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MDR AND THE CLEANING / STERILIZATION INDUSTRY

Sterilization World Forum
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health
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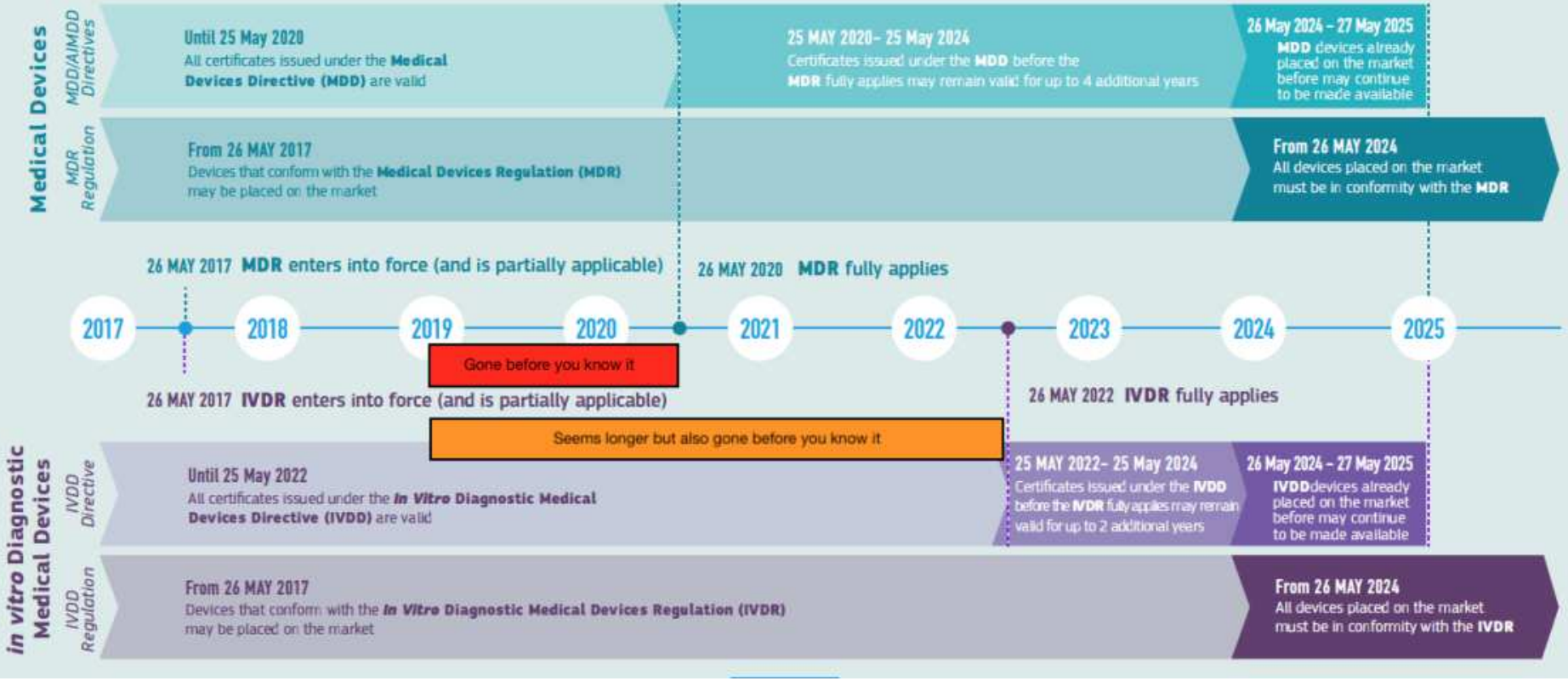
European Commission

Transition Timelines from the Directives to the Regulations

Medical Devices and *in vitro* Diagnostic Medical Devices



Agenda

- Sterilisation / cleaning / disinfection specifics in MDR
    - Where are we with MDR roll-out?
    - Amended definitions
    - SUD reprocessing
    - HPD regime that ties into reprocessing
    - When are you a manufacturer and what are your obligations?
    - When are you product liable?
    - Parts & components

MDR: gap assessment, impact assessment, implementation

Implementation with an unfinished regulatory system

THERE ARE KNOWN KNOWNS
THERE ARE THINGS THAT WE KNOW THAT WE KNOW, THERE ARE
KNOWN UNKNOWNS
THAT IS TO SAY, THERE ARE
THINGS THAT WE NOW KNOW WE DON'T KNOW
BUT THERE ARE ALSO
UNKNOWN UNKNOWNS
THERE ARE THINGS
WE DO NOT KNOW
WE DON'T KNOW
AND EACH YEAR WE DISCOVER
A FEW MORE OF THOSE
UNKNOWN
UNKNOWNS

I can't see why I wouldn't give it a shot. #UnKNOWN_PUNster

Implementation generally

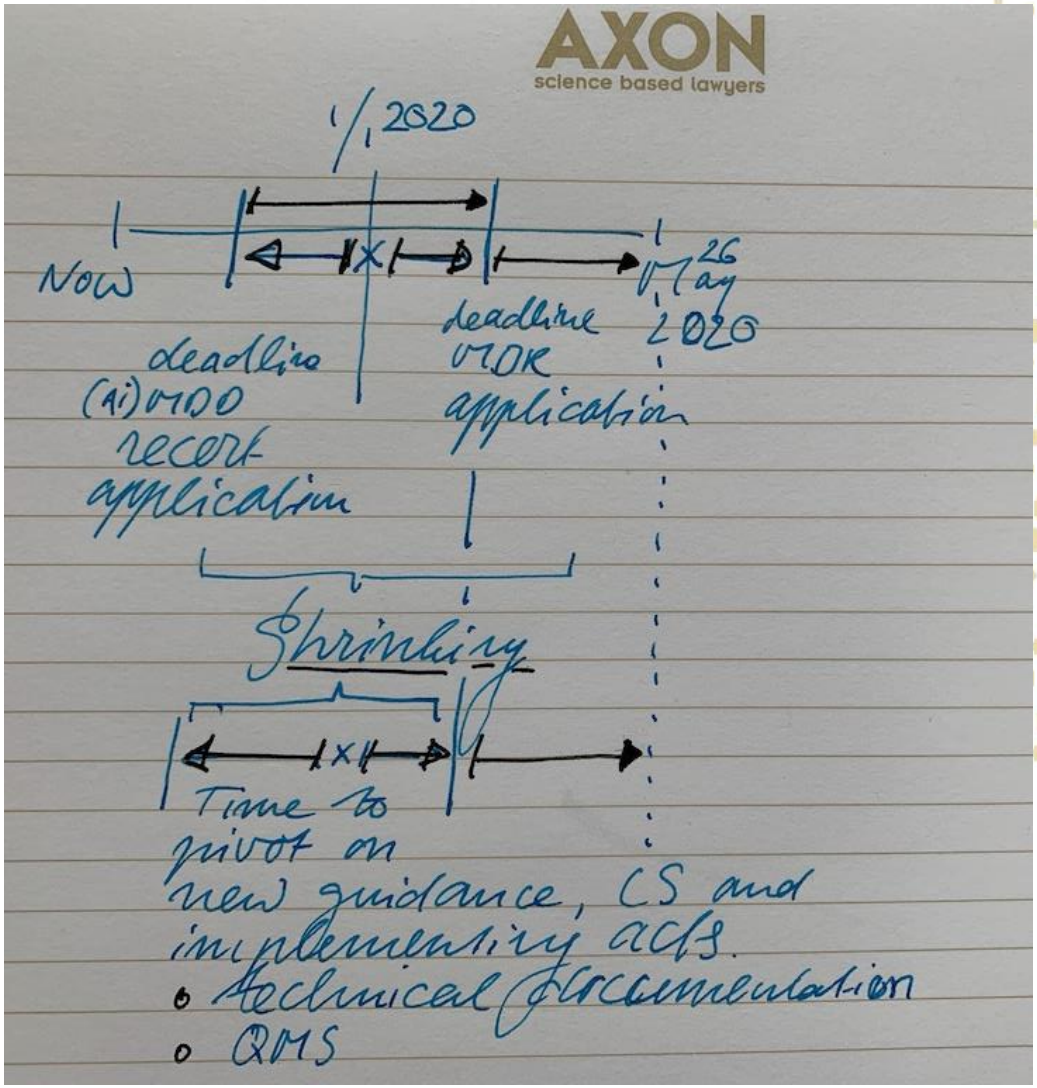
Which	What
Known knowns	• MDR text • Rolling Plan that keeps changing • When to apply at notified body for (AI)MDD recert?
Known unknowns	• Corrigendum – dots, commas and transition? • Common specifications • Implementing acts • Basically all guidance (except MDCG stuff on UDI and CAMD Q&A) • Eudamed functionality by March 2020 • National implementation • Your notified body ready to accept MDR cert application

Unknown unknowns	• National enforcement in case of
	  • bottleneck induced shortages
	  • notified body failing to deliver MDR certificate timely

All over the place unpredictably crazy	• Brexit

Pressure points implementation

- Options and time to implement them are shrinking rapidly
- Sitting on your hands is not an option because reality will paint you into a corner
- You will have to work with what is there and plan for last moment corrections



Cleaning, disinfection and sterilisation products: now devices

Article 2 (1) – definition of medical device expanded:

The following products shall also be deemed to be medical devices:

– devices for the control or support of conception;

products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first subparagraph of this point.

- Placing these products on the market or putting them into service means that the health institution becomes a medical devices manufacturer

Reminder

Article 5 (1) MDR:

"A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose."

- The manufacturer determines the intended purpose
- Whoever changes something about it later becomes a manufacturer himself.

- MDR contains more detail about maintenance than MDR
- MDR forces users to look more seriously at Medical Technology Covenant (already also implemented in AMvB Wkkgz)

    - Version 3.0 (MDR version) in the making - will also have to connect to MDR and IVDR

Manufacturer CE only guarantees performance when maintained as prescribed

- Annex I point 6:
    - “The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.”
- Abnormal conditions of use and/or maintenance not in accordance with instructions: CE expires, manufacturer not liable
- Annex I, point 23.4(k) manufacturer shall specify the nature and frequency of preventive and periodic maintenance and of any preliminary cleaning or disinfection

Manufacturer CE only guarantees performance when maintained as prescribed

Annex I, Section 23.4: Manufacturer shall specify in instructions for use:

- (j) any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons;
    - May also include maintenance personnel
- (k) the nature and frequency of preventive and periodic maintenance and of any preparatory cleaning or disinfection

Manufacturer CE only guarantees performance when maintained as prescribed

- Annex I section 23 IFU requirements:
    - (n) if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses;
    - (o) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements;

New regulatory category of reusable surgical instrument

Annex VIII, 2.3:

- an instrument intended for surgical use
- in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures,
- without a connection to an active device and
- which is intended by the manufacturer to be reused
- after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out

CE certification of class I re-usable instruments

Article 52 (7) (c) MDR:

- For reusable surgical instruments, the manufacturer shall apply the procedures set out in Chapters I and III of Annex IX, or in Part A of Annex XI.
- However, the involvement of the notified body in those procedures is limited to those aspects related to the reuse of the device, in particular
    - cleaning,
    - disinfection,
    - sterilisation,
    - maintenance and functional tests and
    - the corresponding instructions for use
- Not class Ir certified on 26 May 2020: device cannot be placed on market and hospital may not use new instrument

New classification rule for disinfecting / sterilization devices

Rule 16:

- All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, **unless**
    - disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing: class IIb
    - specifically intended to be used for disinfecting, cleaning, rinsing or hydrating contact lenses:class IIb

Not applicable to to devices that are intended to clean devices other than contact lenses by means of physical action only

Manufacturer?

The MDR provides for a number of ways that a sterilisation or cleaning services provider becomes a manufacturer:

- Placing your own device for cleaning, diinfection or sterilisation on the market (article 2 (1))
- Modification of device (article 16)
- Reprocessing (e.g. for third parties) (article 17)
- Placing on the market / using non-CE marked products for sterilisation, disinfecting or cleaning of devices

Being a manufacturer under the MDR has consequences (see article 10)

Definition of reprocessing

Article 2 (39)

- ‘reprocessing’ means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device;

When does a reprocessing provider become manufacturer?

Article 17 Single-use devices and their reprocessing

- If allowed by the member state (article 17 (1)) – NL AMvB in progress
- Any natural or legal person who reprocesses a single-use device to make it suitable for further use within the Union shall be considered to be the manufacturer of the reprocessed device and **shall assume the obligations incumbent on manufacturers** laid down in this Regulation, which include obligations relating to the traceability of the reprocessed device in accordance with Chapter III of this Regulation. **The reprocessor of the device shall be considered to be a producer for the purpose of Article 3(1) of Directive 85/374/EEC.** (article 17 (2))
- Member States may choose to apply the [reprocessing requirements] also as regards single-use devices that are reprocessed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the [reprocssing] requirements. (article 17 (4))

When does a sterilisation services provider become manufacturer?

As regards single-use devices that are reprocessed **and** used within a health institution, Member States may decide not to apply all of the rules relating to manufacturers' obligations laid down in the MDR provided that they ensure that:

- safety and performance of the reprocessed device is equivalent to that of the original device and the requirements for HPDs (article 5 (5))
- the reprocessing is performed in accordance with CS

- Also applies in case of single-use devices that are reprocessed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to that health institution and the external reprocessor complies with the above requirements

    - Unclear if it applies to health institutions reprocessing for each other.

Hospital produced devices

Article 5 (5) MDR – they have to meet Annex I requirements, so also for sterilisation, cleaning and re-use

“With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met […]:

- (e) (iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor,”

Third party parts & components

Non-original parts must be validated and supporting evidence must be available that performance or safety features are not impaired or the intended purpose is changed (Article 23 (1) MDR /20 (1) IVDR).

- Responsibility for the part at the supplier of the part (article 23 (1) MDR /20 (1) IVDR)
- Responsibility CE of the device at end user (article 5 (1) MDR / IVDR)

If the part significantly alters performance or safety characteristics or the intended purpose of the device, it shall be considered a device in itself and shall meet all the requirements set out in the MDR/IVDR (Article 23 (2) MDR / 20 (2) IVDR).

Third parties: parts & components

- Non-OEM replacement parts and components must have supporting evidence that they do not adversely affect the safety and performance of the device
- Non-OEM enhancement parts are devices and must be CE marked separately
    - How will that work in practice? – accessory type evaluation?
    - Is manufacturer obliged to development of supporting evidence for competing non-OEM parts/components?

Sterilization aspects of UDI

Annex VI part B some relevant core data elements of device UDI include:

14. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),
[…]
16. labelled as a single-use device (y/n),
17. if applicable, the maximum number of reuses,
18. device labelled sterile (y/n),
19. need for sterilisation before use (y/n),

Sterilization / cleaning aspects of UDI

UDI carrier requirements (Annex VI part C, 4.10 (and 6.2)) - direct part marking of reusable devices:

“4.10. Devices that are reusable shall bear a UDI carrier on the device itself. The UDI carrier for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device. The requirement of this Section shall not apply to devices in the following circumstances:

(a) any type of direct marking would interfere with the safety or performance of the device;
(b) (b) the device cannot be directly marked because it is not technologically feasible.”

Significant change and sterilization

Many manufacturers will be operating on renewed (AI)MDD certificates in the period May 2020 – May 2024 as allowed under article 120 (3) MDR

- **But:** certificate invalid if 'significant change' occurs (article 120 (3) MDR)

- Significant sterilization related changes (Joint Industry Position):

    - Change of terminal sterilization method
    - Design change which makes the device „more difficult" to sterilize
    - Change of packaging which affects functionality, safety, stability or seal integrity
    - Change of shelf-life, unless validated by using approved protocols and methods

EU secondary law to implement / amend MDR

- Implementing acts underway and may change existing MDR requirements on the fly (e.g. GSPRs)

- Common specifications for reprocessing (still) in preparation

National implementation of MDR/IVDR

- Many legal obligations will follow from national implementation of MDR
    - E.g. national choices on fines and costs of surveillance
    - Reprocessing allowed or not?
    - Outsourced reprocessing allowed or not?
    - Types of devices for hospital production?
    - Require custom made devices manufacturers to submit lists of devices made available
    - Require HCPs and institutions to store UDI of implants
    - Implementation of clinical trial provisions (e.g. require EU representative appointment or not)
    - Etc.

Netherlands implementation act re reprocessing of SUDs

- Reprocessing of SUDs is allowed (article 5)
- Further requirements allowed under article 17 (9) MDR can be imposed by decree:

  A Member State that permits reprocessing of single-use devices may maintain or introduce national provisions that are stricter than those laid down in this Regulation and which restrict or prohibit, within its territory, the following:
  - (a) the reprocessing of single-use devices and the transfer of single-use devices to another Member State or to a third country with a view to their reprocessing;
  - (b) the making available or further use of reprocessed single-use devices.

NL implementation act is MUCH more punitive than current law

- Misleading information provision / advertising (art. 7 MDR / IVDR) criminal offense
- Recidivism of hospitality provisions (*gunstbetoon*) criminal offense
- Pretty steep penalties foreseen (up to 10% of last year's turnover), for device compliance infringements e.g.

    - Infringement of general compliance, clinical evaluation and GSPR requirements
    - Infringement of hospital produced devices provisions

    - This will be a departure from the current IGJ penalty policy with its top penalty of € 900.000

- Costs of surveillance to be passed on to industry
- Infringement of informed consent in device trials criminal offense

Artikel 14 Bestuurlijke boete

1. Onze Minister is bevoegd tot oplegging van een bestuurlijke boete van ten hoogste het bedrag dat is vastgesteld voor de zesde categorie, bedoeld in artikel 23, vierde lid, van het Wetboek van Strafrecht of, indien dat meer is, ten hoogste 10% van de omzet van de onderneming, in het boekjaar voorafgaande aan de beschikking waarin de bestuurlijke boete wordt opgelegd, ter zake van een gedraging die in strijd is met:


ALL
RIK

THANKS FOR YOUR ATTENTION

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