Kanzlei Lücker
MP-Recht

Medical Device Regulation

25th DGRA Annual Congress

May 4th and 5th, 2023 in Bonn
in the former Assembly Room of the German Bundestag
(Plenarsaal)

RAin Dr. Angela Graf (MHMM)

DGRA
DEUTSCHE
GESELLSCHAFT
FÜR
REGULATORY AFFAIRS

Medical Device Regulation

1. Implementation Problems
   - New and higher requirements for all stakeholders e.g. clinical evaluation
   - Unclear requirements e.g. drug-device-combination
   - Inflationary guidance documents - MDCG
   - Infrastructure not yet in place - EUDAMED
   - Lack of resources – Notified Bodies
   - The problem reaches the patients - first supply bottlenecks
2. Extension of the Transitional Periods - Regulation (EG) 2023/607

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Importance of clinical data

Confirmation of

- conformity with relevant general safety and performance requirements
- the evaluation of the undesirable side-effects
- the acceptability of the benefit-risk- ratio

shall be based on clinical data providing sufficient clinical evidence

Clinical data according to MDR

'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

- clinical investigation(s) of the device concerned,
- clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,
- reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,
- clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;

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clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;

'equivalence approach' is still foreseen, but……

Quality of equivalence according to the MDR

- A clinical evaluation may be based on clinical data relating to a device for which **equivalence** to the device in question can be demonstrated.
- It shall be **clearly demonstrated** that manufacturers have **sufficient levels of access to the data relating to devices** with which they are claiming equivalence in order to justify their claims of equivalence.
- The following **technical, biological and clinical characteristics** shall be taken into consideration for the demonstration of equivalence.
- The characteristics listed in the first paragraph shall be similar to the extent that there would be **no clinically significant difference** in the safety and clinical performance of the device.

Consequences

- Data that were crucial part of the clinical evaluation until now cannot be used any more
- **Problem:** There is no consistent distinction between high-risk products and low-risk medical devices

Clinical trials with medical devices will be increasingly necessary to place on the market a medical device.

Equivalence approach not applicable

For implantable products and class III medical devices

→ **clinical investigations as principle**

„To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements laid down in this Regulation should be based on ***clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations*** *that have been carried out under the responsibility of a sponsor. It should be possible both for the manufacturer and for another natural or legal person to be the sponsor taking responsibility for the clinical investigation."*

(Recital 63)

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Drug-Device-combinations

Forms of presentation:

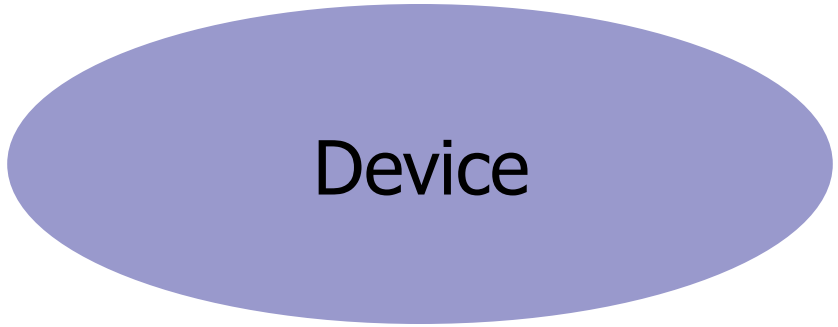
- Medical device with integral drug component (wound irrigation solution, coated stent)
- Drug with integral medical device component (pre-filled insulin syringe)
- "co-packed" products (drug cartridge with inhaler)

Drug-Device-combinations

On which product component is the focus of the function?

New rules: Art. 117 MDR changes Directive 2001/83/EC

(see next slide)



- Rule 14 (formerly rule 13)
- Scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA

Drug is the "main actor

Do drug and medical devices constitute a **"single integral product"**?

Yes

- Authorisation gem. RL 2001/83/EG
- Annex I MDR regarding the medical device part
- No CE-mark, but assessment report of the NB (exept class I)

No

- „Co-packaged device“
- MDR is applicable for the medical device >> Art. 14??? Art. 22 ???
- CE-mark necessary???

No consistent statements/action from EMA, national CA and NB

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MDCG Guidelines

- MDCG Guidelines are **not legally binding.** They are endorsed by the Medical Device Coordination Group (MDCG) in accordance with Article 105 of the MDR and Article 99 of the IVDR.

- They present a **common understanding** of how the MDR and IVDR should be applied in practice aiming at an effective and harmonised implementation of the legislation. They are drafted in collaboration with interested parties represented in the various groups and denominated by the following format: "MDCG Year-Number-revision".

Medical Devices Coordinating Group

Medical Device Coordination Group (MDCG)
members– MD & IVD

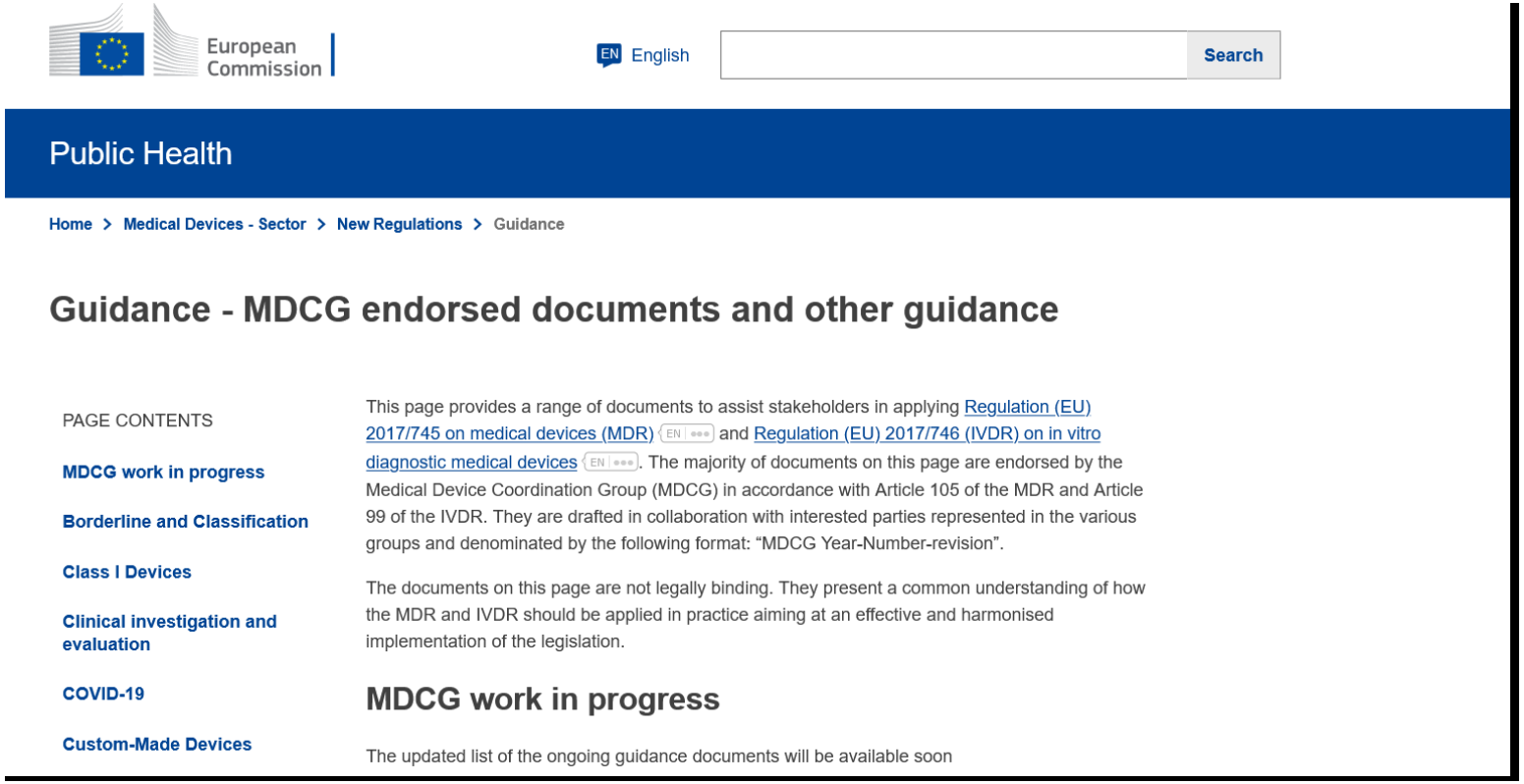
Country	Medical Devices (MD)			In Vitro Diagnostic (IVD)		
	Function	*Name*	*Organisation*	*Function*	*Name*	*Organisation*
Austria	Member	RENHARDT Martin	Federal Ministry of Social Affairs, Health Care and Consumer Protection meddev@bmgf.gv.at	Member	RENHARDT Martin	Federal Ministry of Social Affairs, Health Care and Consumer Protection meddev@bmgf.gv.at
	Alternate	AMON Andreas	Austrian Federal Office for Safety in Health Care (BASG) medizinprodukte@basg.gv.at	Alternate	EBERL Heidrun	Austrian Federal Office for Safety in Health Care (BASG) medizinprodukte@basg.gv.at
Belgium	Member	MEULDERS Frederique	Federal Agency for Medicines and Health Products (FAMHP) meddev@fagg-afmps.be	Member	JAUGNIAUX Alexandre	Federal Agency for Medicines and Health Products (FAMHP) ivd@afmps.be
	Alternate	MARTENS Katrien	Federal Agency for Medicines and Health Products (FAMHP) meddev@fagg-afmps.be	Alternate	POELS Jeroen	Federal Agency for Medicines and Health Products (FAMHP) ivd@afmps.be
Bulgaria	Member	DARAKCHIEV Todor	Bulgarian Drug Agency bda@bda.bg	Member	DARAKCHIEV Todor	Bulgarian Drug Agency bda@bda.bg
Croatia	Member	OŠTARČEVIĆ Suzana	Agency for Medicinal Products and Medical Devices	Member	OŠTARČEVIĆ Suzana	Agency for Medicinal Products and Medical Devices
	Alternate	KRANJČEC Krunoslav	Agency for Medicinal Products and Medical Devices	Alternate	KRANJCEC Krunoslav	Agency for Medicinal Products and Medical Devices
Cyprus	Member	STYLIANOU Androulla	Cyprus Medical Devices Competent Authority cymda@mphs.moh.gov.cy	Member	STYLIANOU Androulla	Cyprus Medical Devices Competent Authority cymda@mphs.moh.gov.cy

Version of 14 October 2022

1

https://health.ec.europa.eu/system/files/2023-03/mdcg_md-ivd_members_en.pdf

MDCG Guidelines



European Commission

English

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Guidance - MDCG endorsed documents and other guidance

PAGE CONTENTS

- MDCG work in progress
- Borderline and Classification
- Class I Devices
- Clinical investigation and evaluation
- COVID-19
- Custom-Made Devices

This page provides a range of documents to assist stakeholders in applying Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices. The majority of documents on this page are endorsed by the Medical Device Coordination Group (MDCG) in accordance with Article 105 of the MDR and Article 99 of the IVDR. They are drafted in collaboration with interested parties represented in the various groups and denominated by the following format: “MDCG Year-Number-revision”.

The documents on this page are not legally binding. They present a common understanding of how the MDR and IVDR should be applied in practice aiming at an effective and harmonised implementation of the legislation.

MDCG work in progress

The updated list of the ongoing guidance documents will be available soon

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

MDCG Subgroups

- Notified Body Organisation (NBO)
- Harmonised standards
- Clinical investigation and Evaluation (CIE)
- Post Market Surveillance and Vigilance (PMSV)
- Market Surveillance (MS)
- Borderline-Product and Classification (B&C)
- New Technologies
- EUDAMED
- Unique Device Identification (UDI)
- International Affairs
- In-vitro-Diagnostics (IVD)
- Nomenclature
- Annex–XVI–Products

MDCG Guidelines concerning the following topics

- MDCG work in progress
- Borderline and Classification
- Class I Devices
- Clinical investigation and evaluation
- COVID-19
- Custom-Made Devices
- EUDAMED
- European Medical Device Nomenclature (EMDN)
- Implant cards
- In-house devices
- Authorised Representatives, Importers, Distributors
- In Vitro Diagnostic medical devices (IVD)
- New technologies
- Notified bodies
- Post-Market Surveillance and Vigilance (PMSV)
- Standards
- Unique Device Identifier (UDI)
- Other topics
- Other guidance documents

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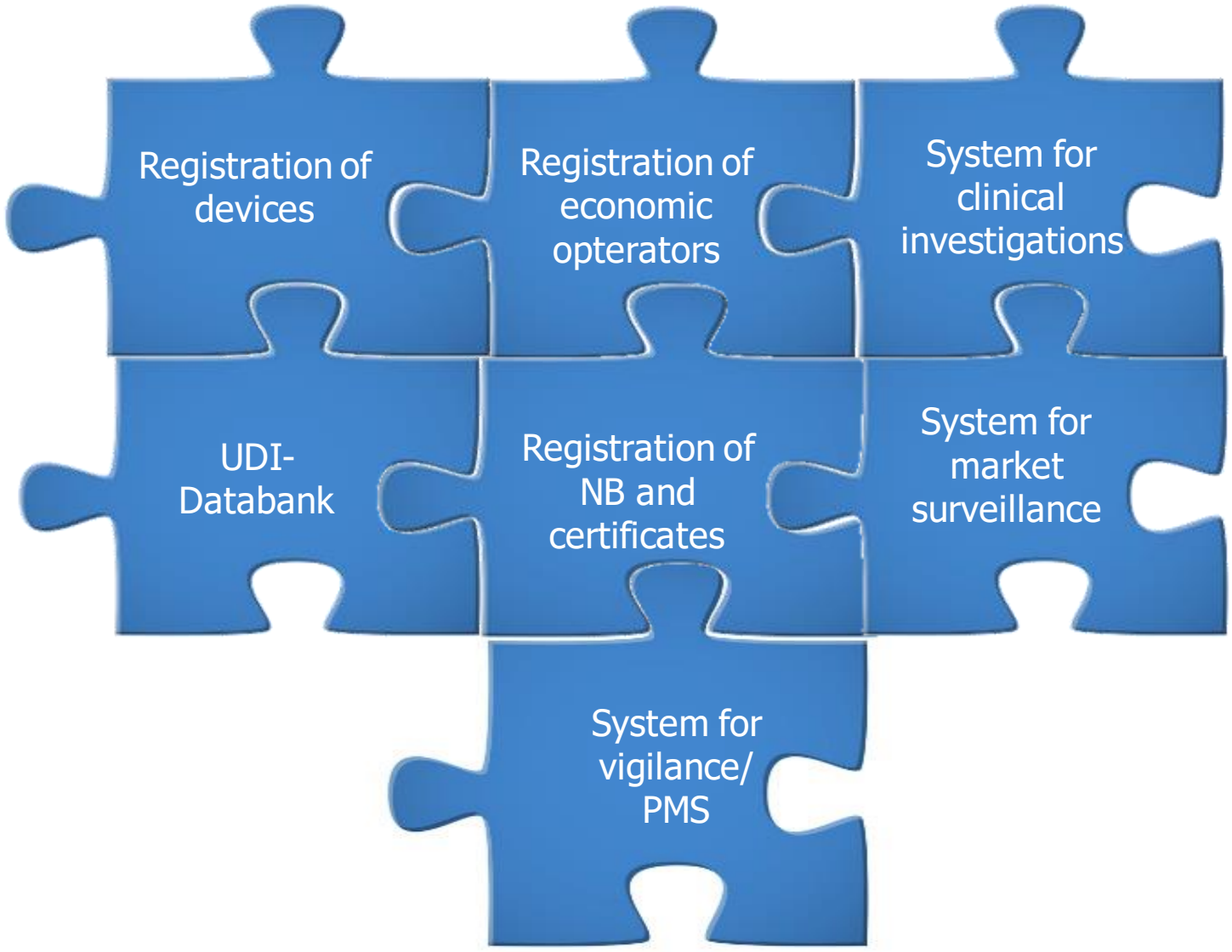
European database on medical devices

Purposes

- Enable the public to be adequately informed about
  - devices placed on the market,
  - the corresponding certificates issued by notified bodies and
  - about the relevant economic operators
  - clinical investigations and
  - sponsors of clinical investigations
- Enable unique identification of devices within the internal market and to facilitate their traceability
- Vigilance Reporting
- Enable the CA of the MS and the Commission to carry out their tasks on a well-informed basis and to enhance the cooperation between them.



Eudamed is the (overloaded) centerpiece of the functionality of the MDR… so…

*„The Commission **concluded** that it will only be possible to make EUDAMED operational once the entire system and its different modules have achieved full functionality and have been subject to an independent audit.*

*Therefore EUDAMED's launch will be done together for medical and in-vitro medical devices, at the original date foreseen for in-vitro medical devices i.e. **May 2022**.*"

- https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en 30.10.2019

Medical Devices
Medical Device Coordination Group Document MDCG 2021-1

MDCG 2021-1

Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional

February 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

State of play

- The module on Actor registration is available since December 2020
- The module on UDI/device registration is available since October 2021
- The module on Notified Bodies and Certificates is available since October 2021 except for the mechanism for scrutiny and the clinical evaluation consultation procedure (CECP) functionalities.
- The remaining module (Vigilance, Clinical Investigation & Performance Studies and Market Surveillance) are under development and will be released when EUDAMED is declared fully functional.

EUDAMED - European Database on Medical Devices

EUDAMED Time line

The European Commission planning – June 2022

Q4 2023	Q1-Q2 2024	Q2 2024	Q2 2024	Q4 2024	Q2 2026
End of the EUDAMED MVP[1] development for all six modules	Independent **Audit**	Audit results presented to the Medical Devices Coordination Group (MDCG)	EUDAMED has achieved full functionality following the outcome of the Audit. **Publication of a Commission notice** in the *Official Journal of the European Union* **(OJEU)**	End of 6 months transitional period after publication of the notice in the OJEU. **The full EUDAMED system (all 6 modules) is released.** The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **Actors, Vigilance, Clinical Investigation & Performance Studies and Market Surveillance modules**	End of 24 months transitional period after publication of the notice in the OJEU The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **UDI/Device and NB & Certificate modules**

[1] EUDAMED Minimum Viable Product (MVP) means that the system developed implements at least the minimum Medical Devices Regulations requirements and allows competent authorities and all stakeholders to comply with their legal obligations.

https://health.ec.europa.eu/system/files/2023-01/md_eudamed_timeline_en.pdf

There is still hope…

Good things come to those who wait

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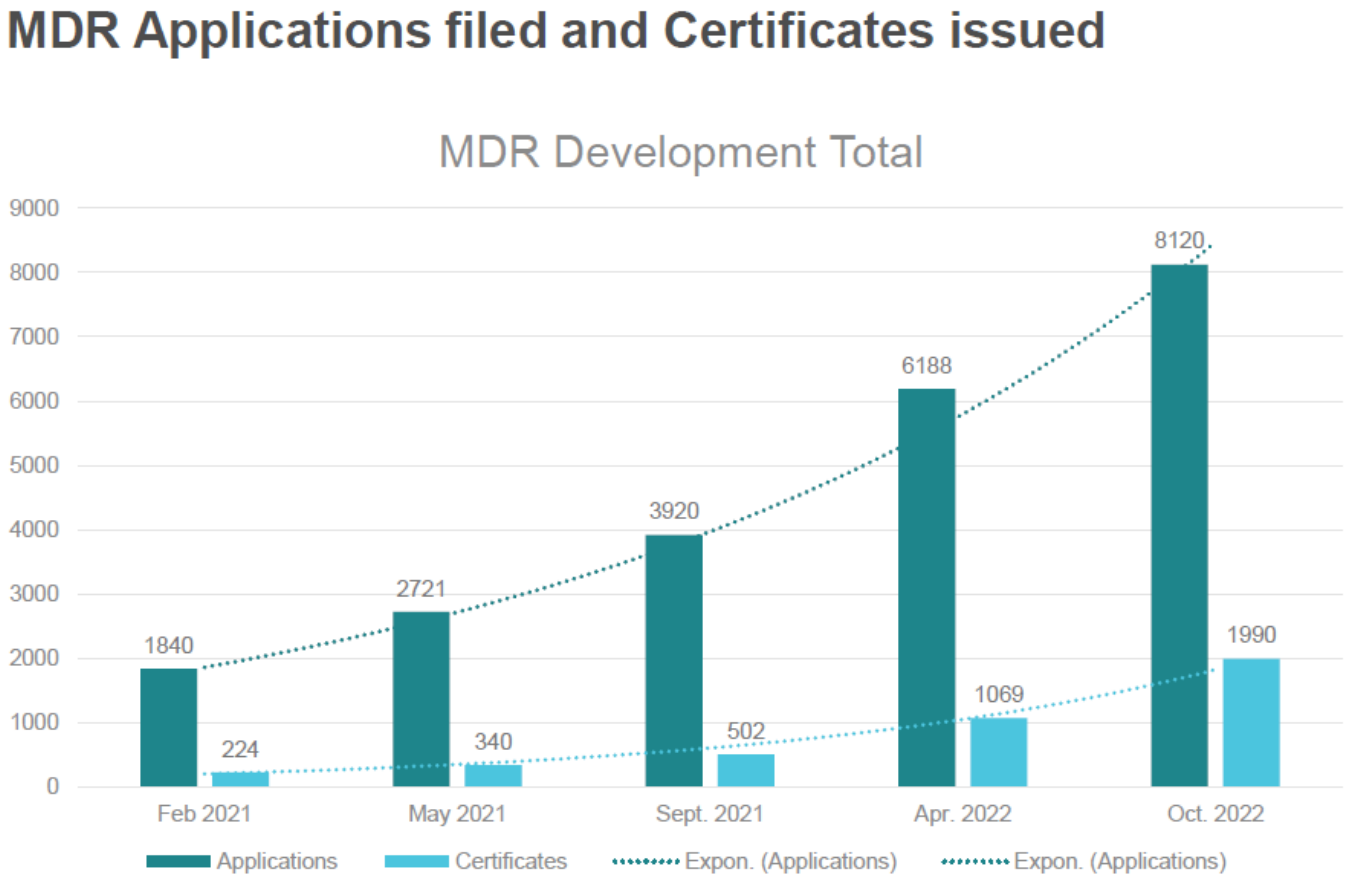
The MDR requires a re-assessment of the entire MD market. At the same time, there is a lack of resources!



Source:
EU Commission: Notified Bodies Survey on certifications and applications (MDR/IVDR) MDCG & Stakeholders 24 (Oct 2022)

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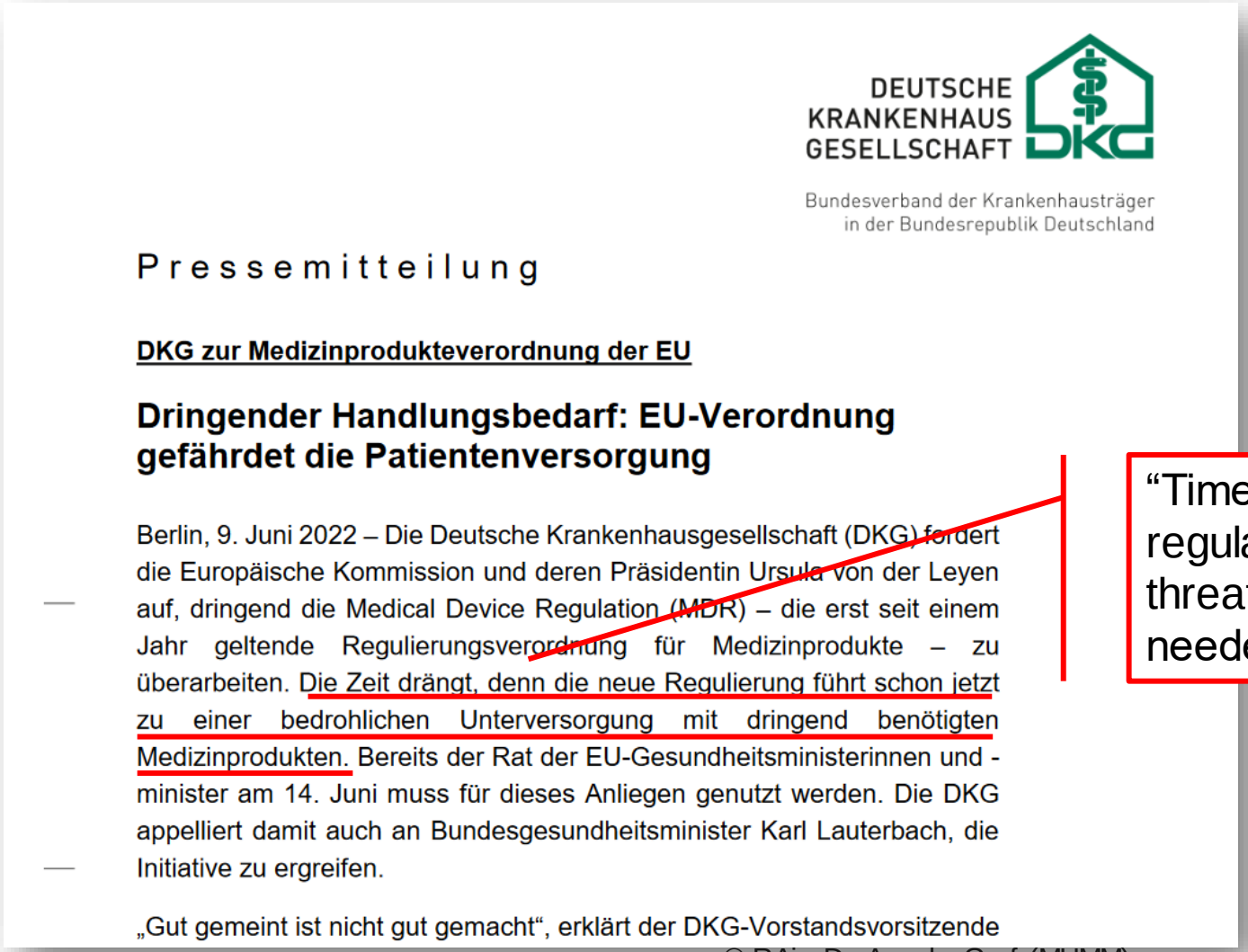
The problem reaches the patients



DEUTSCHE KRANKENHAUS GESELLSCHAFT

Bundesverband der Krankenhausträger in der Bundesrepublik Deutschland

Pressemitteilung

DKG zur Medizinprodukteverordnung der EU

Dringender Handlungsbedarf: EU-Verordnung gefährdet die Patientenversorgung

Berlin, 9. Juni 2022 – Die Deutsche Krankenhausgesellschaft (DKG) fordert die Europäische Kommission und deren Präsidentin Ursula von der Leyen auf, dringend die Medical Device Regulation (MDR) – die erst seit einem Jahr geltende Regulierungsverordnung für Medizinprodukte – zu überarbeiten. Die Zeit drängt, denn die neue Regulierung führt schon jetzt zu einer bedrohlichen Unterversorgung mit dringend benötigten Medizinprodukten. Bereits der Rat der EU-Gesundheitsministerinnen und -minister am 14. Juni muss für dieses Anliegen genutzt werden. Die DKG appelliert damit auch an Bundesgesundheitsminister Karl Lauterbach, die Initiative zu ergreifen.

„Gut gemeint ist nicht gut gemacht", erklärt der DKG-Vorstandsvorsitzende

"Time is pressing, because the new regulation is already leading to a threatening undersupply of urgently needed medical devices."

https://www.dkgev.de/dkg/presse/details/dringender-handlungsbedarf-eu-verordnung-gefaehrdet-die-patientenversorgung/

„The goal of MDR is to protect the European citizen by improving the safety of medical products. This goal probably will be reached in high-volume MD. However in niche fields with low-volume MDs, MDR will result in either withdrawal of MD from the market, or availability at a much higher price. This will not be beneficial for the European patient with an orphan disease..“

http://www.aepc.org/news/the-implications-of-eu-mdr-for-the-treatment-of-congenital-heart-disease

https://dgooc.de/presse/pressemitteilungen/pressemitteilungen-der-dgou/1300-eu-medizinprodukte-verordnung-mdr-drohende-engpaesse-bei-orthopaedischen-und-unfallchirurgischen-implantaten

"It is to be feared that we will soon have to tell some patients: We are sorry, we have to cancel your surgery appointment, we cannot get a suitable prosthesis for you."

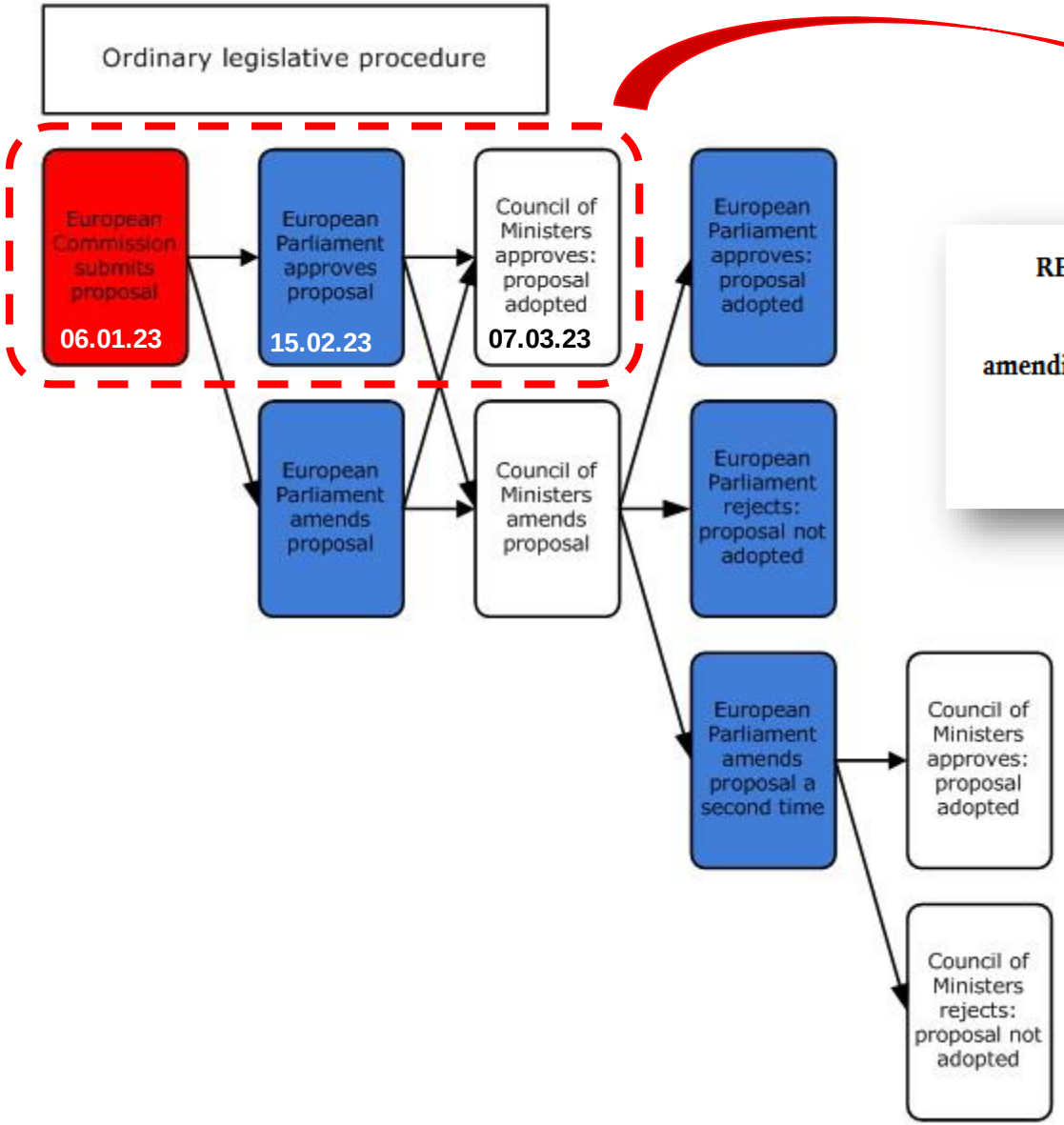
The Medical Device Regulation (MDR) entered into force in 2017 (...). As a result, the first products are already currently no longer available, the last approvals expire in 2024.

Discussed "big" solutions

1. Special regulations for "orphan devices
2. Certificates subjerct to conditions
3. Art. 97 MDR: "Other non-compliance".

4. Renewed change of transitional periods?

With other words…
Who/what will get the cow of the ice???



REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2023

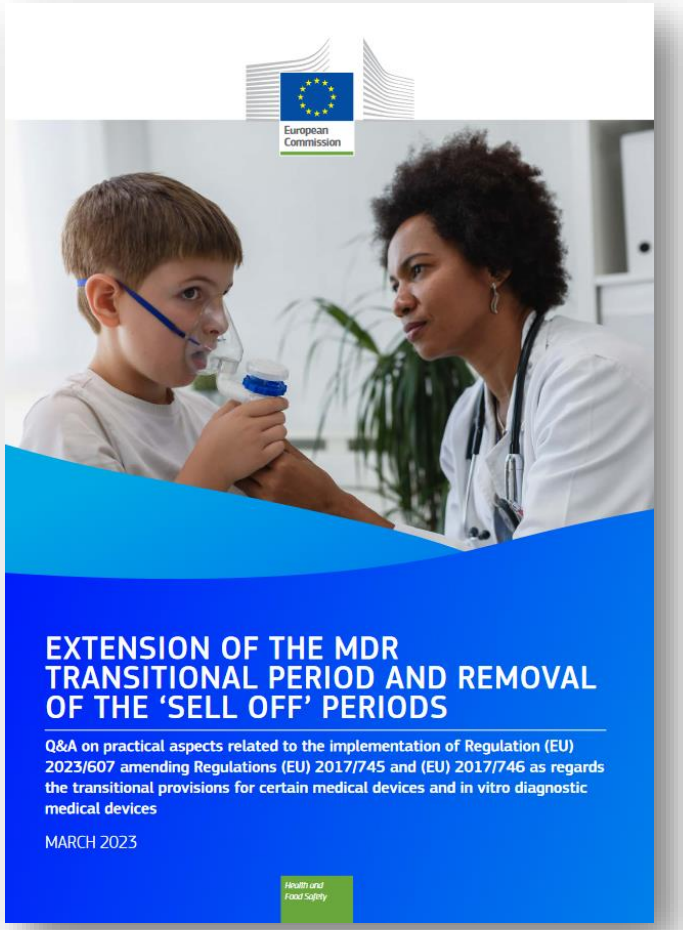
amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

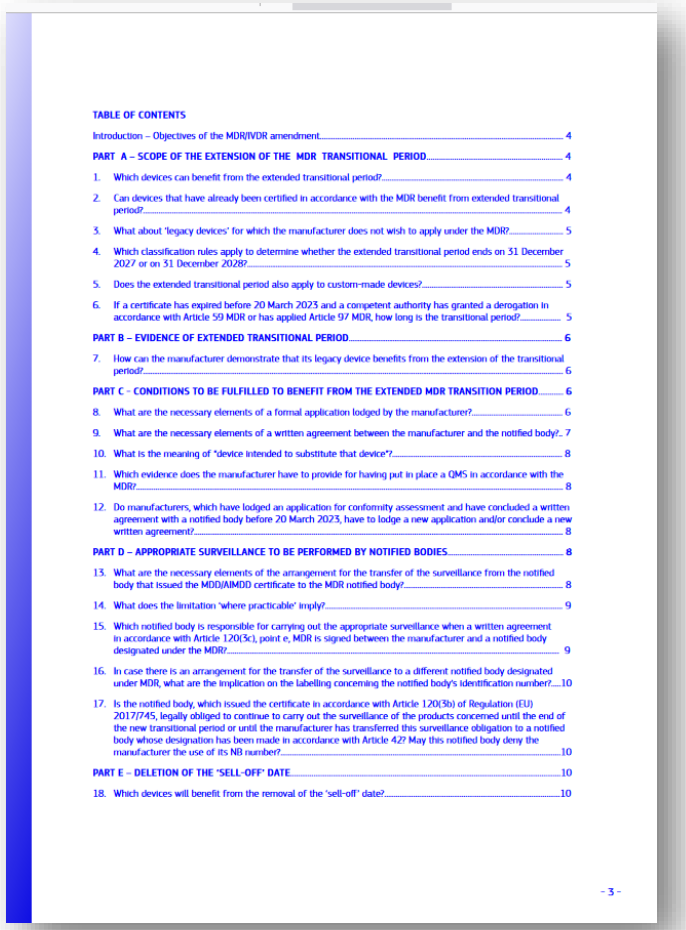
(Text with EEA relevance)

European Journal Publication and at the same time entry into force: **20.03.2023**

More information about the legislative procedure concerning Regulation (EU) 2023/607:
EUR-Lex - 2023_5 - EN - EUR-Lex (europa.eu)

EU legislation remains consistent: maximum complexity!





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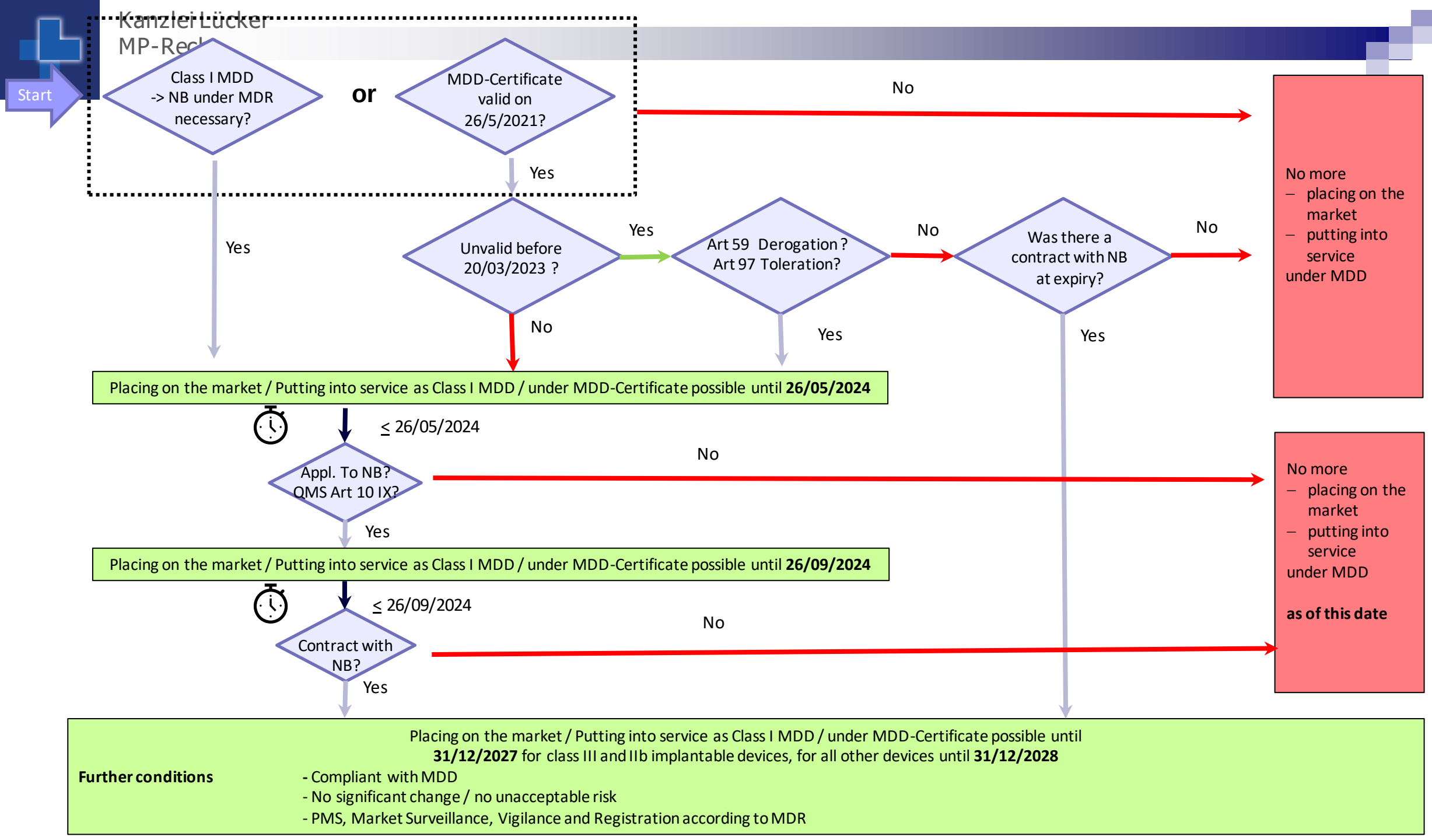
https://health.ec.europa.eu/system/files/2023-03/mdr_proposal_extension-q-n-a_0.pdf


Start
Class I MDD
-> NB under MDR
necessary?
or
MDD-Certificate
valid on
26/5/2021?
No
Yes
Yes
Unvalid before
20/03/2023 ?
Yes
Art 59 Derogation ?
Art 97 Toleration?
No
Was there a
contract with NB
at expiry?
No
No more
– placing on the market
– putting into service
under MDD
Yes
Yes
No
Placing on the market / Putting into service as Class I MDD / under MDD-Certificate possible until 26/05/2024
≤ 26/05/2024
Appl. To NB?
QMS Art 10 IX?
No
Yes
No more
– placing on the market
– putting into service
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as of this date
Placing on the market / Putting into service as Class I MDD / under MDD-Certificate possible until 26/09/2024
≤ 26/09/2024
Contract with
NB?
No
Yes
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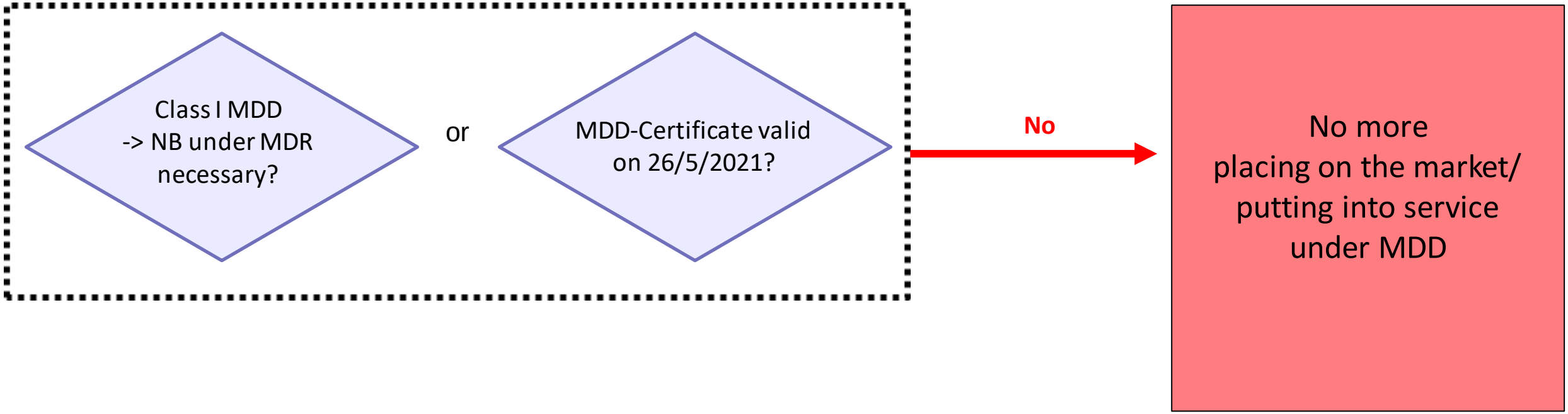

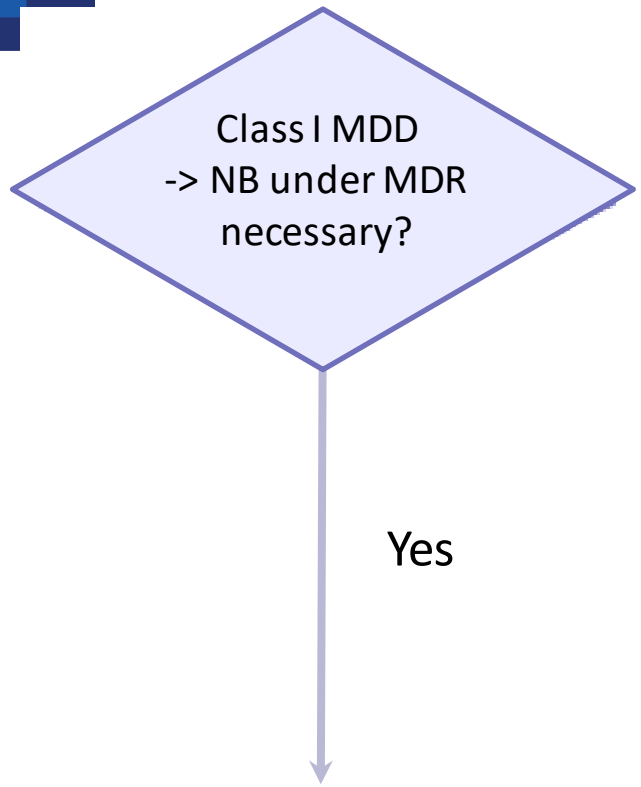

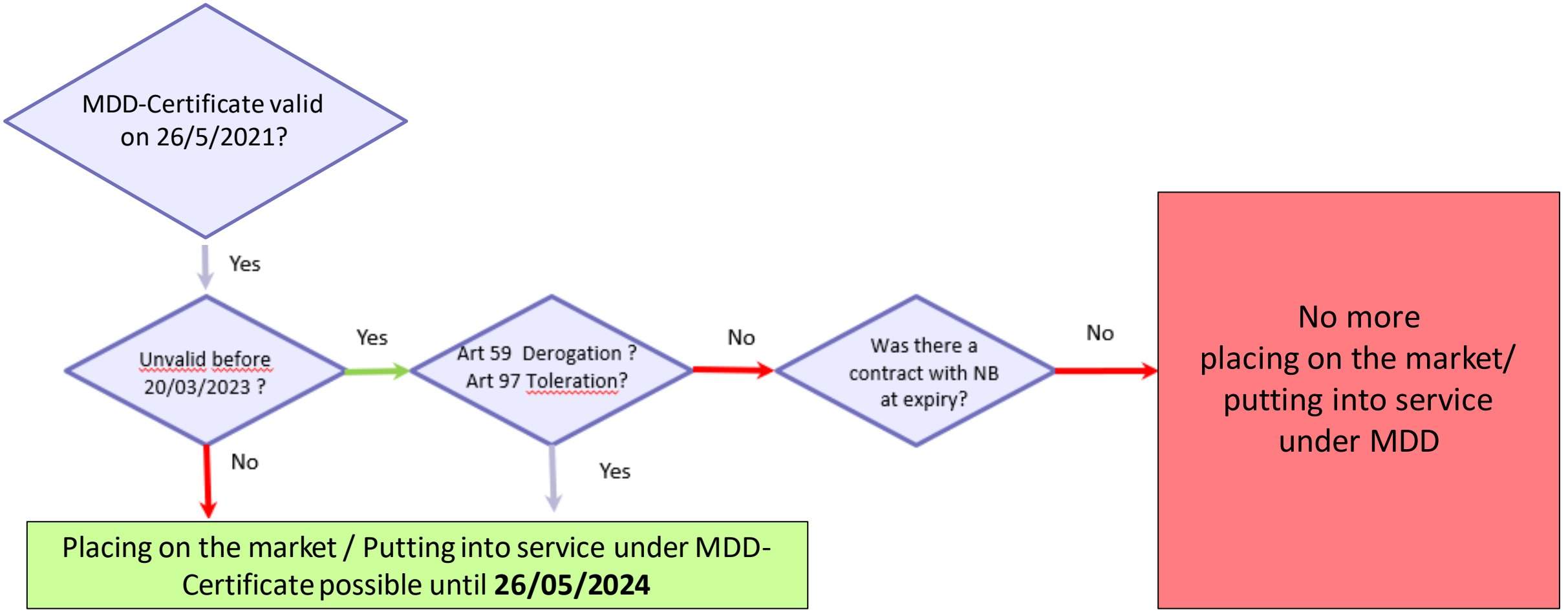

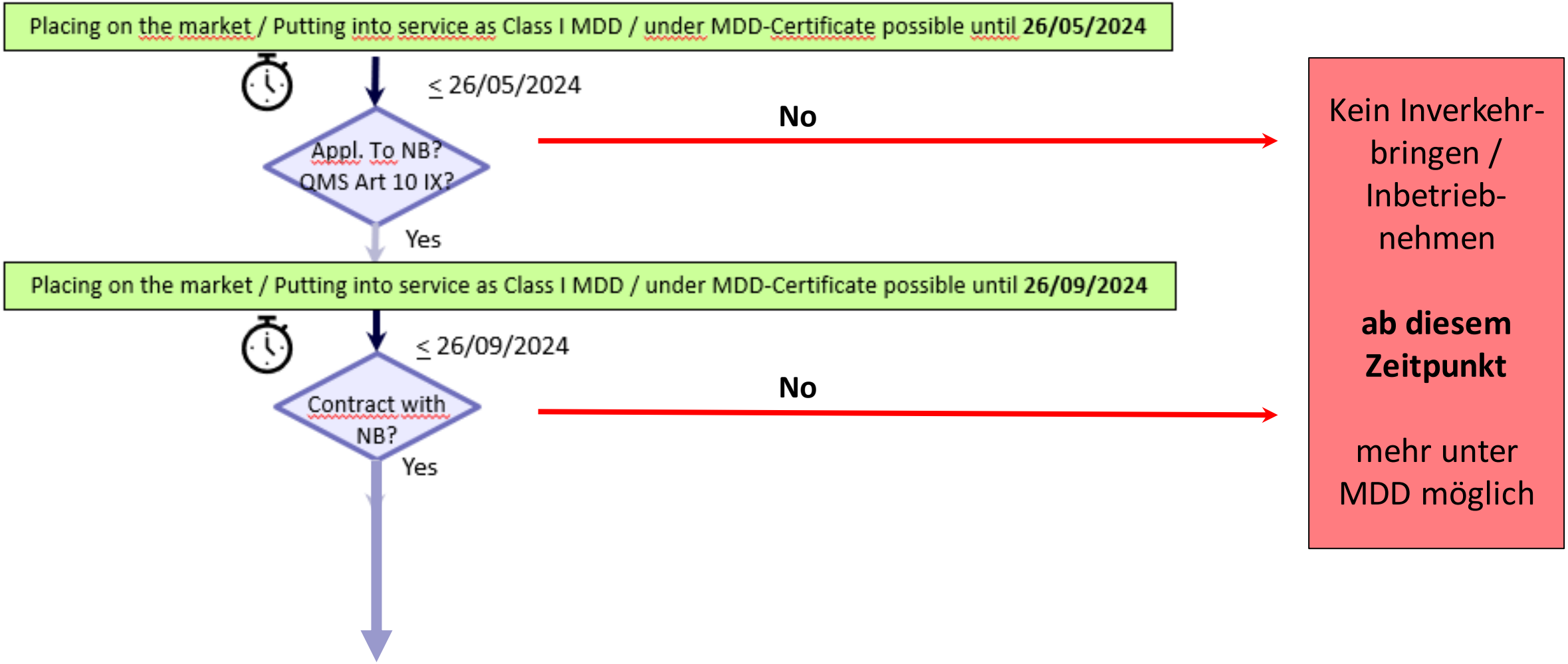

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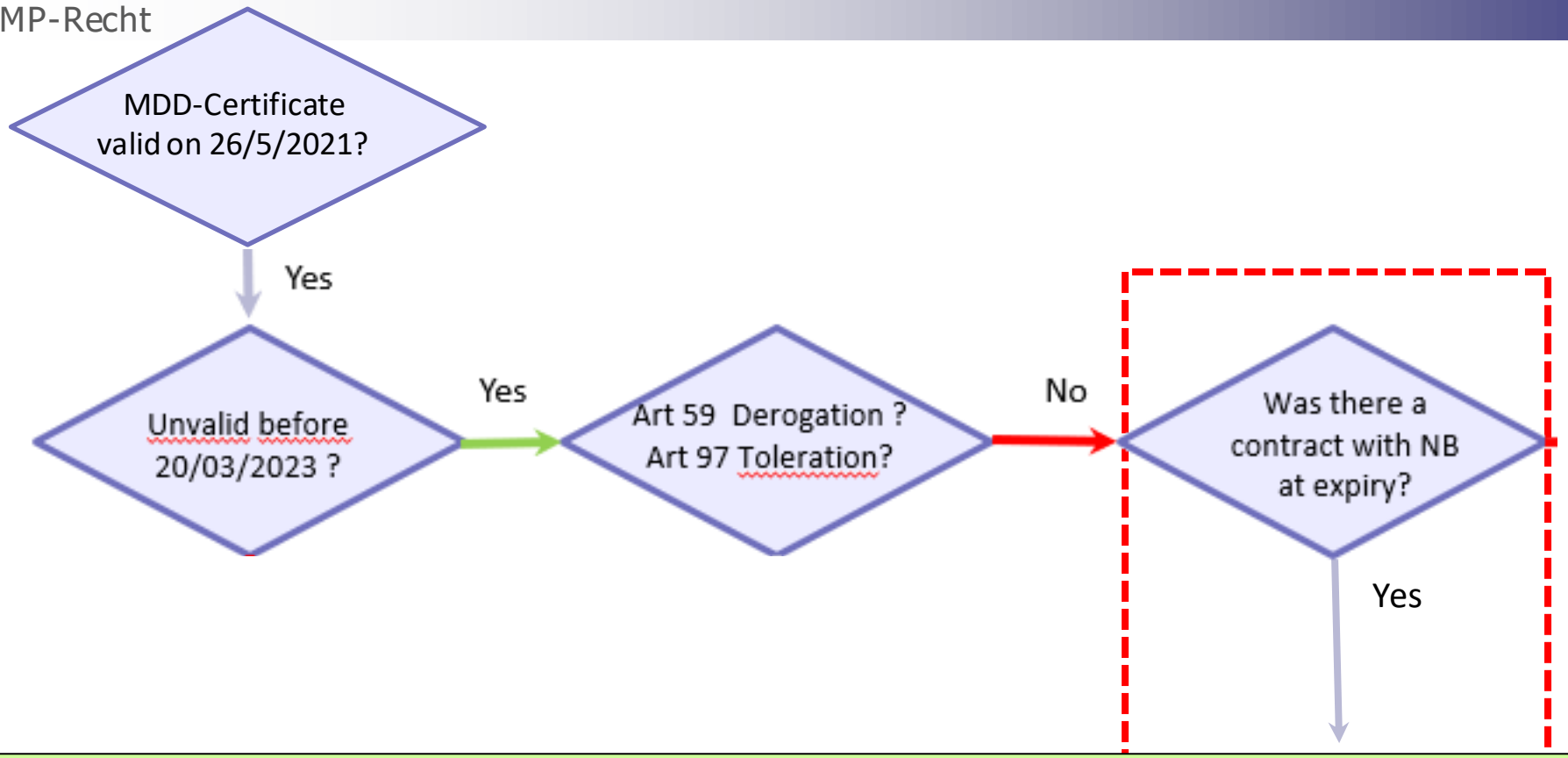

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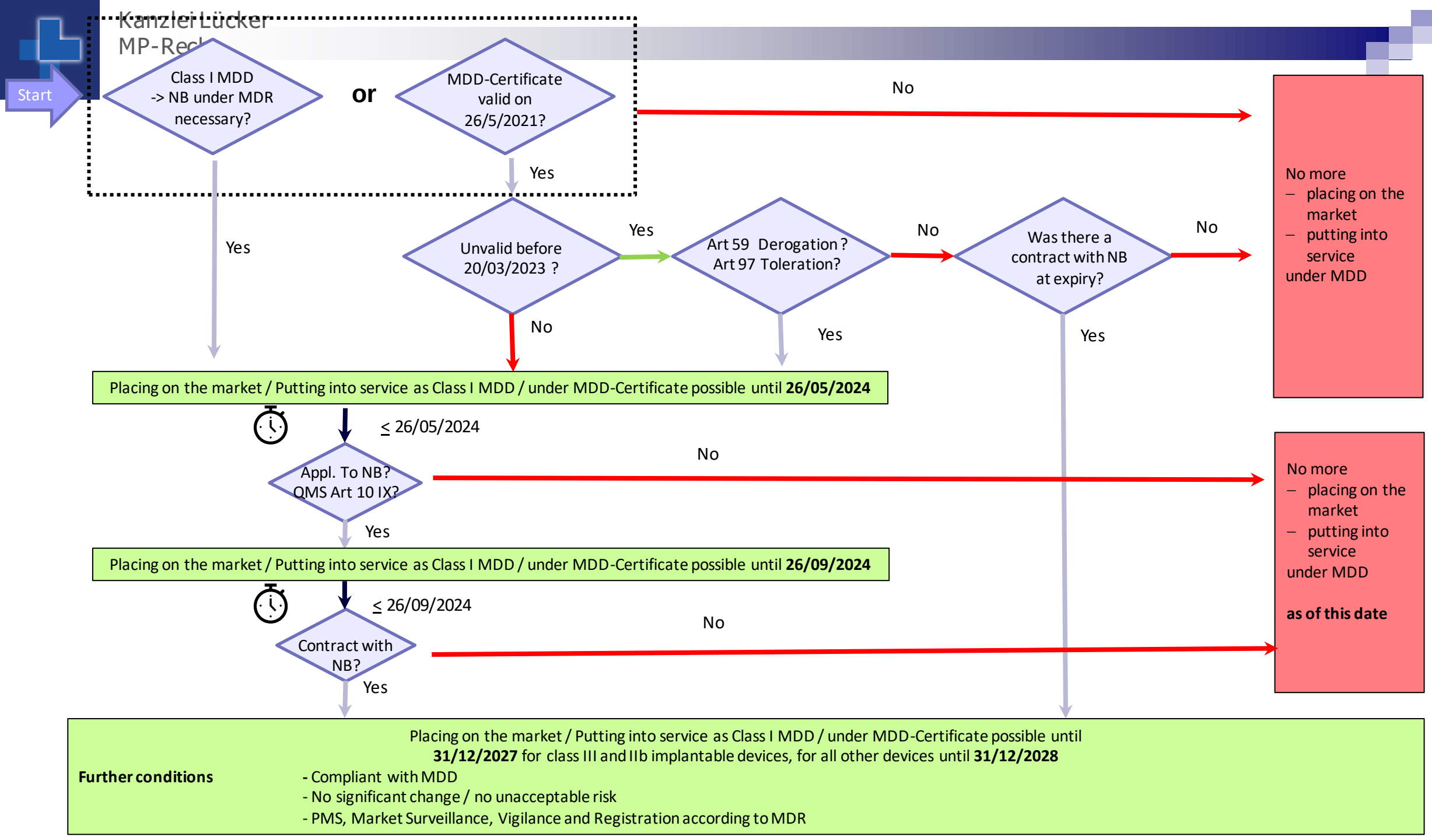
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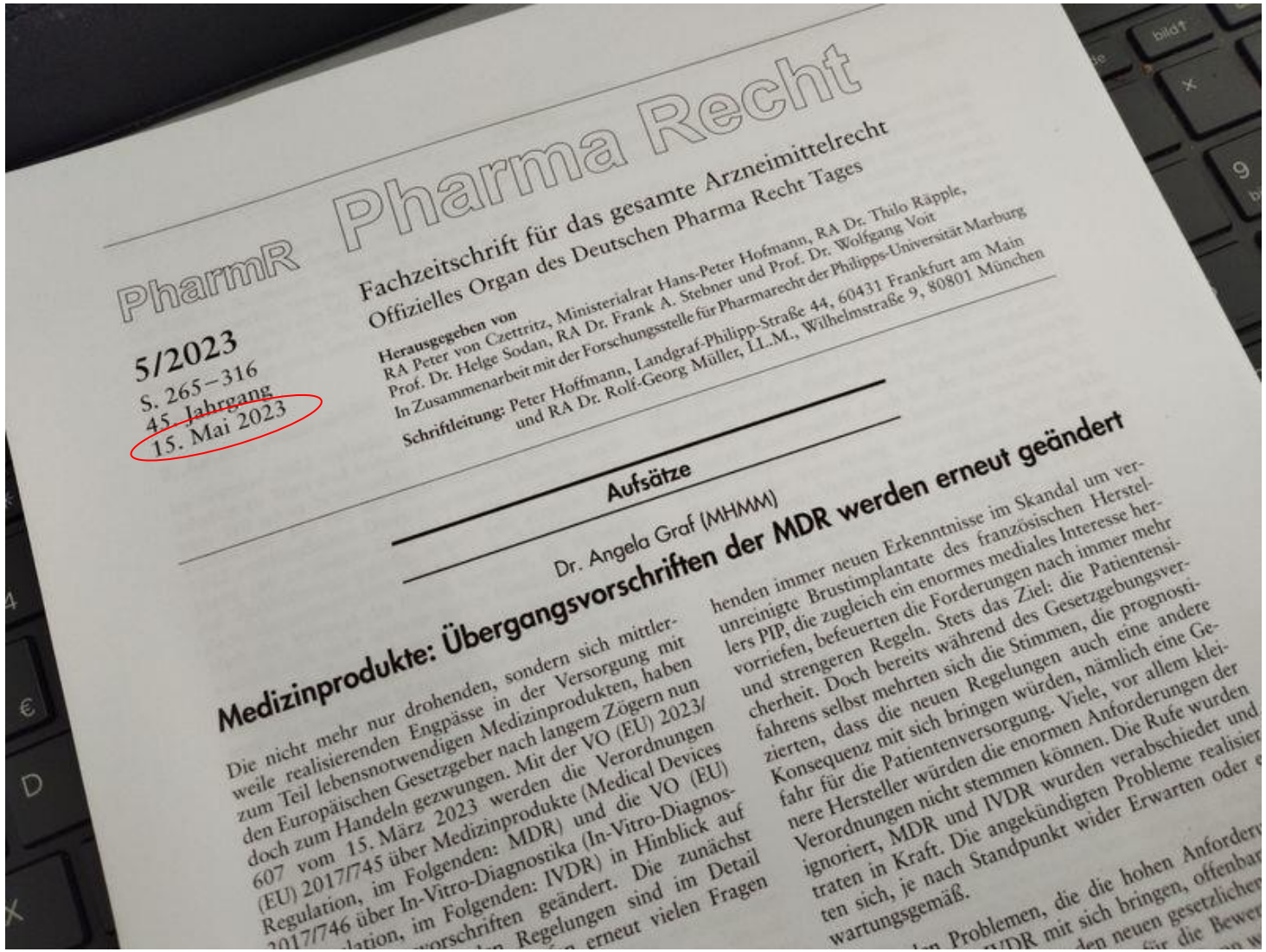
- PMS, Market Surveillance, Vigilance and Registration according to MDR

„We must not be satisfied with this emergency operation. The patient must now go to rehab."

Peter Liese, Health policy spokesman of the Christian Democrats (EVP) in the European Parliament

Argues for a comprehensive revision of the MDRs

https://www.bvmed.de/de/recht/eu-medizinprodukte-verordnung-mdr/kurzinterview-liese-mdr-aenderung



PharmR Pharma Recht

Fachzeitschrift für das gesamte Arzneimittelrecht
Offizielles Organ des Deutschen Pharma Recht Tages

5/2023
S. 265–316
45. Jahrgang
15. Mai 2023

Herausgegeben von
RA Peter von Czettritz, Ministerialrat Hans-Peter Hofmann, RA Dr. Thilo Räpple,
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Aufsätze

Dr. Angela Graf (MHMM)

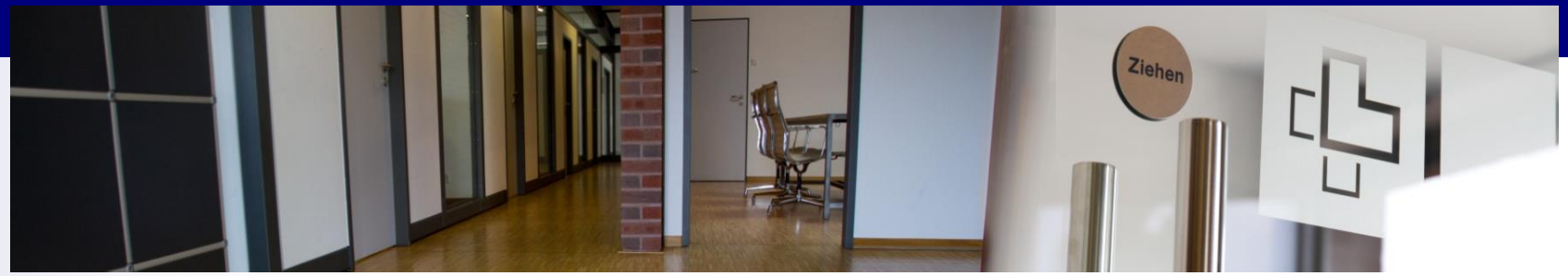
Medizinprodukte: Übergangsvorschriften der MDR werden erneut geändert

Die nicht mehr nur drohenden, sondern sich mittlerweile realisierenden Engpässe in der Versorgung mit zum Teil lebensnotwendigen Medizinprodukten, haben den Europäischen Gesetzgeber nach langem Zögern nun doch zum Handeln gezwungen. Mit der VO (EU) 2023/607 vom 15. März 2023 werden die Verordnungen (EU) 2017/745 über Medizinprodukte (Medical Devices Regulation, im Folgenden: MDR) und die VO (EU) 2017/746 über In-Vitro-Diagnostika (In-Vitro-Diagnostics-Regulation, im Folgenden: IVDR) in Hinblick auf [illegible]vorschriften geändert. Die zunächst [illegible] Regelungen sind im Detail [illegible] erneut vielen Fragen

henden immer neuen Erkenntnisse im Skandal um verunreinigte Brustimplantate des französischen Herstellers PIP, die zugleich ein enormes mediales Interesse hervorriefen, befeuerten die Forderungen nach immer mehr und strengeren Regeln. Stets das Ziel: die Patientensicherheit. Doch bereits während des Gesetzgebungsverfahrens selbst mehrten sich die Stimmen, die prognostizierten, dass die neuen Regelungen auch eine andere Konsequenz mit sich bringen würden, nämlich eine Gefahr für die Patientenversorgung. Viele, vor allem kleinere Hersteller würden die enormen Anforderungen der Verordnungen nicht stemmen können. Die Rufe wurden ignoriert, MDR und IVDR wurden verabschiedet und traten in Kraft. Die angekündigten Probleme realisierten sich, je nach Standpunkt wider Erwarten oder [illegible] wartungsgemäß.

[illegible] Problemen, die die hohen Anforder[illegible] IVDR mit sich bringen, offenbar [illegible] den neuen gesetzlichen [illegible] für die Bewer[illegible]

Vielen Dank!



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