



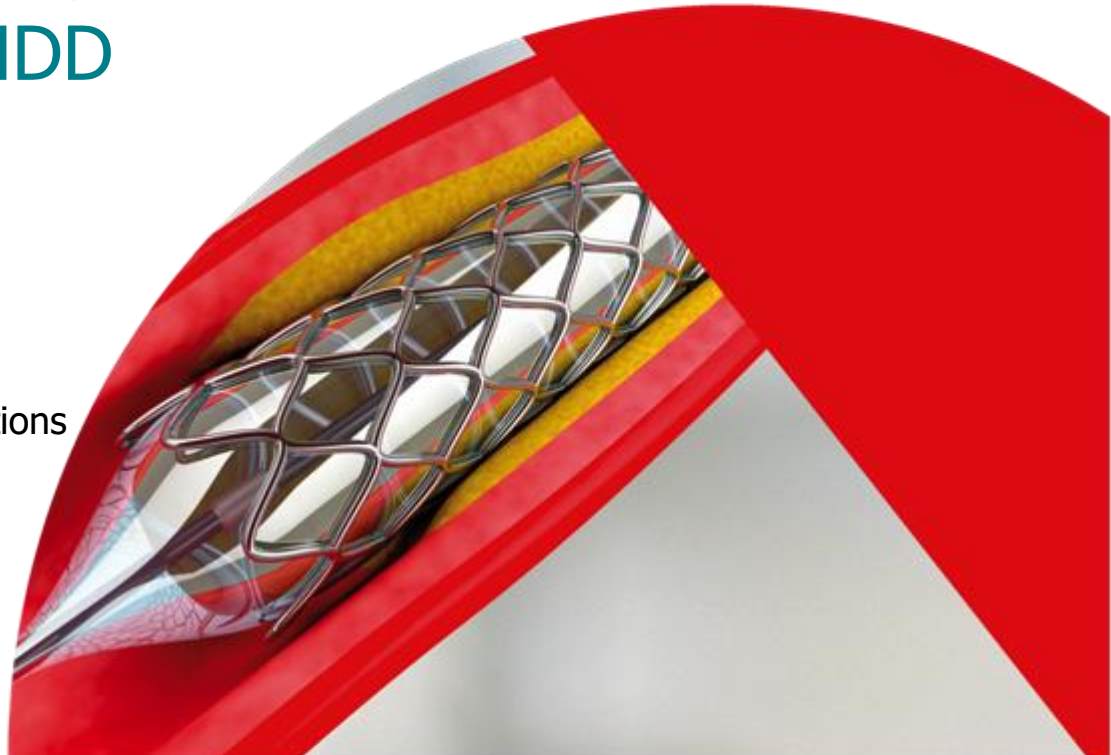
Relationship between the MDR and the former MDD

Ronald Rakos, PhD

The New EU Medical Device and IVD Regulations
August 29-30, 2017



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Relationship between the MDR and the former MDD

Regulation (EU) 2017/745

101 Whereas ... = Why

10 Chapters of 123 Articles = What

XVII Annexes = How



The Directive:

22 Whereas ... = Why

23 Articles = What

X Annexes = How

- Chapter I – Scope and Definitions
- Chapter II – CE Marking, Economic Operators, Reprocessing
- Chapter III – Identification and Traceability of Devices
- Chapter IV – Notified Bodies
- Chapter V – Classification and Conformity Assessment
- Chapter VI – Clinical Evaluation and Investigation
- Chapter VII – Vigilance and Market Surveillance
- Chapter VIII – Cooperation between Member States
- Chapter IX – Confidentiality, Data Protection, Funding, Penalties
- Chapter X – Final Provisions

Regulation (EU) 2017/745

101 Whereas ... = Why

10 Chapters of 123 Articles = What

XVII Annexes = How



- Annex I – General safety and performance requirements
- Annex II – Technical Documentation
- Annex III – Technical Documentation on PMS
- Annex IV – EU Declaration of Conformity
- Annex V – CE Marking of Conformity
- Annex VI – European UDI System
- Annex VII – Requirements to be met by Notified Bodies
- Annex VIII – Classification Criteria
- Annex IX – Conformity Assessment – QMS and Technical Documentation
- Annex X – Conformity Assessment – Type Examination
- Annex XI – Conformity Assessment – Product Conformity Verification
- Annex XII – Procedure for Custom-made Devices
- Annex XIII – Certificates issued by a Notified Body
- Annex XIV – Clinical Evaluation and Post-market clinical follow-up
- Annex XV – Clinical Investigations
- Annex XVI – Products without an intended medical purpose
- Annex XVII – Correlation Table 90/385, 93/42 and Regulation



Key changes

Notified Bodies



- Strengthened designation criteria
- Joint audits: 3 Member States and Commission (FHAA)
- Unannounced audits

Clinical evidence



- Less equivalence, more data for high risk devices
- Publish Safety and Performance data
- Post-market clinical follow-up

Pre-market



- Scrutiny for high risk devices
- Common Specifications
- Responsible person for manufacturers and Authorised Representatives

Key changes

Post-market surveillance and vigilance



- Central database and co-ordination
- Trend reporting
- Enforcement activities

Transparency and traceability



- Devices and Economic Operators registered centrally
- Unique Device Identification (UDI)
- Implant cards, SSCP

Governance and oversight

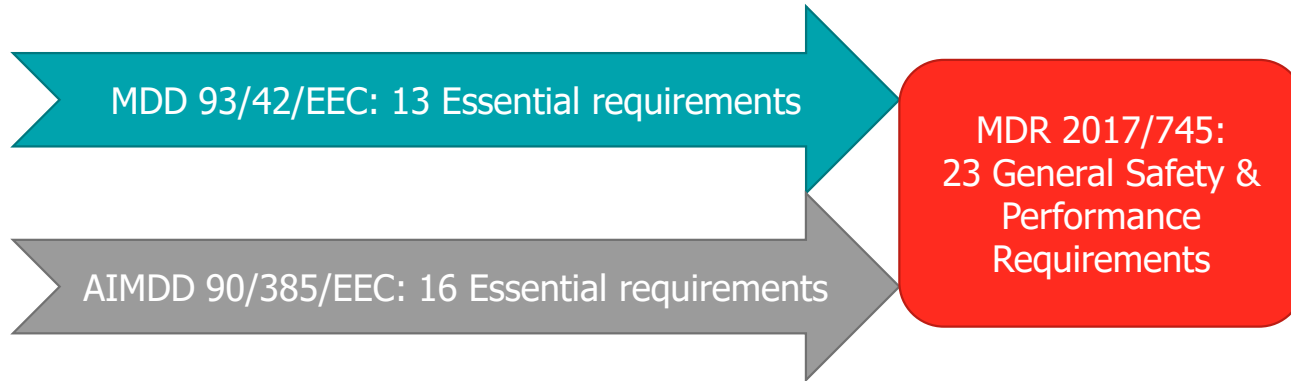


- Central Committee: MDCG
- Expert Panel, Expert Laboratories

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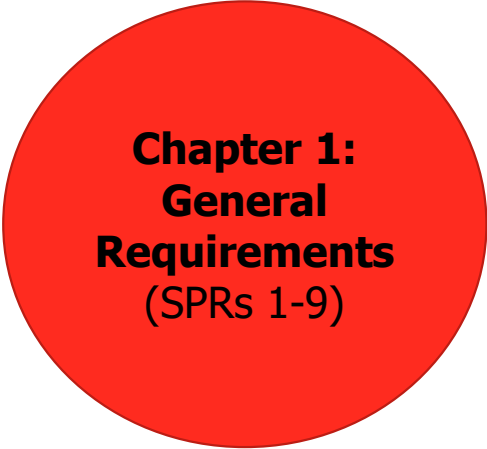
General Safety & Performance Requirements (Annex I)

General Safety & Performance Requirements (Annex I)



- Similar to “Essential Requirements” in Directives.
 - Similar content and topics
 - Some numbering and organizational changes
 - Expanded requirements (Labeling, Risk)
 - New areas of emphasis (from standards and guidances, etc.)
 - Some additional requirements because of merging of MDD with AIMDD
 - Some topics move out of the SPR list into Articles/Annexes (Clinical, medicinal consultation)
 - Some new topics introduced (devices without medical purpose, lay person use, etc.)

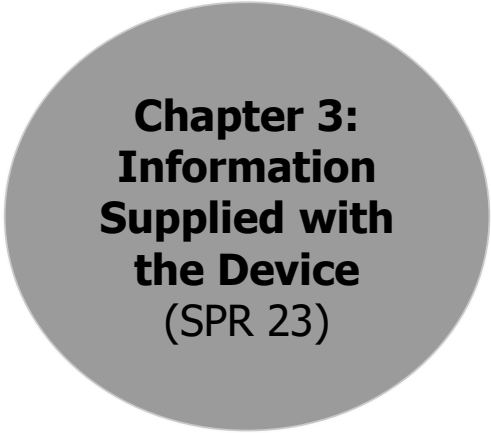
Annex I: Safety and Performance Requirements



**Chapter 1:
General
Requirements**
(SPRs 1-9)



**Chapter 2:
Design and
Manufacture**
(SPRs 10-22)



**Chapter 3:
Information
Supplied with
the Device**
(SPR 23)

Annex I: Safety and Performance Requirements

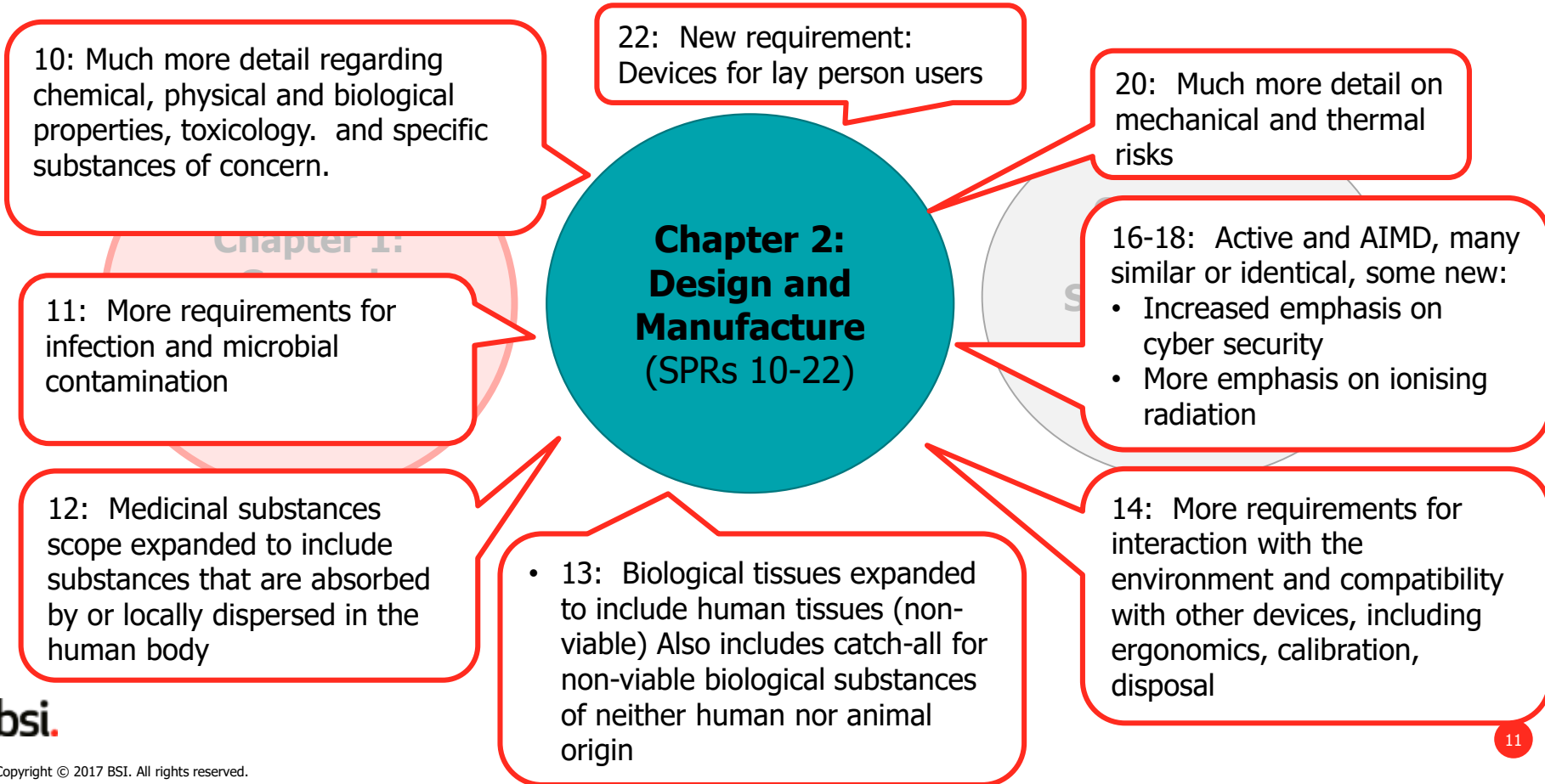
**Chapter 1:
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(SPRs 1-9)

**Chapter 2:
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(SPRs 10-22)

**Chapter 3:
Information
Supplied with
the Device**
(SPR 23)

- 2-5: Much greater emphasis on risk management
- 9: New requirement for devices without a medical purpose
- Remainder similar to Directive

Annex I: Safety and Performance Requirements



Annex I: Safety and Performance Requirements

- Some clarifications on labelling requirements.
- 23.2: Additional requirements for UDI, devices incorporating human or animal tissues, medicines, absorbable devices, and others
- 23.3: Specific requirements for labelling on sterile packaging

23.1: More “general” requirements (eg format, readability, availability, eIFU, etc.)

Chapter 3: Information Supplied with the Device (SPR 23)

23.4: Many new IFU requirements and cross-referencing to articles, including (*among others*):

- Identification of consumable components and how to replace (23.4k)
- Many more specific warning requirements (EMC, medicinal substances, human or animal tissues, CMR and endocrine disruptors) (23.4s)
- Absorbable/dispersible materials (23.4t)
- Information on materials for implants (23.4u)
- Information security measures (23.4ab)

Labeling requirements have changed and expanded significantly

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Classification

MDD, Annex IX -> 18 Rules

MDR, Annex VIII -> 22 Rules

22 Classification rules:

1 - 4 Non-invasive devices



5 - 8 Invasive devices



9 - 13 Active devices



14 - 22 Special rules

Annex VIII - Classification

Some new rules, new definitions, some clarifications, some upclassifications...

Rule 3: Upclassification of **IVF media/solutions for organ storage** to Class III

Rule 8: Upclassification of **surgical meshes** and **spinal devices** to Class III

Rule 9: **Active devices** intended for controlling, monitoring or directly influencing the **performance of active implantable devices** are Class III

Rule 11: Upclassification of some **softwares** (decision making SW, monitoring of physiological parameters) from Class I to IIa

...



Annex VIII – new rules

Rule 19: Nanomaterials – Class IIa/IIb/III



Rule 20: Invasive devices with respect to body orifices, [...] intended to administer medicinal products by inhalation are classified as Class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they are classified as Class IIb



Rule 21: Devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, or applied on skin and that are absorbed by or locally dispersed in the human body – Class IIa/IIb/III



Rule 22: Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as Class III - Upclassification from Class IIb to Class III



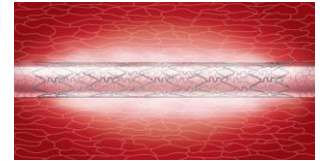
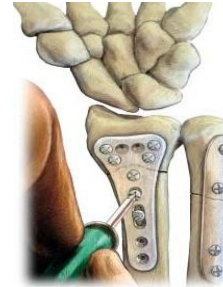
Article 1 – Scope – Annex XVI – No medical purpose

- **Contact lenses** or other articles intended to be introduced into or onto the eye;
- Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of **modifying the anatomy or fixation of body parts** with the exception of tattooing products and piercings;
- Substances, combinations of substances, or articles intended to be used for **facial or other dermal or mucous membrane filling** by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing;
- **Equipment** intended to be used to **reduce, remove or destroy adipose tissue**, such as equipment for liposuction, lipolysis or lipoplasty;
- High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light **equipment**, for **skin resurfacing, tattoo or hair removal** or other skin treatment;
- **Equipment** intended for **brain stimulation** that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

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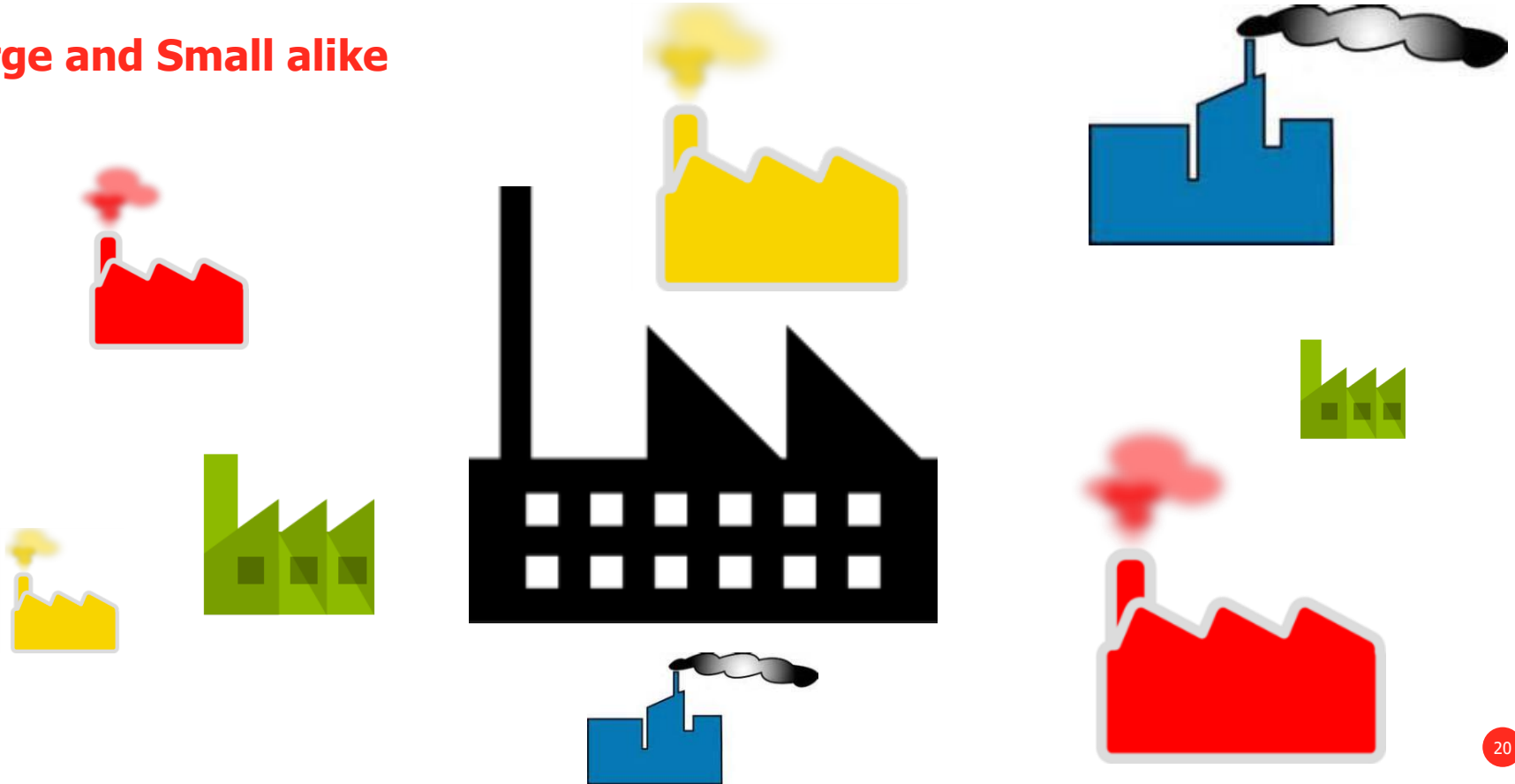
What and Who is impacted?

All Devices



All Manufacturers

Large and Small alike



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Conclusions and More Resources

Conclusions

- Become familiar with the MDR.
- Conduct MDR impact assessment on your business.
- Do your due diligence now:
 - TeamNB website: Lists members with intention to apply for MDR/IVR designation
 - NANDO website: Lists NB's and current designation scope.

http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.pdf&refe_cd=93%2F42%2FEEC&requesttimeout=900

Plan how to:

- Maintain MDD in your organization till end of grace period.
 - Implement MDR in your organization.
 - Handle Significant changes & Intended Use changes from Date of Application
 - Implementation of PMS, Vigilance, Registration, Incident Reporting and Responsible Person from Date of Application
 - Continuously check for changes to: Common Specifications, Implementing Acts and Delegated Acts as and when published.
- Hire competent people.

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

Please ask if you want any extra information from BSI.

