The EU-MDR from a Notified Body Perspective

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Agenda for this presentation...

- The New Medical Device Regulation
- Timelines for Compliance
- Changes to Roles and Responsibilities
- Device Definitions - Scope
- Rules & Classification
- Conformity Assessment Routes
- Safety & Performance Requirements - SPR
- Standards & Common Specification
- Clinical Evaluation & Clinical Investigations
- PMS, PMCF & Vigilance
- Unique Device Identification – UDI
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017


(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,
Structure of the Regulations
MDR – (EU) 2017/745

Recitals – 101 ‘Whereas’ statements which justify the adoption of the Regulation

Chapter I – Scope and definitions (Articles 1 – 4)

Chapter II – Making available on market, Economic Operators (Articles 5 – 24)

Chapter III – Identification, Traceability and Registration of devices and Economic Operators (Articles 25 – 34)

Chapter IV – Notified Bodies (Articles 35 – 50)

Chapter V – Classification & Conformity Assessment (Articles 51 – 60)

Chapter VI – Clinical Evaluation & Clinical Investigations (Articles 61 – 82)

Chapter VII – PMS, Vigilance and Market Surveillance (Articles 83 – 100)

Chapter VIII – Co-operation (Articles 101 – 108)

Chapter IX – Confidentiality, Data Protection, Funding and Penalties (Articles 109 – 113)

Chapter X – Final Provisions (Articles 114 – 123)

Annex I – General Safety and Performance Requirements
Annex II – Technical Documentation
Annex III – Technical Documentation on PMS
Annex IV – EU DoC
Annex V – CE marking of conformity
Annex VI – Information for registration of devices and Economic Operators
Annex VII – Requirements to be met by NBs
Annex VIII – Classification Rules
Annex IX – Conformity Assessment – QMS and Technical
Annex X – Conformity Assessment – Type examination
Annex XI – Conformity Assessment – Product conformity verification
Annex XII – Certificates issued by a NB
Annex XIII – Custom-made Devices
Annex XIV – Clinical Evaluation and PMCF
Annex XV – Clinical Investigations
Annex XVI – Products without an intended Medical Purpose
Annex XVII – Correlation table

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MDD & AIMDD now MDR - # of pages

Why the big increase?

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MDR - Goals of the Commission*

- Wider scope of medical devices / updated classifications
- Stronger supervision of independent assessment bodies by national authorities
- More powers for assessment bodies for a thorough assessment
- Clearer rights & responsibilities for various economic operators
- Extended EUDAMED database on medical devices
- Better traceability of medical devices
- Stricter requirements for clinical evidence
- Better coordination between various entities

MDR is a major update to MDD

Significant Impact on
- Manufacturers
- Notified Bodies
- Competent Authorities
- EU commission

What is common between this animal and NB’s?

- Rare Species!?  
  - ~60 left currently
- More NBs expected to disappear under MDR
- A very busy time anticipated for all remaining NBs with re-certifications to MDR & IVDR

https://www.worldwildlife.org/species/amur-leopard
Impact on NBs

- Designation and Monitoring – new process
  - Joint assessments
  - Expected to be lengthy and rigorous
- Increased supervision of NBs
  - Peer-review of NB work
- Competence and Resource requirements more stringent
  - Importance to in-house staff
  - In-house clinical experts
What can manufacturer do?

1. Study the MDR
2. Search for training offers / Visit events like this one today
3. Consider to contact a Notified Body at an early stage
4. ...to be continued in this presentation...
MDR Transition (Article 120)

- **Adoption of MDR**: 05 May 2017
- **Entry in to Force**: 25 May 2017
- **Date of Application**: 26 May 2020
- **MDD/AIMDD certificate validity**: 4 years
- **MDD/AIMDD certificate void on**: 27 May 2024
- **No more « making available or putting into service » of devices covered by MDD/AIMDD certificates**: 27 May 2025
- **MDD/AIMDD Annex IV certificates void on**: 27 May 2022
- **MDD/AIMDD certificates can be issued/re-issued/renewed**: 26 May 2020
- **MDR certificates**: N/A
- **NBs designation under MDR**: 26 Nov 2017
- **NBs can apply for designation**: 26 Nov 2017
Transition timelines

Important points

• After 26 May 2020, devices certified under MDD/AIMDD can only be placed on market if:
  ➔ They continue to comply with applicable Directives
  ➔ There are no significant changes in the design and intended purpose
  ➔ However, following MDR requirements will apply:
    - post-market surveillance,
    - market surveillance,
    - vigilance,
    - registration of economic operators
    - registration of devices
What can manufacturer do?

1. Study the MDR
2. Search for training offers / Visit events like this one today
3. Consider to contact a Notified Body at an early stage
4. Prepare your transition plan, with timescales
5. Factor any additional resources & costs into budgets
6. ...to be continued...
Changes to Medical Device Supply chain requirements
Key roles in medical devices supply and distribution chain

- Increased scrutiny of subcontractors and suppliers
- New requirements for manufacturers of devices without a medical purpose
- New contractual requirements, product liability, records and retention, involvement in corrective action and investigations, person responsible for regulatory compliance
- New requirements for manufacturers of devices without a medical purpose
- New CE requirements for device manufacturers (e.g. Class III custom devices, Class Ir, etc.); person responsible for regulatory compliance (next slide)
- Builds upon requirements from Directives 2001/95/EC (General Product Safety) and 85/374/EEC (liability for defective products); Clarifies when legal manufacturer responsibilities are assumed

Builds upon requirements from Directives 2001/95/EC (General Product Safety) and 85/374/EEC (liability for defective products); Clarifies when legal manufacturer responsibilities are assumed
Person responsible for regulatory compliance

Article 15

- Required for both Manufacturers and Authorised Representatives
- Must have expertise in medical devices, including degree and four years’ professional experience
- Responsible for ensuring:
  - Product conformity checked via appropriate QA release
  - Technical documentation and Declaration of Conformity maintained
  - PMS & reporting obligations are met
  - Investigational devices: statement of safety and compliance with SPRs
Requirements within medical devices distribution chain

General obligations described in Article 10

General obligations described in Article 11

General obligations described in Article 13

General obligations described in Article 14
What can manufacturer do?

1. Study the MDR
2. Search for training offers / Visit events like this one today
3. Consider to contact a Notified Body at an early stage
4. Prepare your transition plan, with timescales
5. Factor any additional resources & costs into budgets
6. Verify and renew contracts with subcontractors and suppliers
7. Factor in all new requirements for manufacturers from Article 10 & 15
8. ...to be continued...
European Medical Device Regulations 2017/745 Scope

In:

- Medical Devices from 93/42/EEC (Recital 6)
- Active Implantable Medical Devices from 90/385/EEC (Recital 6)
- medical devices incorporating (non-viable) human tissues (Recital 11)
- devices similar to medical devices, but without a medical purpose (Recital 12)
In:
- Medical Devices from 93/42/EEC (Recital 6)
- Active Implantable Medical Devices from 90/385/EEC (Recital 6)
- medical devices incorporating (non-viable) human tissues (Recital 11)
- devices similar to medical devices, but without a medical purpose (Recital 12)

Out (largely unchanged):
- in vitro diagnostics
- medicinal products
- cosmetics
- food
- products containing viable tissues or cells of human or animal origin (Recital 13)
Rules & Classification
Rules

New MDR
Rules 1 – 4: Non-invasive devices
Rules 5 – 8: Invasive devices
Rules 9 – 13: Active Devices
Rules 14 – 22: Special rules

MDD
Rules 1 – 4: Non-invasive devices
Rules 5 – 8: Invasive devices
Rules 9 – 12: Active devices
Rules 13 – 18: Special rules
## Rules 1 - 4: Non-invasive devices (in comparison with MDD)

<table>
<thead>
<tr>
<th>Rule 1</th>
<th>Rule 2</th>
<th>Rule 3</th>
<th>Rule 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No change</td>
<td>• Addition of “cells and tissues” to the existing language</td>
<td>• Addition of human tissues and cells to blood, body liquids and other liquids</td>
<td>• Addition of injured mucous membrane to injured skin</td>
</tr>
<tr>
<td></td>
<td>• Blood bags moved to MDR Rule 2 from Rule 18 of MDD</td>
<td>• Intended for implantation or administration vs. Intended for infusion in MDD</td>
<td>• Replacement of ‘wounds’ with injuries to skin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inclusion of organ storage solutions, IVF media into the rule which are class III</td>
<td>• Also covers invasive devices that come into contact with injured mucous membrane</td>
</tr>
</tbody>
</table>
### Rules 5 – 8: Invasive devices (in comparison with MDD/AIMD)

<table>
<thead>
<tr>
<th>Rule 5</th>
<th>Rule 6</th>
<th>Rule 7</th>
<th>Rule 8</th>
</tr>
</thead>
</table>
| • No change – clarifications only | • All devices intended specifically for direct contact with heart or central circulatory system now class III similar to devices in contact with central nervous system | • All devices intended specifically for direct contact with heart or central circulatory system now class III similar to devices in contact with central nervous system | • AIMD devices and accessories are class III  
• Breast implants and surgical meshes are class III  
• Total and partial joint replacements are class III  
• Spinal disc replacement implants or implantable devices that come into contact with spinal column are class III with some exceptions (screws, wedges, plates and instruments) |

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## Rules 9 – 13: Active Devices (in comparison with MDD/AIMD)

<table>
<thead>
<tr>
<th>Rule 9</th>
<th>Rule 10</th>
<th>Rule 11</th>
<th>Rule 12</th>
<th>Rule 13</th>
</tr>
</thead>
</table>
| • Addition of active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.  
• Addition of active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III. | • Addition of ‘monitoring’ to diagnosis;  
• Active devices intended for diagnosis in clinical situations where the patient is in immediate danger as class IIb | • New rule on software  
• Classifications range from class III – class I | • Rule 11 in MDD  
• No change | • Rule 12 in MDD  
• No change |
## Rules 14 – 18: Special rules

<table>
<thead>
<tr>
<th>Rule 14</th>
<th>Rule 15</th>
<th>Rule 16</th>
<th>Rule 17</th>
<th>Rule 18</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Devices with medicinal substances)</td>
<td>(Contraceptive devices, Devices for prevention of transmission of STDs)</td>
<td>(Disinfectants, sterilizers)</td>
<td>(Devices for recording x-ray diagnostic images)</td>
<td>(Devices utilizing human or animal derivatives)</td>
</tr>
<tr>
<td>• Rule 13 in MDD</td>
<td>• Rule 14 in MDD</td>
<td>• Rule 15 in MDD</td>
<td>• Rule 16 in MDD</td>
<td>• Rule 17 in MDD</td>
</tr>
<tr>
<td>• Clarification that medicinal product can be derived from human blood or plasma</td>
<td>• No change</td>
<td>• Addition of sterilisers to disinfectants</td>
<td>• No change – language clarified</td>
<td>• Addition of cells (to tissues)</td>
</tr>
<tr>
<td>• 'Liability to act' taken out</td>
<td></td>
<td>• Disinfectants or sterilisers become IIb only if they are used for invasive devices and as the end point of processing</td>
<td></td>
<td>• Addition of human origin cells and tissues or derivatives</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• The exception about contact with intact skin only, applies only to animal tissue and does not apply to human tissues or cells</td>
<td></td>
</tr>
</tbody>
</table>
Rules 19 – 22: Special rules

**Rule 19**
(Devices incorporating or consisting of nanomaterials)
- New rule
- Classifications from III to IIa based on potential for internal exposure

**Rule 20**
(Body-orifice invasive devices intended to administer medicines by inhalation)
- New rule
- Classification IIa or IIb
- IIb if they impact the safety and performance of the medicine or intended to treat life-threatening conditions

**Rule 21**
(Devices consisting of substances and introduced into the body via body orifice or skin and that are absorbed by or locally dispersed)
- New rule
- Classification from IIa to III based on where they are used and whether they or their products of metabolism are absorbed

**Rule 22**
(Active therapeutic device with an integrated or incorporated diagnostic function)
- New rule
- Class III
- Only applies if such devices significantly determine the patient management
- Closed loop systems or automated external defibrillators
What can manufacturer do?

1. Study the MDR
2. Search for training offers / Visit events like this one today
3. Consider to contact a Notified Body at an early stage
4. Prepare your transition plan, with timescales
5. Factor any additional resources & costs into budgets
6. Verify and renew contracts with subcontractors and suppliers
7. Factor in all new requirements for manufacturers –Article 10
8. Verify all new rules and classification to identify applicable changes for your products and product groups
9. ...to be continued...
MDR - Routes to conformity
MDR – Route to conformity – no or minor changes

- Art 52(8) – Custom made non-implantable devices
- Art 52(7) – Class I devices (non-sterile/non-measuring/non-reuseable)
- Art 52(7) – Class Is/Im/Ir devices
- Art 52(6) – Class IIa devices
- Art 52(4) – Class IIb non-implantable devices
- Art 52(3) – Class III non-implantable devices

New class Ir

MDD Annex VI (final inspection route) no longer available
**Art 52(8) – Custom made class III implantable devices**

- Custom made class III Implantable devices
  - Annex XIII
    - Technical Documentation
  - Annex IX
    - Chap 1 - QMS
  - Annex XI – Part A
    - Production
    - Quality Assurance
  - Declaration
    - Annex XIII Section 1*
  - CE Marking (Annex V)
    - CE 0086

**MDD comparison:**
- NB involvement required for Class III implantable devices

* Declaration contents include, but not limited to:
  - Name of Person Authorised to make out prescription,
  - Name of Healthcare Institution
  - Identification of Particular Patient (name or acronym or unique code)
  - Meets Requirements of Annex I
Art 52(4) – Class IIb implantable devices

- Class IIb implantable devices*
  - Annex IX QMS
  - Annex IX Section 4 Technical Documentation for every device
  - Annex X Type Examination
  - Annex XI – Part A Production Quality Assurance
  - Annex XI – Part B Product Verification
  - Declaration of conformity (Annex IV)
  - CE Marking (Annex V) CE 0086

* except for sutures, staples, dental fillings & braces, tooth crowns, screws, wedges, plates, wires, pins, clips & connectors

MDD comparison:
- Analogous to class III devices under MDD/AIMDD
Art 52(4) + Art 54 – Class IIb Active devices intended to administer and/or remove medicines (rule 12)

Class IIb Active devices intended to administer and/or remove medicines (Rule 12)

Annex IX QMS

Annex II & III
Technical Documentation
*sampled per GDG and assessed per Annex IX Chapter II

Annex X Type Examination

Annex XI – Part A
Production Quality Assurance

Annex XI – Part B
Product Verification

Clinical Evaluation Consultation – Annex IX Sec 5 or Annex X Sec 6

Declaration of conformity (Annex IV)

CE Marking (Annex V)
CE 0086

MDD comparison:
• Addition of scrutiny procedure for devices covered by Rule 12
Annex IX
Class III implantable (including devices with medicinal substances, human tissue or animal tissue derivatives)*

Annex IX QMS

Annex IX Section 4 Technical Documentation

Annex X
Type Examination

Annex XI – Part A Production Quality Assurance

Annex XI – Part B Product Verification


Clinical Evaluation Consultation – Annex IX Sec 5 or Annex X Sec 6

Declaration of conformity (Annex IV)

CE Marking (Annex V)
CE 0086

Art 52(3) + Art 54 – Class III implantable devices

MDD comparison: Addition of scrutiny procedure
Annex IX – Section 5 / Annex X – Section 6 / Article 55

**Notified Body Review**

- Manufacturer’s Clinical Evaluation
- NB Clinical Evaluation Report
- PMCF Plan
- IFU
- Summary of Safety and Performance

**EU Commission**

- Benefit: Risk Determination
- Consistency w/ indications
- PMCF Plan

**Notified Body Review**

- Restrict indications
- Limit duration of certificate
- Undertake specific PMCF studies
- Adapt IFU or Summary of Safety and Clinical Performance
- Impose other restrictions

**Notified Body Certificate**

* Duly justify if advice not followed

**Notified Body Certificate**

Complete Conformity Assessment

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What can manufacturer do?

1. Study the MDR
2. Search for training offers / Visit events like this one today
3. Consider to contact a Notified Body at an early stage
4. Prepare your transition plan, with timescales
5. Factor any additional resources & costs into budgets
6. Verify and renew contracts with subcontractors and suppliers
7. Factor in all new requirements for manufacturers –Article 10
8. Verify all new rules and classification to identify applicable changes for your products and product groups
What can manufacturer do?

9. Identify those products which require an up-classification
10. Define the applicable route of conformity assessment
11. ...to be continued...
Overview, Annex I
Safety and Performance Requirements
Top-Level Structure & Overall Trends

- Overall Structure and Trends:
  - Some numbering and organizational changes
  - Overall similar content and topics (some title changes: i.e. construction → manufacturing)
  - Expanded requirements (Labeling, Risk)
  - New areas of emphasis (from standards and guidances, etc.)
  - Some additional requirements because of merging of MDD with AIMDD
  - Some topics move out of the SPR list into Articles/Annexes (Clinical, medicinal consultation)
- Some new topics introduced (devices without medical purpose, lay person use, etc.)

MDD: 13 Essential requirements
AIMD: 16 Essential requirements
MDR: 23 Safety & Performance requirements
Annex I, Safety and Performance Requirements

- **Chapter 1: General Requirements** (SPRs 1-9)
- **Chapter 2: Design and Manufacture** (SPRs 10-22)
- **Chapter 3: Information Supplied with the Device** (SPR 23)
Annex I, Safety and Performance Requirements

Chapter 1: General Requirements (SPRs 1-9)

• Much greater emphasis on risk management (2-5)
• New requirement for devices without a medical purpose (9)
• Rest similar to Directive

Chapter 3: Information Supplied with the Device (SPR 23)
Annex I, Safety and Performance Requirements

Much more detail regarding chemical, physical and biological properties, and specific substances of concern. Addresses mechanical as well as toxicological suitability (10)

Greatly expanded scope of requirements with respect to infection and microbial contamination (11)

Medicinal substances scope expanded to include substances that are absorbed by or locally dispersed in the human body (12)

New requirement: information for lay users (22)

Much more detail on mechanical and thermal risks (20)

Active and AIMD, many similar or identical, some new:
- Increased emphasis on info security (17, 18)
- More emphasis on ionising radiation (16)

Expanded requirements for interaction with the environment and compatibility with other devices, including ergonomics, calibration, disposal (14)

• Biological tissues expanded to include human tissues (rendered non-viable) (13)
• Also includes catch-all for non-viable biological substances of neither human nor animal origin
Chapter 1: General Requirements (SPRs 1-9)

Annex I, Safety and Performance Requirements

- Some clarifications on labelling requirements. Additional requirements for UDI, devices incorporating human or animal tissues, absorbable devices, AIMDs (23.2)
- Specific requirements for labelling for sterile packaging (23.3)

Many more new requirements and cross-referencing to articles, including:
- Requirements for special training or facilities (23.4j)
- Identification of consumable components and how to replace (23.4k)
- Many more specific warning requirements (EMC, medicinal substances, human or animal tissues, CMR and endocrine disruptors) (23.4s)
- Absorbable/dispersible materials (23.4t)
- Information on materials for implants (23.4u)
- Information security measures (23.4ab)

More “general” requirements (e.g. format, readability, availability, eIFU, etc.)

Chapter 3: Information Supplied with the Device (SPR 23)
Standards and Common Specifications
Harmonised Standards

**Directives**

shall presume compliance with ERs of devices in compliance with ...the harmonised standards

MDD, IVDD, AIMDD – Article 5.1

**Regulations**

Devices that are in conformity with the relevant harmonised standards or the relevant parts of those standards...shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

MDR, IVDR – Article 8.1

**Harmonised standards will continue to provide presumption of conformity with the requirements of Regulations (similar to the Directives)**

Monographs from European Pharmacopeia considered as harmonised standards as long as their references are published in the Official Journal
Common Specifications

- ‘common specifications’ (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system (Article 2)
- Concept borrowed from IVDD (common technical specifications)

Article 9 (MDR + IVDR)
Commission will adopt CS.....
- Where no harmonised standards exist
- Relevant harmonised standards are not sufficient
- Need to address public health concerns
- After consulting with MDCG and published via implementing acts

Devices in conformity with CS....shall be presumed to be in conformity....with Regulation requirements

Manufacturers shall comply with the CS..... unless they can duly justify that... their solutions ensure a level of safety and performance.. that is at least equivalent to the CS
Will be CS’s above all?

Common Specifications
- Harmonised Standards
- EN standards (not harmonized)
- International (ISO/IEC)
- EU National (BS/DIN/FN)
- Other National (ASTM/ANSI)
- Manufacturer’s specifications
What can manufacturer do?

1. Study the MDR
2. Search for training offers / Visit events like this one today
3. Consider to contact a Notified Body at an early stage
4. Prepare your transition plan, with timescales
5. Factor any additional resources & costs into budgets
6. Verify and renew contracts with subcontractors and suppliers
7. Factor in all new requirements for manufacturers –Article 10
8. Verify all new rules and classification to identify applicable changes for your products and product groups
What can manufacturer do?

9. Identify those products which require an up-classification
10. Define the applicable route of conformity assessment
11. Revise your technical documentation in line with Annex I to provide suitable solutions to demonstrate compliance (old ER checklist)
12. Revise your list with adopted standards and common specifications ones they are out
13. ...to be continued...
Requirements for Clinical Evaluations and Clinical Investigations
Requirements defined:

- Chapter VI: Clinical Evaluations and Clinical Investigations
- Annex XIV Part A: Clinical Evaluation
- Annex XV: Clinical Investigations

Conformity assessment procedures, particularly Annex IX (QMS), also provide detail on requirements for NB assessment of clinical data
Requirements for Clinical Evaluation

Same basic principles apply (Chapter VI, Appendix XIV):

- Device or equivalent
- Literature review or clinical investigation
- Data must be sufficient to demonstrate safety, performance and risk/benefit

Key issues unchanged:
- Equivalence
- Quality and completeness of data
- Risk-benefit
- Adequacy of PMCF
- Competence of evaluators and assessors
- MedDev 2.7.1 rev 4
Requirements for Clinical Investigation

Chapter VI, Article 61(6)

- Implants previously CE-marked do not require clinical investigation providing:
  - Clinical evaluation is based on “sufficient” clinical data
  - Complies with relevant product-specific Common Specification (if such exists)
- or
  - are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connects and
  - Comply with relevant product-specific Common Specification
Changes to Conformity Assessment Procedures

1. **EU Consultation** for Class III implants and Class IIb devices intended to administer or remove a medicinal product
2. Increased requirements for Notified Body assessments
3. Requirements for report content / CEAR (Recital 56)
Requirements for Clinical Evaluation Assessment Report - CEAR

Annex IX:

- NB must:
  - Challenge equivalence and document conclusions
  - Verify clinical evidence in terms of
    → Safety, performance, benefit-risk
    → Risk management
    → IFU
    → User training
    → Adequacy of PMCF
  - Determine if PMCF follow up is required

- NB must document in CEAR and provide to manufacturer as part of overall technical documentation assessment report

- **Annex X** has similar requirements, but refers back to **Annex XIV** for clinical evaluation assessment requirements
Requirements for report content

Annex VII Section 4.5.5:

- NB **CEAR** must cover:
  - Intended use
  - Clinical evaluation planning
  - Literature search methodology
  - Documentation from the literature search
  - Clinical investigation
  - Validity of equivalence claims
  - PMS and PMCF
  - Justifications if no clinical investigation
  - Justification if no PMCF
What can manufacturer do?

1. Study the MDR
2. Search for training offers / Visit events like this one today
3. Consider to contact a Notified Body at an early stage
4. Prepare your transition plan, with timescales
5. Factor any additional resources & costs into budgets
6. Verify and renew contracts with subcontractors and suppliers
7. Factor in all new requirements for manufacturers –Article 10
8. Verify all new rules and classification to identify applicable changes for your products and product groups
What can manufacturer do?

9. Identify those products which require an up-classification
10. Define the applicable route of conformity assessment
11. Revise your technical documentation in line with Annex I to provide suitable solutions to demonstrate compliance (old ER checklist)
12. Revise your list with adopted standards and common specifications ones they are out
13. Update your CER in line with MedDev 2.7/1 rev 4
14. Include new requirements from chapter VI & annexes XIV, XV
15. Demonstrate how sufficient levels of access to data is achieved
16. ...to be continued...
Requirements for PMS & PMCF

Requirements defined:

- Chapter VII: Post-market Surveillance, Vigilance and Market Surveillance
- Annex III: Technical Documentation on Post-market Surveillance
- Annex XIV Part B: Post-Market Clinical Follow Up

Mostly formalising rather than “new”, however...

- Conformity assessment procedures, particularly Annex IX, also reference requirements for NB assessment of PMS & PMCF
- Also referenced in Chapter VI (Clinical Evaluation and Clinical Investigation)
Requirements for PMS & PMCF

However:

- Greater emphasis on specific features of **PMCF plan**
- Reference to conformity with product-specific CS if applicable
- Greater emphasis on factors affecting scientific validity (e.g. appropriateness of methods, specific objectives, adequately justified time schedule)
- More explicit linkages to outputs of CER and risk management
- PMS and PMCF plans required as part of certification application and QMS assessment
- PMCF evaluation report for Class III devices and implants shall be updated at least annually
Vigilance
Requirements for PMCF

Requirements defined:

- Chapter VII: Post-market Surveillance, Vigilance and Market Surveillance

Mostly formalising rather than “new”, however...
Requirements for Vigilance

However:

• Greater provision for Competent Authorities (CA) investigation into unsafe or non-compliant devices (Articles 95 – 99)

• Trend reporting (Article 88)

Manufacturers must report “any statistically significant increase in the frequency or severity of incidents” – implies appropriate expertise and statistical analysis
Requirements for Vigilance

However:

- Greater provision for CA investigation into unsafe or non-compliant devices (Articles 95 – 99)
- Trend reporting (Article 88)
- Field safety notices should include reference to UDI and SRN (Article 89(8))
- Implementing Acts (Article 91)

Gives the Commission space to amend requirements or definitions with respect to vigilance issues, vigilance reporting and FSCA, PSUR, etc.
Requirements for Vigilance

However:

• Greater provision for CA investigation into unsafe or non-compliant devices (Articles 95 – 99)
• Trend reporting (Article 88)
• Field safety notices should include reference to UDI and SRN (Article 89(8))
• Implementing Acts (Article 91)
• New EUDAMED – more data, greater accessibility (Recitals 44-49, Article 33, Article 92, Article 100)

Article 33:  
• Includes data on certification status, vigilance, PMS, market surveillance, corrective actions, etch  
• Information submitted by manufacturers, NBs and CAs as appropriate
SSCP & PSUR
Requirements for SSCP and PSUR

Requirements defined:

- **Recitals 48 – 49**
- **Article 32** *(Summary of Safety and Clinical Performance)*
- **Article 86** *(Periodic Safety Update Report)*

- **SSCP** required for Class III and implantable devices
- Draft submitted as part of the application for certification to NB
- Identifies device, intended use, safety and performance characteristics and summary of technical and clinical evidence of conformity
- Updated whenever PMS data affects conclusions *(Article 62(11))*
- Validated by NB and made available to the public via EUDAMED
- Requirements for content may be amended by implementing acts

- **PSUR** updated annually for Class IIb and Class III devices
- Summarises latest conclusions on risk-benefit, main findings of PMCF
- Sales and usage data
- Must be submitted to NB for review annually (Class III and implants)
- NB approves updates and submits to EUDAMED with comments
What can manufacturer do?

1. Study the MDR
2. Search for training offers / Visit events like this one today
3. Consider to contact a Notified Body at an early stage
4. Prepare your transition plan, with timescales
5. Factor any additional resources & costs into budgets
6. Verify and renew contracts with subcontractors and suppliers
7. Factor in all new requirements for manufacturers –Article 10
8. Verify all new rules and classification to identify applicable changes for your products and product groups
What can manufacturer do?

9. Identify those products which require an up-classification
10. Define the applicable route of conformity assessment
11. Revise your technical documentation in line with Annex I to provide suitable solutions to demonstrate compliance (old ER checklist)
12. Revise your list with adopted standards and common specifications ones they are out
13. Update your CER in line with MedDev 2.7/1 rev 4
14. Include new requirements from chapter VI & annexes XIV, XV
15. Demonstrate how sufficient levels of access to data is achieved
16. Identify and apply the requirements for PMS, PMCF, SSCP and PSUR
17. ...to be continued...
UDI
Unique Device Identification
(Traceability)
Why?
Recital “Whereas” 5

...to promote the global convergence of regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on:

- Unique Device Identification
- general safety and performance requirements
- technical documentation
- classification rules
- conformity assessment procedures
- clinical investigations (evidence for IVDR)
What?
(Article 2)
Article 2 - Definition

‘Unique Device Identification’ (‘UDI’) means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;
Article 27

GS1
- not-for-profit standards agency
- numeric codes licenses must be renewed at set periods
- used in the pharmaceutical supply chain

HIBCC
- Health Industry Business Communications Council
- non-profit organization
- alphanumeric codes are acquired after paying a one-time fee
- used in the healthcare industry supply chain

ICCBBA
- International Council for Commonality in Blood Banking Automation
- used for blood products, tissues, and organs for transplant
Where to place the UDI and where is it stored?
Article 27

UDI carriers shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.

Shipping container is a container where the traceability is controlled by a process specific to logistics systems.
Article 27

*not commercially available on its own

*unique @ all levels of packaging

*if significant space constraint on the unit of use package the UDI may be placed on the next higher package level
**Article 27**

- The UDI shall be used for **reporting** serious incidents and field safety corrective actions

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**Report Form**

**Manufacturer's Incident Report**

**Medical Devices Vigilance System**

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<table>
<thead>
<tr>
<th>Nomenclature system (preferable GMDN)</th>
<th>Nomenclature code</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMDN</td>
<td></td>
</tr>
<tr>
<td>Nomenclature text</td>
<td></td>
</tr>
<tr>
<td>Commercial name/brand name/make</td>
<td></td>
</tr>
<tr>
<td>Model number</td>
<td>Catalogue number</td>
</tr>
<tr>
<td>Serial number(s) (if applicable)</td>
<td>Lot/batch number(s) (if applicable)</td>
</tr>
</tbody>
</table>
Article 27

- The Basic UDI-DI, as defined in Part C of Annex VI, of the device shall appear on the EU declaration of conformity referred to in Article 19.
As part of the technical documentation referred to in Annex II, the manufacturer shall keep up-to-date a list of all UDIs that it has assigned.

The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unequivocal way and shall include:

1. DEVICE DESCRIPTION, SPECIFICATION, VARIANTS & ACCESSORIES
   - Device description and specification + UDI
   - Reference to previous / similar generations of the device

2. INFORMATION SUPPLIED BY THE MANUFACTURER

3. DESIGN AND MANUFACTURING INFORMATION

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT

6. PRODUCT VERIFICATION AND VALIDATION
   - Pre-clinical and clinical data
   - Additional information in specific cases
Annex I – Safety & Performance Requirements

• **SPR# 23.2 Information on the label**

  • The label shall bear the following particulars:
    • (a)
    • (b)

  • (h) the unique device identification (UDI) carrier according to Article 27(4) and Annex VII Part C.

  • (r)
  • (s)
A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability, in particular any change of one of the following UDI database data elements require a new UDI-DI:

- a) Name or Trade name
- b) Device version or model
- c) Labelled as single use
- d) Packaged sterile
- e) Need for sterilization before use
- f) Quantity of devices provided in a package
- g) Critical warnings or contraindications: e.g. containing latex or DEHP
Article 27 – Storage of UDI

- **Economic operators** – the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to:
  - class III implantable devices;
  - And others qualified via delegated acts in future

- **Health institutions** - the UDI of the devices which they have supplied or they have been supplied with if those devices belong to **class III implantable devices**.
  - Member States shall encourage, and may require, health institutions to store UDIs of other devices as well.

- Member States shall encourage, and may require, healthcare professionals to store the UDI of the devices with which they have been supplied.

- ‘economic operators’
  - Manufacturer
  - Authorised Representative
  - Importer
  - Distributor
  - Those who place procedure packs on the market

- ‘health institution’
  - organisation whose primary purpose is the care or treatment of patients or the promotion of public health

- Class III implantable devices
- + Implementing Act
Article 28 – UDI database

- The Commission, after consulting the MDCG shall set up and manage a ‘UDI database’
- Manufacturers are required to submit at least the UDI-DI to NBs as part of their application
- Once certificates are issued, manufacturers are required to submit all the UDI information (including the UDI-PI) to the UDI database before placing the devices on the market
Article 27 – Traceability

- Raw Materials
- Warehouse
- Distribution
- Disposal
- Manufacture EU AR
- Import
- Health Institution
- Healthcare Professional
When
(Article 123)
## Key Dates

<table>
<thead>
<tr>
<th>Key Dates</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>From what point in time will GS1, HIBCC and ICCBBA be considered as designated UDI issuing entities? (Article 123,3i)</td>
<td>• May 26, 2019</td>
</tr>
<tr>
<td>When will UDI carriers need to be placed on the label of devices and all higher levels of packaging? (Article 123,3f)</td>
<td>• May 26, 2021 - Implantable devices and Class III devices;</td>
</tr>
<tr>
<td></td>
<td>• May 26, 2023 - Class IIa and IIb (non-implantable) devices</td>
</tr>
<tr>
<td></td>
<td>• May 26, 2025 for Class I devices</td>
</tr>
<tr>
<td>How soon will the UDI carrier need to be placed on reusable devices? (Article 123,3g)</td>
<td>• May 26, 2023 - reusable Implantable devices and reusable Class III devices;</td>
</tr>
<tr>
<td></td>
<td>• May 26, 2025 - reusable Class IIa and reusable IIb (non-implantable) devices;</td>
</tr>
<tr>
<td></td>
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14. Include new requirements from chapter VI & annexes XIV, XV
15. Demonstrate how sufficient levels of access to data is achieved
16. Identify and apply the requirements for PMS, PMCF, SSCP and PSUR
17. Apply for a SRN and implement the UDI system in line with your transition plan
18. ...to be continued and not exhaustive
Thank you very much for your attention