MDR by the Numbers

Michelle Lott, RAC
Principal & Founder, leanRAQA

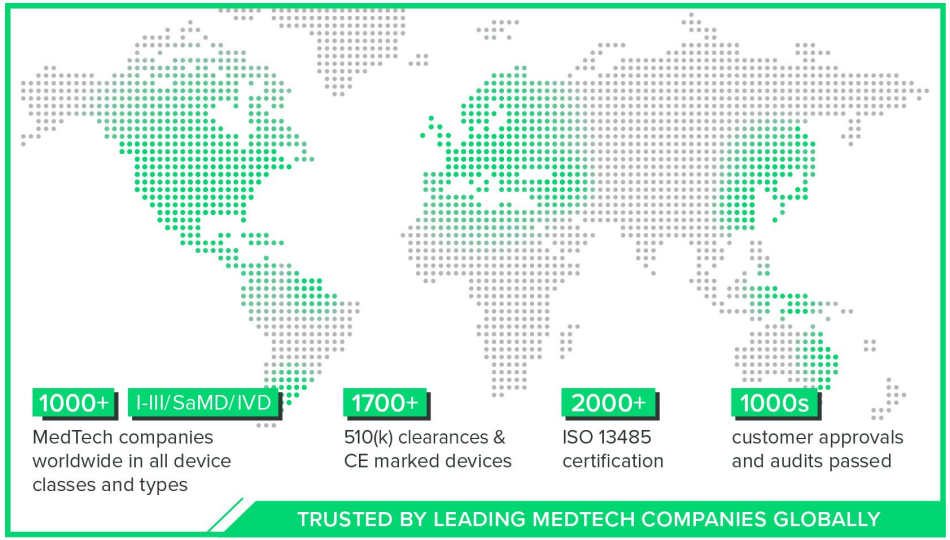
MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

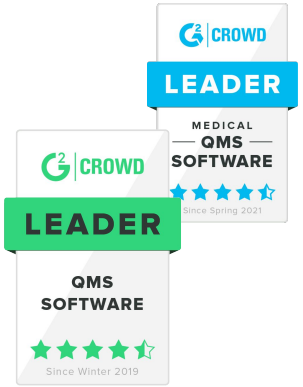
100+
years industry experience

522k
podcast listeners

200k+
look to us for the latest in quality

#1
blog and podcast in the industry





"Best eQMS I have ever used..."

This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry. ***It is simple, intuitive and easy to use...*** We are successfully implementing a Quality Culture.

- Director of Regulatory Affairs & Quality Assurance

"Modern QMS Software and Outstanding Customer Service."

★★★★★

"Demystifying QMS and Regulatory Requirements"

★★★★★

"Makes your QMS Simple and Effective"

★★★★★

greenlight guru

About leanRAQA

- Expert in RAQA for >20 years
- Advisor on FDA GMP Advisory Committee
- Master Grief Counselor

Michelle Lott
Principal and Founder

Morty
Chief **E**ntertainment **O**fficer

Chopper
Chief **F**un **O**fficer

Lucy
Chief **T**herapy **O**fficer

Lilly King
Chief **C**hewing Officer

Agenda

- *Where We Stand*
- *Theory of Constraints*
- *What Happened to Harmonization?*
- *Second Verse, Same as the First*
- *MDCG Guidance*
- *TeamNB Position Papers*
- *Final Thoughts on MDR*

To prepare this presentation*

- **People interviewed** ***n*** **= 20 NBs**
  - From industry: **15**
  - From Notified Bodies: **5**
- **Hours interviewing people and collecting experiences: 80+**

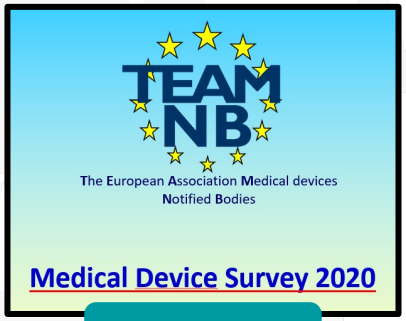
MedTech Europe Survey Report, July 2022

MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation

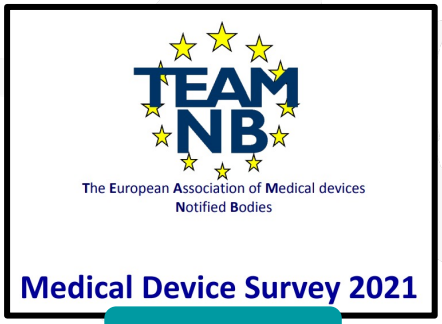
n **= 475 responses**

n **= 47 responses**

Notified Body Survey on Certificates and Applications, October 2022



n **= 26 NBs**



n **= 30 NBs**

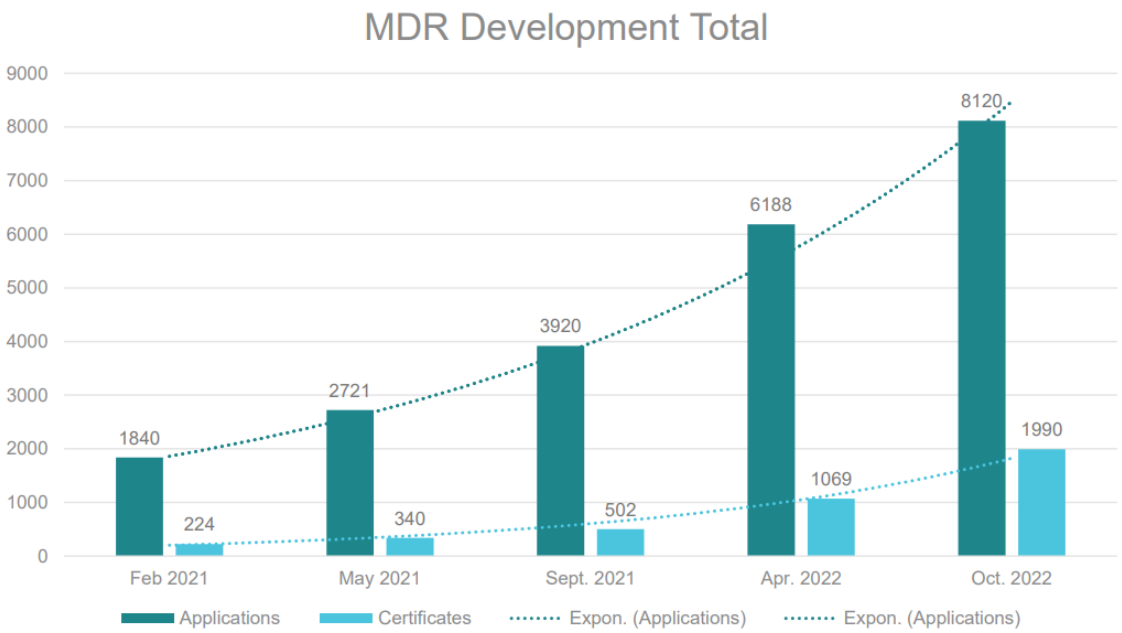
TeamNB surveys 2020 and 2021

*Information is current to the best of our knowledge as of this webinar but is subject to change.

Where We Stand

A Growing Problem

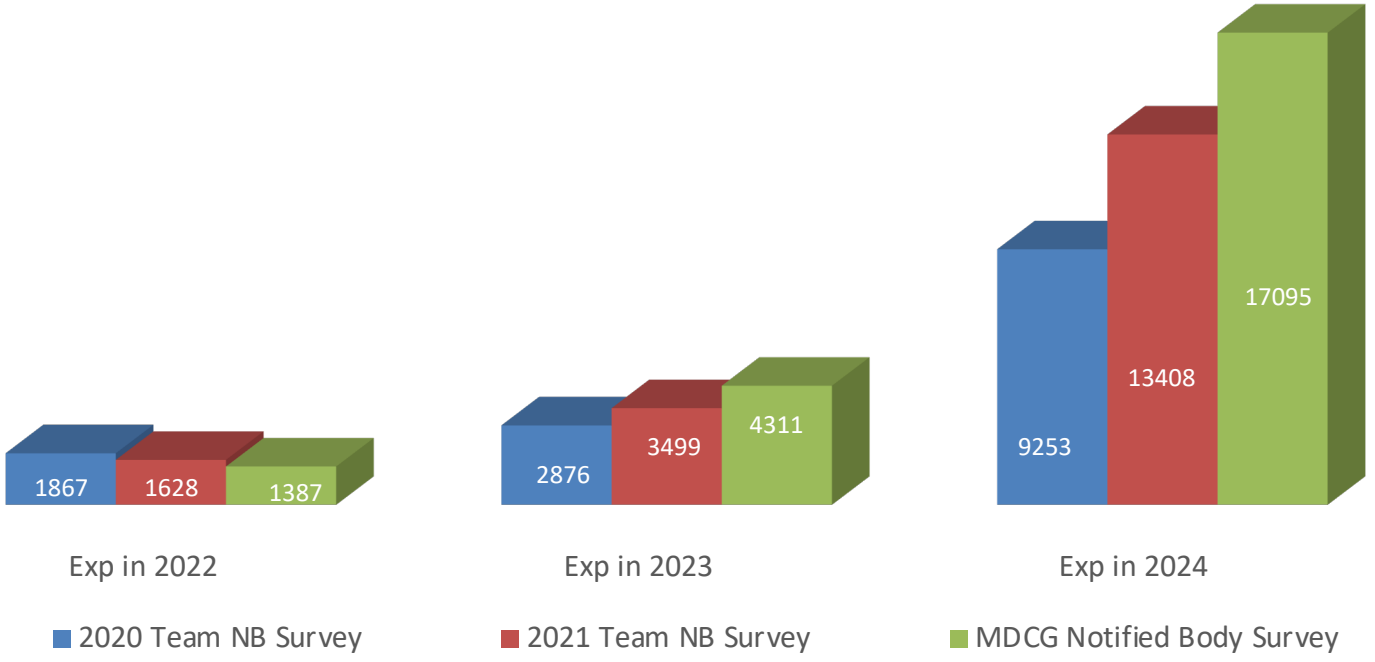
MDR Applications filed and Certificates issued



Notified Body Survey on Certificates and Applications, October 2022

A Tale of Three Surveys

Expiring MDD and AIMDD certificates (by year)

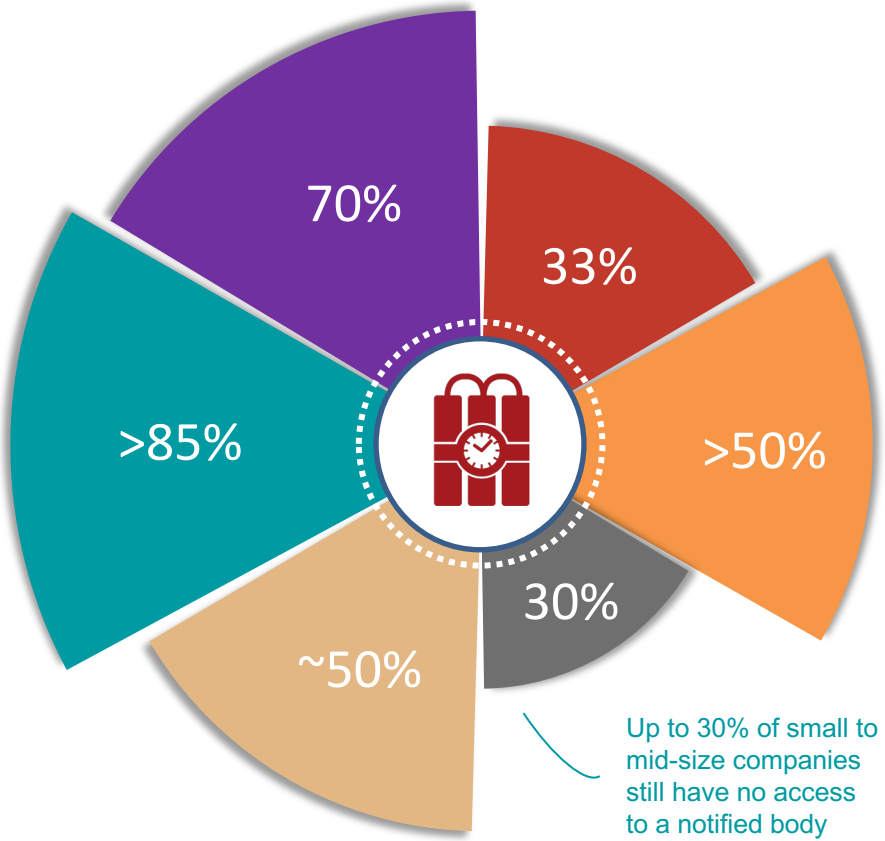


TeamNB surveys 2020 and 2021

MDCG Notified Body Survey, October 2022

MDR by the Numbers

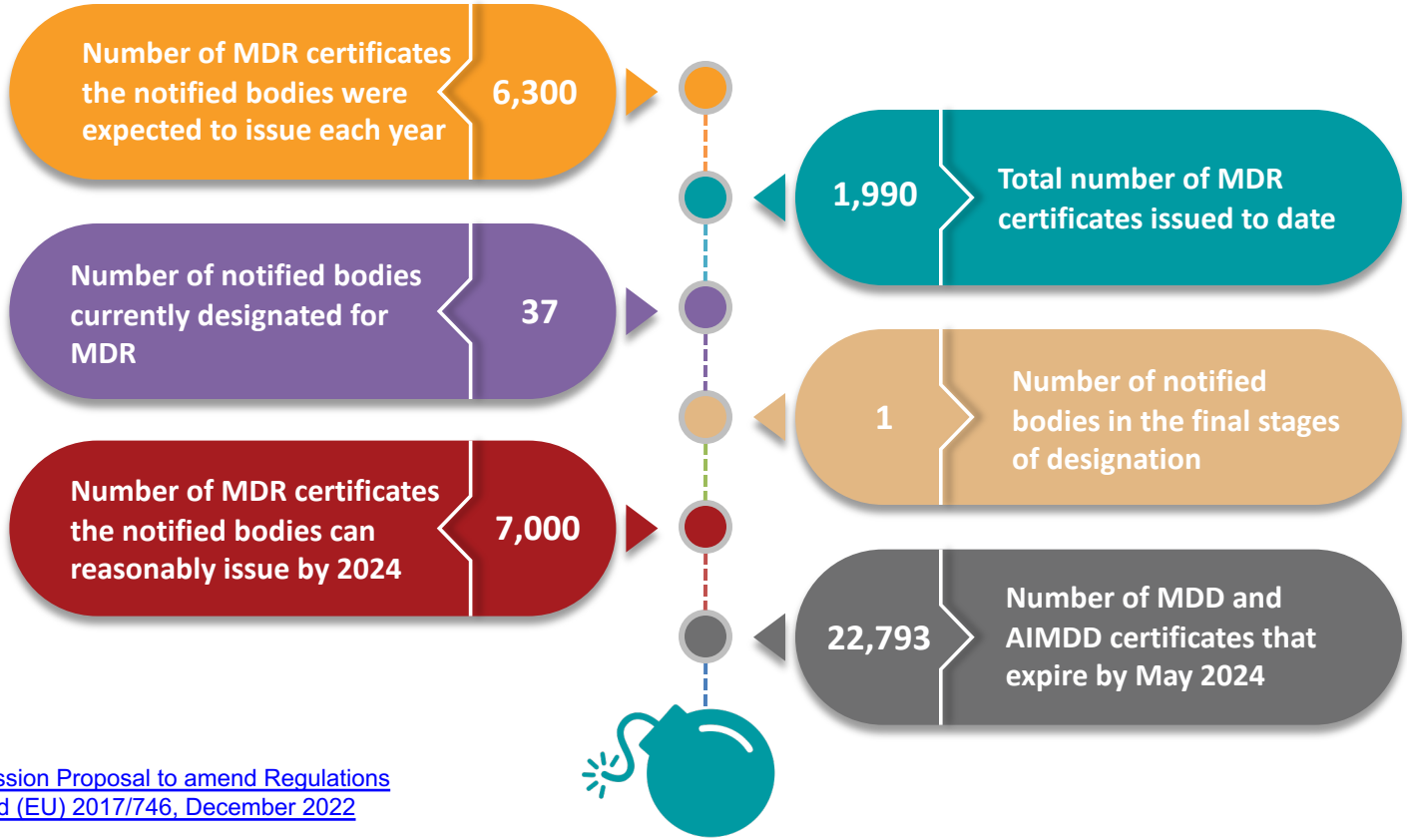
- >85% of MDR certificates pending for the >500,000 devices previously certified under MDD or AIMDD
- 70% of submitted industry applications are still under review
- >50% of companies surveyed are planning portfolio reductions
- 33% of the devices sold by some companies surveyed will be discontinued
- ~50% of companies are deprioritizing the EU as their market entry point



Up to 30% of small to mid-size companies still have no access to a notified body

*MedTech Europe Survey Report, July 2022

MDR by the Numbers

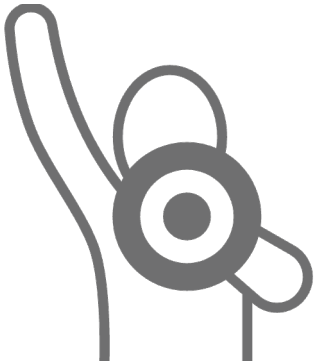


European Commission Proposal to amend Regulations (EU) 2017/745 and (EU) 2017/746, December 2022

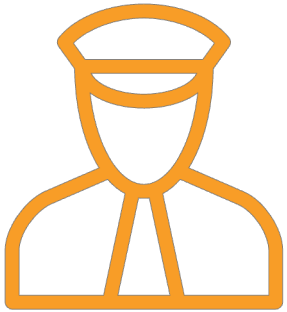
Theory of Constraints

Three Stake Holders

Industry

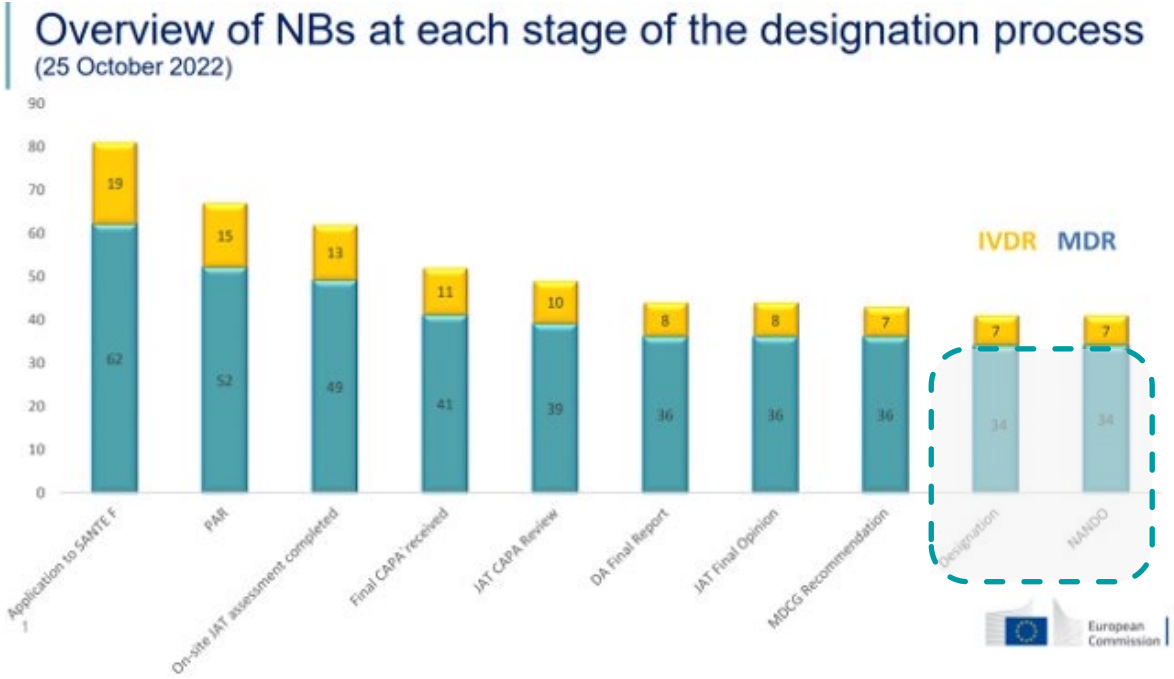


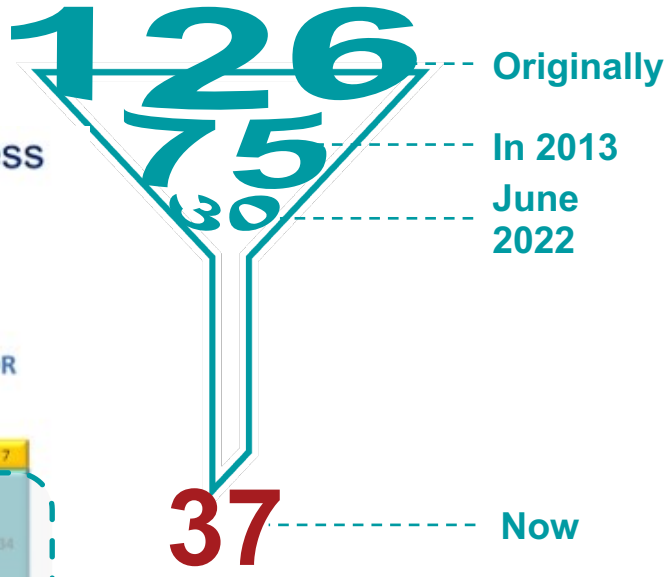
Competent Authorities



Notified Bodies

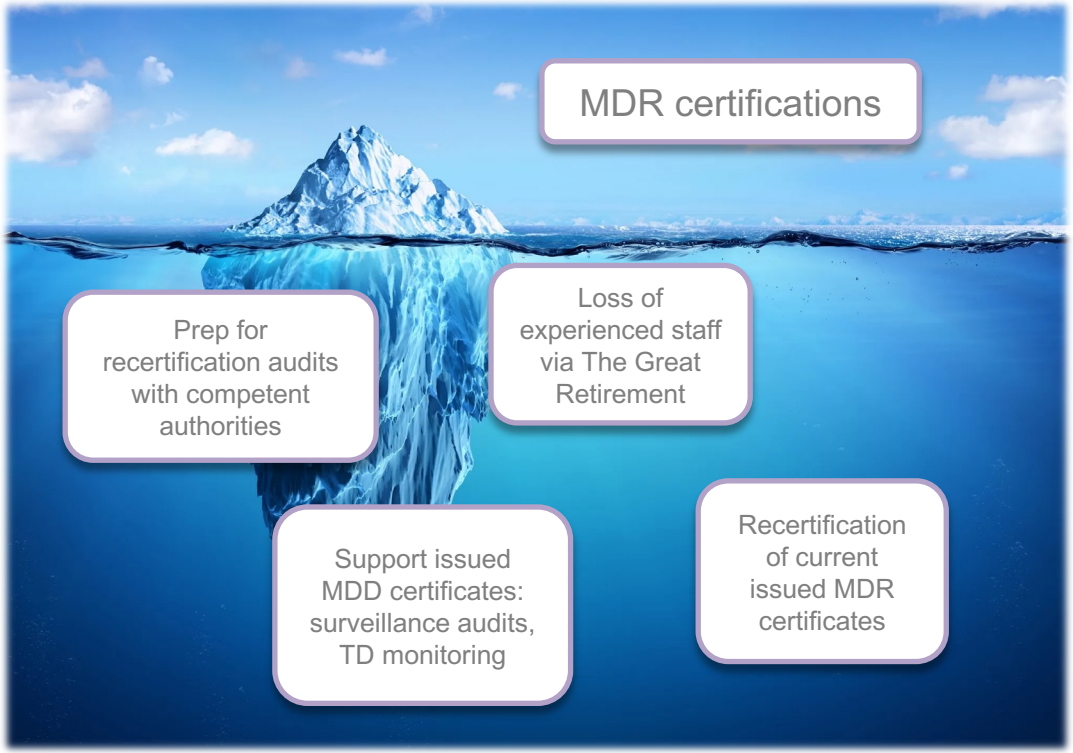
Reduction of NBs designated under MDD to MDR





Source: [European Commission update, October 2022]

Notified bodies are trying not to drown…



Main Challenges for Manufacturers

Clinical Evaluation, Testing and Verification Requirements

Requirements for Legacy Devices

Establishing a Quantitative Benefit-Risk Ratio

EUDAMED

Volume of Guidance Documents/Duplication of Effort

The Number One Problem

Why it's so challenging?

Causing:

New Biases in Review

Out of Practice Clinicians Reviewing Newest Technology

Clinicians Stuck Behind Desk Instead of Treating Patients

The Reviews Are In

The Reviews Are In

NOW PLAYING: MDR!

"The EU is headed for a problem that most people don't know they have" *a concerned citizen*

"This is going to be a six-figure problem"
someone who knows what he's talking about

"The MDR has this hare-brained, stupid rule in it" *every regulatory consultant ever*

"Seek not to be understood but to understand" *St. Francis*

Still a Major Cluster

What Happened to Harmonization?

EU diversity: A complicated picture

CE

EEA

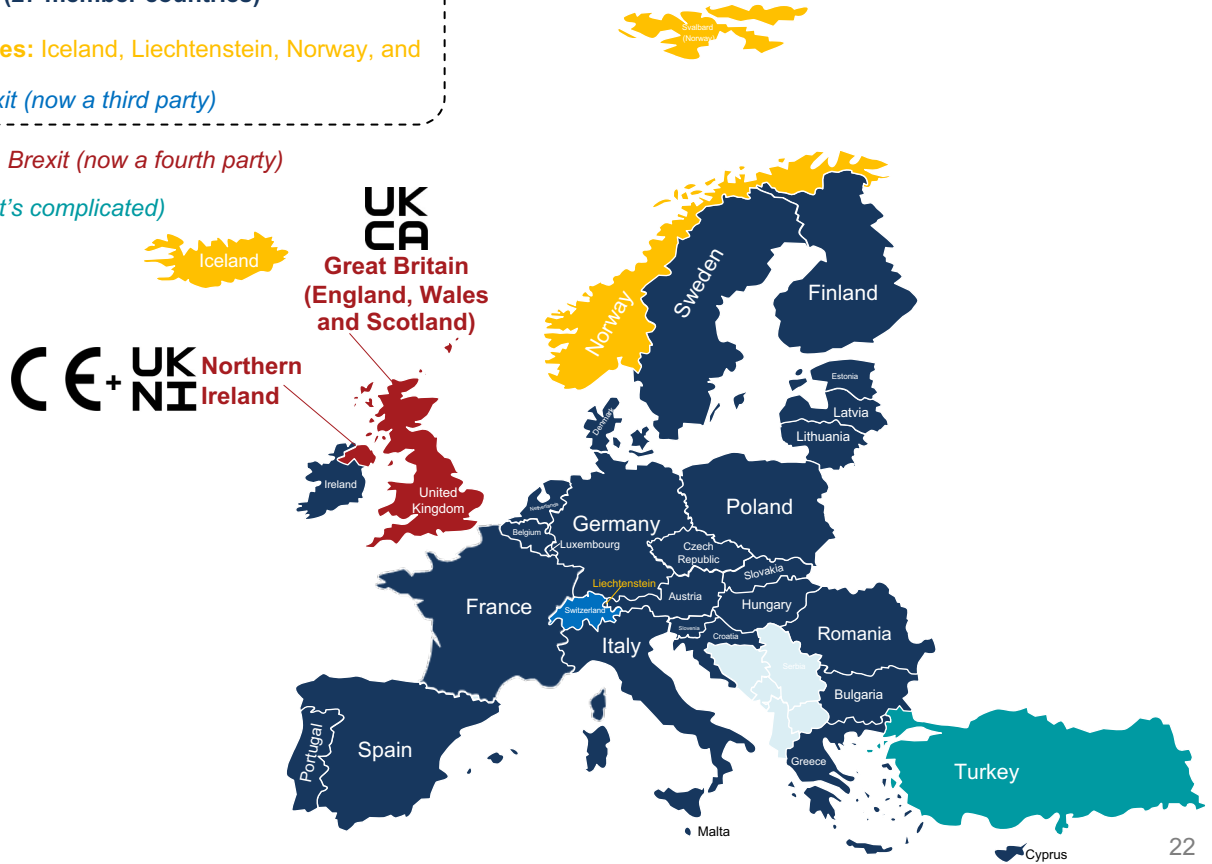
EU Member States (27 member countries)

EFTA Member States: Iceland, Liechtenstein, Norway, and

Switzerland → *Swixit (now a third party)*

United Kingdom → *Brexit (now a fourth party)*

Turkey → *Turkxit? (it's complicated)*



UKCA update

Extended deadlines:

- If continuing to place CE marked products on the GB market until the 31 December 2024:
  - UK product regulations are amended, you will have the flexibility to choose between the UKCA and CE markings
  - EU regulations are amended, you will need to follow the EU regulation as it applied on 31 December 2020 to supply those goods to the GB market using the CE marking or meet the UK regulation and place a UKCA mark on the product
  - GB will also allow conformity assessment activities for CE marking undertaken by 31 December 2024 to be used by manufacturers as the basis for the UKCA marking, until 31 December 2027.

UKCA update

- July 2024 is for the start of UKCA as mandatory for UK.
  - In an non-official response made by the UK government, they said that they will try to have a transition period of 3-5 years for products that are already registered in the UK under CE marking or UKCA.
  - Any **significant changes of your product after July 2024** will require UKCA immediately
    - Need an Approved Body to get this marking and there are only 4 approved bodies
- To reduce labelling costs, GB will allow businesses to affix the UKCA marking and include importer information for products from EEA countries on an accompanying document or label until 31 December 2027.

The Switzerland Story

"(The) Parliament's instructions to the Federal Council…enable Switzerland to accept medical devices with FDA approval for the welfare of its own population. Until now, healthcare providers and patients in Switzerland have only had access to medical devices with an EU certificate. It is essential that the order be implemented swiftly and pragmatically. Waiting cannot be an option if patient safety is at risk"

Swiss-MedTech, November 28, 2022

FDA

The Switzerland Story

May 2020

Swiss Councillor Damian Müller recommends allowing FDA cleared devices to mitigate delays and device access roadblocks introduced by MDR

May 2021

MDR goes into full effect. A 3-year transition period is granted to allow notified bodies sufficient time to certify all devices with expiring MDD certificates

May 2021

Switzerland's Mutual Recognition Agreement with the EU expires and is not renewed

Oct 2022

Team NB survey indicates that only 1,990 MDR certificates have been issued to date. This contradicts EC prediction of *6,300 certificates per year*

Nov 2022

Swiss Parliament National Council votes to adapt Swiss law to allow FDA 510(k) approved devices on the Swiss market (as well as CE-marked devices)

Early 2023

Swiss Federal Council meets to write and enact the new legislation

December 2022: EC proposes three-year extension of MDR transition timeline due to lack of sufficient NB and support infrastructure

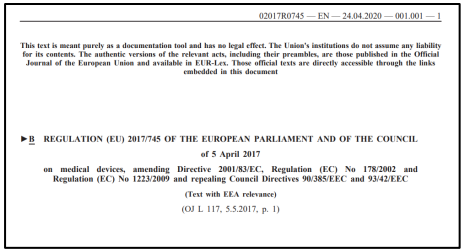
What Union?

- **France, Germany and Ireland proposed postponing the MDR deadline beyond May 2024**
  - Manufacturers, trade groups and regulators have raised concerns about the capacity of the notified bodies to handle the workload

- This is NOT the harmonized regulatory landscape the EC envisioned, especially among EU member states

Second Verse, Same as the First

The See-Saw of Indecision



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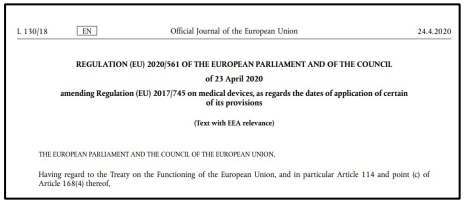
This text is meant purely as a documentation tool and has no legal effect. The Union's institutions do not assume any liability for its contents. The authentic versions of the relevant acts, including their preambles, are those published in the Official Journal of the European Union and available in EUR-Lex. Those official texts are directly accessible through the links embedded in this document

►B REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017
on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
(Text with EEA relevance)
(OJ L 117, 5.5.2017, p. 1)

"The necessary common specifications shall be adopted by 26 May 2021." (April 2017)



L 130/18 EN Official Journal of the European Union 24.4.2020

REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 23 April 2020
amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and point (c) of Article 168(4) thereof,

"…it is appropriate to defer the application of those provisions of Regulation (EU) 2017/745 by one year" (April 2020)

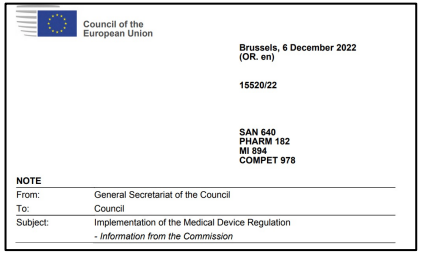
MDCG 2022-11

MDCG Position Paper

Notice to manufacturers to ensure timely compliance with MDR requirements

JUNE 2022

"From 27 May 2024, the MDR will be fully applicable to all medical devices…From that date, medical devices not certified under the MDR will have no access to the EU market." (June 2022)



Council of the European Union

Brussels, 6 December 2022
(OR. en)

15520/22

SAN 640
PHARM 182
MI 894
COMPET 978

NOTE

From:	General Secretariat of the Council
To:	Council
Subject:	Implementation of the Medical Device Regulation - *Information from the Commission*

"Hold that thought….." (December 2022)

MDR is coming… or is it?

"Despite considerable progress over the past years, the overall capacity of conformity assessment ('notified') bodies remains insufficient to carry out the tasks required of them. In addition, many manufacturers are not sufficiently prepared to meet the strengthened requirements of the MDR by the end of the transition period. This is threatening the availability of medical devices on the EU market"

"After the expiry of the certificates issued under the Directives and without a valid MDR certificate, manufacturers are no longer allowed to place these medical devices on the EU market. This may cause shortages of medical devices, putting patient safety at risk. It is also likely to have a significant negative impact on innovation and business activity in the medical technology sector within the EU"

European Commission Proposal to amend Regulations (EU) 2017/745 and (EU) 2017/746, December 2022

Who, What, When and How Long?

- It applies to those manufacturers who have a signed written agreement *by September 26, 2024*
- It also applies to those manufacturers whose application has been impacted by a lack of notified body resources

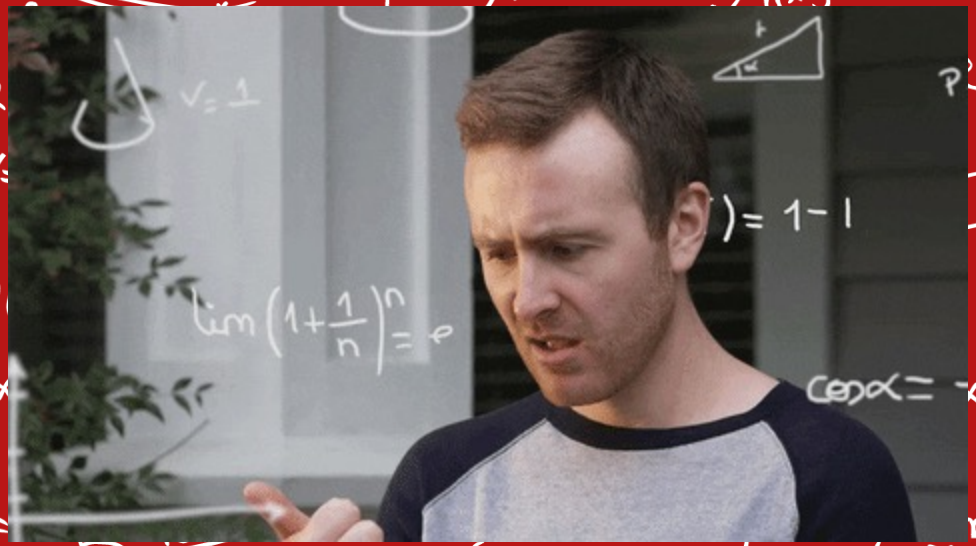
The extension ONLY applies to **legacy devices with valid MDD certificates meeting specified criteria**

The transition period is extended from 26 May 2024 until **31 December 2027 for certain higher risk devices** (class III and class IIb implantable devices unless subject to other exemptions)

The transition period is extended until **31 December 2028 for medium and lower risk devices** (other class IIb devices and class IIa, class Im, Is and Ir devices)

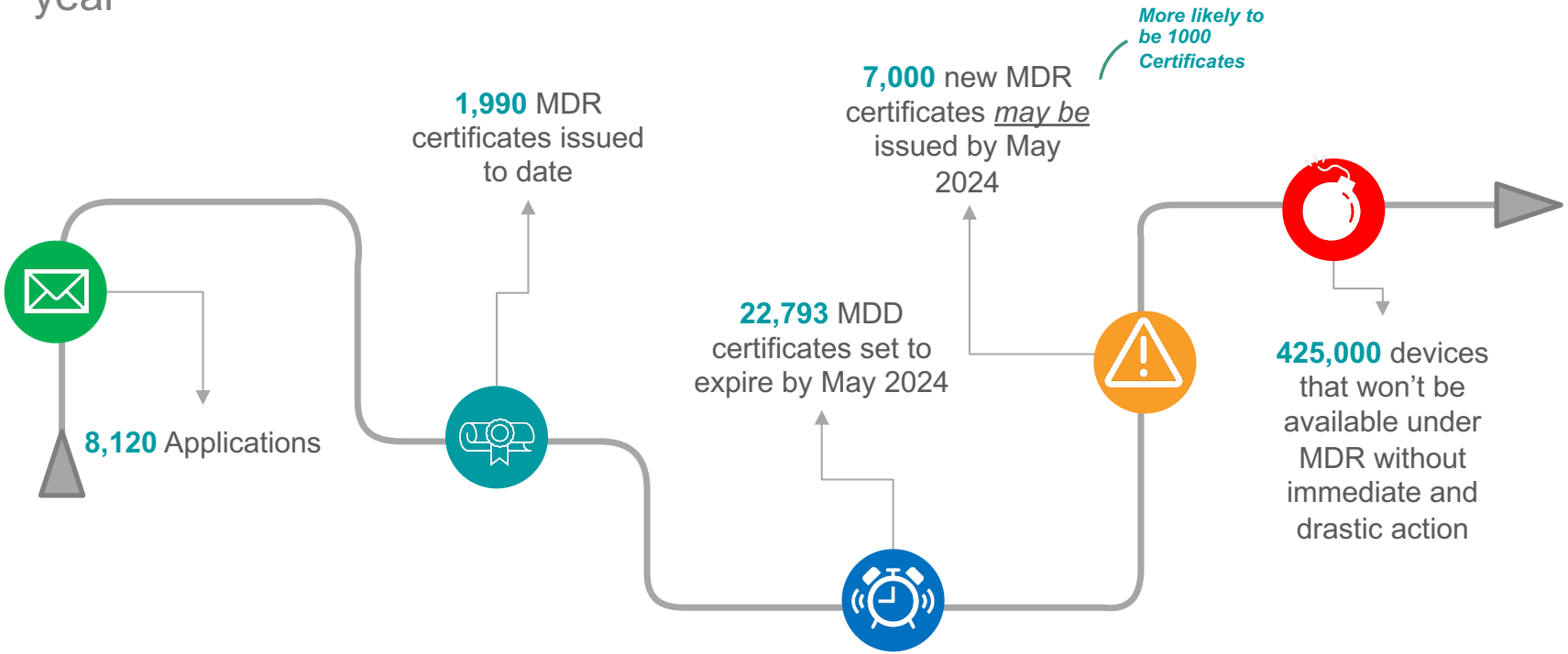
For legacy devices (still under MDD)

- ✓MDD products with active certificates must have MDR application *submitted and accepted* by a Notified Body by May 26, 2024 and *contract signed* by September 26, 2024
- ✓OR prove you have *contacted a "considerable" number* of designated notified bodies and undergo derogation process in Article 97
- ✓Must continue to comply with MDD and add QMS compliant for MDR Article 120 no later than May 26, 2024
- ✓No significant change
- ✓Do not present an unacceptable risk
- ✓No sell off date IF placed on the market before the end of the new transition period. The previous was May 27, 2025.

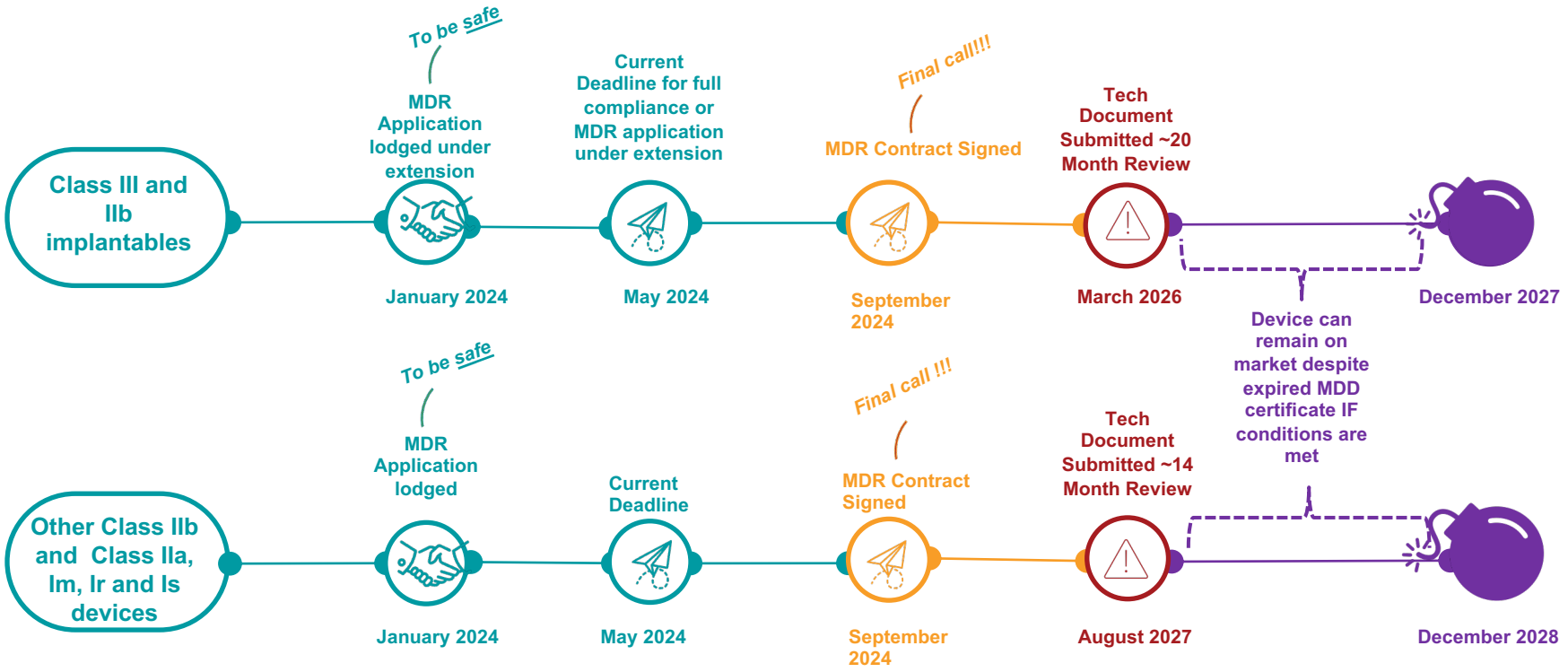


It Just Doesn't Add Up

- According to the EC, notified bodies can issue 6,300 MDR certifications per year



For legacy devices (still under active MDD certs)



Notified Bodies feel constraints remain

- Does not help with the capacity or workload and come 2028 they feel they will still be in the same boat
- They don't have visibility to the "tidal wave" coming because so many manufacturers have yet to apply for MDR
- Proposal not clear regarding MDD certificate maintenance

Bias built into the timeline?

- Creates a natural priority and pressure for Notified Bodies to process higher risk applications to meet the 2017 deadline and get to the 2018 applications later

- What about innovation? For new devices, where do you fall in the queue given that you do not have a certificate expiring? Should you actually wait to submit until 2029?

- Those who put their applications in early could potentially be penalized by this system.

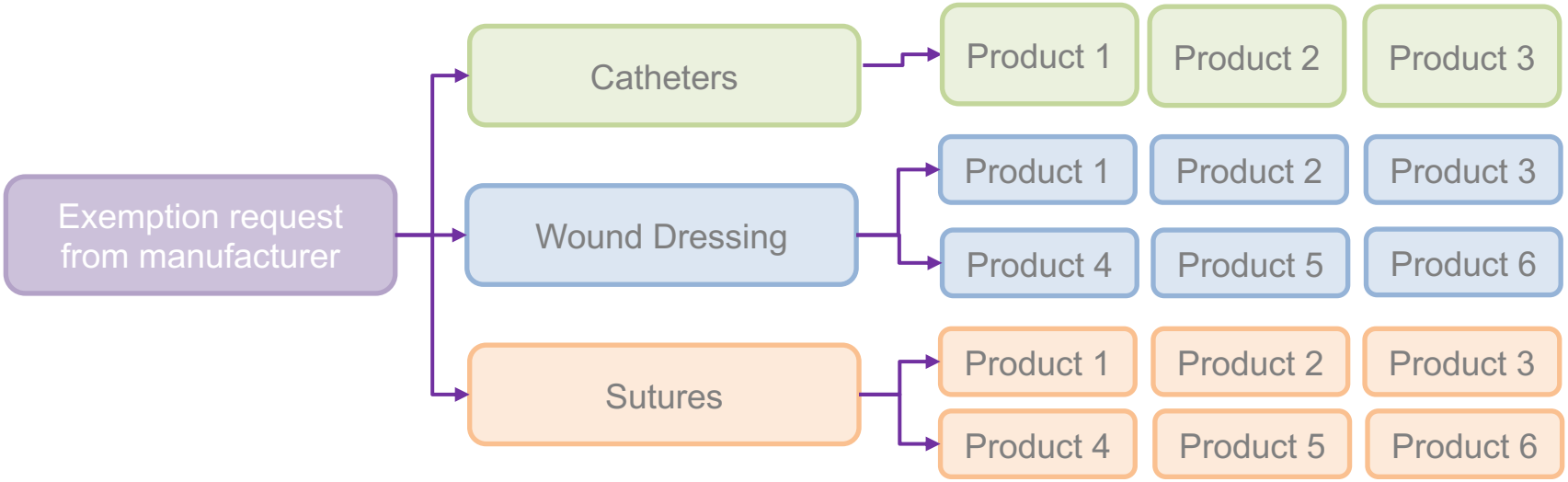
"False start. Offense. 2 years."

Two Articles Diverge in a Wood….

Article 59	Article 97
Allows **EACH** EU Member State competent authorities to decide that a device can be brought to market without a valid CE mark	Allows a **SINGLE** EU Member State competent authorities to decide that a device can remain on market without a valid CE mark
Manufacturers don't have to plan on pursuing CE marking	Manufacturers must show evidence they are working toward MDR certification
Prepare documentation to demonstrate to a national competent authority the device is compliant. Ensure post-market surveillance data of other markets, or equivalent or similar devices, is available and of high quality. Be able to demonstrate your device is of critical importance and there is no suitable alternative.	Prepare documentation per checklist in MDCG 2022-18 for demonstration to a competent authority that the device is a low-risk, legacy device. Demonstrate a "reasonable effort" to contact a "considerable number" of Notified Bodies Most applications will be given 12 month window to receive their CE Mark.

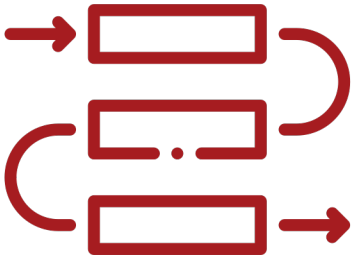
Legacy Devices and Article 97 (MDCG 2022 – 18)

- Manufacturers must file one exemption request *per product*, NOT per family



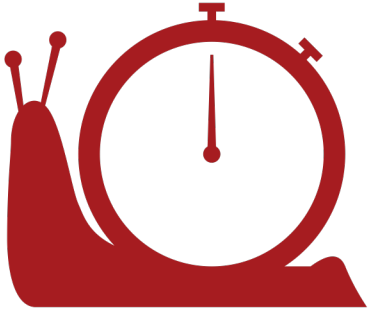
MDCG 2022-18 *Position Paper on the Application of Article 97 MDR to Legacy Devices*

Competence of Competent Authorities



No QMS of their Own

How to ensure consistency when qualifying products?



Government Bodies

Hiring is slow. Training is slow.

Change is very slow.

Smaller Budgets

How do they fund their increased role in MDR?

MDCG Guidance

MDCG Guidances – The Plan for 2023

- **MDCG guidance documents planned to be released in 2023**
  - Ongoing guidance development and deliverables of MDCG Subgroups
    - Notified Bodies Oversight
    - Standards
    - Clinical Investigations and Evaluations
    - PMSV
    - Market Surveillance
    - New Technologies
    - Eudamed
    - IVD
    - Nomenclature
    - Annex XVI

Read the MDCGs written for NBs

- **Not just the ones addressed to manufacturers**
  - Learn how *they* assess you
  - Use templates provided
  - This is how NBs reports are structured

- **These have twice as much detail as those for manufacturers**
  - *ALL* of the efforts to alleviate backlog have been directed at the notified bodies, not manufacturers
  - Use their guidance documents as your template

Notified bodies

Reference	Title	Publication
MDCG 2021-23	Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746	August 2021
MDCG 2021-18	Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/746 (IVDR)	July 2021
MDCG 2021-17	Applied-for scope of designation and notification of a conformity assessment body – Regulation (EU) 2017/745 (MDR)	July 2021
MDCG 2021-16	Application form to be submitted by a conformity assessment body when applying for designation as notified body under the in vitro diagnostic devices regulation (IVDR)	July 2021
MDCG 2021-15	Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices regulation (MDR)	July 2021
MDCG 2021-14	Explanatory note on IVDR codes	July 2021
MDCG 2020-17	Questions and Answers related to MDCG 2020-4: "Guidance on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions"	December 2020
MDCG 2020-14	Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR)	August 2020
MDCG 2020-12	Guidance on transitional provisions for consultations of authorities on devices incorporating a substance which may be considered a medicinal product and which has action ancillary to that of the device, as well as on devices manufactured using TSE susceptible animal tissues	June 2020
MDCG 2020-11	Guidance on the renewal of designation and monitoring of notified bodies under Directives 90/385/EEC and 93/42/EEC to be performed in accordance with Commission Implementing Regulation (EU) 2020/666 amending Commission Implementing Regulation (EU) 920/2013	May 2020
MDCG 2020-4	Guidance on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions	April 2020
MDCG 2020-3	Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD	March 2020
MDCG 2019-14	Explanatory note on MDR codes	December 2019
MDCG 2019-13	Guidance on sampling of devices for the assessment of the technical documentation	December 2019
MDCG 2019-12	Designating authority's final assessment form: Key information (EN)	October 2019
MDCG 2019-10 rev.1	Application of transitional provisions concerning validity of certificates issued in accordance to the directives	October 2019
MDCG 2019-6 v2	Questions and answers: Requirements relating to notified bodies	October2019
MDCG 2018-8	Guidance on content of the certificates, voluntary certificate transfers	November 2018
NBOG BPG 2017-2	Best practice guidance on the information required for personnel involved in conformity assessment	February 2018
NBOG BPG 2017-1	Best practice guidance on designation and notification of conformity assessment bodies	February 2018
NBOG F 2017-8	Review of qualification for the authorisation of personnel (IVDR)	February 2018
NBOG F 2017-7	Review of qualification for the authorisation of personnel (MDR)	February 2018
NBOG F 2017-6	Preliminary assessment review template (IVDR)	February 2018
NBOG F 2017-5	Preliminary assessment review template (MDR)	February 2018

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

Notable MDCG Guidances

For Notified Bodies

- MDCG 2019-6 (Rev 4): Requirements relating to Notified Bodies (Oct 2022)
- MDCG 2022-13: Designation, re-assessment and notification of conformity assessment bodies and notified bodies (Aug 2022)
- MDCG 2022-4: Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD (Dec 2022)
- MDCG 2022-14 Position Paper: Transition to the MDR and IVDR – NB capacity and availability of medical devices and IVDs (Aug 2022)

For Manufacturers

- MDCG 2022-11 Position Paper: Notice to manufacturers to ensure timely compliance with MDR requirements (June 2022)

MDCG Guidances for Notified Bodies

- **For Notified Bodies**
  - MDCG 2019-6 (Rev 4): Requirements relating to Notified Bodies (Oct 2022)
  - MDCG 2022-13: Designation, re-assessment and notification of conformity assessment bodies and notified bodies (Aug 2022)
  - MDCG 2022-4: Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD (Dec 2022)
  - MDCG 2022-14 Position Paper: Transition to the MDR and IVDR – NB capacity and availability of medical devices and IVDs (Aug 2022)

MDCG 2019-6

- **NBs are not obliged to follow MDCGs**, but are encouraged as they reflect interpretation of EU law.
- **Clarifications related to MDR definitions** for reviewers – "Two years professional experience", "employed", "permanent availability of personnel with relevant clinical expertise"
- **Process requirement clarifications** – auditing suppliers and subcontractors, allocation of resources, changes which need prior approval by NB

MDCG Guidances for Notified Bodies

- **For Notified Bodies**
  - MDCG 2019-6 (Rev 4): Requirements relating to Notified Bodies (Oct 2022)
  - MDCG 2022-13: Designation, re-assessment and notification of conformity assessment bodies and notified bodies (Aug 2022)
  - MDCG 2022-4: Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD (Dec 2022)
  - MDCG 2022-14 Position Paper: Transition to the MDR and IVDR – NB capacity and availability of medical devices and IVDs (Aug 2022)

MDCG 2022-13

- **Provides instructions for Conformity Assessment Bodies (CABs)** which apply for designation as a NB or re-assessment
- On-site and off-site assessment activities
- Instructions for the **Final Assessment report** (including non-compliances) and submission to commission
- **Publication in NANDO** – designating authority notifies to the Commission and other Member States

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MDCG 2022-4

- **Provides instructions on surveillance activities** to be performed by NBs as defined in Article 120(3)
- Clarifies responsible NB for surveillance of product for **'legacy devices' under MDD, MDR or transition**
- **Includes comparison table of QMS requirements** under MDD v MDR

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MDCG 2022-14

- **Urges NBs to increase capacities** through hybrid audits, appropriate surveillance, leveraging evidence, develop schemes to **allocate capacity for SMEs and first-time applicants**
- Commits to review guidance to **eliminate administrative workload**
- For ‘safe and effective legacy devices’, the **complexity of conformity assessments should be reduced** and more pragmatism ensured
- Commitment to **provide additional guidance to assist with practical application of Clinical Evaluation** (specifically for legacy devices)

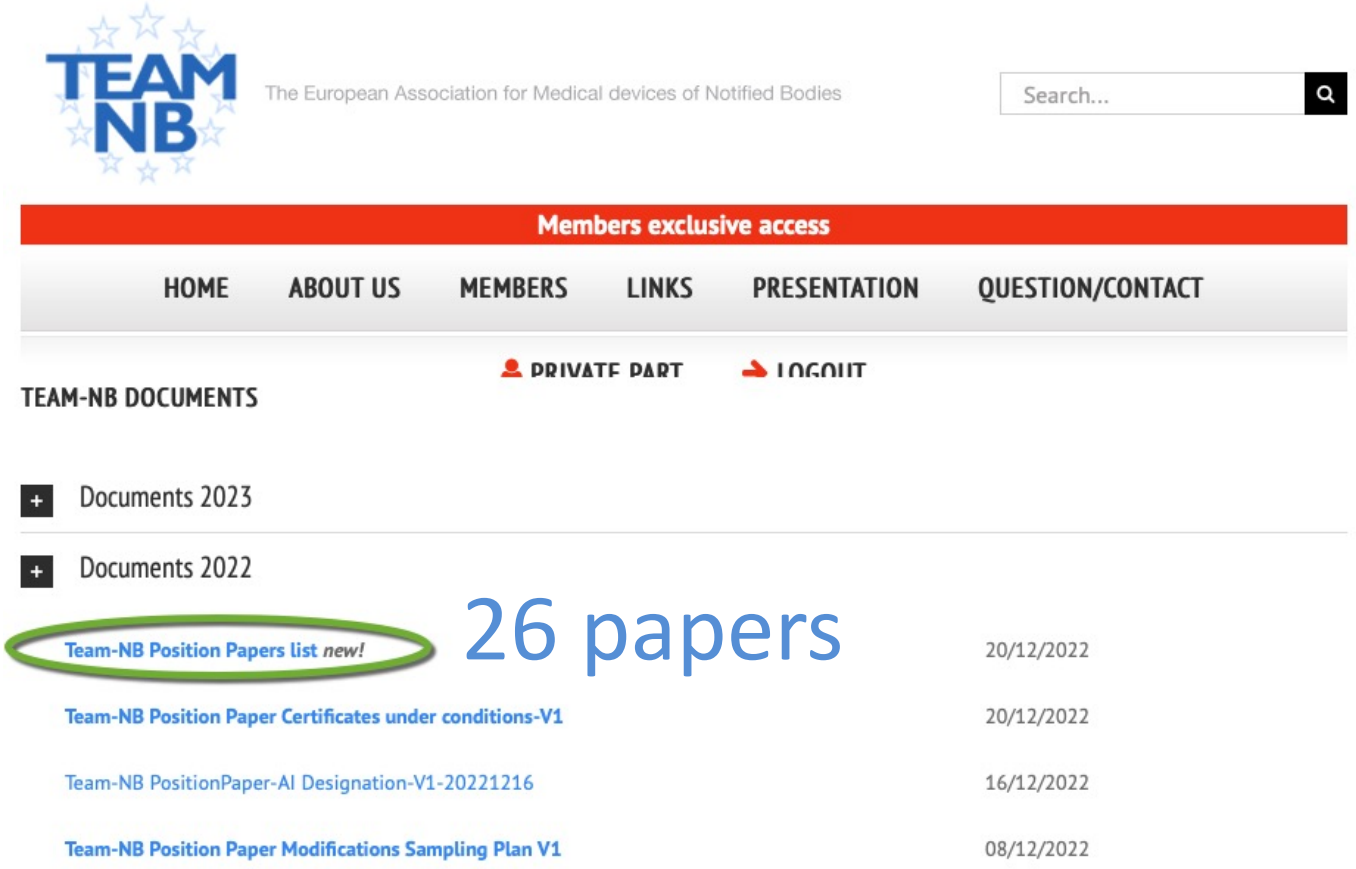
MDCG Guidances for Manufacturers

- For Manufacturers
  - MDCG 2022-11 Position Paper: Notice to manufacturers to ensure timely compliance with MDR requirements (June 2022)

- "It is essential that all manufacturers adjust their system, finalise transition to the MDR and apply to a notified body, **submitting complete and compliant applications, as soon as possible** and well **in advance of the end of the transition period**…"
- No Excuses

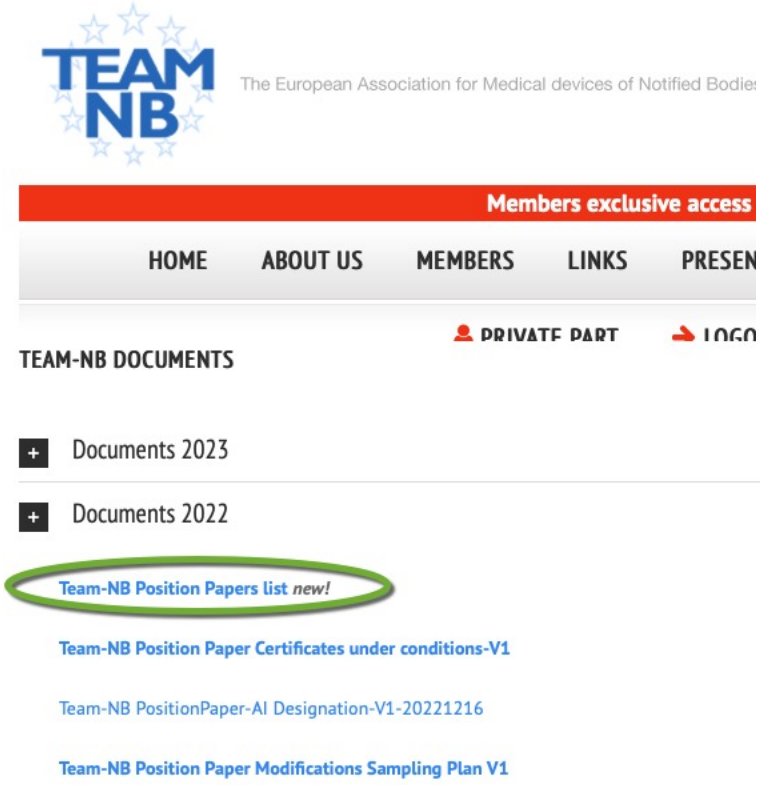
TEAM NB Position Papers

Team NB Position Papers



26 papers

Team NB Position Papers



[Modifications Sampling Plan]

[Article117 NB-Opinion Template]

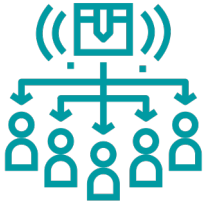
[Cyber Security]

[Best Practice Guidance for ... Technical Documentation]

Final Thoughts on MDR

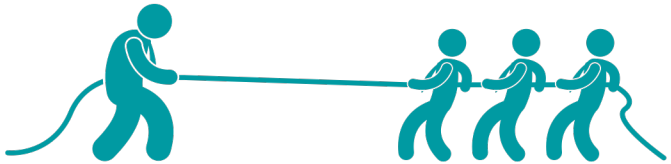
I talked to 5 competitors

- …and they ALL said the same thing



Portfolio Management

Do you need all six suture types or is one sufficient?



Push vs. Pull Documentation

Provide everything upfront. NB are not going to ask twice.

Clinical Reviews

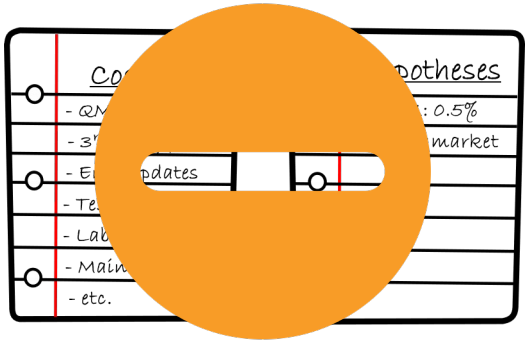
How many resources are dedicated to your clinical plan?

Just Start

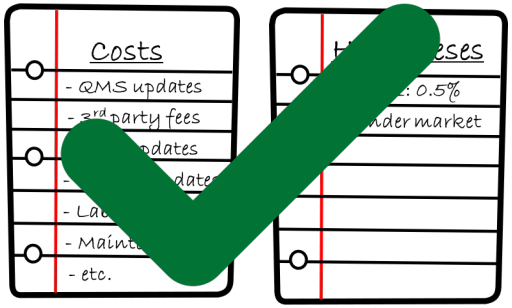
It's a long process. NB can't do proper resource planning without knowing what's in their pipeline.

Know your costs and products *for each market*

Switzerland or UKCA

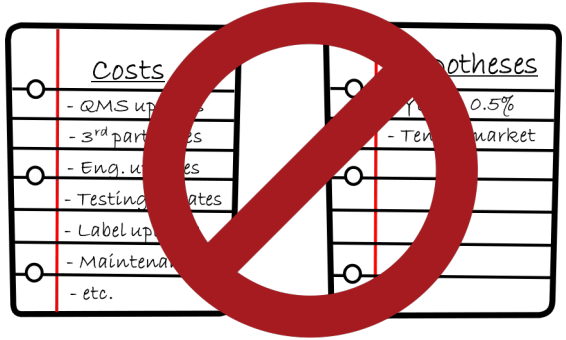


Australia and New Zealand



The US

The EU



Read, prepare and pay attention to the details

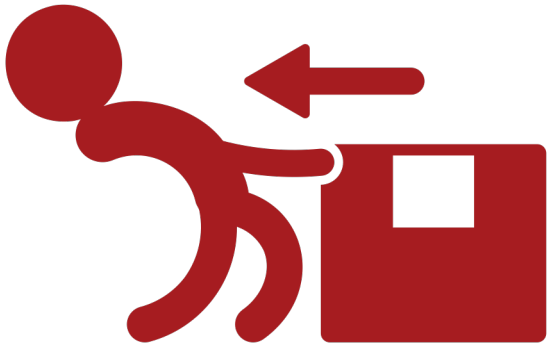
- All of the original EC assumptions about the transition to MDR have been proven invalid
- This latest extension will NOT resolve all MDR issues
  - The top problems now will still be the top problems in a few years
- The concessions made by the EC benefit the notified bodies, not you
- The companies that did the right things at the right time STILL may be the only ones who survive

Frenemies

- Industry needs to work with their Notified Body. **No "if", "and" or "buts allowed.**

- Take advantage of **conversations regarding expectations** with your notified bodies
  - Not considered consulting any longer – actively *encouraged* by the Competent Authorities

Changing Strategy to Documentation Review



Under MDD

Notified Bodies would pull the documentation out of industry with additional requests.

Under MDR

Industry is expected to push all relevant documentation to Notified Bodies. No longer will NB tease out documentation

Clinical Take Aways

Surveys	Clinical needs a multi part plan including ongoing surveys as part of PMCF. Need feedback good and bad.
Inclusive Data	Include unfavorable data. If you don't you loose trust *instantly*.
Marketing is Active	Increased role in PMCF activities along with sharing the message about device availability under MDR.
"SofC" vs. WET	"Standard of Care" device (MDCG 2020-6) vs WET (Article 61(6b)) discussion with your NB, not to be confused with SOTA and SOC search for the CER process
Not Equivalence	Can use data from similar devices but be mindful its not an equivalence discussion. Need to prove safety and efficacy of your own device.

Just Do it Already….

There Must Be Some Kind of Way Outta Here….

There must be some kind of way outta here…

Said the joker to the thief.

There's too much confusion….

I can't get no relief.

Your regulatory strategy

Your regulatory submissions

Your quality systems and compliance

Your audit management

Your due diligence

Your technical support

Your grief counseling

leanRAQA

Your Michelle Lott, RAC

michelle@leanRAQA.com

520.275.9838

companies	industries
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mid-sized	cosmetics
small	food
startup	dietary supplements

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Questions?

michelle@leanraqa.com