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Relevant Certification for Medical Devices

Ronel Liebenberg
Product Certification Executive

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Market Intelligence & Legislation

- Stringent requirements in place to ensure **patient and user safety**, as well as the performance of the device.
- Compliance to the new Medical Devices- and IVD Regulations, which will supersede the current Directives in 2020 and 2022, respectively (**CE mark**)
- Manufacturers need to make sure they understand the **new QMS requirements** for CE mark, to maintain regulatory compliance.

Difference between a Directive and a Regulation?

EU Directive:

- Applicable to all Member States
- Sets certain aims, requirements and concrete results that must be achieved in every Member State
- Sets a process for it to be implemented by Member States
- National authorities **must create or adapt their legislation to meet these aims** by the date specified in each given Directive

EU Regulation:

- **Immediately applicable and enforceable by law in all Member States**
- As good practice, Member States issue national legislation that defines the competent national authorities, inspection and sanctions on the subject matter.

EU Directives lay down certain end results that must be achieved in every Member State. National authorities have to adapt their laws to meet these goals, but are free to decide how to do so. **Regulations** are the most direct form of EU law - as soon as they are passed, they have binding legal force throughout every Member State, on a par with national laws. National governments do not take action themselves to implement EU regulations, but do ensure their national law does not define the subject matter any further.

What exactly is changing?

- Medical Devices Directive **AND** Active Implantable Directive



- Medical Devices Regulation (EU 2019/745)

- In Vitro Diagnostic Directive



- In-Vitro Diagnostic Regulation (EU 2017/746)

MDR / IVDR Status update

A little clarity ...

Publication of the adopted MDR & IVDR:

5 May 2017

The meanings of some words:

Entry into force

- Publication of the new Regulation in EU Official Journal + 20 Days

DoA = Date of application

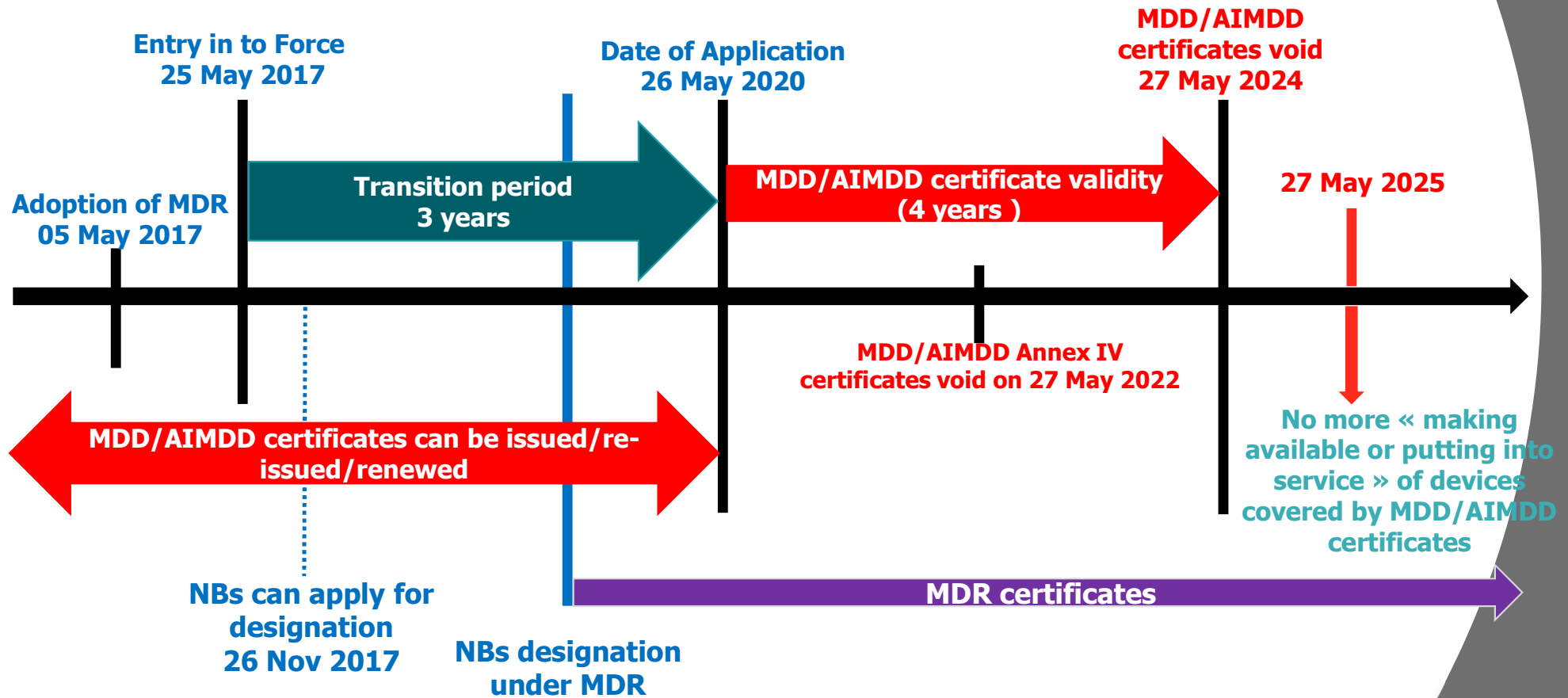
'Transition period'

- 3 years after entry into force for MDR
- 5 years after entry into force for IVDR

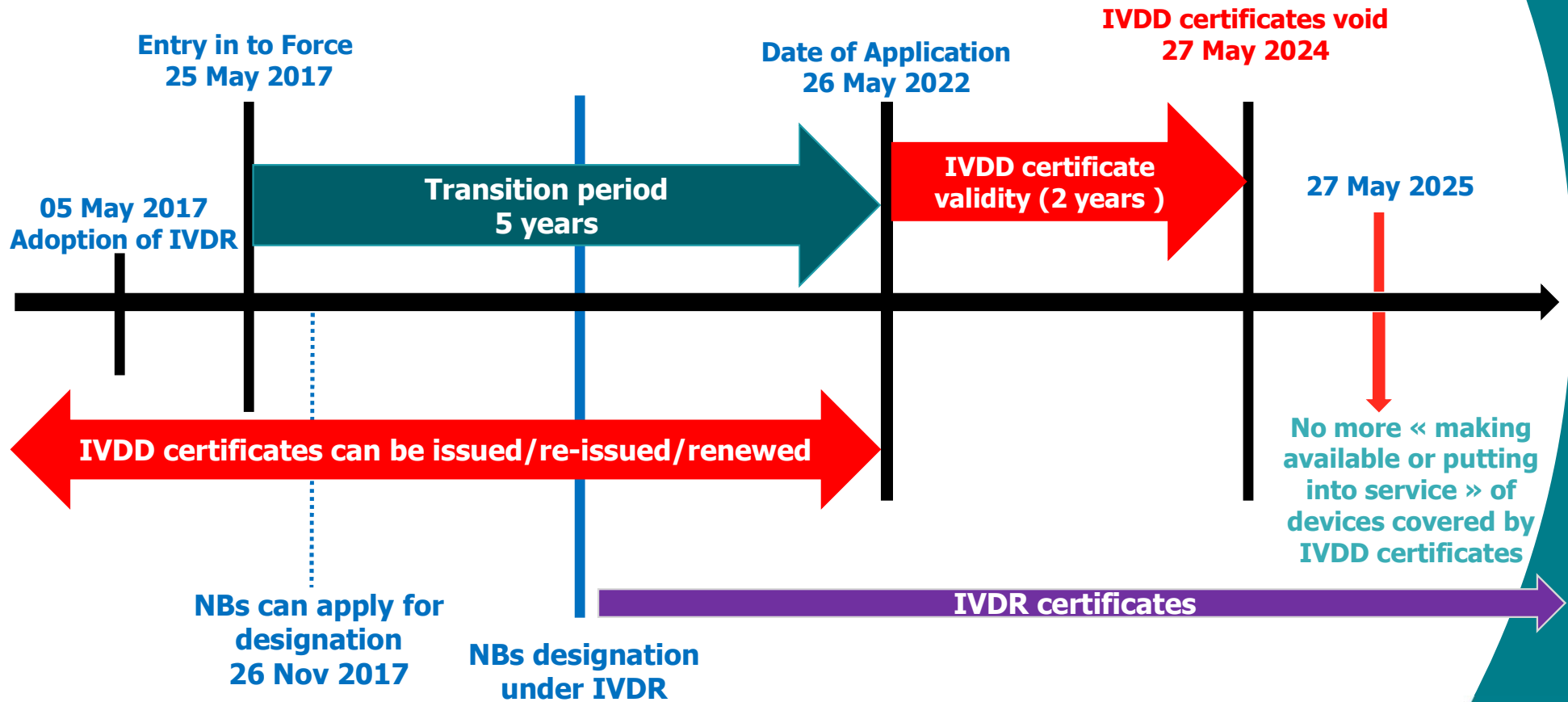
Important News: Transition Timelines

- **Certificates issued** by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate
- **Certificates** issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from **25 May 2017** shall remain valid until the end of the period indicated on the certificate, which shall not exceed **five years** from its issuance. They shall however become **void** at the latest on **27 May 2024**
- After 26 May 2020, devices certified under MDD/AIMDD (**26 May 2022 for devices certified under IVDD**) can only be placed on market if:
 - ⇒ They continue to comply with applicable Directives
 - ⇒ There are no significant changes in the design and intended purpose
 - ⇒ However, following MDR/IVDR requirements will apply
 - post-market surveillance,
 - market surveillance,
 - vigilance,
 - registration of economic operators
 - registration of devices

MDR Transition (Article 120)



IVDR Transition (Article 110)



Achieving Compliance through Organizational Resilience...

In a world of dynamic change, organizations want predictable outcomes & sustainability –

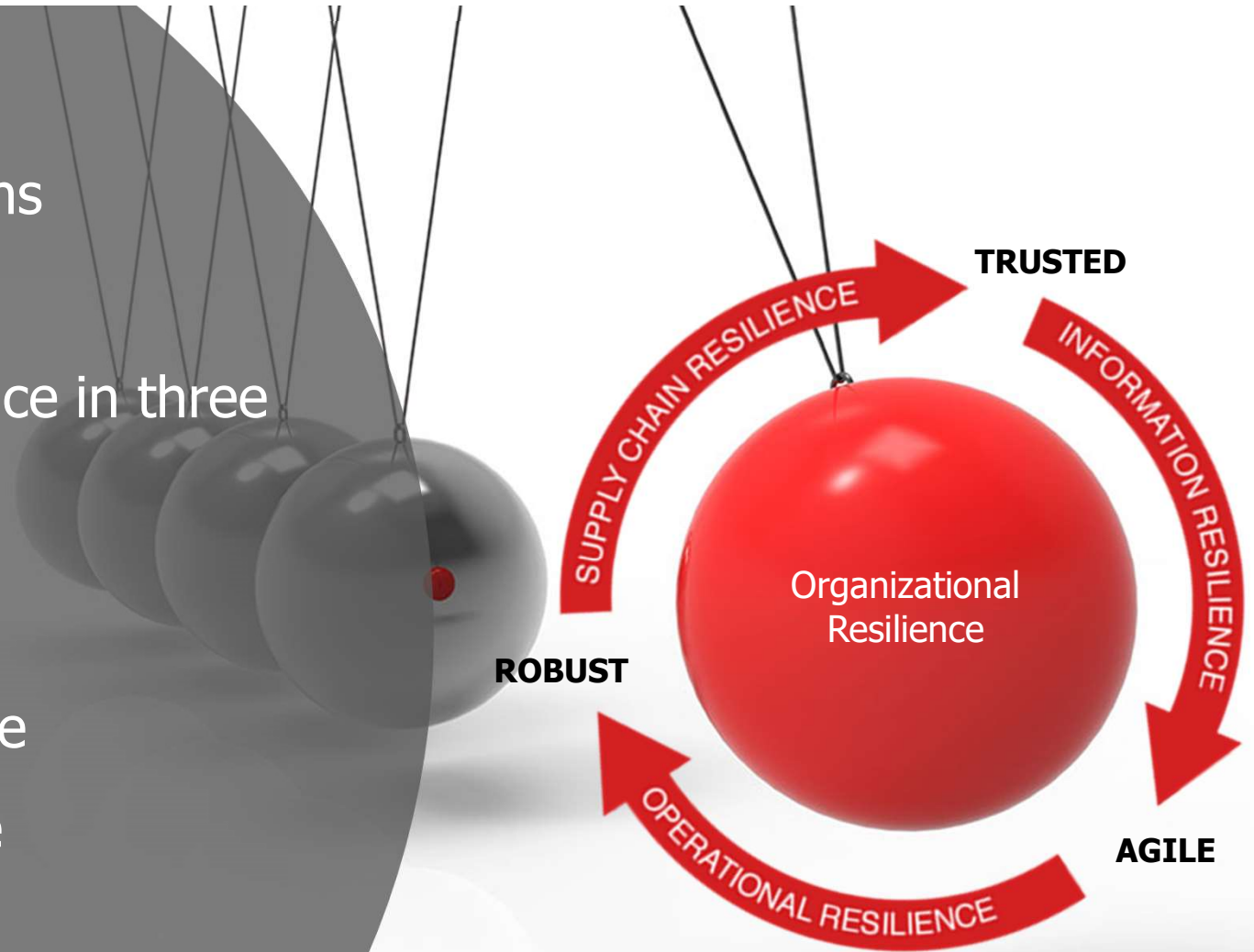
Organizational Resilience equips companies with the culture & approach to thrive in this environment


To our clients, it means partnering to achieve compliance through organizational resilience in three key areas:

Operational resilience

Supply chain resilience

Information resilience





We can make a
difference in your
business today
through...

- Consulting / GAP analysis
- Training
- Testing
- Auditing
- Certifying
- Software
- Knowledge/standards



QMS Certification

Maintain regulatory compliance with ISO 13485 certification

- ISO 13485 is a stand-alone QMS
- ISO 13485 is an effective solution to meet the comprehensive requirements for a QMS.
- ISO 13485:2016 the Medical Device QMS standard, has been harmonized to the European Medical Device Directives.
- Adopting ISO 13485 provides a practical foundation for manufacturers to address the Medical Device Directives and regulations as well as demonstrating a commitment to the safety and quality of medical devices

CE Mark

Transition
&
BREXIT
ready

- BSI first EU notified body to achieve designation to the Medical Device Regulation (MDR)
- BSI can provide conformity assessments to the full scope of the new MDR;
- BSI can offer CE certification in both the UK and Netherlands;



Other news:

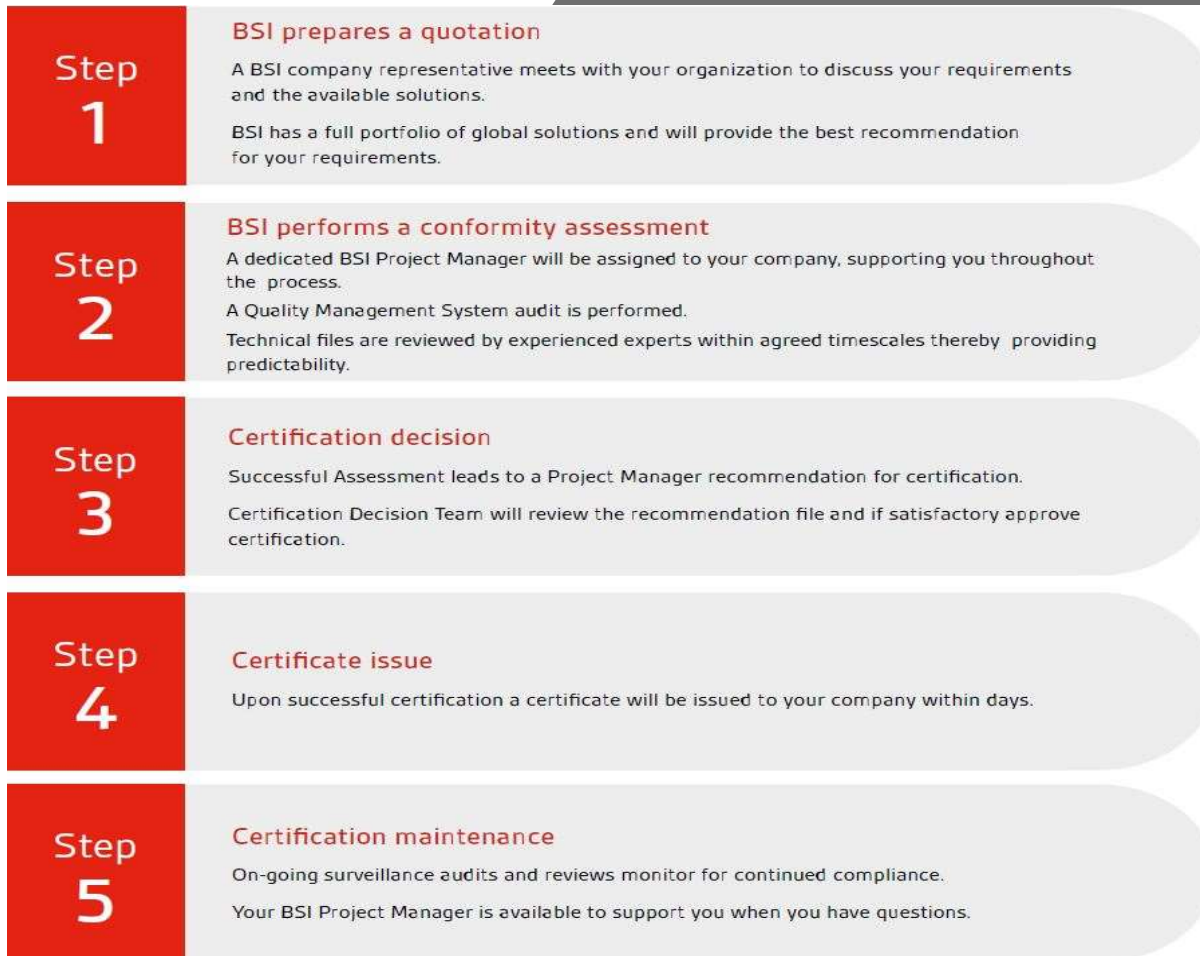
- BSI can offer UKAS-accredited certification to ISO 13485:2016;
- BSI also obtained RVA accreditation for ISO 13485 in 2018 with SANAS accreditation for the South African market soon to follow!



Certification Process

Who better to partner with than the people who developed the world's leading best practices?.

Certification Process



Clients say...

A word cloud of client feedback on a dark asphalt background. The words are arranged in various sizes and orientations. The most prominent words are 'Experts In Field' in large blue letters, 'Trusted' in large red letters, and 'Reliable' in large white letters. Other words include 'Innovative', 'Consultative', 'Value for Money', 'Responsible', 'Robust', 'Customer Focused', 'Secure', 'Thought Leader', 'Agile', 'Market Leader', 'Has Integrity', 'Easy To Do Business With', 'Experts In My Industry', and 'Bureaucratic'.

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Where can I find full details of the changes?

bsigroup.com/MDR-revision
bsigroup.com/IVDR-revision

Webinars: bsigroup.com/webinars

Whitepapers:
bsigroup.com/whitepapers



Thank you

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Please contact us for further
assistance, in making
excellence a habit ...