Your Regulatory Partner

MDR – 9 months to go
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MDR – 9 months to go
Status and some reflections

- DoA was postponed by corr. 2 in April 2020 to 26 May 2021
- Upclassified class I devices postponed to 26 May 2024
  - PMS, Vigilance apply, registration of EO still apply from DoA

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MDR – 9 months to go
Status and some reflections

- MDR Notified Bodies (16)

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 1912	DARE!! Services B.V.	Netherlands
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 2460	DNV GL Presafe AS	Norway
NB 0297	DQS Medizinprodukte GmbH	Germany
NB 0459	GMED	France
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 2862	Intertek Medical Notified Body AB	Sweden
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

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MDR – 9 months to go
Status and some reflections

Notified Bodies

- Availability
- Check their scope
- Pricing

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IVDR – 21 months to go
Status and some reflections

- IVDR Notified Bodies (4)

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	United Kingdom
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

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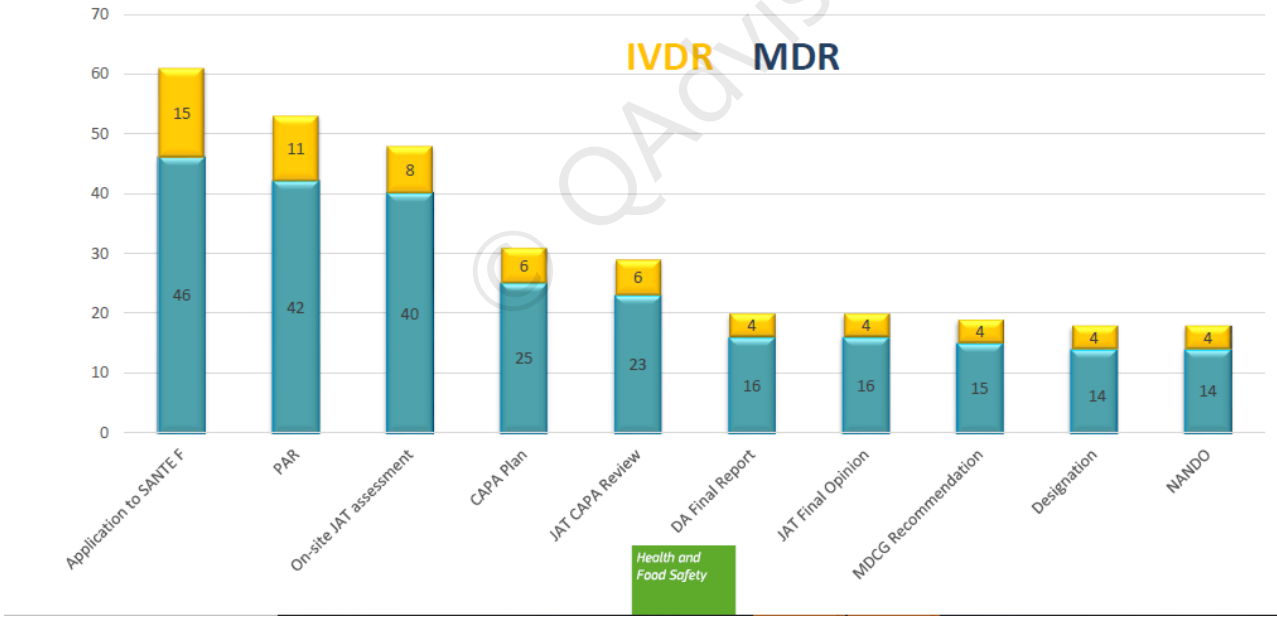
MDR – 9 months to go
Status and some reflections

4.5 Notified Bodies under MDR/IVDR (SANTE F)

- **Joint Assessment Progress Report (update 22nd June 2020)**



Graph issued by EU Commission

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IVDR – 21 months to go
Status and some reflections

Lobbying ongoing to extend DoA for IVDR

- Lack of NB
- Lack of guidance
- Covid-19
- Common Specifications
- European Reference Labs
- Risk EU loose many non-EU made devices

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MDR – 9 months to go
Status and some reflections

New/revised guidance docs by MDCG

- Ca 40 guidances + ca 20 for NBs
  - Clinical, UDI, Eudamed, SW, General
- Ca 30 more guidances planned

Some are useful some are not

https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

Upgraded website at EU COM with useful information

https://ec.europa.eu/health/md_sector/overview_en

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MDR – 9 months to go
Status and some reflections

MDCG - Medical Device Coordination Groups

- 11 - In vitro Diagnostic Medical Devices (IVD)
- 01 - Notified Bodies Oversight (NBO)
- 03 - Clinical Investigation and Evaluation (CIE)
- 09 - Unique Device Identification (UDI)
- 02 - Standards
- 04 - Post-Market Surveillance & Vigilance (PMSV)
- 07 - New Technologies
- 05 - Market Surveillance
- 12 - Nomenclature
- 13 - Annex XVI
- 08 - EUDAMED
- 06 - Borderline and Classification (B&C)
- 10 - International Matters

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MDR – 9 months to go
Status and some reflections

Harmonized standards

- Likely no standards harmonized to MDR & IVDR before 26 May 2021
- A new mandate for EU COM needs to be formed and approved, beginning 2021
- Compliance with Regulations can be demonstrated anyway - but more complex for Mfg and NB&CA
- Guidance to be issued by EU COM

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MDR – 9 months to go
Status and some reflections

Other

- UK Brexit?
- UK RP?
- Swiss AR and Importer?
- Turkey?

MDR – 9 months to go
Status and some reflections

- Keep calm
- Continue the good work
- Be prepared to adjust based on new info
- No one has all the answers
- Discuss with colleagues and seek advice
- Prepare your organization to manage the gray

The art of Regulatory

Managing the 100 shades of gray

- R&D is science
- Quality is common sense
- Regulatory is politics