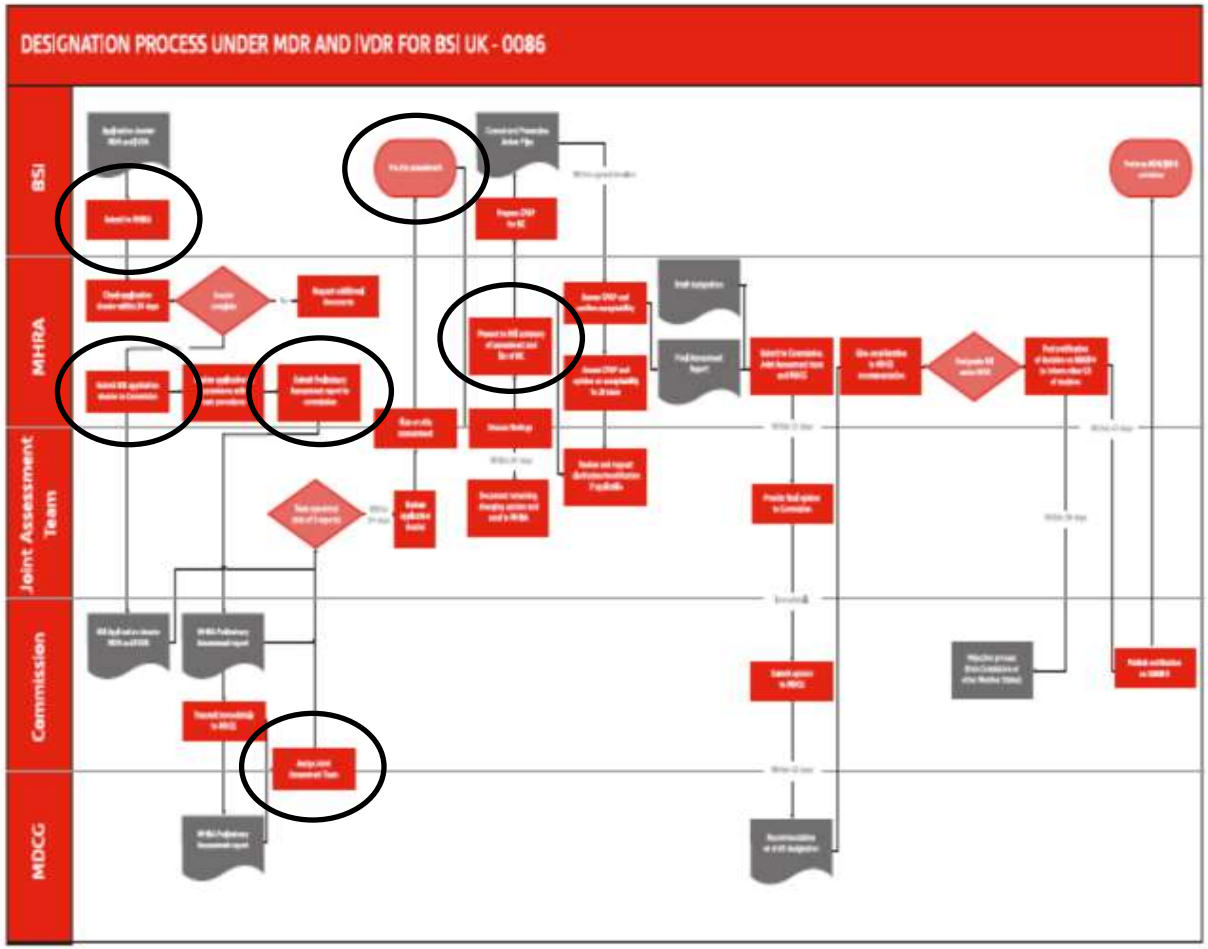
MDR:

- 27 Nov Application
- 14 Dec Comp. Check
- 09 -14 Apr. 1st EU JAT
- Responded to NC
- MDR Close Out Audit **September 26-28th 2018**
- **Designation Target Q1 2019**

IVDR

Audit Date 4th November 2018

Designation Q4 2019

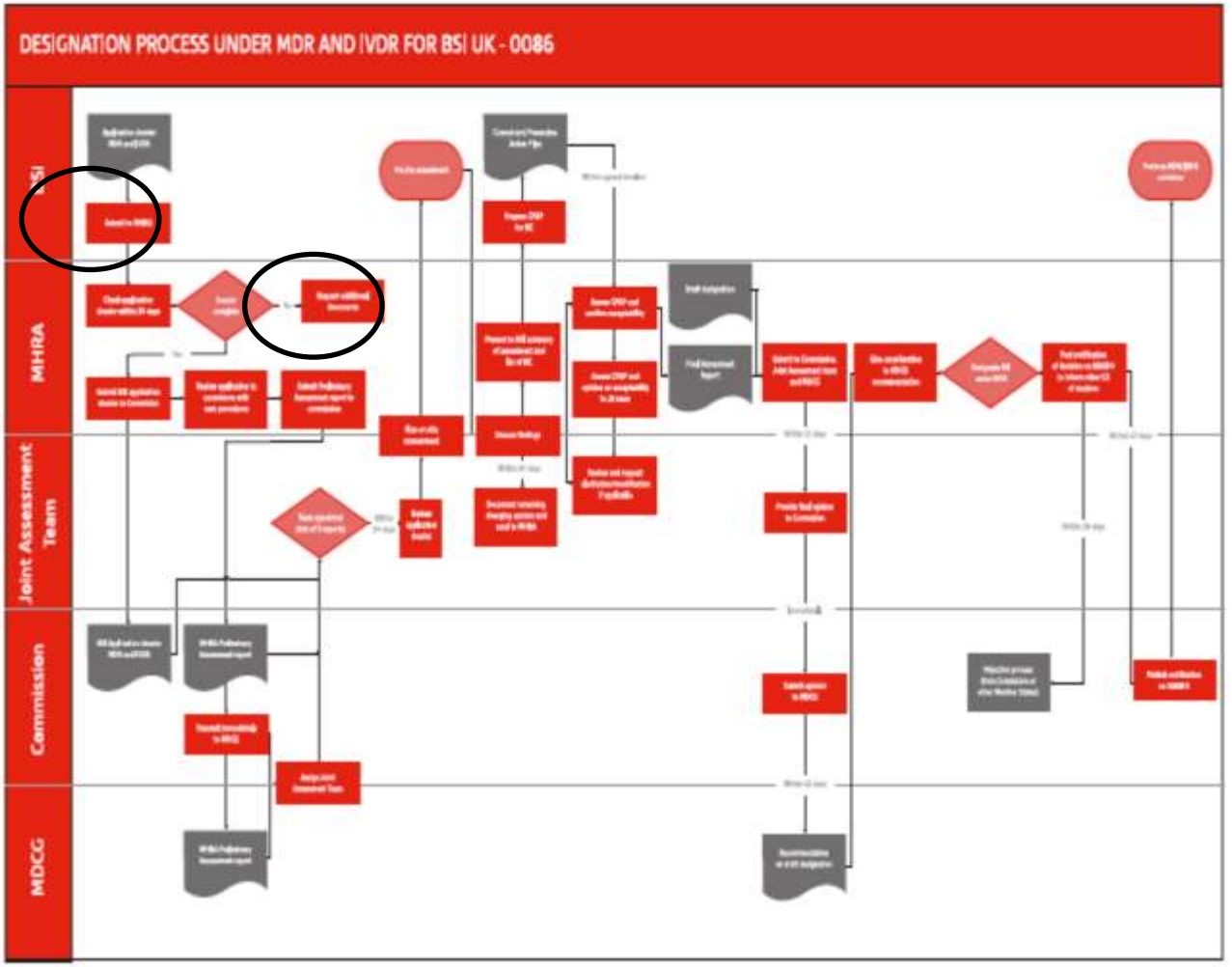


EU MDR – Designation – Article 38-40 / 38-40

MDR & IVDR:

- 27 & 28 2017 Nov Applications
- 28 Dec. 2017 Completeness
- Check
- Submission
- MDR Awaiting Preliminary Assessment date rom IGJ Q4 2018
- MDR Designation Q2-Q3 2019

- **IVDR Submitting Procedures**
- IVDR Designation Anticipated late 2019



Finally There is Not Much Runway Left to Land your MDR/ IVDR Projects …

- Understand where you need to be and by when (i.e. Project times) also which flight BA 93/42 or BA 745 you wish to take.
- Make sure you fully understand your necessary scheduled departure date(s) to arrive safely and remain on the market in your destination geography.
- Work with your "Travel Agent" (NB) to ensure your reservation is in place early so your Technical Documentations review has a seat once the NB is designated!
- Maybe an indirect route via destination (MDD) with a 2 -3 year stopover before progressing to the final destination of (MDR) is your better option.
- Flight times and scheduled may change and so might routes so keep close to your Travel agent (NB) and stay informed.
- Good luck with your journey.

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Client Communication: An urgent notice of the timelines for all MDD and AIMDD certificate renewals and reviews.

2 June 2018

Dear BSI Client,

Important information: New BSI Policy for renewals and reviews of CE certificates under the MDD / AIMDD.

The final text of the new European Medical Devices Reg... ...lished in May 2017, we are now a year into the transition period for this critical

June 2018- December 2018

BSI will accept signed applications for Standard or CE Dedicated reviews

From January 2019

BSI will ONLY accept signed applications for **CE Dedicated** reviews

31 March 2019

Deadline for BSI receiving **all** signed work authorisation forms/proposals and full review documentation

What do I need to do now?

We very strongly recommend you now plan your transition to MDR and/or if you intend to apply for early renewals, then please plan in accordance with the dates we have communicated above for efficient transition to MDR.

Notified Bodies may not have the capacity to complete all the anticipated additional MDD/AIMDD work within the last 6-9months of the MDR transition period, and so we are requesting timely

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bsigroup.com/MDRrevision
bsigroup.com/IVDRrevision
bsigroup.com/medical-devices/brexit-medical-devices