What are the Regulatory Implications of BREXIT?

Does this impact the

"Seismic"

concurrent EU regulatory changes?

Gary Slack, Senior Vice President,
Global Medical Devices

Howard Kerr, CEO

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- Firstly this is a draft and could be rescinded in a non-negotiated outcome!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

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

Non–Negotiated (or Hard) BREXIT

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

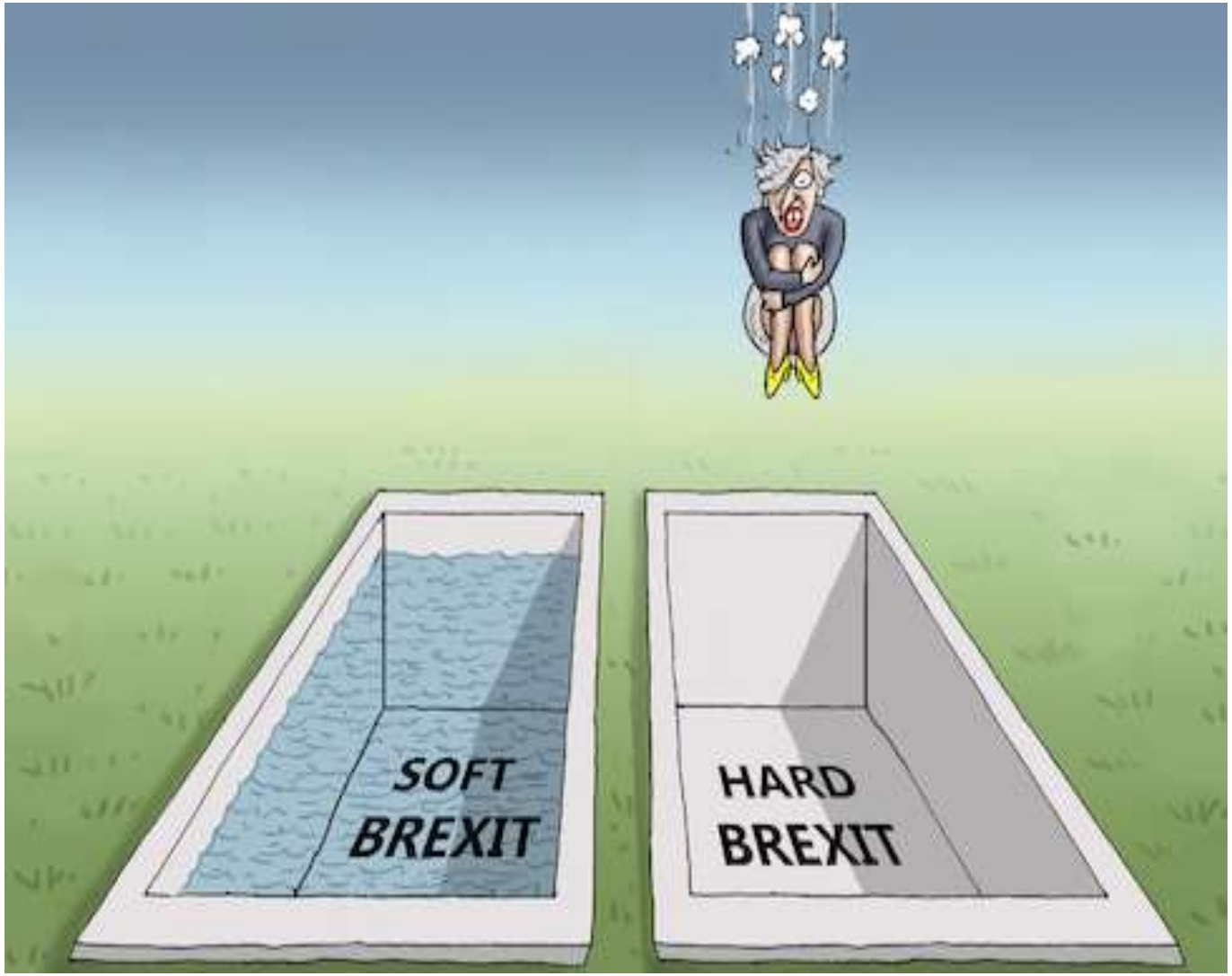
EU CUSTOMS BORDER

Export from UK and import into free circulation in EU

Manufacture in EU

* unless product is duty free

If Required Full Migration to Our Netherlands NB Within Target Timelines



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

Initial Designation

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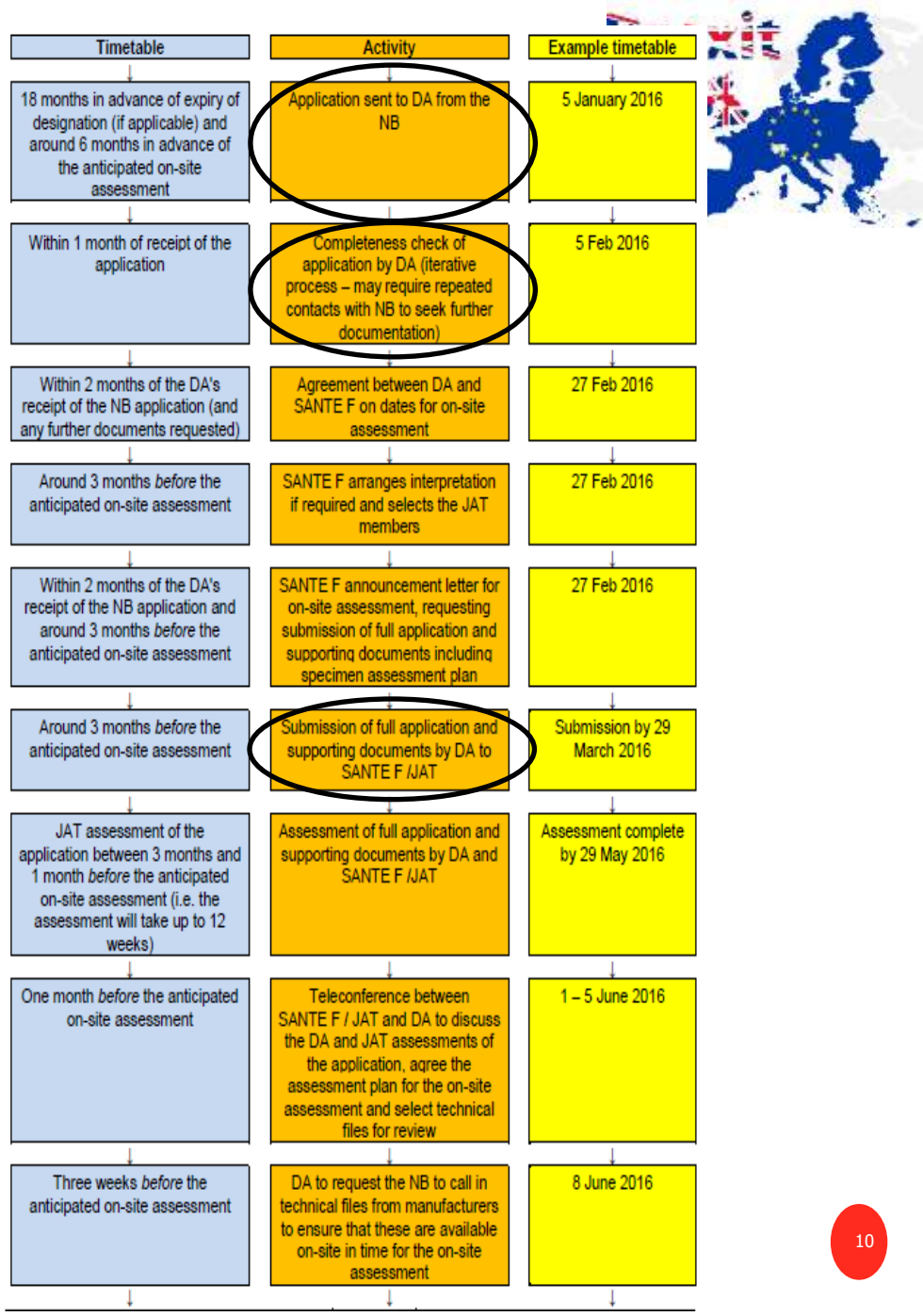
MDD & AIMDD

MDD & AIMD:

- 07 Feb 2017 Application
- 01 March 2017 Completeness check
- Full Application 16 June 2017
- 16 June 2017 Inc. IVD Application



Timetable	Activity	Example timetable
18 months in advance of expiry of designation (if applicable) and around 6 months in advance of the anticipated on-site assessment	Application sent to DA from the NB	5 January 2016
Within 1 month of receipt of the application	Completeness check of application by DA (iterative process – may require repeated contacts with NB to seek further documentation)	5 Feb 2016
Within 2 months of the DA's receipt of the NB application (and any further documents requested)	Agreement between DA and SANTE F on dates for on-site assessment	27 Feb 2016
Around 3 months *before* the anticipated on-site assessment	SANTE F arranges interpretation if required and selects the JAT members	27 Feb 2016
Within 2 months of the DA's receipt of the NB application and around 3 months *before* the anticipated on-site assessment	SANTE F announcement letter for on-site assessment, requesting submission of full application and supporting documents including specimen assessment plan	27 Feb 2016
Around 3 months *before* the anticipated on-site assessment	Submission of full application and supporting documents by DA to SANTE F /JAT	Submission by 29 March 2016
JAT assessment of the application between 3 months and 1 month *before* the anticipated on-site assessment (i.e. the assessment will take up to 12 weeks)	Assessment of full application and supporting documents by DA and SANTE F /JAT	Assessment complete by 29 May 2016
One month *before* the anticipated on-site assessment	Teleconference between SANTE F / JAT and DA to discuss the DA and JAT assessments of the application, agree the assessment plan for the on-site assessment and select technical files for review	1 – 5 June 2016
Three weeks *before* the anticipated on-site assessment	DA to request the NB to call in technical files from manufacturers to ensure that these are available on-site in time for the on-site assessment	8 June 2016

MDD & AIMDD

MDD & AIMD:

- 11-15 September 2017 Joint Audit
- 20 November 2017 JAT Report
- March 2018 Verification CAPA plan
- **08-10 May 2018 Follow up JAT**
- Responding with CAPA Plan
- CA & Des. Auth. (NL MOH). Recommendation
- EU Com/Mem. State CA Comments (1 month)
- **Expected Designation Q3 2018**

Usually 4 to 5 days on site	On-site assessment in accordance with assessment plan agreed between the DA and the JAT	29 June – 3 July 2016
Within 45 days of completion of the on-site assessment	Production of JAT draft report and submission to DA for comments	17 August 2016
Within 25 days of receipt of the draft JAT report	Receipt of comments from DA; production of final JAT report and submission to DA	11 Sept 2016
Can take **several months** following completion of the on-site assessment	DA verification of NB's CAPA plan, further on-site assessments (if necessary) and subsequent production of final DA report and summary (in English)	7 March 2017 (8 months following completion of on-site assessment)
On receipt of the DA final report	Upload of final DA and final JAT reports into CIRCABC by SANTE F	11 March 2017
On receipt of the DA final report	SANTE F to arrange for JAT members to review uploaded DA report	Up to 11 April 2017
Within one month of the upload of DA and JAT final reports	Comment period for Commission services and other DAs	Up to 11 April 2017

If there are **no comments / questions** submitted to the DA from either other DAs or the JAT or the Commission services

	DA (re-)designates the NB and sends notification to NANDO	12 April 2017 **(END OF PROCESS)**

If there <u>are</u> **comments / questions** submitted to the DA from either other DAs or the JAT or the Commission services

DA has one month in which to respond to questions. Questions may be sent, at the latest, one month after upload	Response from DA	For question sent on 11 April, DA response will be 11 May 2017

MDD, AIMDD and IVDD

Following the initial DA response to questions raised, the Commission and/or other DAs have one month in which to make recommendations (i.e. at the latest three months after upload)	If recommendations are made by the Commission and/or other DAs concerning the DA's decision to designate	Recommendations may be made by 11 June 2017 at the latest (i.e. one month after initial DA response)
DA has two further weeks after receipt of recommendations to answer these (i.e. at the latest three and a half months after upload)	Response from DA to recommendations	27 June 2017 at the latest
At the latest three and a half months after upload	Transmission of designation decision to NANDO	27 June 2017 (END OF PROCESS)

MD & AIMD:
- Applications Q3 2018
- Certificates Q3 2018

IVDD:
- 18/19 June 2018 IGJ Audit
- Designation late 2018

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RVA – Accreditation

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
EP
ms dam
nd

ocatie	Certificatie Schema
John 1066 E Amsterdam Nederland	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 Knowhill, Milton Keynes, MK5 8PP Verenigd Koninkrijk	ISO 13485:2003 en EN ISO 13485:2012 ISO 13485:2016

Norm / Normatief document	eschema[1]
ISO 9001:2008 (tot 15-09-2018) ISO 9001:2015	Kwaliteitssysteemcertificatie, vo erkl nen (verwijzing naar IAF codes en NACE re ar g): 3 voedings- en genotmiddelen 4 textiel en textielproducten 9 drukkerijen 12 chemische industrie 14 rubber en kunststoffen

Deze bijlage is goedgekeu 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

Breaking News

Manufacturers can apply for a second certificate or

Move their certificate in future

A Great Team Effort …

BSI will provide a more comprehensive client communication on this in the coming weeks including timelines.

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

Initial Designation
Maintaining Designation

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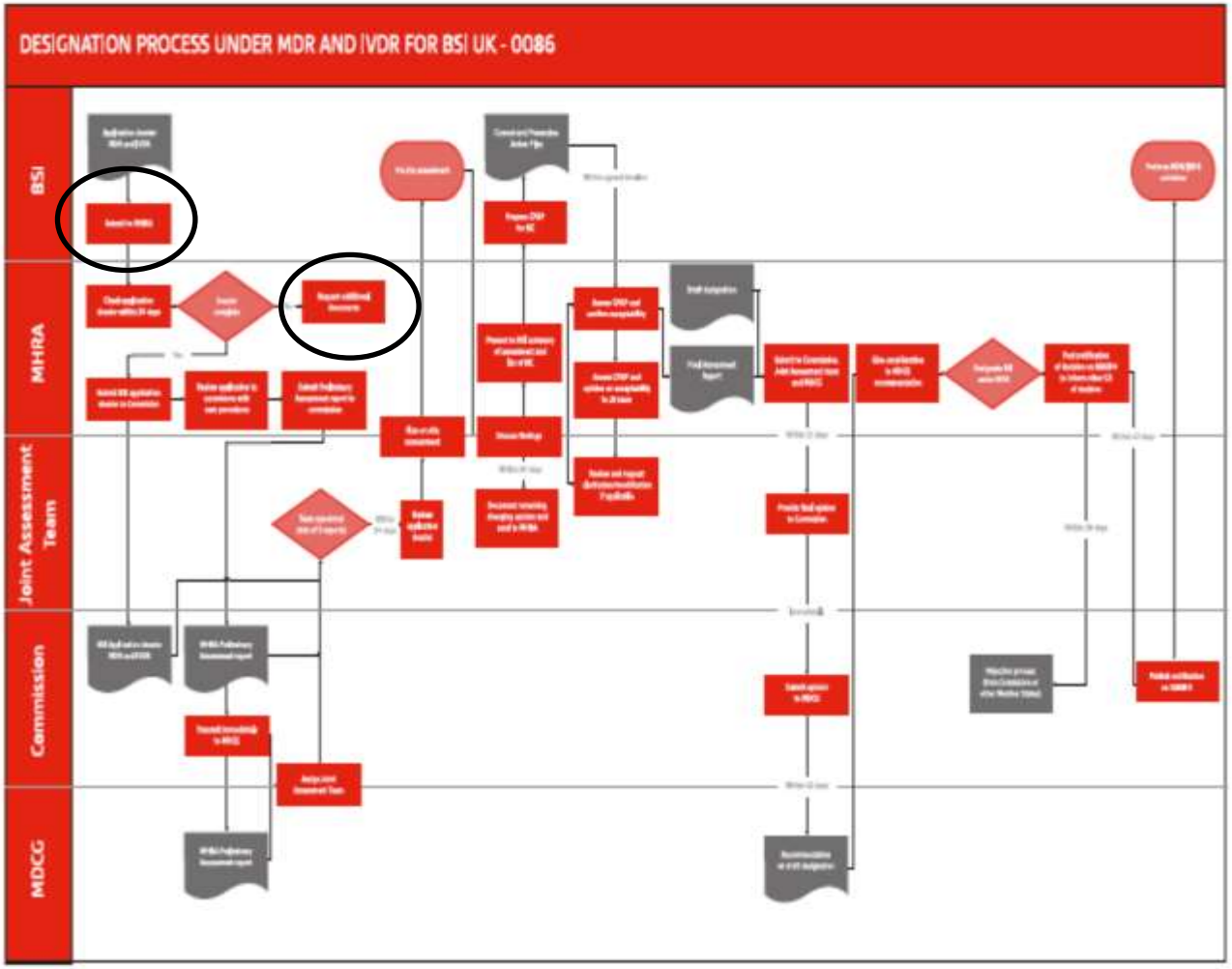
EU MDR / IVDR – Designation – Article 38-40 / 38-40

MDR & IVDR:

- 27 & 28 Nov Applications
- 28 Dec. Completeness
- JA Expected 09/18 MDR &
- Q4 2018 IVDR
- Aiming for Designation H1 2019



UK to NL Migration

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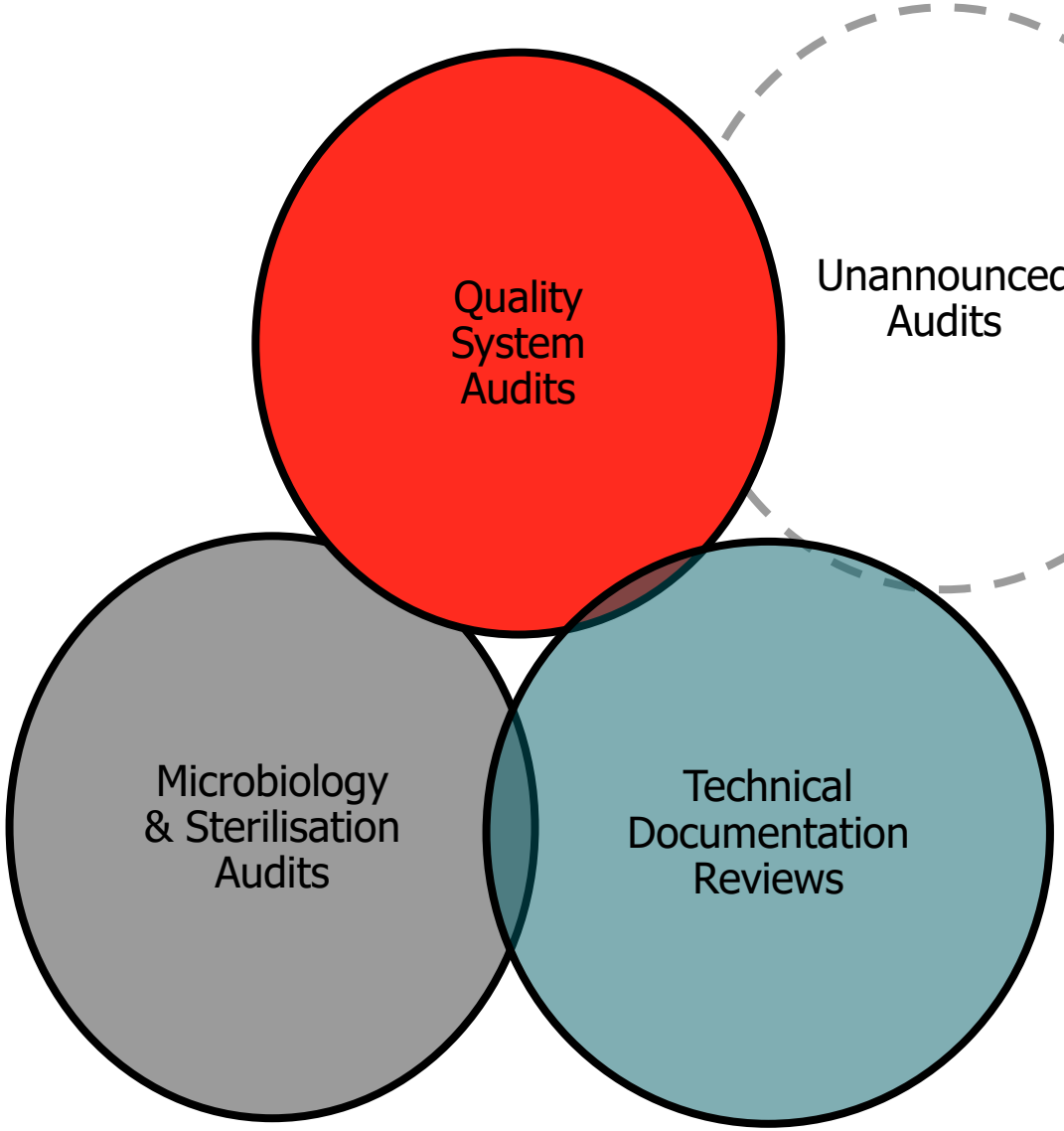
BSI Conformity Assessment



Identical Competence

Identical Processes

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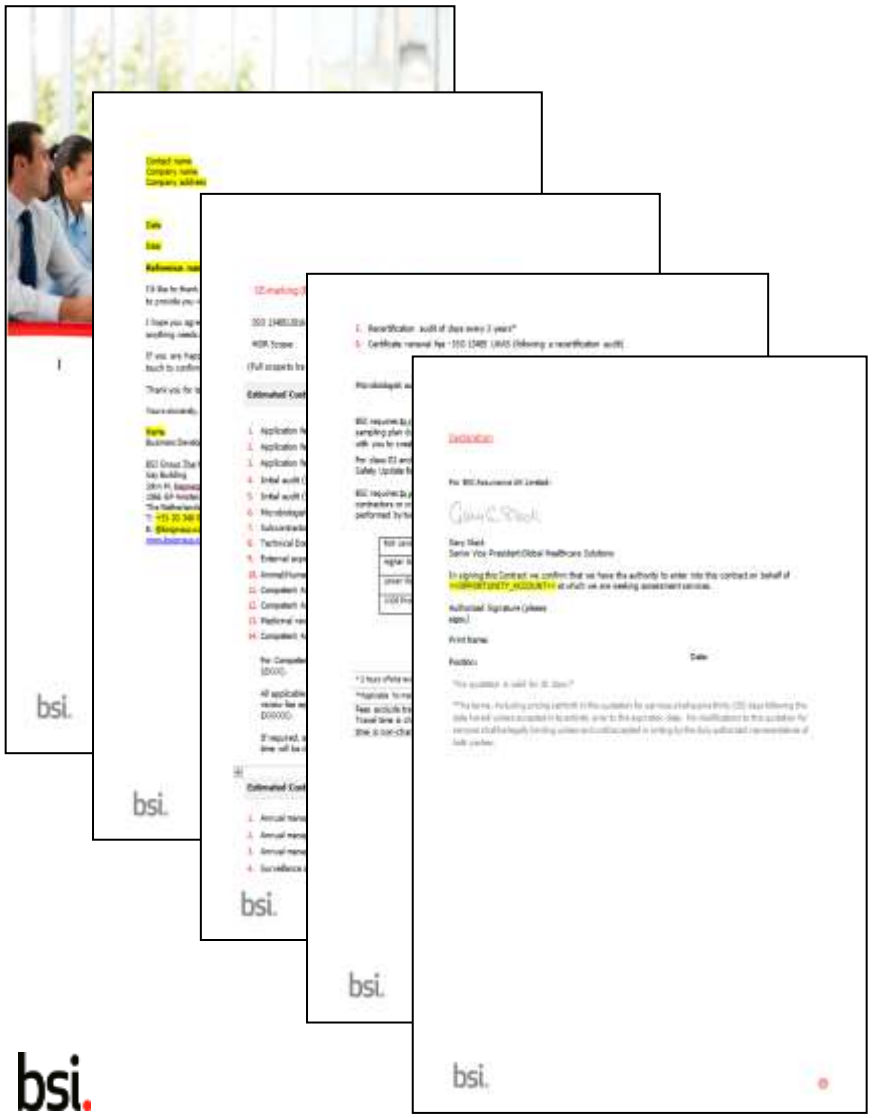
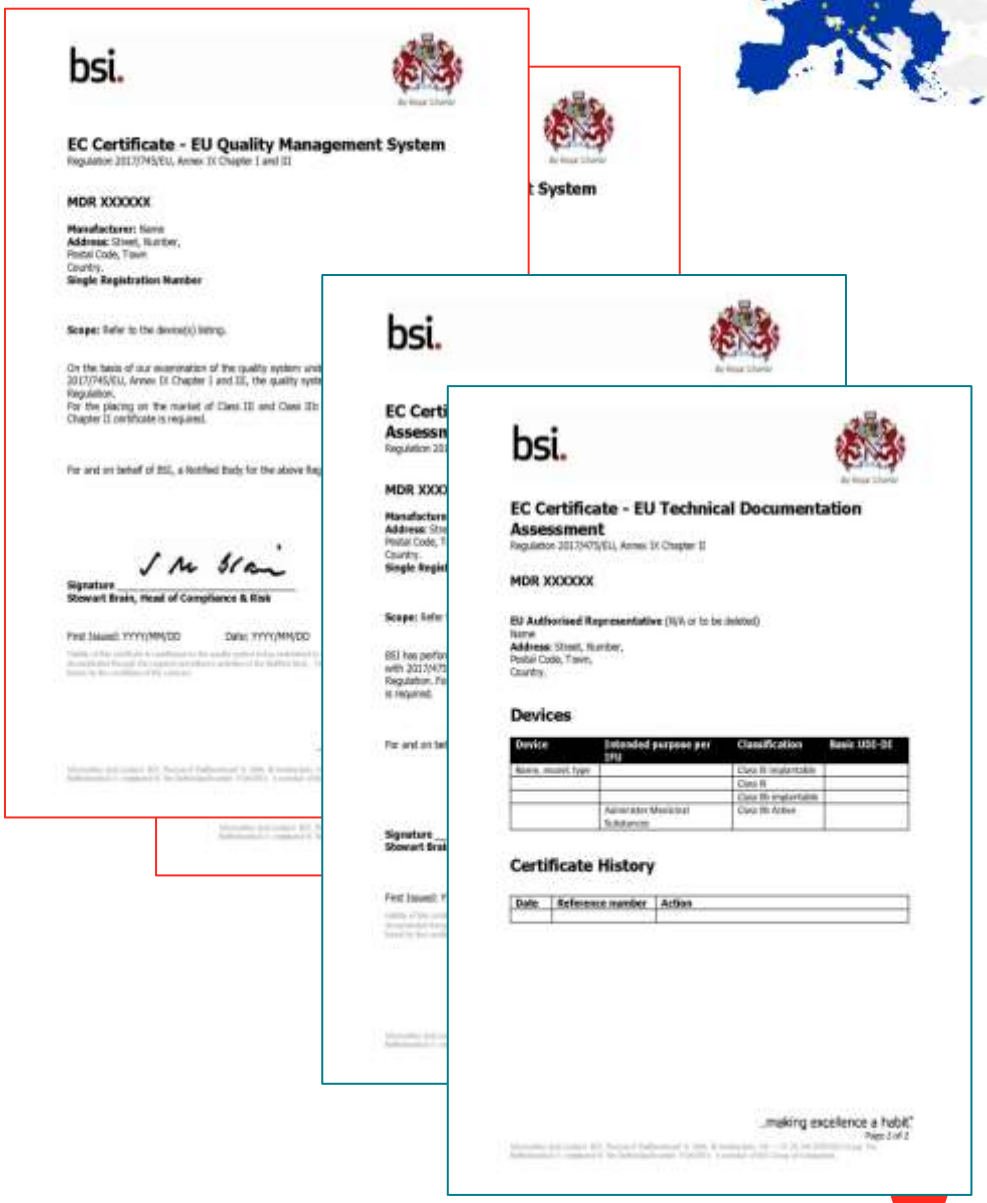
Contracts and Certificates





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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)

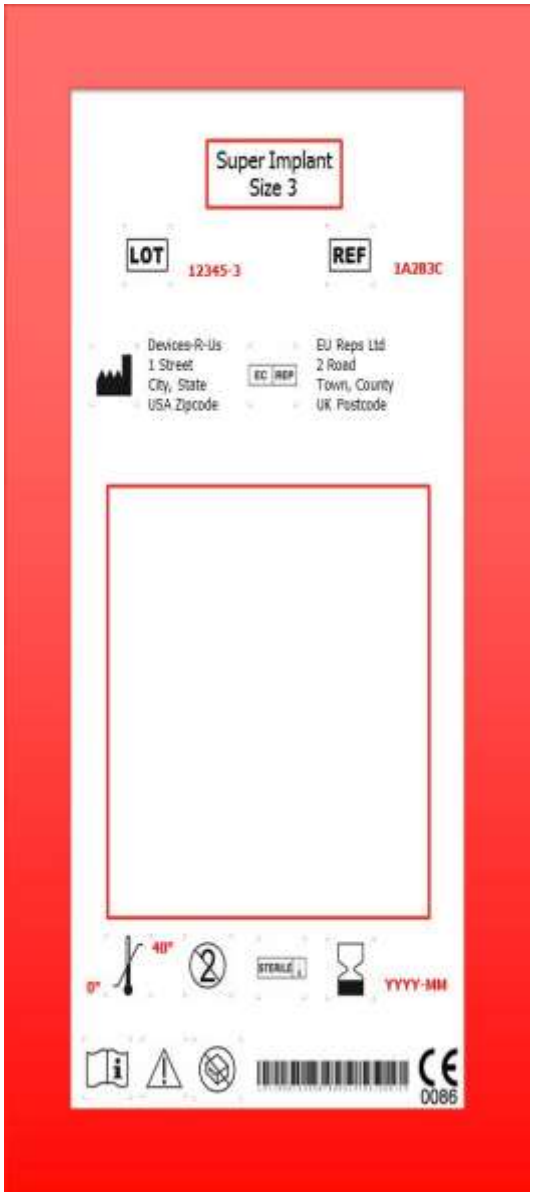
(b)

(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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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 **Too** Late

(Irrespective of BREXIT)

- Deadlines & Timelines are Pressing
- The System Lacks 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)

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...making excellence a habit.™