Ministerie van Volksgezondheid,
Welzijn en Sport

# Veldbijeenkomst implementatie MDR/IVDR

27 november 2019

Ministerie van Volksgezondheid,
Welzijn en Sport

# Programma

1. Best practices door het veld
   - Verschillende voorbeelden van zowel fabrikanten als zorginstellingen

2. Nationale ontwikkelingen
   - Update wetgeving
   - Update CCMO

   *Pauze*

3. Europese ontwikkelingen

4. Vraag en antwoord

   *Afsluiting en borrel*

Ministerie van Volksgezondheid,
Welzijn en Sport

- Best practices door het veld
  1. *Nefemed en Firevaned*
  2. *FHI en FME*
  3. *NFU en NVZ*

# Best practices door het veld

- Firevaned en Nefemed
- Patrick Bakker – Zimmerbiomet
- Leander Leijh - Medux

NEFEMED
PARTNER IN DE ZORG

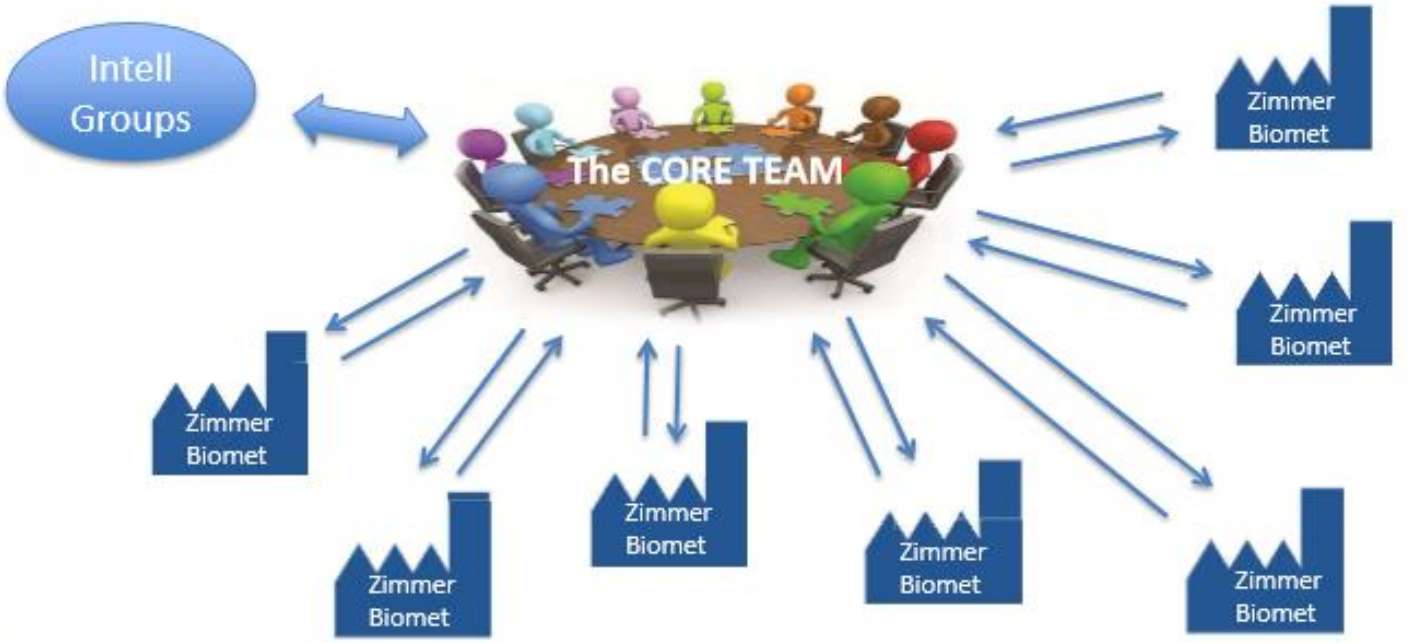
# Best practices door het veld: MDR

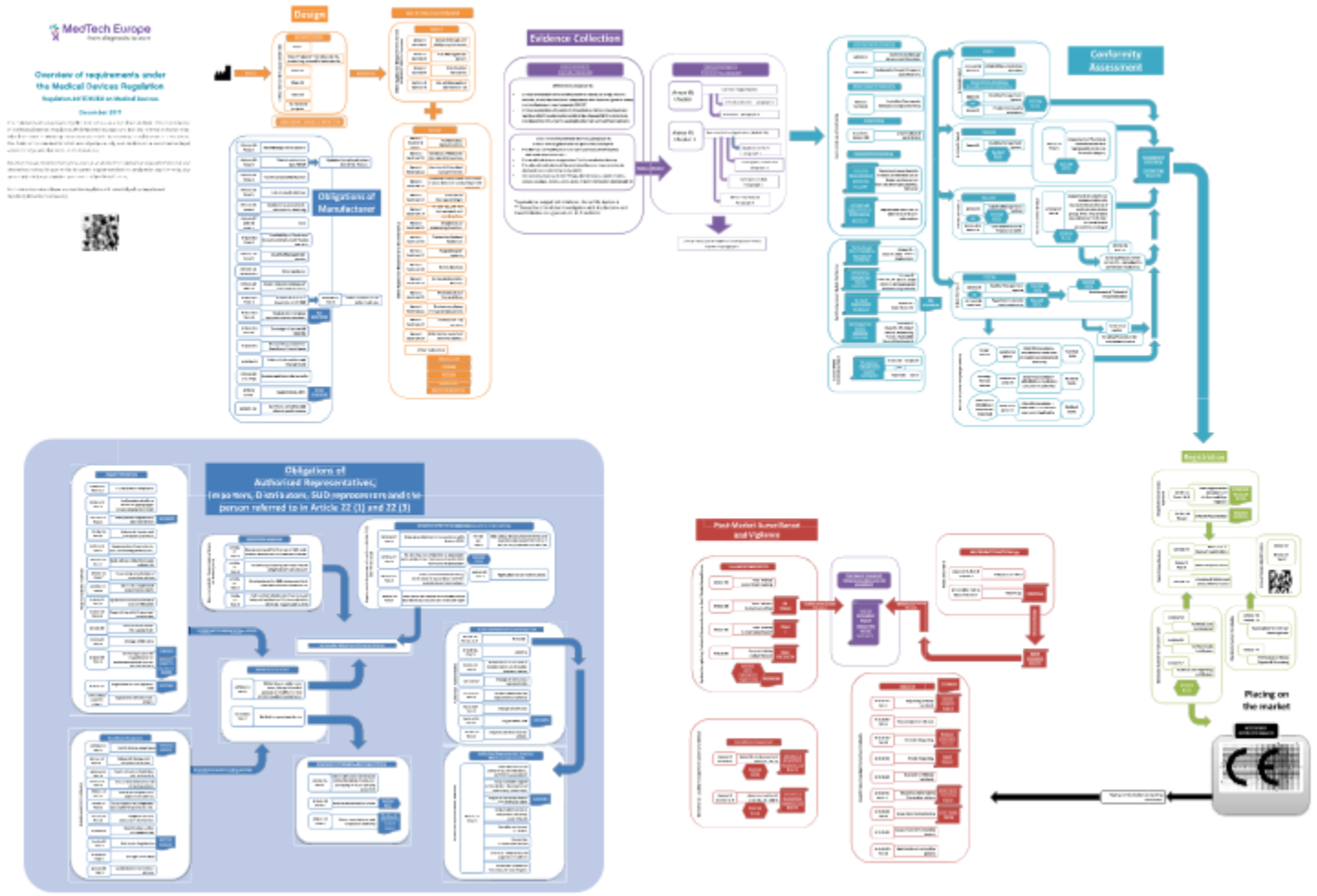
Patrick Bakker
QA/RA Specialist
Zimmer Biomet
Nederland B.V.

# *Ons inzetten voor de hoogste norm van patiëntveiligheid, kwaliteit en integriteit*

We zetten ons in voor de hoogste norm van patiëntveiligheid en kwaliteit in onze producten en diensten en erkenning voor integriteit en ethisch zaken doen.

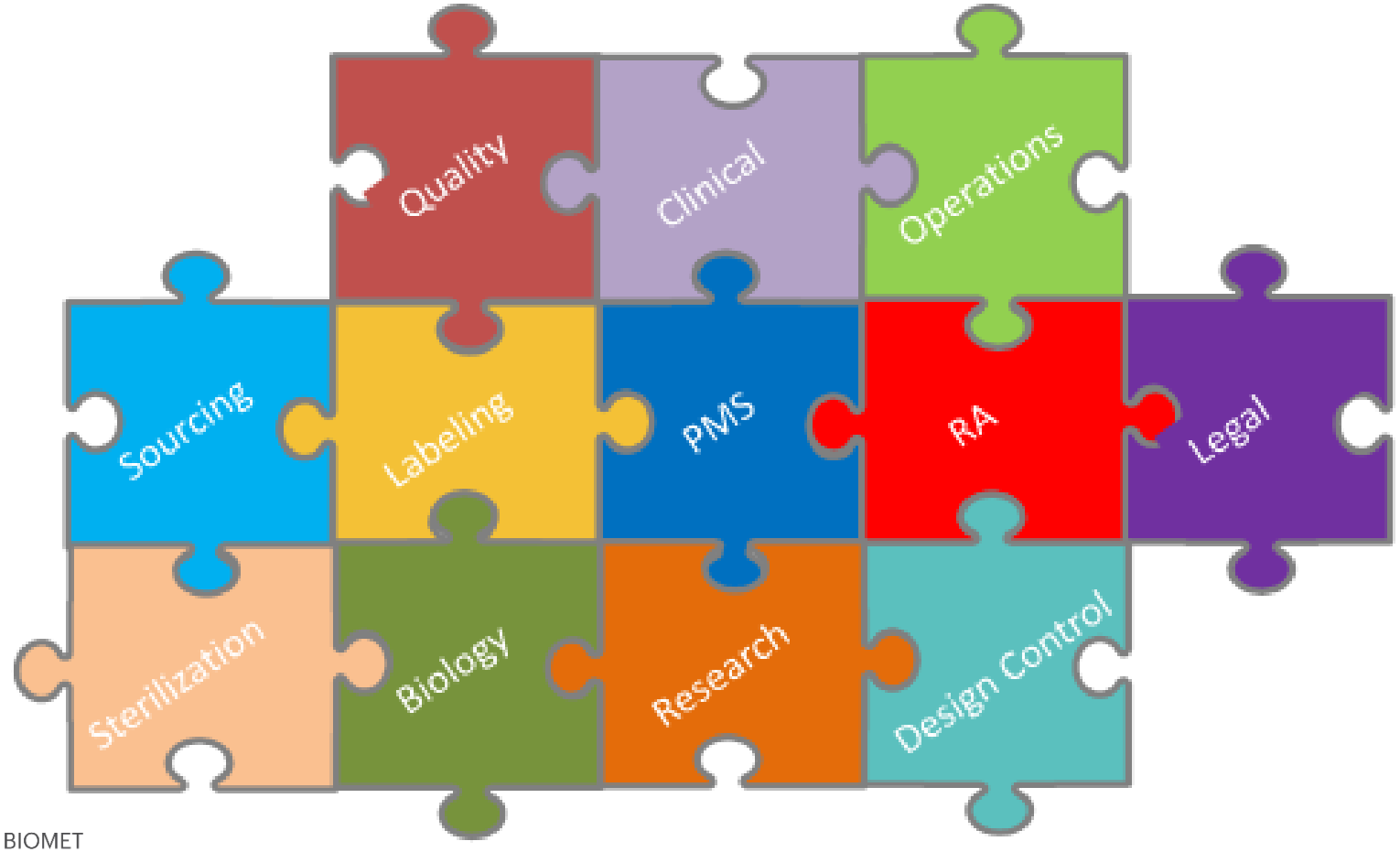
# Implementation at the local level




This flowchart has been prepared by MedTech Europe as a 'high-level overview' of the requirements of the Medical Devices Regulation.

# Interne puzzel

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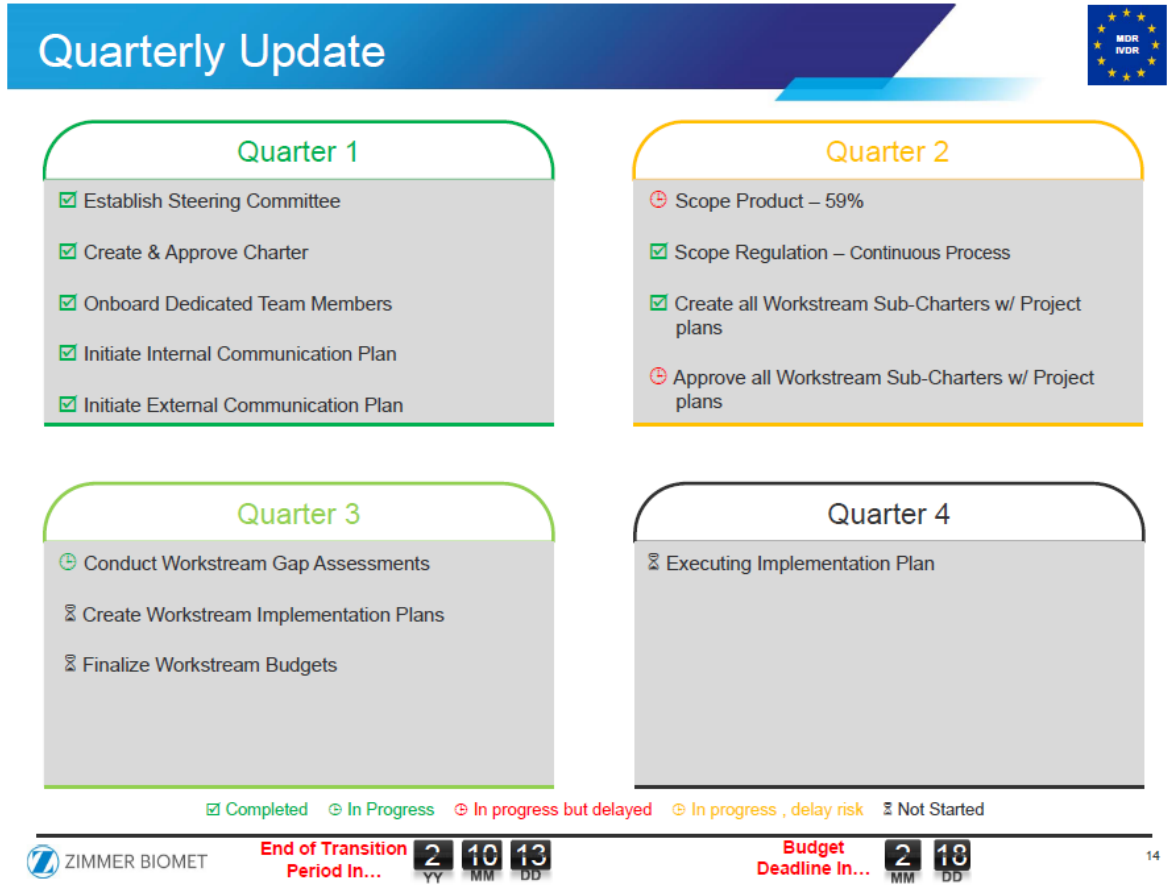
# Uit presentatie 12 july 2017



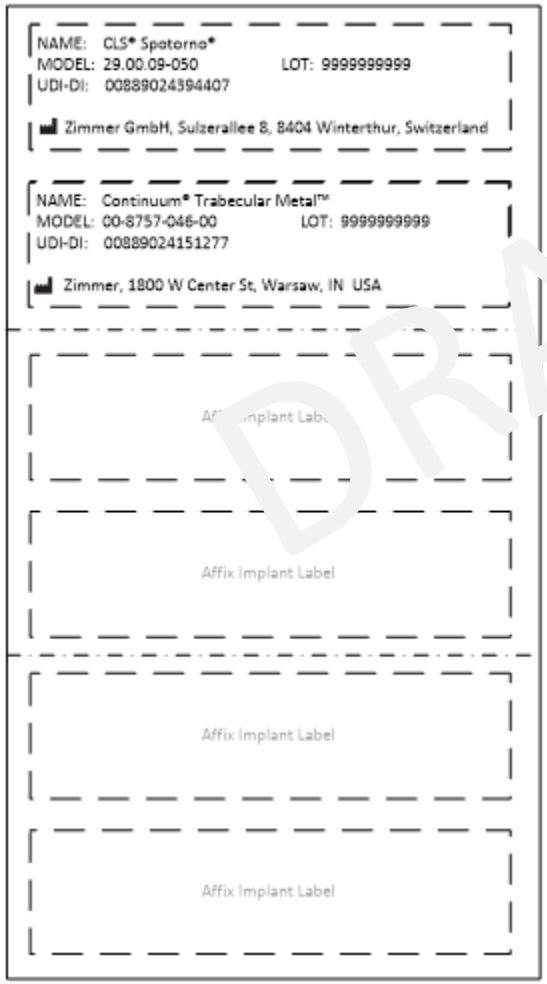
# Veranderen

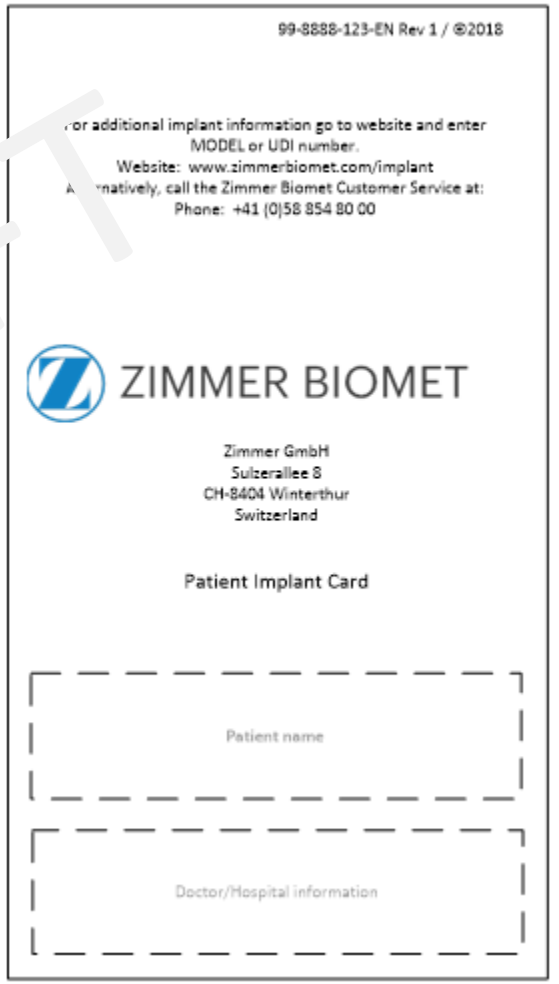

Who wants change?
Who wants to change?
Who wants to lead the change?

# Voorbeeld

**Implantaatkaart (Artikel 18 MDR)**

**Patient Card Draft**

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# Best practice

Enkele punten als voorbeeld:

- e-IFU
- Hogere mate van samenwerking met onze toeleveranciers
- Afnemers/ziekenhuizen sterkere ketenpartner
- door MDR wordt er in de transitie al steeds meer dezelfde taal gesproken, partijen begrijpen elkaar beter.

Bedankt voor uw aandacht!

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+31 6 2395 6414

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medux

# Implementatie MDR

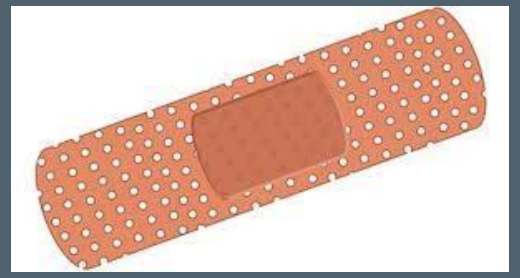
25-11-2019, Leander Leijh

# Inhoud

- Voorbereiding op de MDR
- Risico’s en kansen
- Waar staan we nu
- What’s next

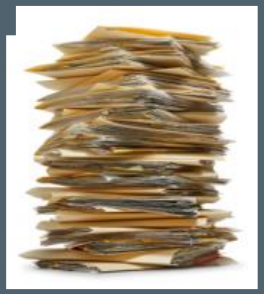
# Voorbereiding op de MDR

- Vaststellen van de belangrijkste wijzigingen
- Benoemen van de thema's die invloed kunnen hebben vanuit onze rol
- Deelnemen in branche overleggen
- Vaststellen van risico's en op zoek naar kansen



# Risico’s en kansen

- Grootste risico’s:
  - Verhoging van administratieve lasten
  - Niet kunnen continueren bepaalde producten
  - Onvoldoende aandacht voor verschillen tussen risicoklassen
  - Toename in kosten
- Kansen:
  - Toonaangevend zijn door in te spelen op de risico’s
  - Versterken samenwerking in de keten
  - Optimaliseren kwaliteit en daarmee kosten reduceren



# Waar staan we nu?

- Nog niet alles is bekend, maar veel al wel
- Fit-Gap analyse op processen
- Dialoog met toeleveranciers
- Afstemming met klanten; wat leeft daar?
- In samenspraak met branche kijken naar mogelijkheden om zaken te vereenvoudigen

# What's next?

- Veel moet nog komen en geconcretiseerd worden in de keten
- Tot medewerker niveau uitleggen wat de impact op werk is
- Doorrekenen gevolgen en vaststellen financiële impact

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meer
mogelijk
maken.

**Medux B.V.**

Reactorweg 160
3542 AD Utrecht

**www.medux.nl**

# Best practices door het veld

- FHI en FME
- Rick Paauw - Medtronic

# EU MDR

## VELDBIJEENKOMST

## @ VWS

November 27  2019

Medtronic

# MDR IMPLEMENTATION ACTIVITIES AT MEDTRONIC

We **analyzed the changes** and the impact to our company and products.

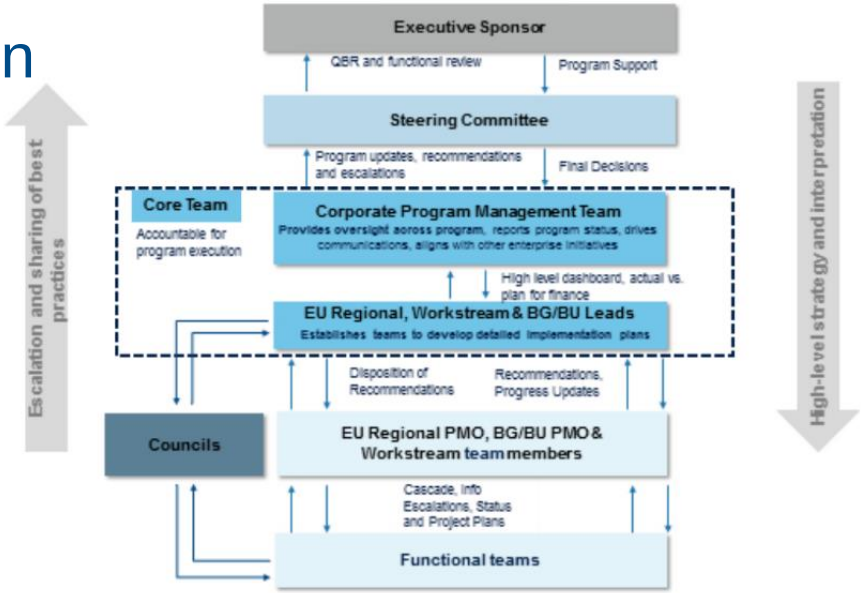
>76,000 models (CFNs)*
> 95,000 barcodes (GTINs)*
>2/3 of products sold outside EU as well

*Based on SAP report 11/29/2016; adjustment needed to remove obsolete materials and associated information.

>1530 technical documents
>750 CERs, 13 Notified Bodies
> 97,000 package labels
>140 quality systems covering
>65,000 quality documents

We then **took action** to address the implementation across the company.

| Article Chapter | Key Regulated Elements | Related Annexes |
|---|---|---|
| Scope & Definitions | Devices with non-viable human tissues, Devices for aesthetic purposes, Definitions of economic operators | Annex XVI |
| Making Available of Medical Devices | Common Specifications, Economic Operators, SUD Reprocessing, PRRC, Implant Cards, DoC, System & Procedure Packs | Annexes I, IV, V, XII |
| Identification and Traceability | UDI Database Structure and Data Elements, UDI Definitions, Registration of Economic Operators & Devices, SSCP | Annex VI |
| Notified Bodies | Notified Body Qualification Requirements, Designation Process and Auditing by Competent Authorities | Annex VII |
| Classification & Conformity Assessment | Up-classifications, Conformity Assessment Procedures, Panel Review and Scrutiny, Safety and Performance Requirements | Annexes I, II, VIII, IX, X, XI, XIII |
| Clinical Evaluation & Investigation | Restriction of Equivalence Reference, Clinical Investigation Application, Conduct and Reporting | Annexes II, XIV & XV |
| Post-Market Surveillance | Post-Market Plan, Periodic Safety Report, Incident and Trend Reporting (Vigilance), Market Surveillance by CAs | Annex III |



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# CHANGES TO VIGILANCE REPORTING CRITERIA

We mapped the regulatory requirements by data of application.

| | MDR | | | |
|---|---|---|---|---|
| **Regulatory Requirements by DoA** | **Class I (nm,ns,nr)** | **Class Ir si** | **Class I (s,m), Class IIa, IIb** | **Class III, IIb implantables** |
| QMS recertification for MDR | | | | |
| NB QMS/Tech Doc review for MDR | | | | |
| Economic Operator definition/contracting | | | | |
| Technical Documentation (incl GSPR) | | | | |
| DoC updates | | | | |
| Economic operator registration | | | | |



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# CHANGES TO VIGILANCE REPORTING CRITERIA

Reporting will increase, based on historical data and MDR requirements.

| MEDDEV 2.12 rev 8 Vigilance Reporting | Current MDD/AIMDD | EU MDR |
|---|---|---|
| 5.1.7 Report immediately, but no later than 2 days | Reportable | Reportable (no change) |
| 5.1.7 Report immediately, but no later than 10 days | Reportable | Reportable (no change) |
| ----- Report immediately, but no later than 15 days (CZ) | Reportable | Reportable (no change) |
| 5.1.7 Report immediately but no later than 30 days | Reportable –> 30 days | Reportable -> 15 DAYS (CHANGE) |
| 5.1.2 Periodic summary reporting | Reportable | Reportable (conditions&format changed) |
| 5.1.1.B No evidence event is product related and/or device tested satisfactorily | Not reportable | Not Reportable<br>15 day deadline may impact |
| 5.1.1.C No risk of death or serious injury | Not reportable | Not Reportable (no Change) |
| 5.1.3.1 Deficiency of a device found by user prior to its use | Not Reportable | Reportable (CHANGE) |
| 5.1.3.2 Event caused by patient conditions | Not Reportable | Reportable (CHANGE) |
| [illegible] | Not Reportable | Reportable (CHANGE) |
| [illegible] | [illegible] | Reportable (CHANGE) |



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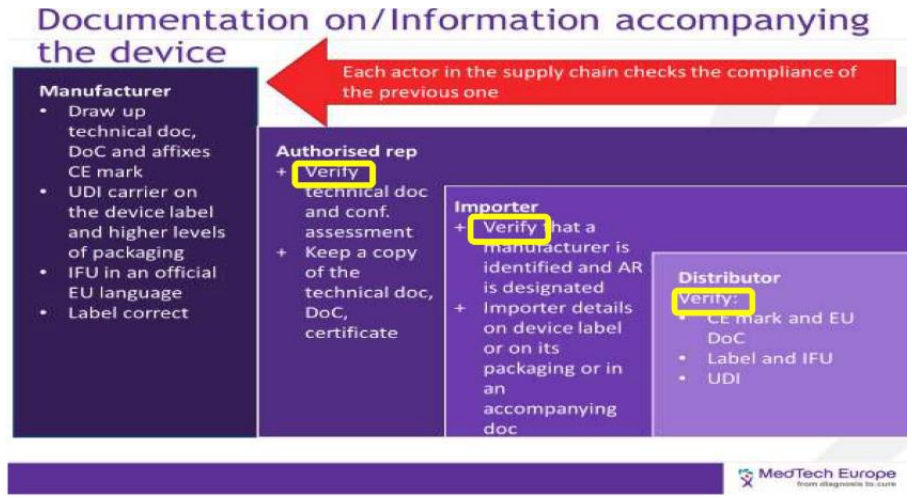
# ECONOMIC OPERATORS WITHIN MEDTRONIC

| 1 MANUFACTURER | 3 IMPORTER | 4 DISTRIBUTOR | 4 DISTRIBUTOR | CUSTOMER |
|---|---|---|---|---|
| Medtronic Inc., Minimed Inc., Covidien LLC,... | MEDTRONIC BV Heerlen or Netherland | LOCAL EUROPEAN SALES OFFICES | "EXTERNAL DISTRIBUTOR" | |
| BUs | EOC 2&3, Rolo, Alcala, Leipzig | MDT Gmbh, MDT France,... | | |
| BU QS / BU QS / BU QS | 1 QS EMEA Logistics | 1 QS EMEA Market | | |
| BU | AUTHORIZED | | | |



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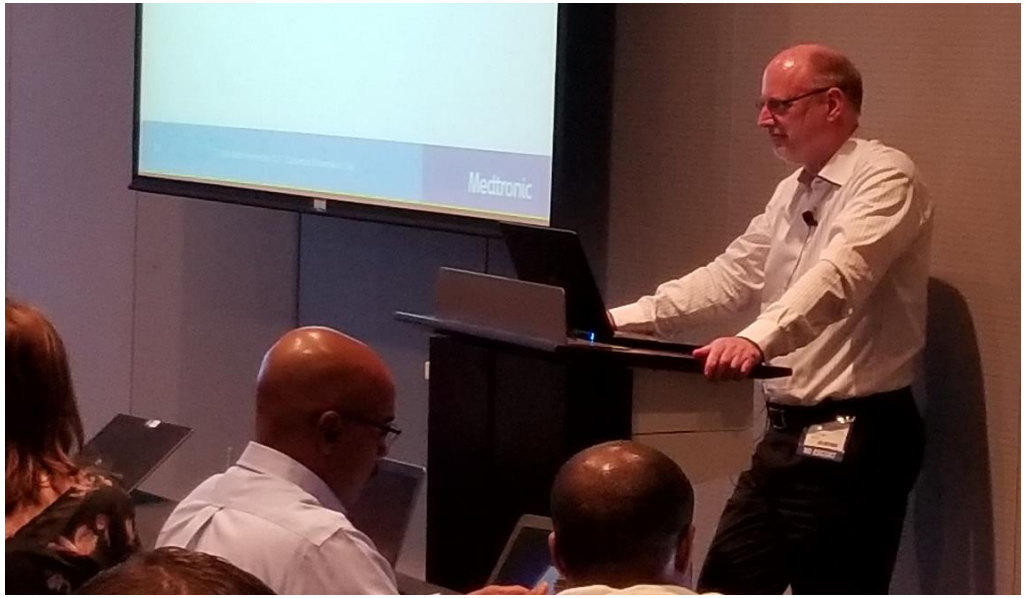
# TRAINING OF ALL EMPLOYEES ON EU MDR

## Face-to-face sessions




## eLearning and WebEx sessions

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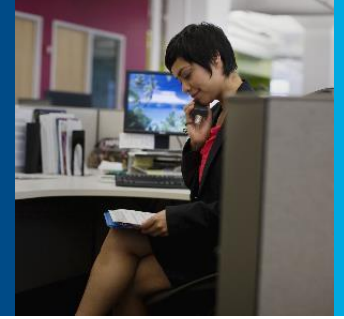
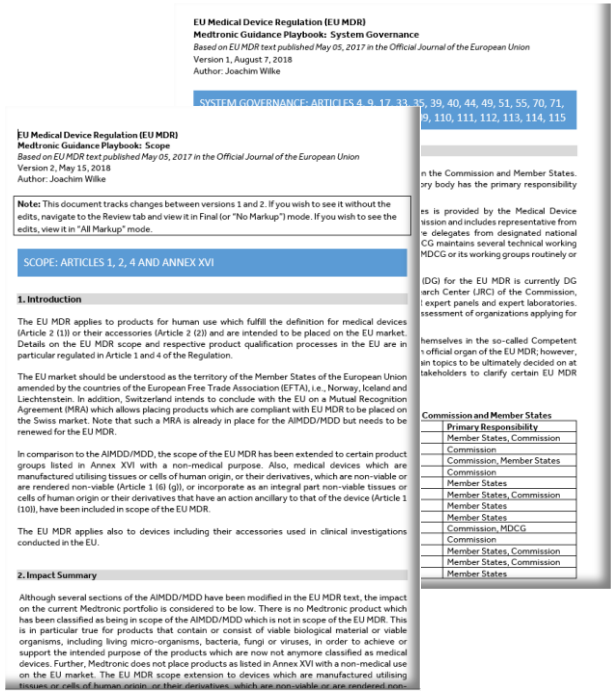
# GUIDANCE AND INTERPRETATION



## We developed a **playbook**



EU Medical Device Regulation (EU MDR)
**Medtronic Guidance Playbook: System Governance**
*Based on EU MDR text published May 05, 2017 in the Official Journal of the European Union*
Version 1, August 7, 2018
Author: Joachim Wilke

SYSTEM GOVERNANCE: ARTICLES 4, 9, 17, 33, 35, 39, 40, 44, 49, 51, 55, 70, 71, 9, 110, 111, 112, 113, 114, 115

EU Medical Device Regulation (EU MDR)
**Medtronic Guidance Playbook: Scope**
*Based on EU MDR text published May 05, 2017 in the Official Journal of the European Union*
Version 2, May 15, 2018
Author: Joachim Wilke

**Note:** This document tracks changes between versions 1 and 2. If you wish to see it without the edits, navigate to the Review tab and view it in Final (or "No Markup") mode. If you wish to see the edits, view it in "All Markup" mode.

SCOPE: ARTICLES 1, 2, 4 AND ANNEX XVI

**1. Introduction**

The EU MDR applies to products for human use which fulfill the definition for medical devices (Article 2 (1)) or their accessories (Article 2 (2)) and are intended to be placed on the EU market. Details on the EU MDR scope and respective product qualification processes in the EU are in particular regulated in Article 1 and 4 of the Regulation.

The EU market should be understood as the territory of the Member States of the European Union amended by the countries of the European Free Trade Association (EFTA), i.e., Norway, Iceland and Liechtenstein. In addition, Switzerland intends to conclude with the EU on a Mutual Recognition Agreement (MRA) which allows placing products which are compliant with EU MDR to be placed on the Swiss market. Note that such a MRA is already in place for the AIMDD/MDD but needs to be renewed for the EU MDR.

In comparison to the AIMDD/MDD, the scope of the EU MDR has been extended to certain product groups listed in Annex XVI with a non-medical purpose. Also, medical devices which are manufactured utilising tissues or cells of human origin, or their derivatives, which are non-viable or are rendered non-viable (Article 1 (6) (g)), or incorporate as an integral part non-viable tissues or cells of human origin or their derivatives that have an action ancillary to that of the device (Article 1 (10)), have been included in scope of the EU MDR.

The EU MDR applies also to devices including their accessories used in clinical investigations conducted in the EU.

**2. Impact Summary**

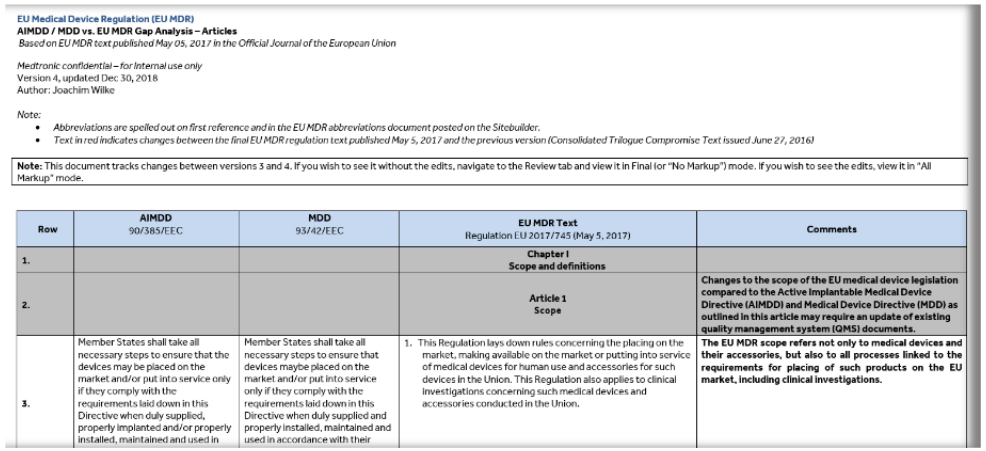
Although several sections of the AIMDD/MDD have been modified in the EU MDR text, the impact on the current Medtronic portfolio is considered to be low. There is no Medtronic product which has been classified as being in scope of the AIMDD/MDD which is not in scope of the EU MDR. This is in particular true for products that contain or consist of viable biological material or viable organisms, including living micro-organisms, bacteria, fungi or viruses, in order to achieve or support the intended purpose of the products which are now not anymore classified as medical devices. Further, Medtronic does not place products as listed in Annex XVI with a non-medical use on the EU market. The EU MDR scope extension to devices which are manufactured utilising tissues or cells of human origin, or their derivatives, which are non-viable or are rendered non-

n the Commission and Member States.
ory body has the primary responsibility
es is provided by the Medical Device
ission and includes representative from
e delegates from designated national
CG maintains several technical working
MDCG or its working groups routinely or
(DG) for the EU MDR is currently DG
arch Center (JRC) of the Commission,
expert panels and expert laboratories.
ssessment of organizations applying for
hemselves in the so-called Competent
official organ of the EU MDR; however,
in topics to be ultimately decided on at
takeholders to clarify certain EU MDR

Commission and Member States

| | Primary Responsibility |
|---|---|
| | Member States, Commission |
| | Commission |
| | Commission, Member States |
| | Commission |
| | Member States |
| | Member States, Commission |
| | Member States |
| | Member States |
| | Commission, MDCG |
| | Commission |
| | Member States, Commission |
| | Member States, Commission |
| | Member States |

## We conducted a gap analysis



EU Medical Device Regulation (EU MDR)
**AIMDD / MDD vs. EU MDR Gap Analysis – Articles**
*Based on EU MDR text published May 05, 2017 in the Official Journal of the European Union*

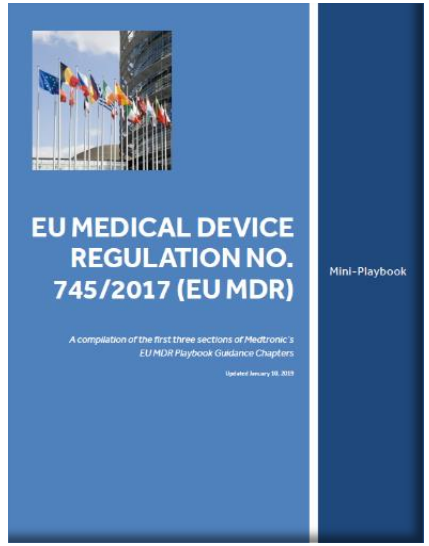
*Medtronic confidential – for internal use only*
Version 4, updated Dec 30, 2018
Author: Joachim Wilke

*Note:*
- *Abbreviations are spelled out on first reference and in the EU MDR abbreviations document posted on the Sitebuilder.*
- *Text in red indicates changes between the final EU MDR regulation text published May 5, 2017 and the previous version (Consolidated Trilogue Compromise Text issued June 27, 2016)*

**Note:** This document tracks changes between versions 3 and 4. If you wish to see it without the edits, navigate to the Review tab and view it in Final (or "No Markup") mode. If you wish to see the edits, view it in "All Markup" mode.

| Row | AIMDD 90/385/EEC | MDD 93/42/EEC | EU MDR Text Regulation EU 2017/745 (May 5, 2017) | Comments |
|---|---|---|---|---|
| 1. | | | **Chapter I Scope and definitions** | |
| 2. | | | **Article 1 Scope** | **Changes to the scope of the EU medical device legislation compared to the Active Implantable Medical Device Directive (AIMDD) and Medical Device Directive (MDD) as outlined in this article may require an update of existing quality management system (QMS) documents.** |
| 3. | Member States shall take all necessary steps to ensure that the devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied, properly implanted and/or properly installed, maintained and used in | Member States shall take all necessary steps to ensure that devices maybe placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their | 1. This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. This Regulation also applies to clinical investigations concerning such medical devices and accessories conducted in the Union. | **The EU MDR scope refers not only to medical devices and their accessories, but also to all processes linked to the requirements for placing of such products on the EU market, including clinical investigations.** |

## We monitor changes and make updates






Medtronic


# FME Zorg

FME ZORG

# EU MEDICAL DEVICE REGULATION (EU) 2017/745

## MDR CHALLENGES

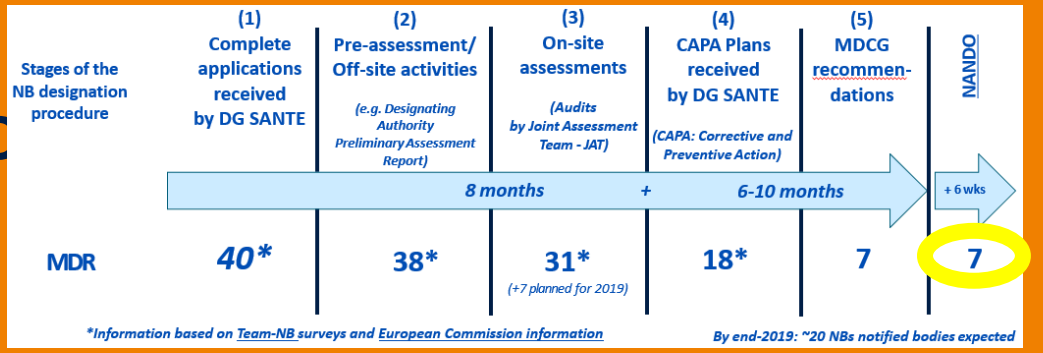
- Notified Body designation
- Drug device combination consultation
- Grace period
- PMCF
- MDR product information requests from customer
- Eudamed (2 years postponed)
- Local Laws

FME POWERED BY DUTCH TECHNOLOGY

FME ZORG

# EU MEDICAL DEVICE REGULATIC (EU) 2017/745

## NOTIFIED BODY DESIGNATION




**Medical Device recertifications delay**

Currently thousands of life saving/changing devices are waiting at the desk of the Certification Bodies waiting for certificates to be issued. These are piling up since CB's don't have the resources to issue the certificates prior May 2020.

Proven and/or essential / life-saving technologies maybe interrupted / not available due to a (currently perceived) capacity issue at notified bodies – to issue renewal certificates under the current guidance (MDD/AIMD – derogation till May 2024)

**State of the art definition discussion**

Some of the above referenced products, may not meet the "state of the art" definition – should have been covered under AIMD/MDD Certification – the real issue may be the absence of additional or "sufficient" clinical data, as required per the MDR. Although they have been in the market for years without patient safety issues or concerns.

Smaller companies discontinue because they don't have the resources/budget. This might contribute to more product disruption / shortage / total unavailability of certain products.

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# EU MEDICAL DEVICE REGULATION (EU) 2017/745
## DRUG DEVICE COMBINATION CONSULTATION

MedTech Europe
from diagnosis to cure

**Device-drug combination products:**
**Shall the 210-day pharma authority consultation be repeated for legacy products?**

**10 May 2019**

MedTech Europe is seeking a clarification on the appropriate procedure to be applied by Notified bodies in upgrading devices compliant to Directives 93/42 on Medical Devices (MDD) and 90/385 on Active Implantable Medical Devices (AIMD), which incorporate a substance which could be considered a medicinal product, to the requirements of Regulation 2017/745 on Medical Devices (MDR).

MedTech Europe's interpretation of Section 5.2 of Annex IX of the Regulation 2017/745 is that, in principle, there will not be the need to require again a scientific opinion from one of the competent bodies established in the Directive 2001/83 on Medicinal Products for Human Use or with medicinal substance and the way it is

- FME is aligned with the MedTech position paper regarding:

**Device-drug combination products and if the 210-day pharma authority consultation shall be repeated for legacy products**

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# EU MEDICAL DEVICE REGULATION (EU) 2017/745
## DRUG DEVICE COMBINATION CONSULTATION

Section 5.2 (a) of Annex IX of the Regulation 2017/745
Devices that incorporates

- **as an integral part** ,  - **a substance**,  - **which, if used separately**

may be considered to be a medicinal product within the meaning of Dir. 2001/83/EC

Section 5.2 (b)

The NB shall, seek a scientific opinion from a CA designated in accordance with Directive 2001/83/EC or from the EMA…

Section 5.2 (f)

- Before any change is made with respect to an ancillary substance,…., the manufacturer shall inform the NB.
- The NB shall seek the opinion of the medicinal products authority, in order to confirm that the quality and safety of the ancillary substance remain unchanged.

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# EU MEDICAL DEVICE REGULATION (EU) 2017/745
## DRUG DEVICE COMBINATION CONSULTATION

**Interpretation of the AIMD, MDD and MDR, is that there is no change to the rationale, or the scope for a scientific consultation.**
**Therefor it could be possible for a NB to evaluate the existing data, to determine whether the scientific opinion, independently under which legal regime it was delivered, is positive and in place.**

This should be possible as long as there is no change in:
- the medicinal substance
- the manufacturing process
- and the way its integrated with the device remain the same

To comply with the MDR it's our interpretation of section 5.2 of annex IX, that a scientific opinion in accordance with Directive 2001/83 is not required again

This will avoid, a repetition of an unchanged Pharma Authority consultation with a potential delay up to 210 days

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# EU MEDICAL DEVICE REGULATION (EU) 2017/745

## GRACE PERIOD

**The European Commission is considering a corrigendum for extending the grace period for class I products - specifically, class I reusable surgical instruments and up-classified class I devices that require a notified body review by the date of application (DoA).**

This would allow four additional years to comply and allow more time to focus on higher-risk devices.

It means an additional Grace period for:

- Class Ir
- Up-classified class I devices that require a notified body review by the (DoA)
  Stand-alone SW could also benefit from the corrigendum if up-classified by MDR, (rule 11)

What about ?

- Class I products/software that become or that stay class I - Most likely not covered
- New products previously not falling under the MDD/AIMD - No, not covered
  For Annex XVI implementing acts may contain a grace period, unclear yet

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# EU MEDICAL DEVICE REGULATION (EU) 2017/745

## POST MARKET CLINICAL FOLLOW-UP

Article 61 (11): The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's PMCF plan …..

Clinical centers foresee challenges to meet the manufacturers expectations because:

- # of registries will likely increase
- Hospital will get a large amount of request got from Manufacturers to collect & share clinical data
- Hospitals don't have the budget / resources to facilitate these requests
- Hospitals have a lot of data but this can't easily pulled from the systems
- Providing manufacturers access to the hospitals system is difficult from GDPR / AVG point of view
- ....

STAKEHOLDERS NEED TO WORK TOGETHER TO UNDERSTAND EACH OTHERS…., ….

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# EU MEDICAL DEVICE REGULATION (EU) 2017/745
## MDR PRODUCT INFORMATION REQUEST

| | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 1. Article no. | 2. Z-Index nummer (Zicode) | 3. Supplier article no. | 4. Article name / description | 5. Ref number | 6. Intended Use Article | 7. CE-mark | 8. Conform regulations | 9. Certificate code (CE certificate or Declaration of conformity ID) | 10. Certificate expiry date | 11. Current risk class MDD/IVD | 12. New risk class MDR/IVDR | 13. Notified Body no. | 14. Is the medical device covered by a clause in Art 12 MDD 93/4 | 15. Name Manufacturer | 16. European representative when manufacturer is not EU | 17. Piece UDI (EAN) | 18. Inner carton EAN | 19. Outer carton EAN | 20. Pallet amount | 21. Single use |

| | V | W | X | Y | Z | AA | AB | AC | AD | AE | AF | AG | AH | AI | AJ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 22. Is education before processing for re-use of the product necessary? | 23. Is the item sterile ? | 24. If not sterile: is sterilisation possible? If yes, please fill out attachment | 25. Is training for safe use required? | 26. Specific storage conditions (indicate temp.) | 27. Are there specific requirements regarding waste processing of the product? | 28. Article contains latex | 29. Article contains phtalates | 30. Article contains *Bisphenol A* | 31. The product is made using nanotechnology | 32. If item is supplied sterile, is the shelf life less than 24 months after sterilization? | 33. Attachment name (Specification document [illegible] Sterile Products | 34. Attachment name (CE [illegible] | 35. Attachment name (Declaration of conformity) | 36. Attachment name IFU (Instruction For Use) |

**STATEMENT:**
The new EU Medical Device Regulation (MDR) is welcomed by Medtronic as it will strengthen the system for "CE marking" of medical devices and post-market surveillance of CE marked devices. Medtronic is committed to ensuring the quality, safety and performance of its products and therapies. We will continue to excel in meeting the strengthened standards and goals of the MDR, and as we transition the certification of our products.

**New Regulation**

- The European Union has adopted and published a new regulation related to medical devices.
- This new regulation strengthens the current system for "CE marking" of medical devices, including new requirements for post-market surveillance.
- The new regulation begins to apply as of May 26, 2020. The regulation provides for continuity from the current to the enhanced rules in the form of transition provisions, meaning that products with valid certificates under the current directive(s) can be made available until 2025 as long as they additionally meet a certain number of the MDR requirements such as post-market surveillance.
- The new regulation introduces several important improvements to modernize the current system, including control of manufacturers, importers, authorized representatives and distributors, increased requirements for clinical evidence and technical documentation, requirements related to risk management and vigilance reporting, an EU database for important information related to medical devices, and overall increased transparency.

**What's changed?**

- Medical Devices are transitioning from being CE marked under the two current (and separate) pieces of legislation, the Medical Devices Directive and the Active Implantable Medical Devices Directive, to being CE marked under a single new Medical Device Regulation.
- In general, the regulation retains all the requirements of the Directives, while adding some new ones. Compared to the current Directives, the new regulation emphasizes a life-cycle approach to safety, a reinforced emphasis on clinical data, and increased transparency via a publicly accessible European database on devices.

**Product availability and transition timelines**

- The MDR will apply from the 26th May 2020. With many thousands of products to be then assessed under the revised system from that date, the MDR allows a gradual phasing in to avoid market disruption, [illegible] with transition from Directives to a Regulation.
- The system provides a transition for the following to happen:
  - Applications for the many thousands of devices currently on the market under the Directives are submitted by manufacturers to be reviewed under the Regulation
  - The Notified Bodies review these applications including assessment of the data and assessments of the individual design and manufacturing sites.
    During that time:
    - Products with effective certificates under the current directives can be placed on the market until May 2024
    - one additional year is allowed for products already placed on the market to be made available (e.g., by a distributor).
    - After May 2025, products certified under the current directive(s) can no longer be made available on the EU market.
- During the transition, EU Member State authorities and Notified Bodies will continue to oversee the EU market, ensuring that medical devices are safe and perform as intended, regardless of whether they are CE marked under the current Directives or the new Regulation.
- Medtronic has created a comprehensive implementation plan to ensure that our products meet the certification requirements of the new regulation.
- Regulatory documentation such as Declarations of Conformity, certificates, labels and instructions for use issued under the current Directives, remain valid until transition is complete, and can be used in regulatory submissions and tenders.

STAKEHOLDERS NEED TO WORK TOGETHER TO UNDERSTAND EACH OTHERS. ….., ….

| | A | B | C | D | E | F | G | H | I | J |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | *Veld:/Field: Rood verplicht/Oranje verplicht indien van toepassing / Red mandatory/Orange mandatory if applicable* | *ZXL Artikelnummer ZXL TradeItem ID* | *ZXL ArtikelOmschrijving ZXL TradeItem description* | *ZXL Leverancier number ZXL Supplier number* | *Artikelnummer TradeItem ID* | *Artikelnummer Fabrikant (PCN/REF) Manufacturer part number (MPN/REF)* | *MDR relevant (Y/N) MDR relevant (Y/N)* | *UOMkleinsteBasisEenheid UOMSmallestBaseUnit* | *Barcode BasisEenheid GTIN Barcode BaseUnit GTIN* | *Barcode BasisEenheid HIBC Barcode BaseUnit HIBC* |
| 2 | *Verwachte input:/Expected input:* | *n.v.t./not applicable* | *n.v.t./not applicable* | *n.v.t./not applicable* | *n.v.t./not applicable* | *n.v.t./not applicable* | *Boolean* | *Tekst/Text* | *Numeriek/Numeric* | *Tekst/Text* |

| | K | L | M | N | O | P | Q | R |
|---|---|---|---|---|---|---|---|---|
| 1 | *UOM Binnendooseenheid UOM InnerboxUnit* | *Barcode BinnendoosEenheid GTIN Barcode InnerboxUnit GTIN* | *Barcode BinnendoosEenheid HIBC Barcode InnerboxUnit HIBC* | *UOM Besteleenheid UOM OrderUnit* | *Barcode Besteleenheid GTIN Barcode OrderUnit GTIN* | *Barcode Besteleenheid HIBC Barcode OrderUnit HIBC* | *Risico-klasse medische producten (Huidig) Risk-class medical tradeItems (Current)* | *Risico-klasse medische producten (Nieuw) Risk-class medical tradeItems (New)* |
| 2 | *Tekst/Text* | *Numeriek/Numeric* | *Tekst/Text* | *Tekst/Text* | *Numeriek/Numeric* | *Tekst/Text* | *Tekst/Text* | *Tekst/Text* |

FME POWERED BY DUTCH TECHNOLOGY

FME ZORG

# EU MEDICAL DEVICE REGULATION (EU) 2017/745

## EUDAMED DELAYED

**Eudamed** - Database intended to increase the transparency of the medical device regulatory system.

Certain parts will be available to the public:

- Economic operators
- Devices registered
- Certificates
- Field safety notices
- Parts of vigilance reports
- Clinical study protocols/reports
- Summary of Safety and Clinical Performance (SSCP)

EUDAMED DELAYED WITH 2 YEARS

MCDG guidance expected Dec/Jan timeframe

FME POWERED BY DUTCH TECHNOLOGY

FME ZORG

# EU MEDICAL DEVICE REGULATION (EU) 2017/745
## LOCAL LAWS

What local laws (derogation laws) are expected before DOA.

IGJ is working on a guidance document regarding PMS reporting.

- What else in the pipeline
- What is the role of TA's
- Collaboration is key to guarantee continuity of care

FME POWERED BY DUTCH TECHNOLOGY

# Best practices door het veld

- NFU en NVZ
- Astrid Verkaar - NVZ

# Veldbijeenkomst MDR/IVDR

**Astrid Verkaar**

3 december 2019

Nederlandse Vereniging van Ziekenhuizen

# Implementatie MDR en IVDR in ziekenhuizen

- Voldoen aan wet- en regelgeving
- Noodzakelijk: duiding en toetsingskader om optimaal te kunnen werken
- Wetgeving mag veilige patiëntenzorg niet in de weg zitten

# Rol NVZ en NFU

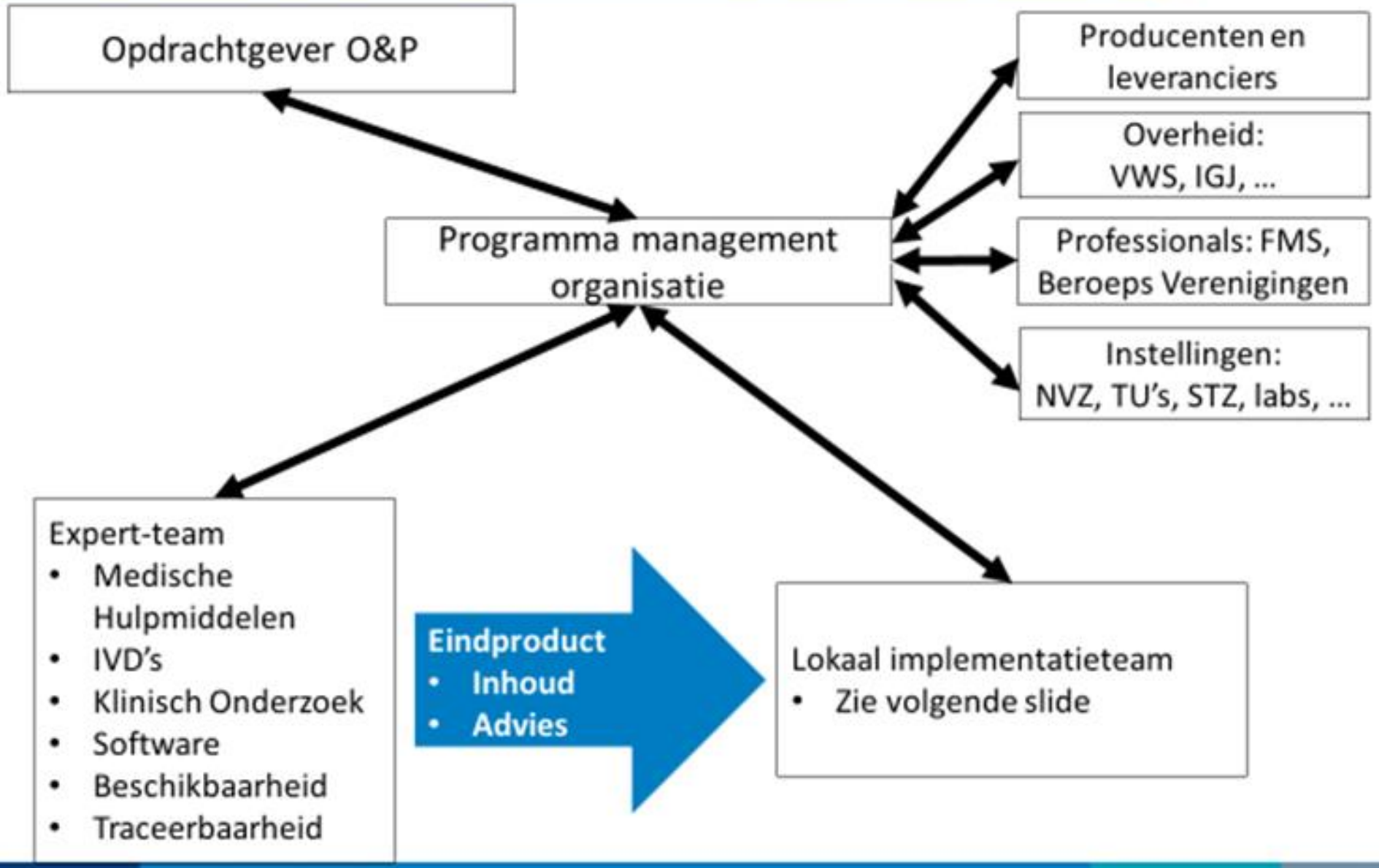
# NFU: programma “Veilige patiëntenzorg door veilige technologie”

- Belangrijkste veranderingen zijn in kaart gebracht (17)
- Expertteams geformeerd:
  - Beschikbaarheid
  - Traceerbaarheid
  - Klinisch Onderzoek
  - Medische Hulpmiddelen

# De veranderingen 1/2

| # | Verandering | MDR en/of IVDR | Belanghebbende | Uitvoering door | Wat moet er gebeuren? |
|---|---|---|---|---|---|
| V1 | Alle Medische hulpmiddelen (inclusief klasse III-implantaten) krijgen een unieke identificatiecode zodat traceerbaarheid voor de patiënt geborgd is. Daar bovenop is voor klasse III-implantaten de verplichting om de implantaatgegevens te registreren zodat ze aan de patiënt kunnen worden verstrekt samen met de implantaatkaart | MDR | Patient | Expertteam Traceerbaarheid | De inclusielijst wordt uitgebreid met alle klasse III implantaten. Huidige implementatie van het UIR dient te worden uitgebreid met de klasse III implantaten. Er is dus geen nieuw (elektronisch) systeem nodig.<br>Onderzoeken welke voordelen dit kan bieden voor supply chain management |
| V2 | De patiënt krijgt een implantaatkaart mee als een hoog risico implantaat is toegepast bij de patiënt LET OP: Geldt zowel voor risicoklasse IIb als III implantaten (behalve hechtingen, krammen, tandheelkundige vullingen, tandheelkundige beugels, kronen, schroeven, wiggen, platen, draden, stiften, clips en connectoren) | MDR | Patient | Expertteam Medische hulpmiddelen | Borgen dat zorgverleners een implantaatkaart van de fabrikant mee kunnen geven waarbij de arts ook de identiteit van de patiënt op de implantaatkaart vermeldt (met sticker of pen) |
| V3 | Er komt een nieuwe Europese databank met voor alle partijen transparante en passende informatie: EUDAMED | MDR en IVDR | Patient,<br>Zorgverlener,<br>Lab medewerker, Onderzoeker | Expertteams Medische hulpmiddelen en IVD's en Traceerbaarheid | Hoe krijg je juiste informatie in en uit Eudamed, vanuit onze verschillende rollen (zorgaanbieder, onderzoeker, fabrikant) |
| V4 | circa 85% van alle IVD's komt onder toezicht van notified bodies te vallen, terwijl dat nu hooguit 20% is | IVDR | Lab medewerkers | Expertteams IVD's en Beschikbaarheid | Borgen dat producten met de juiste certificeringen worden geleverd<br>Borgen dat (diagnostische) testen beschikbaar blijven voor de patiëntenzorg |
| V5 | 'in-huis' gemaakte testen mogen uitsluitend gemaakt en gebruikt worden binnen de eigen zorginstelling onder strikte voorwaarden (zie artikel 5.5 IVDR):<br>- mogen niet worden overgedragen aan een andere rechtspersoon;<br>- er moet sprake zijn van een passend kwaliteitsmanagementsysteem;<br>- een gelijkwaardige test is niet op de markt verkrijgbaar | IVDR | Lab medewerkers<br>Zorgverleners | Expertteam IVD's | Voorkomen dat dit leidt tot kostenverhogingen en beschikbaarheidsrisico's. Borgen dat er geen risico's worden gelopen en organiseren van een passend kwaliteitsmanagementsysteem. Voorkomen dat referentiefunctie academische labs in gevaar komt. |
| V6 | Zodra een test door een fabrikant op de markt is gebracht die qua prestatieniveau gelijkwaardig is aan de in huis gemaakte test, mag een ziekenhuis niet (meer) een eigen test maken en gebruiken | IVDR | Lab medewerkers | Expertteam IVD's | Voorkomen dat dit leidt tot kostenverhogingen en beschikbaarheidsrisico's<br>Voorkomen dat referentiefunctie academische labs in gevaar komt |
| V7 | Door de strengere regels voor markttoelating, meer producten die in een hogere risicoklasse gaan vallen en minder notified bodies, zal markttoelating duurder worden, een langere doorlooptijd hebben en zorgen dat fabrikanten hun portfolio gaan saneren | MDR en IVDR | Zorgverlener | Expertteam Beschikbaarheid | Voorkomen dat dit leidt tot kostenverhogingen en beschikbaarheidsrisico's |

# Organisatie programma MDR / IVDR
## Relatie met stakeholders

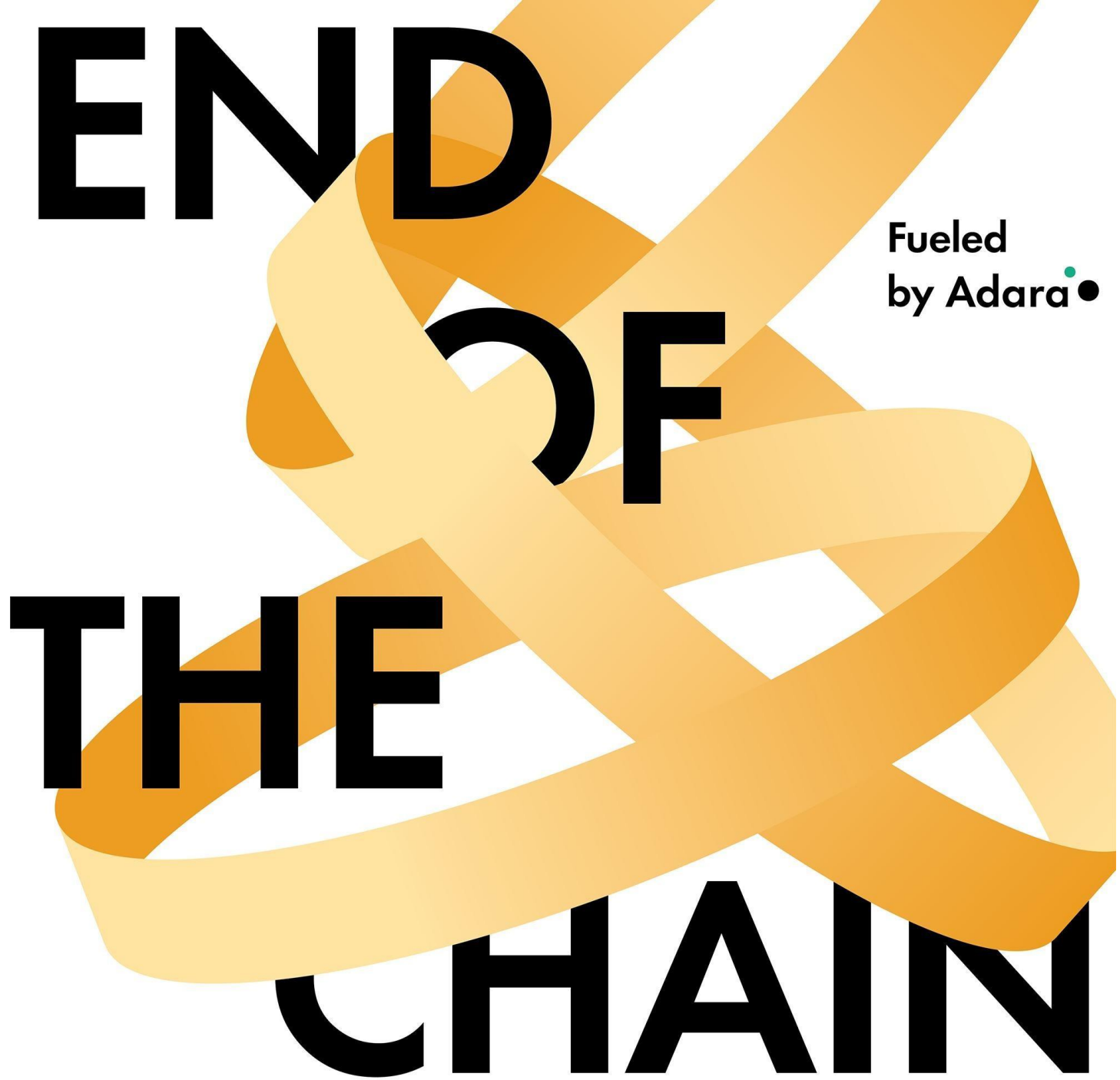


# Stand van zaken

- Programma is gestart en verloopt volgens planning
- Handvatten (waar mogelijk gevalideerd) gereed begin 2020
- Handvatten worden beschikbaar gesteld voor gebruik in alle ziekenhuizen/zorginstellingen

# END OF THE CHAIN

Fueled by Adara



# Zorgen

- Vertragingen en onduidelijkheden
- Guidances komen te laat / duiding van wetgeving ontbreekt
- Aanwijzen van notified bodies / tijd voor (her)certificering dringt
- Uitstel van Eudamed
- Gebrek aan informatie om continuïteit van zor te realiseren

Ministerie van Volksgezondheid,
Welzijn en Sport

# Nationale ontwikkelingen

1. Wet- en regelgeving
   - Maartje van der Avert

2. CCMO
   - Anneriet Heemskerk

# Nationale wetgeving

- Besluit medische hulpmiddelen
- Regeling medische hulpmiddelen
- Planning: in eerste kwartaal 2020 gereed

# Update CCMO

- CCMO

# Verordening Medische Hulpmiddelen EU no 2017/745 hoofdstuk VI (art 61-82): klinisch onderzoek

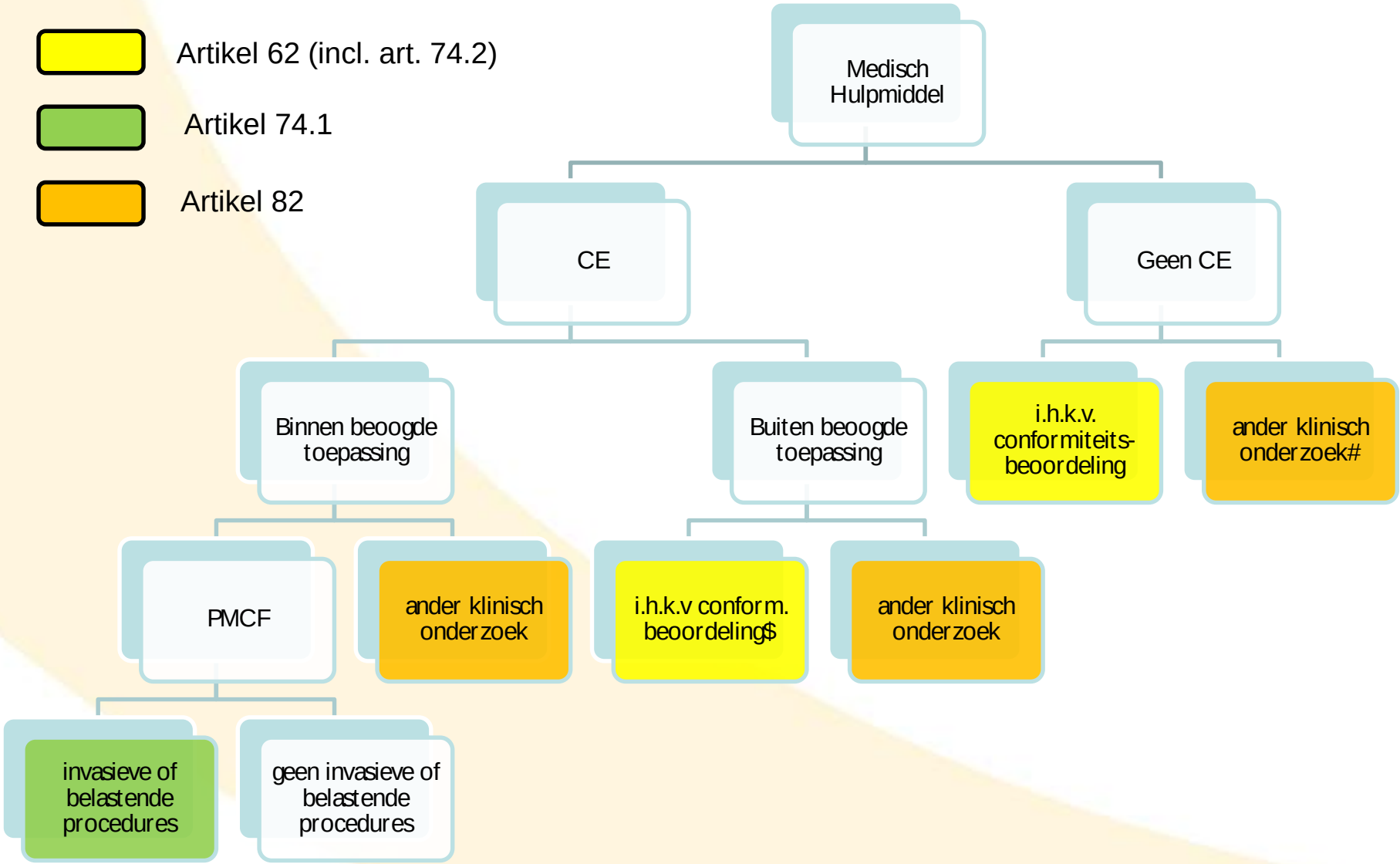
Centrale
Commissie
Mensgebonden
Onderzoek

Veldbijeenkomst, 27 november 2019

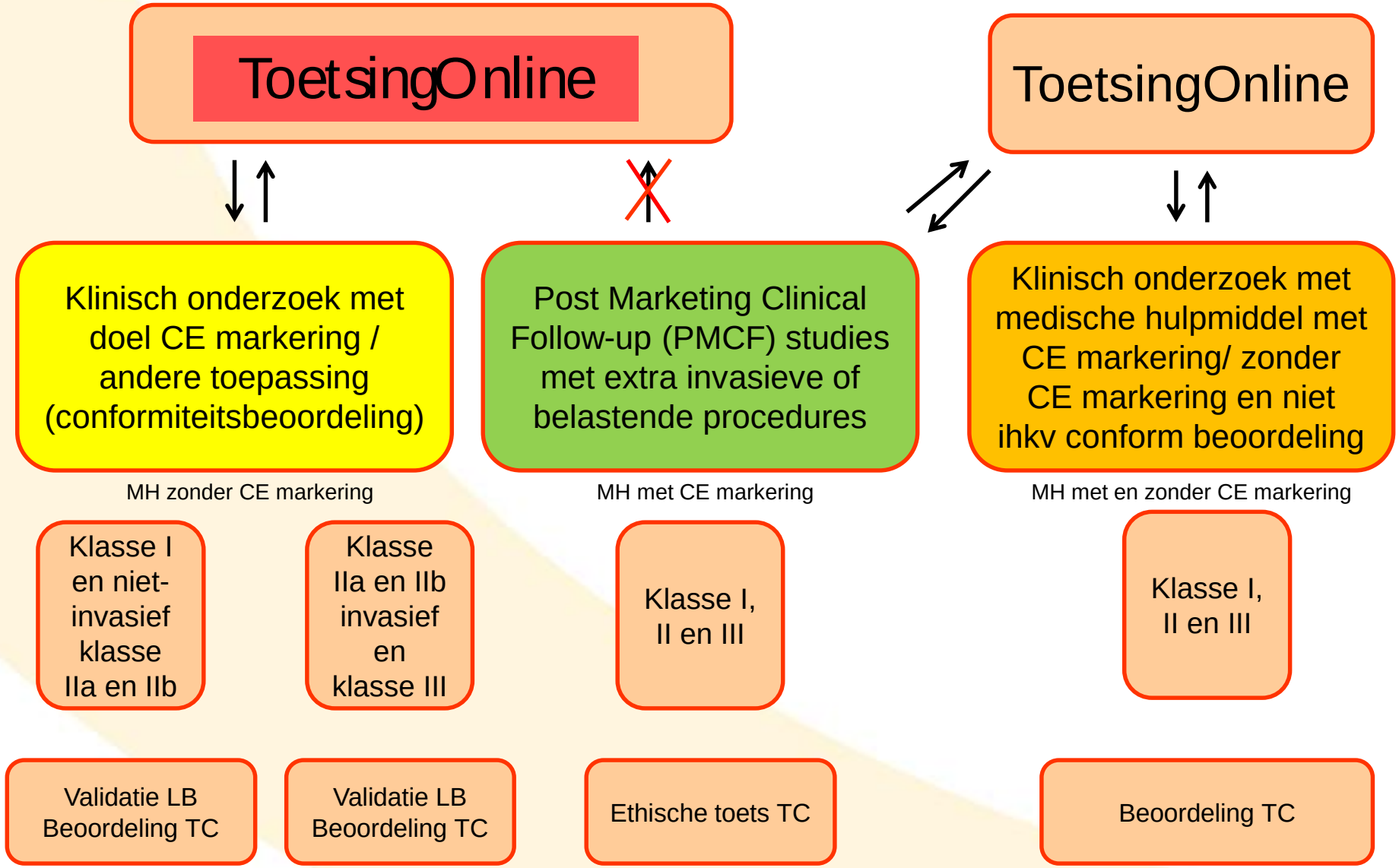
Anneriet Heemskerk
Landelijk Bureau CCMO

# Stappenplan

- Artikel 62 (incl. art. 74.2)
- Artikel 74.1
- Artikel 82




$ (artikel 74, lid 2)
# bijvoorbeeld in-house products


ToetsingOnline
ToetsingOnline
Klinisch onderzoek met doel CE markering / andere toepassing (conformiteitsbeoordeling)
Post Marketing Clinical Follow-up (PMCF) studies met extra invasieve of belastende procedures
Klinisch onderzoek met medische hulpmiddel met CE markering/ zonder CE markering en niet ihkv conform beoordeling
MH zonder CE markering
MH met CE markering
MH met en zonder CE markering
Klasse I en niet-invasief klasse IIa en IIb
Klasse IIa en IIb invasief en klasse III
Klasse I, II en III
Klasse I, II en III
Validatie LB Beoordeling TC
Validatie LB Beoordeling TC
Ethische toets TC
Beoordeling TC

# Wat zijn de praktische gevolgen? (1)

**Onder andere:**

- Classificatieregels aangepast: laag → hoog risico medisch hulpmiddel
- Meer klinische data nodig voor verkrijgen CE-markering
- Verplichting fabrikant: post marketing clinical follow up (PMCF) studies
- Toetsingscriteria → geen grote wijzigingen tov huidige situatie muz hoog risico medische hulpmiddelen zonder CE markering (art 62) → toets aan gemeenschappelijke specificaties (GS) of geharmoniseerde normen
- Indieningsdossier → geen grote wijzigingen tov huidige situatie muz medische hulpmiddelen zonder CE markering (art 62) → CEP
- Notificatieplicht IGJ komt te vervallen

# Wat zijn de praktische gevolgen? (2)

Onder andere:

- Start gecoördineerde multinationale beoordeling ??? Voorlopig voortzetting van de nationale indieningen
- Overgangsbepaling MDR (art.120): Studies met positief besluit < 26 mei 2020 hoeven niet opnieuw beoordeeld (conform MDR) te worden door een erkende METC/CCMO
- Vigilantiebepalingen (registratie en melden SAE en SADE) – art 80: geldt voor al het lopende en nog te starten te onderzoek vanaf 26 mei 2020

# Waar werken wij ondermeer aan?

- Leidraad voor METCs
- Kennisnetwerk

**contact**

**ccmo@ccmo.nl**

**information**

**http://www.ccmo.nl**

Centrale
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Onderzoek

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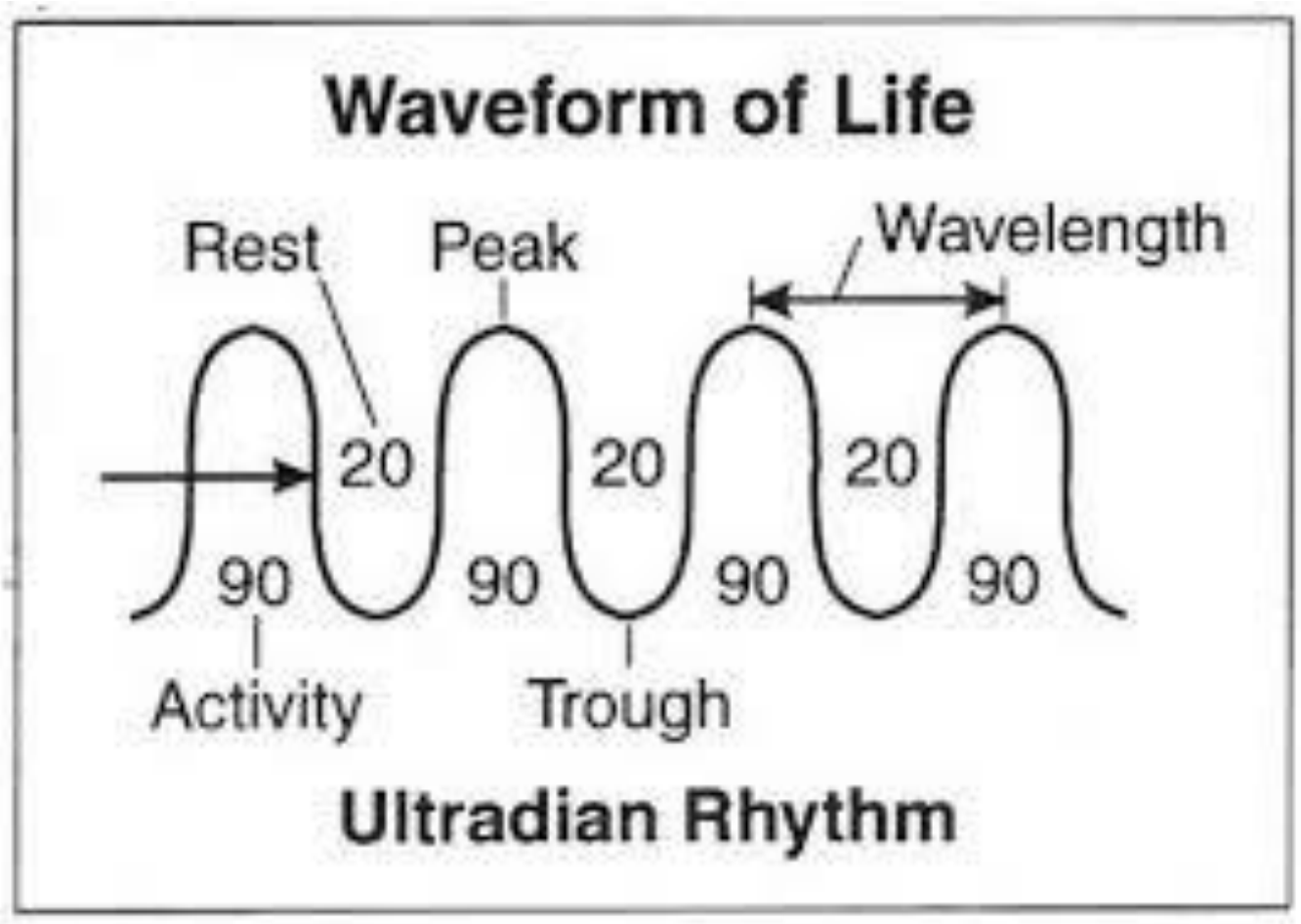
# Pauze


Waveform of Life
Rest
Peak
Wavelength
20
20
20
90
90
90
90
Activity
Trough
Ultradian Rhythm

Ministerie van Volksgezondheid,
Welzijn en Sport

# Europese ontwikkelingen

1. MDCG/CAMD
2. Eudamed
3. Notified bodies
4. Brexit

*Maartje van der Avert (VWS) en*
*Laura de Vries (IGJ)*

# CAMD – 16/17 oktober

- Overgang van DG Grow naar DG Santé
- Nationale wetgeving
- JAMS – Joint Action on Market Surveillance
  - WP4: joint manufacturer inspections
  - WP5: Clincial Process and Resource development
- Opvolger ITF en TSG: CAMD Operational
- Working Group
- Brexit

# MDCG – in vogelvlucht...

- CTS under IVDD
- Common specifications under IVDR
- Transparantie
- Communication campaign
- Volgende MDCG: 13 december 2019
- Verslagen in het Commissieregister

# MDCG – Guidances onlangs gepubliceerd of in aantocht

- Implant card – juni 2019
- Person responsible for regulatory compliance – juni 2019
- SCHEER guidelines phthalates – juni 2019
- Summary of Safety and Clinical Performance – augustus 2019
- Diverse guidances over notified bodies – oktober 2019
- Guidance Qualification and classification of software – oktober 2019
- Guidance Klasse I (eind 2019 in final draft)
- Guidance Clinical / Performance Evaluation of Software (eind 2019 in final draft)
- Guidance on Cybersecurity (eind 2019 in final draft)

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

# MDCG – Stand van zaken notified bodies

- Inmiddels 7 notified bodies aangewezen voor MDR en 2 notified bodies aangewezen voor IVDR
  - Begin november 2 Nederlandse notified bodies aangewezen

- Link: https://ec.europa.eu/docsroom/documents/35043

# EUDAMED

# MDCG – Gemeenschappelijke specificaties Annex XVI

- Verdiepende sessie georganiseerd op 22 maart 2019 (verslag beschikbaar)
- Informele consultatie afgerond, opmerkingen worden nu verwerkt
- Volgende stap: start formele adoptieprocedure
- Onderdeel adoptieprocedure: formele consultatie, hopelijk voor kerst
- Na publicatie: vervolg op eerdere verdiepende sessie
  - 28 januari 2020: groepen 1-3
  - 4 februari 2020 : groepen 4-6

# MDCG – Expert Panels

- Formele deadline aanmelden expert panels is gesloten op 24 november
- Aanmelding staat nog wel open voor specifieke deelterreinen waar onvoldoende experts aangemeld zijn.

- Commissie (JRC) start komende periode met de selectie.

- Aanmelding expert panels

# Brexit

- Uitstel van no-deal Brexit tot uiterlijk 31 januari 2020.
- 12 december Britse Parlementsverkiezing.
- Risico op no-deal scenario Brexit blijft onverminderd hoog.
- Overstap van SGS naar België loopt nog
- Advies: leun niet achterover maar benut de extra tijd die u nu gegund wordt.

- Etikettering: géén overgangsperiode van 6 maanden na no-deal in januari

# Vragen?


BORREL
&
BABBEL