MDR & IVDR Implementation

Thursday 11 March 2021

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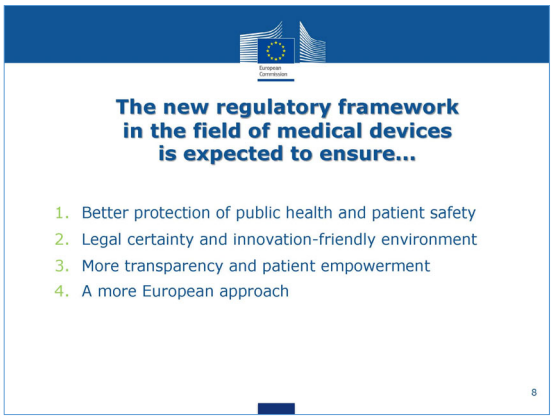
MDR & IVDR Expectations



2

MDR & IVDR Expectations

1. Better protection of public health and patient safety

- Strict pre-market control of high-risk devices with involvement of experts
- Inclusion of certain aesthetic devices
- Reinforced designation and oversight of Notified Bodies
- Reinforced rules on clinical evaluation and clinical investigation
- Strict rules for substance-based devices
- Strict rules for use of hazardous substances
- Introduction of UDI

2. Legal certainty and innovation-friendly environment

- Use of 'regulation' as a regulatory tool
- Clarification of scope for both MD and IVDs
- Stronger role for the Commission on the regulatory status of products
- Clarification of regime applicable to devices manufactured and used in the same healthcare institution
- Clarification of responsibilities of economic operators
- New rules for software / apps

3. More transparency and patient empowerment

- Establishment of EU database on medical devices (EUDAMED) with a large part to be made publicly available
- Introduction of an implant card to be provided to patients
- Summary of safety and performance for all Class III and implantable devices available in EUDAMED
- New obligations for manufacturers and authorised representatives aimed at protecting consumers / patients

4. More European approach

- Registration of devices and economic operators at the EU level
- Improved coordination between Member States in the fields of vigilance and market surveillance
- Confirmation and strengthening of the EU joint assessment procedure for notified bodies
- Introduction of a coordinated assessment of clinical investigations conducted in more than one Member State

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MDR & IVDR Implementation

Agenda:

1. Reinforced designation and oversight of Notified Bodies
2. Use of 'regulation' as a regulatory tool
3. Reinforced rules on clinical evaluation and clinical investigation

… priorities in the plan

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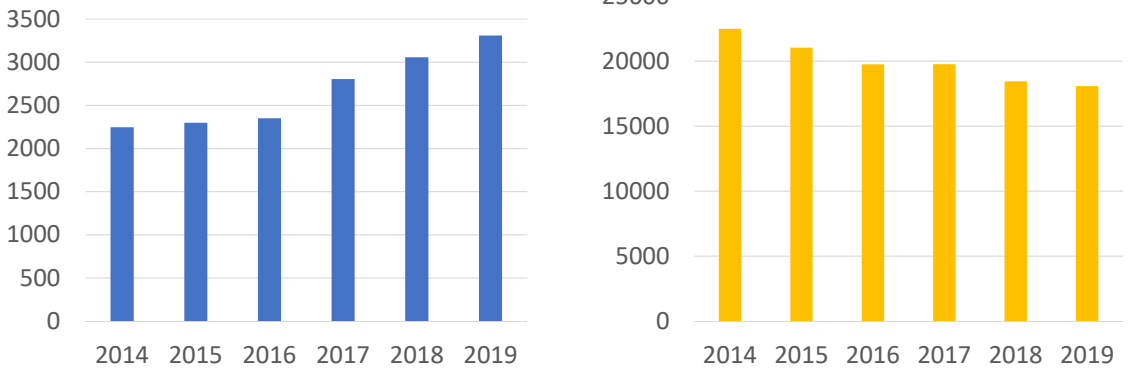
1. Notified Bodies – Resource

N=26 NBs



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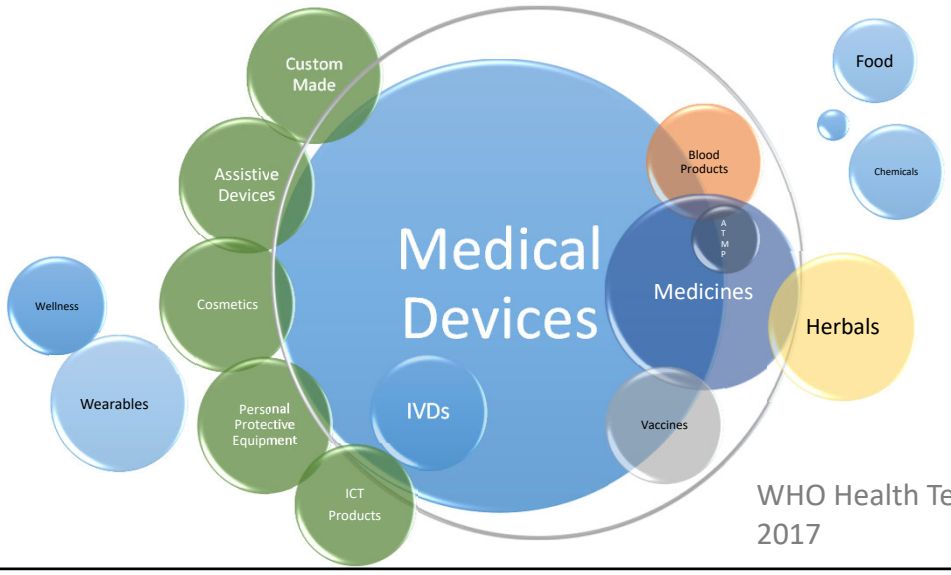
1. Resource



WHO Health Technologies 2017

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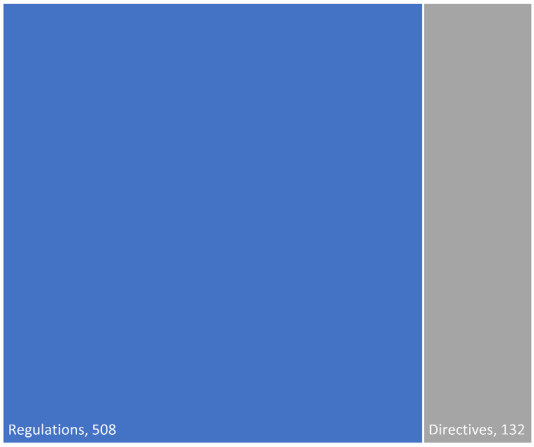
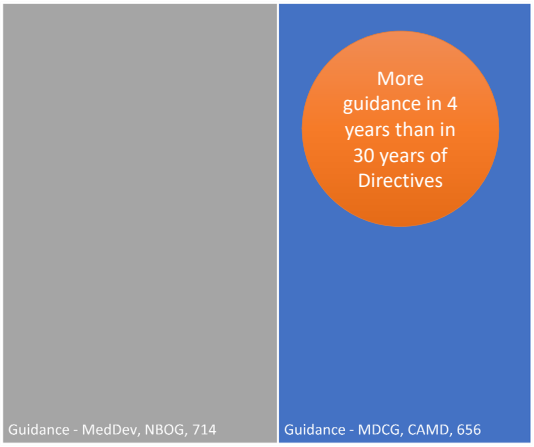
2. Regulation





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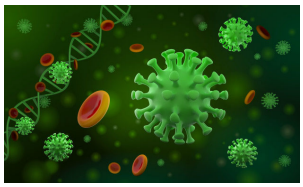
2. Regulation – Remote Audits

IAF ID3 2011, ID4 2018, ID12 2015
UKAS TPS 62 2016



Audits postponed in North America
Mar 2020

Audits postponed in Europe
Feb 2020

Audits postponed in China
Jan 2020

MDSAP Transmittal
2020 03, 04 & 05

MDCG 2020-4

UKAS TPS 73

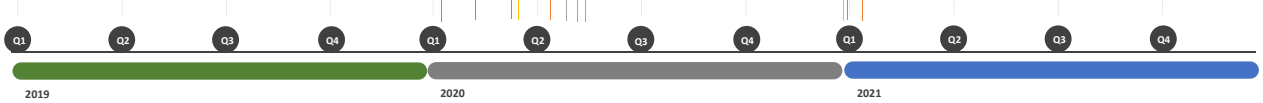
SCC 2020 12

RvA T051

MDSAP Transmittal
2020 10

MDCG 2020-17

Commission Notice
2021/C 8/01



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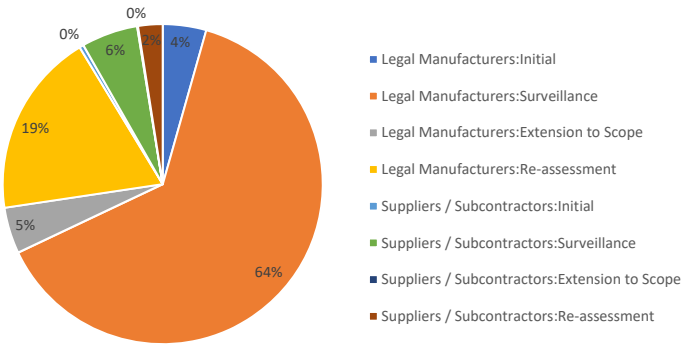
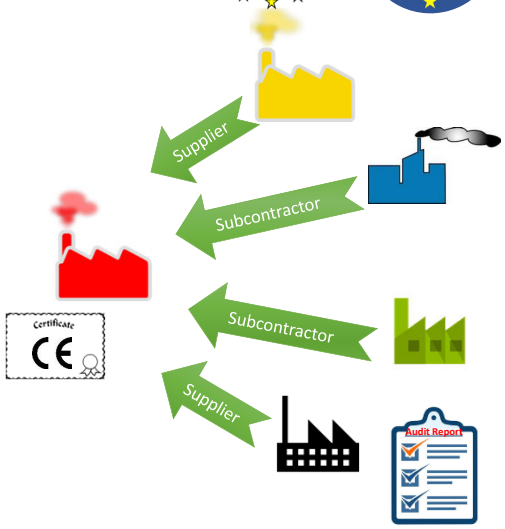
2. Regulation – Remote Audits n=37 – Nov 2020

How many audit days has your Notified Body completed remotely (AIMDD/MDD/IVDD)?





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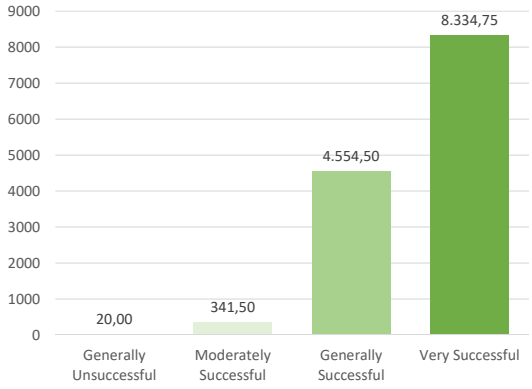
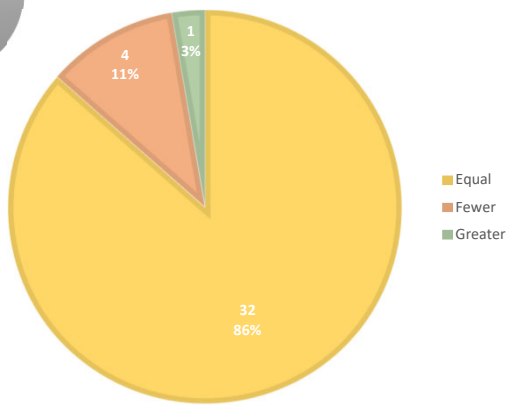
2. Regulation – Remote Audits n=37 – Nov 2020

Total Number of Days of Remote Audits vs Experience of Remote Auditing



>13,000 days

OF NCS – ON SITE COMPARED TO REMOTE



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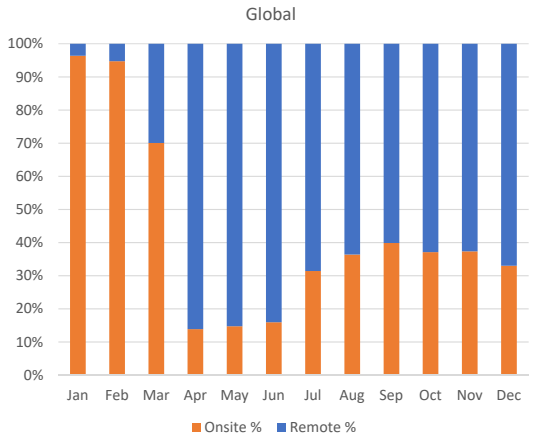
2. Regulation – Remote Audits



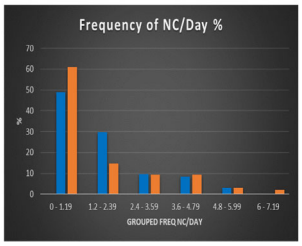


Figure 2 Grouped frequency data Remote (Blue) and Onsite (Orange)

n=100 remote & on site – Stage 2, CAV, re-assessment

Figure 6 Average NC/Day per clause for remote cohort (Blue) and onsite (Orange)

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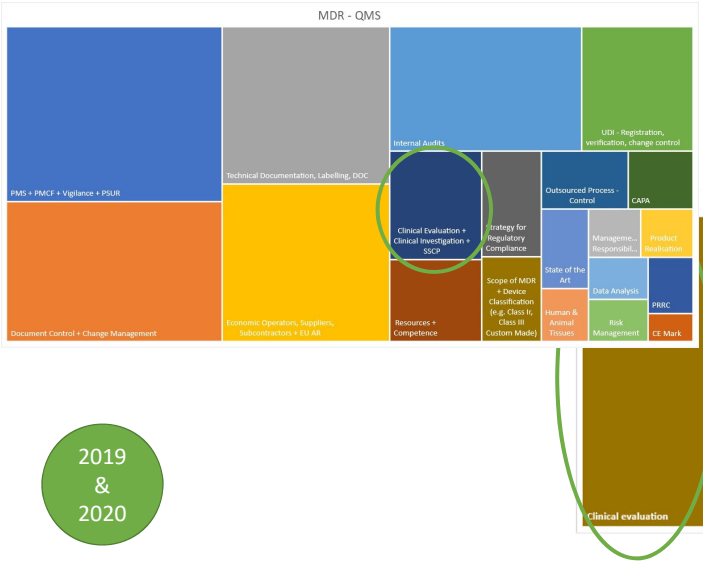
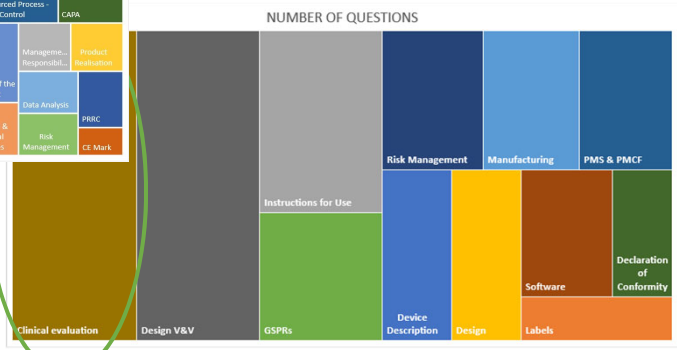
3. Reinforced Rules on Clinical / Performance





2019 & 2020

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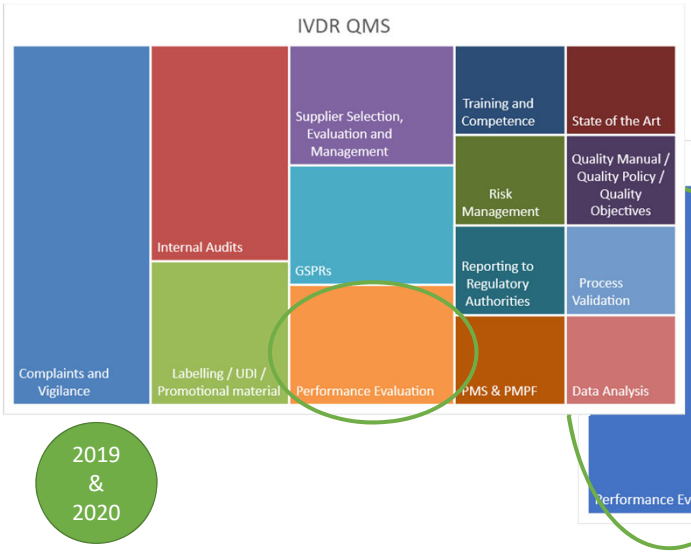
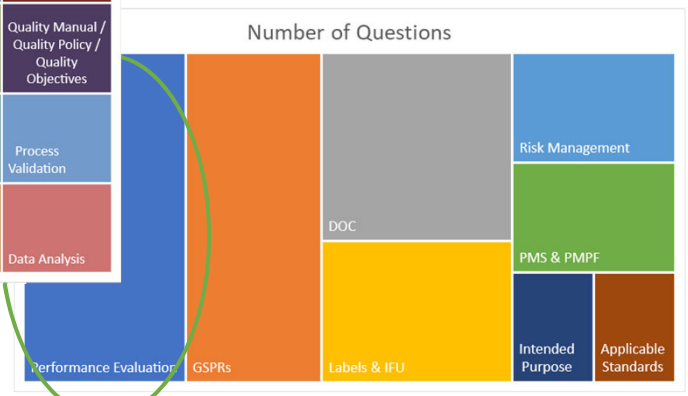
3. Reinforced Rules on Clinical / Performance





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MDR & IVDR Expectations

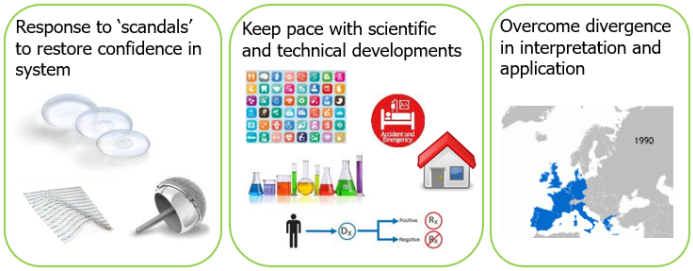
Meeting of Medical Device Competent Authorities and Notified Bodies – Brussels, 27 October 2016

Keynote speech by Director Carlo Pettinelli at the meeting with Medical Device Competent Authorities and Notified Bodies Brussels, 27 October 2016

Ladies and Gentlemen,

I would like first of all to thank all of you for being here today and for accepting the Commission's invitation. This is the first official meeting with all Competent Authorities and Notified Bodies following the agreement on the new texts in June.

And I was particularly keen to ensure that the first official presentation of the European Commission on the new Regulations took place today, before any other external occasion. This is because the Commission is aware that smooth implementation of the new system relies on three basic actors: the European Commission, the Member States and the Notified Bodies. Good and continuous cooperation among these three actors is the **real key to guarantee a successful implementation**.



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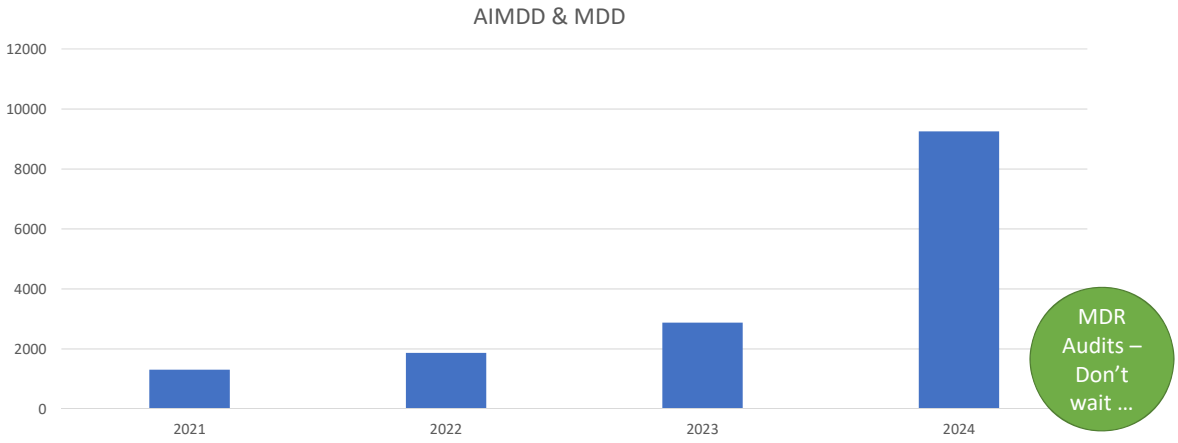
Expiring Certificates n=21 – Jan 2021



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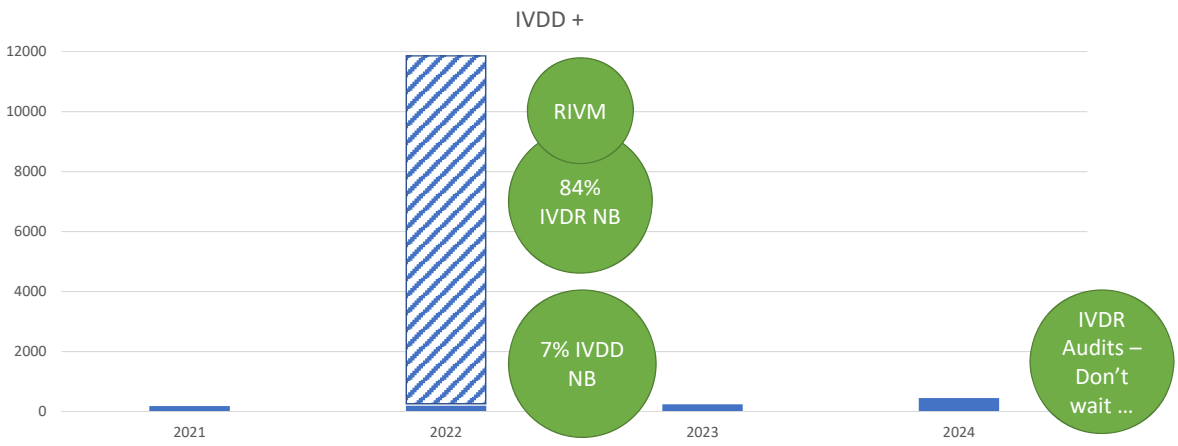
Expiring Certificates n=21 – Jan 2021



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Questions & Answers