B|BRAUN
SHARING EXPERTISE

MEDICAL DEVICE REGULATION (MDR)
EUROPE

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07 Nov 2019 - GS1 Healthcare Conference, New Delhi

AGENDA

I. MDR overview
II. UDI requirements
III. EUDAMED
IV. Conclusion

EU Regulation MDR 2017 / 745

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KEY DATES

MDR Publication → 05 May 2017
Entry into force → 26 May 2017
Date of Appl. → 26 May 2020
Transition Period → 26 May 2024

5.5.2017 EN Official Journal of the European Union L 117/1

Council of the European Union

(Legislative acts)

REGULATIONS

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Chapter	Subject
I	Scope / Definitions
II	Making available +putting into service, obligations economic operators, reprocessing, CE marking, …
III	Identification, traceability, registration of economic operators + devices, EUDAMED, …
IV	Notified Bodies
V	Classification / conformity assessment
VI	Clinical evaluation / investigation
VII	Post-market surveillance, vigilance, market surveillance
VIII	Cooperation between MS, Med Dev Coord. Group, expert panels, …
IX	Confidentiality, data protection, funding, penalties
X	Final provisions

Anx	Subject
I	General safety + performance requirements
II	Technical documentation
…	…
VI	Registration + UDI
…	…
XVII	…

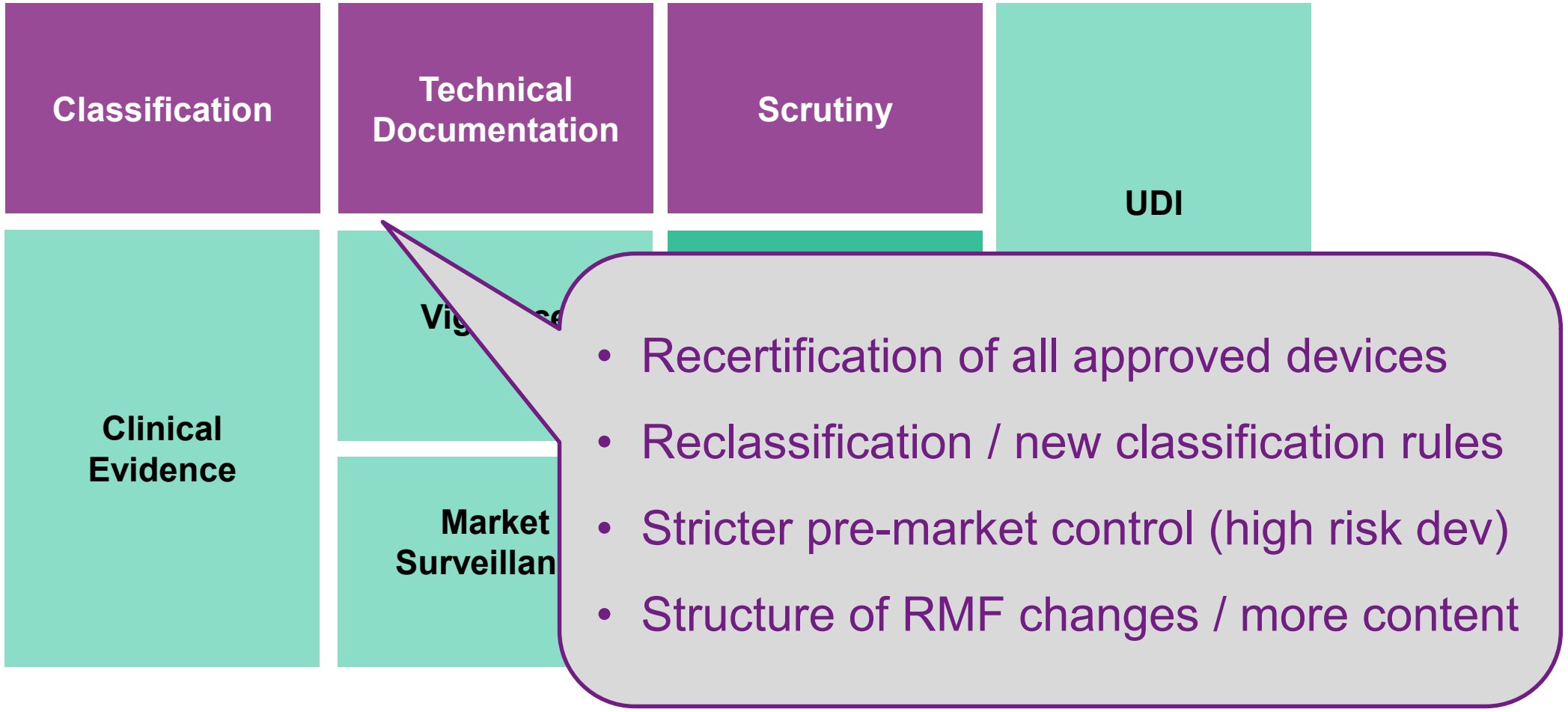
10 chapters - 123 articles - 17 annexes
175 pages - replaces the MDD 93/42/EC

S C O P E
all Medical Devices
Except :
Custom-made dev
Perform.study/investig. dev

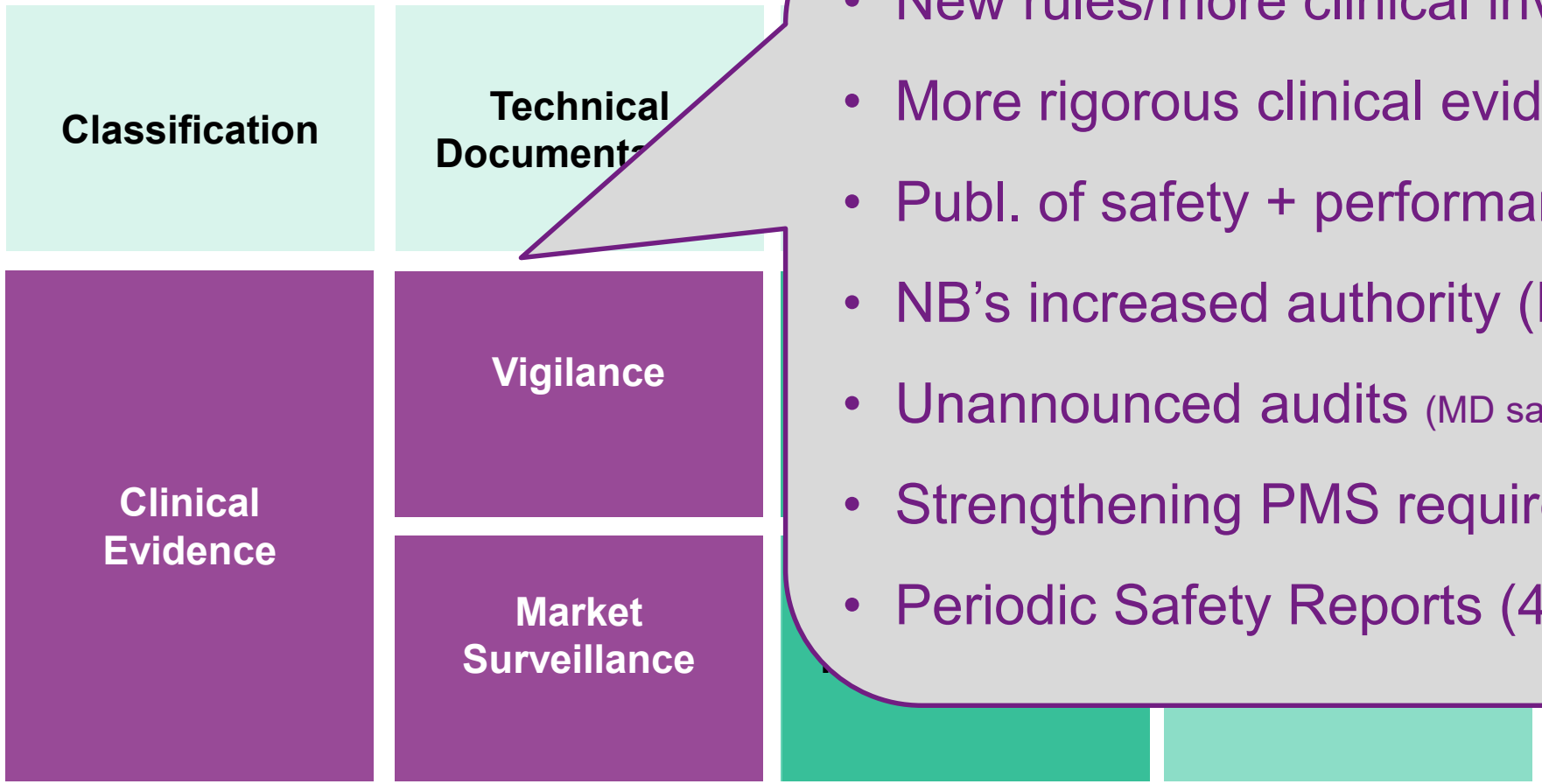
MDR Building Blocks

Classification	Technical Documentation	Scrutiny	UDI
Clinical Evidence	Vigilance	Person responsible for Regulatory Compliance	
	Market Surveillance	Notified Bodies	EUDAMED

MDR Building Block 1



MDR Building Block 2



- New rules/more clinical investigat.
- More rigorous clinical evidence
- Publ. of safety + performance data
- NB's increased authority (PMS)
- Unannounced audits (MD sample checks)
- Strengthening PMS requirem. MFR
- Periodic Safety Reports (4 types)

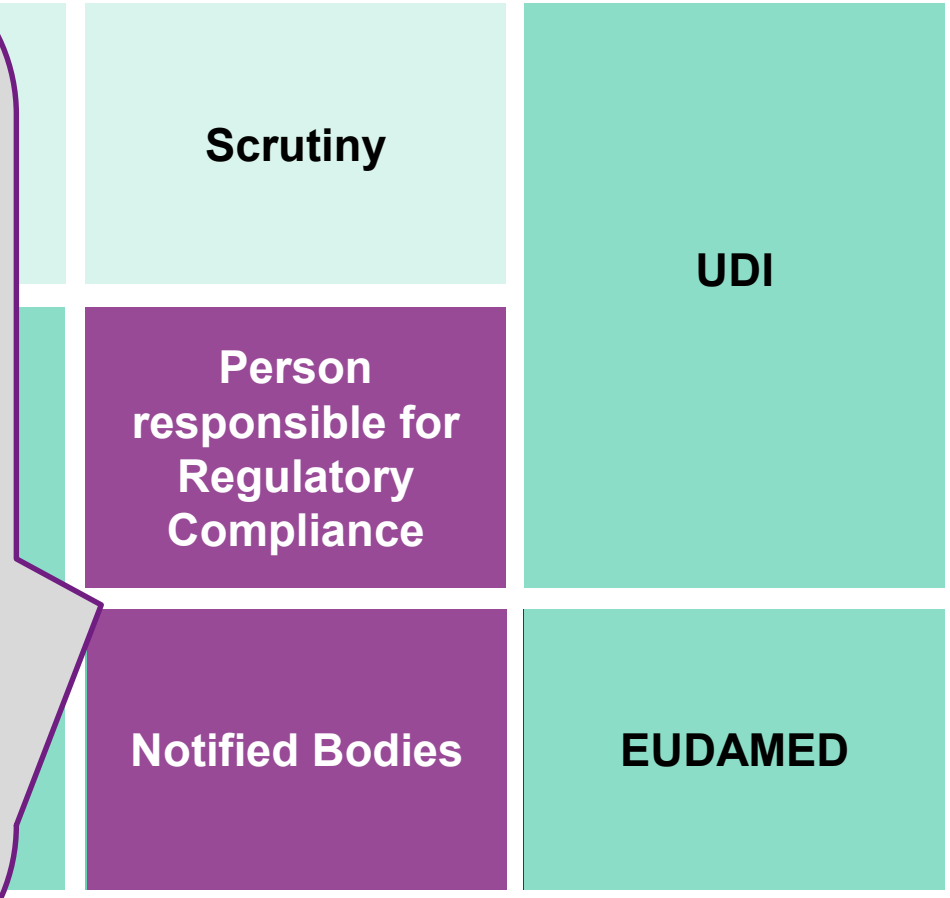
MDR Building Block 3

Person responsible for :

- product conformity checked before batch release
- Tech. doc up-to date
- Vigilance reports, FSCA, …

NB :

- re-accreditation
- Strengthened designation criteria
- Number will be reduced



MDR Building Block 4

UDI Requirements in a Nutshell

In accordance with the new rules, any manufacturer before placing a device on market shall assign to the device and to all higher levels of packaging a UDI.

The UDI carrier shall be placed on the label of the device, on all higher levels of packaging and in some cases on the device itself.

Before a device is placed on the market the manufacturer shall ensure that the information – related to the device in question - referred to in Part B of Annex VI of the two Regulations (MDR / IVDR) is correctly submitted and transferred to the UDI database.

The manufacturer is the entity responsible for complying with all UDI related requirements.

4 Issuing Entities
GS1 – HIBCC – ICCBBA – IFA

UDI Labeling + Direct marking

UDI placed on Device Labels

AIDC + HRI
- all package levels (excl. shipper)
- UDI containing DI + PI

Space constraints
- on Base Pack → UDI on next Higher Package Level
- to print both AIDC + HRI → AIDC has the higher priority

Single-use devices of EU risk-class I or IIa
- no UDI on Base Pack require

Special rules for certain device categories
- Software, Kits, Proc. Packs, Complex Systems, OTC, …

AIDC technology neutral

AIDC Quality acc. IE rules (ISO quality grade)

UDI placed on the Device itself

Reusable devices subject of DM

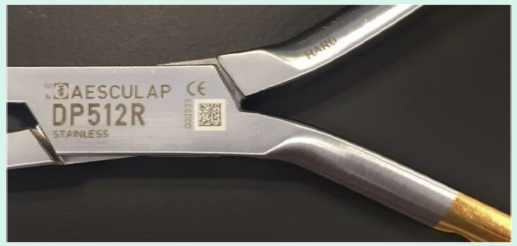
AIDC + HRI
- UDI containing DI + PI

Permanent readable throughout the intended lifetime

Exceptions:
- DM interferes with the safety/performance
- Technologically not feasible
- Space constraints (AIDC has the higher priority)

AIDC technology neutral

AIDC Quality according to the IE rules (ISO quality grade)



UDI Labeling Requirements

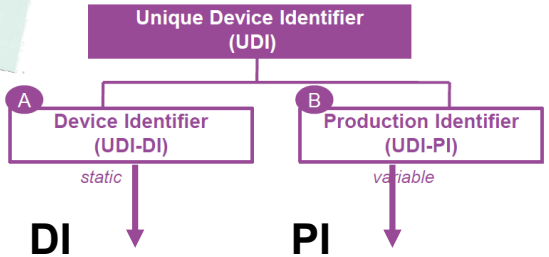
UDI Carrier : AIDC & HRI

Remark : UDI Carrier means AIDC + HRI (human-readable Information), in case of significant space constraints on the label → AIDC has the higher priority.

Category	Unpackaged Item DM (direct marking)	Base Package	Bulk Package (higher package config.)	Remarks
Single-use MedDev				
• Risk-class 1 + 2a	-	-	DI + PI	
• Risk-class 2b	-	DI + PI	DI + PI	
• Risk-class 3	-	DI + PI	DI + PI	
Reusable MedDev				need sterilization/disinfect. prior to use
• all risk-classes	DI + PI	DI + PI	DI + PI	DM not required if : • it interferes with safety or performance of the device • not technologically feasible
Implants				
• active / non-active	-	DI + PI	-	• active : PI must incl. Serial No • non-active : PI may incl. Serial No
Others				
• Systems / Proc. Packs	-	DI + PI	DI + PI	
• MedDev Software	DI + PI	DI + PI	-	
• Configurable Devices	DI + PI	-		
• OTC exclusively	-	-	DI	
• OTC + other channels	-	-	DI + PI (non-concatenated)	

Risk-class depending
- Labeling requirements
- implementation timelines

2021 – 2023 – 2025 (DM + 2Y)



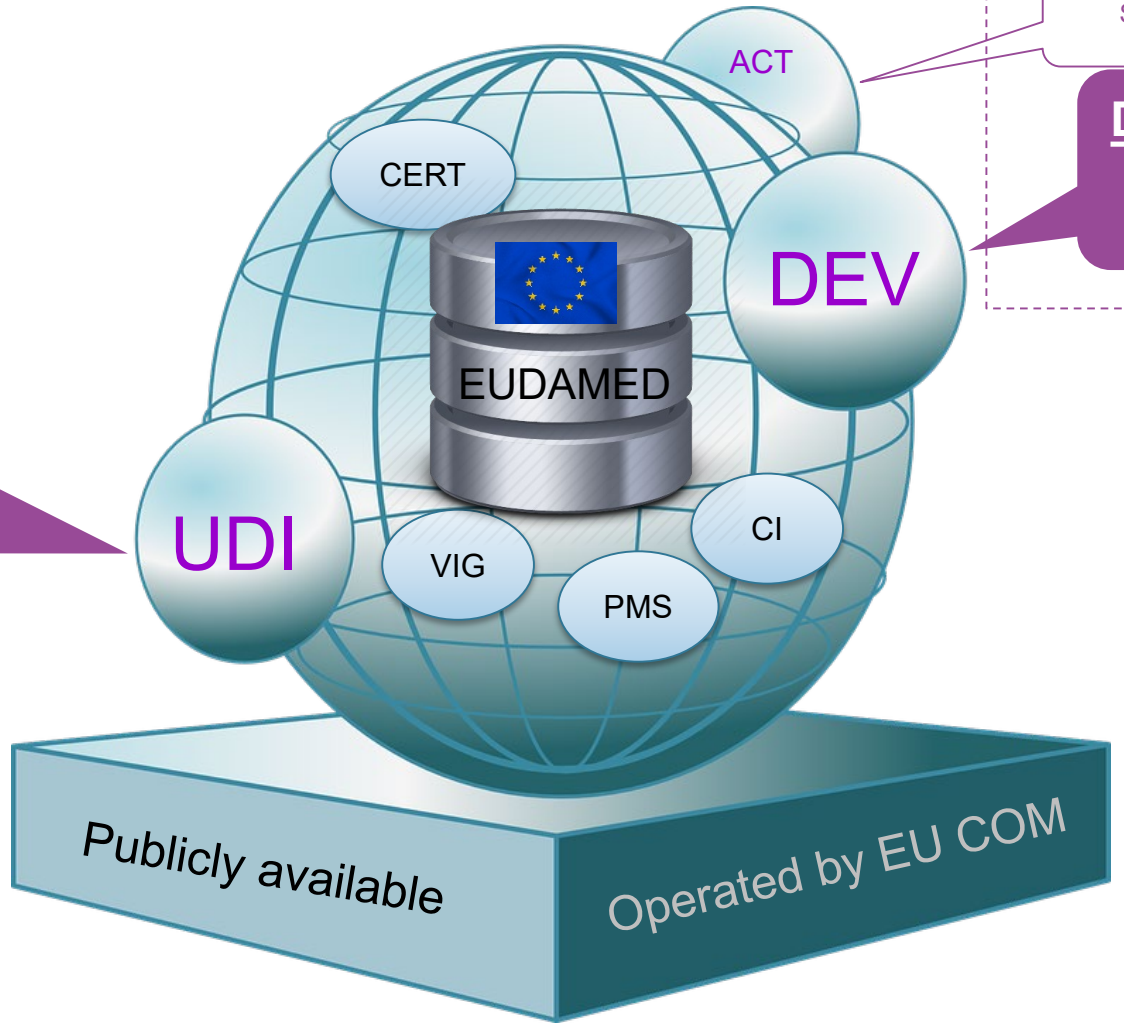
DI
- i.e. GTIN

PI
- Lot/Batch
- Exp. Date
- Serial No
- Manuf. Date

Device as per Regulation (EU) 2017/745 (MDR)	Implantable devices and Class III devices	Class IIa and Class IIb devices	Class I devices
Placing UDI-carriers on the labels of devices MDR Article 123(3)(f), Article 27(4)	26 May 2021	26 May 2023	26 May 2025
Direct marking of the reusable devices MDR Article 123(3)(g), Article 27(4)	26 May 2023	26 May 2025	26 May 2027

EUDAMED – Core of the legislation

Complex DB-System
with different modules
& functionalities



REG

Manufacturer, Authorized Rep, Syst/Proc-Pack Producer, Importer, Notified Body

Device - Registration
Data for an entire FAMILY of devices

UDI
Data for SINGLE devices & package levels
(highest data granularity)

6 Modules :

- REG – Registration
  - ACT – Actor (SRN)
  - DEV – Device (Basic UDI)
- UDI
- CERT – Certificates
- VIG – Vigilance
- PMS – Market Surveillance
- CI – Clinical Investigation

Device Family : Characteristics + Identification

Consists of one or many family members (single devices)

All family members:

- **share the same documentation**
  - **Certificate (incl. CERT for free-sale)**
  - **Declaration of conformity (DoC)**
  - **Technical documentation (Regulatory Master File)**
  - **Summary of safety and clinical performance**
- **have the same**
  - **intended purpose**
  - **EU device risk-class**
  - **essential design and manufacturing characteristics**

Family to be identified by a ‘BASIC UDI-DI’

Independent from packaging	**Does not appear on labeling**	**Referenced in tech. documents**	**Main access key to EUDAMED**

Device Identifier Types

Basic UDI-DI (GS1 Standard = Global Model Number)

FIGURE 1. Structure of the GMN for regulated healthcare medical devices

Global Model Number (GMN)		
GS1 Company Prefix →	Model reference →	Check characters
N_1 … N_i X_{i+1} …	variable length $X_{j\ (j<=23)}$	X_{j+1} X_{j+2}

GMN

UDI-DI
- Lowest package level (Base Pack) of the devices with a device label
- Can also be the device itself (e.g. in case of reusable devices / direct marking)

DM-DI
- DI of the unpackaged reusable device (in case the device is direct marked)

Package-DI
- Higher package configurations (e.g. Box of 10 Pieces, Carton of 100 Pieces)
- Shipper case is out of scope

Unit-of-Use DI
- In case the lowest package level (Base Pack) contains more than 1 piece

GTIN

GTIN

GTIN

GTIN

How does that fit together?

Hierarchy of a Device Family (example)

- *Basic UDI-DI*
- *UDI-DI*
- *DM-DI*
- *Unit-of-Use DI*
- *Package-DI*

Basic UDI-DI

Modell ‚AT100'

Declaration of Conformity (DoC)
Techn. documentation
Certificates

„Device Family"
- 1 - 1
- 1 - n

„Family Members"
- 1 - 1
- 1 - n

REF ‚AT100A'	REF ‚AT100B'	REF ‚AT100C'	REF ‚AT100X'
Label • CE marked • English CRS • Gauge 14 • …	Label • CE marked • English CRS • Gauge 18 • …	Label • CE marked • French/German CRS • Gauge 14 • …	Label • CE marked • Polish CRS • Gauge 10 • …

„Package Levels"

Level	Qty	DI	Qty	DI	Qty	DI	Qty	DI
UoU	**UoU-DI**		1	D				
Base Pack	1	A	15	E	**UDI-DI**	**DM-DI**	1	I
2nd	50	B	45	F	10	H		
3rd	250	C	-	-			**Package-DI's**	

level of GTIN allocation according GS1 Standards
(always linked to a pack.level)

GS1 : DI = GTIN

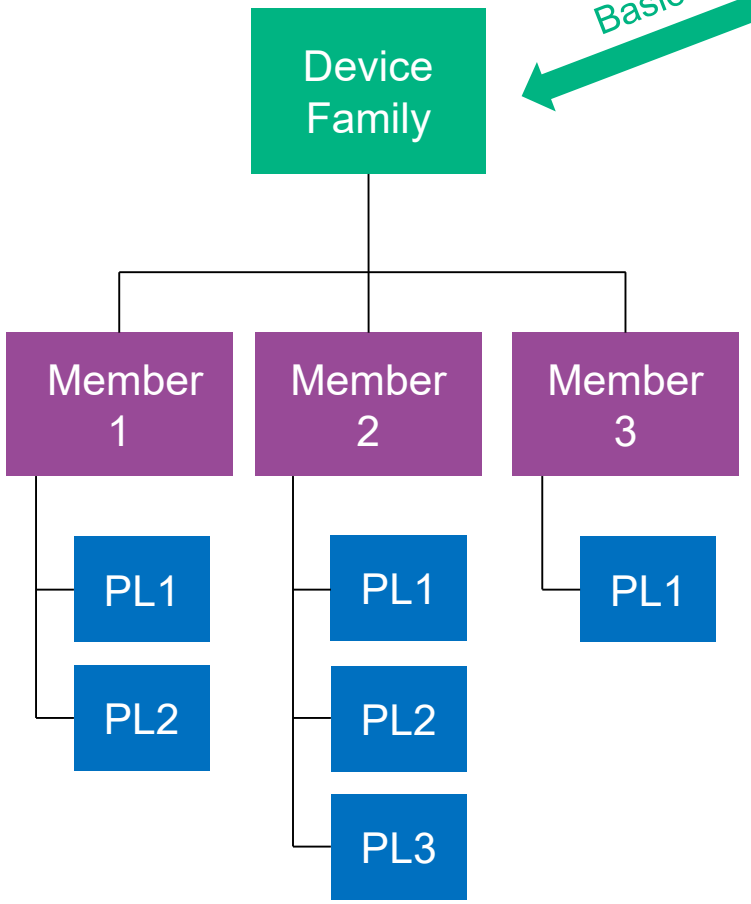
RULE : an UDI-DI can only be linked to ONE Basic UDI-DI

EUDAMED Data Elements Modules : DEV & UDI

MODULE

DEV

UDI

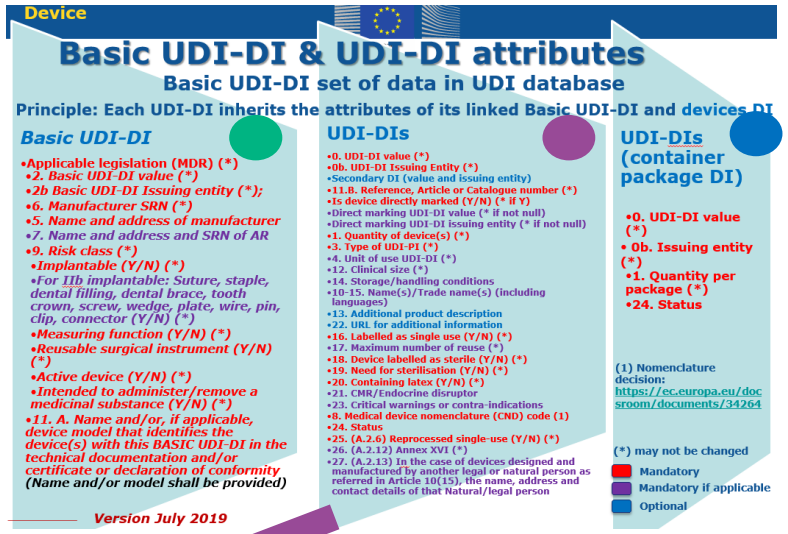


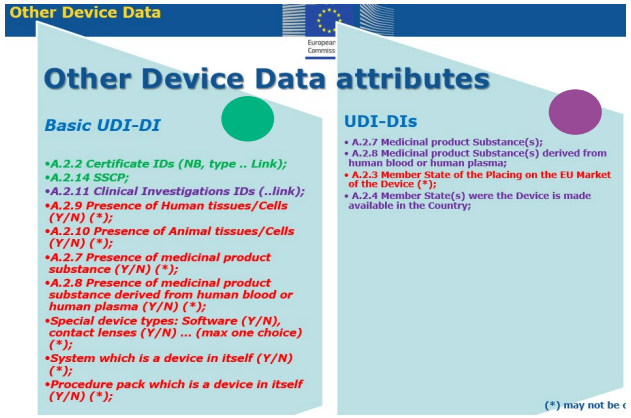
Basic UDI-DI

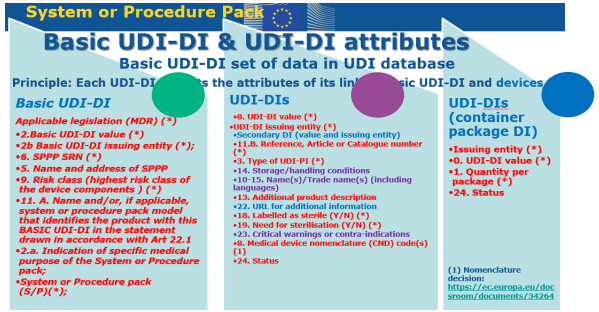
UDI-DI

UoU-DI + DM-DI

Package-DI







3 different data sets

- Data for a device family → Basic UDI-DI
- Data for a single devices → UDI-DI (+ UoU-DI + DM-DI)
- Data for a package level of a single device → Package-DI

- Limited data set for Systems or Procedure Packs

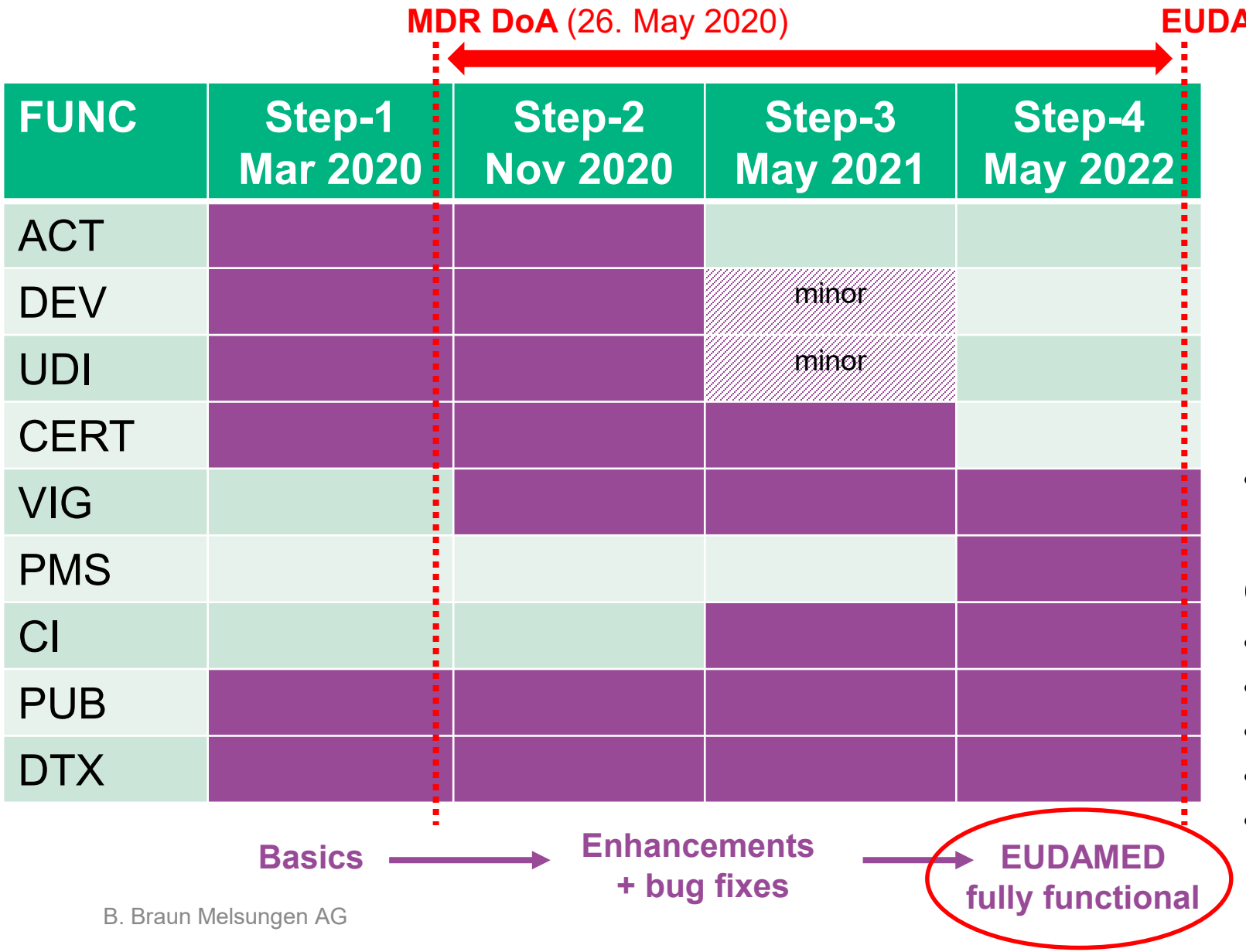
EUDAMED – Data input options

Web based forms
- Manual input - time consuming
- Only for a low number of devices suitable

Bulk upload via web form
- XML data – validation against 100’s of rules
- Semi-automatic communication in one direction (failed uploads logged)

Machine-to-Machine (M2M)
- Mass data (high number of devices)
- XML data – validation against 100’s of rules
- Full-automatic communication in both directions
- Requires an access point for secure data transmissions (eDelivery)

EUDAMED Development Roadmap



2 years delay !

Decision: 31. Oct 2019

How to bridge the gap?

- apply corresponding MDD provisions

Consequences? (MFR, NB, CA)

- BUDI/UDI-DI assignment?
- Tech. Doc?
- Incident reporting?
- Transition period (May 2024)?
- …

→ to be analyzed

EUDAMED – what's so special?

- **Interdependencies between the EUDAMED modules – it's not just data, it's process management.**
- **MFR to implement new processes and to define new roles and responsibilities.**
- **Complexity of the IT project.**
- **Late publication of technical specs + data validation rules for M2M data input option.**
- **Digitalization of regulatory processes.** (COM, CA, NB, and EO's)

Conclusion (1) : Main Obligations in relation to UDI

Manufacturers

- UDI assignment
- Placement of the UDI carrier
- Initial data submissions into EUDAMED
- Updates EUDAMED records within 30 days in case of data changes

Distributors and Importers

- Verify whether a UDI has been assigned by MFR

All Economic Operators and Health Institutions

For risk-class 3 implantable devices:

- Store and keep - preferably by electronic means - the UDI of the devices which they have supplied or which they have been supplied

Remark: expansion of the scope possible through implementing acts!

Conclusion (2)

MDR is a complex regulation – **UDI is just one part**

Regulation describes the **WHAT** (available since May 2017)

Tech. Specs + Impl. Guidance to describe the **HOW**
- → Late publication / some are still pending !
- → Growing list of guidance docs available

Concept of **Basic UDI-DI** is a **'Novum'**
- → Must be well defined & implemented by MFR !

EUDAMED is the heart of the MDR

a functioning DB-system is key!

MDR implementation is the biggest challenge for MFR since years!
- new processes + data handling, tech. doc. changes, new certification, multi-million budget -

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THANK YOU VERY MUCH
FOR YOUR TIME

QUESTIONS ?