Article 120 (3)
What is due in 2020?

Suzie Halliday
04 December 2019
Information presented within this webinar is based on our current understanding of the Regulation

Subject to change
Article 120 Clause 3

“... a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC ... provided there are no significant changes in the design or intended purpose.”

“However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.”
Agenda

1. Significant changes in the design or intended purpose
2. Post-market surveillance
3. Market surveillance
4. Vigilance
5. Registration of economic operators
6. Registration of devices
1. Significant Changes
Significant Changes

93/42/EEC – Class IIa and IIb devices – some design changes and indication changes, could previously be implemented without prior approval from NB

Article 120 changes – apply to all classes of device

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**Article 120**

**Transitional provisions**

3. By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.
CHAPTER 1

SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

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.

Article 120

Transitional provisions

1. From 26 May 2020, any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void.

NBs can issue addenda to Directive certificates to fulfil Article 120 (3) “... continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.”
2. Post Market Surveillance &
3. Market Surveillance
Post Market Surveillance – Requirements

MDD & AIMDD
- MDD – conformity annexes (II, III, VII)
- AIMDD – conformity annexes (2 and 3)
- MedDev 2.12/1 (rev 8) – Guidelines on a Medical Devices Vigilance System

MDR
- Chapter VII: Post-Market Surveillance, Vigilance and Market Surveillance
- Annex XIV (Part B): Post Market Clinical Follow Up
Post Market Surveillance – Requirements

Article 2(44):
Clinical evaluation: a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer.

Article 83
• “For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device.”

Annex III 1.1b says PMS should include: “a PMCF plan as referred to in Part B of Annex XIV, or a justification as to why a PMCF is not applicable.”
PMS – What’s changing from MDD/AIMDD to MDR?

• Requirements are more explicit and prescriptive with respect to:
  – What data should be gathered
  – How it should be gathered
  – How it should be used
  – Timescales for updates, review and validation

• New requirements for publicly available information and sharing of information across Member States

PMS - Annex III (1a):
• Serious incidents, FSCA, information from PSURs
• Non-serious incidents and data on any undesirable side-effects
• Sales, complaints and trend reporting
• Data from literature, databases and/or registers
• Other market feedback (eg provided by users, distributors and importers)
• Publicly available information on similar medical devices
PMS – What’s changing from MDD/AIMDD to MDR?

• Requirements are more explicit and prescriptive with respect to:
  – What data should be gathered
  – How it should be gathered
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  – Timescales for updates, review and validation

• New requirements for publicly available information and sharing of information across Member States

PMCF - Annex XIV Part B:
• Safety and performance throughout device lifetime
• Side-effects and contraindications, including previously unknown side-effects
• Emergent risks
• Information on possible systematic misuse or off-label use
PMS – What’s changing from MDD/AIMDD to MDR?

- Requirements are more explicit and prescriptive with respect to:
  - What data should be gathered
  - How it should be gathered
  - How it should be used
  - Timescales for updates, review and validation

- New requirements for publicly available information and sharing of information across Member States

**PMS - Annex III (1b):**

- Proactive and systematic
- Enable comparison with similar devices on the market
- Methods to assess the data, including indicators and threshold values
- Statistical methods for trending and monitoring increases in frequency or severity of incidents
- Protocols for communication with CA, NB, EO & users
- Procedures for corrective actions
PMS – What’s changing from MDD/AIMDD to MDR?

• Requirements are more explicit and prescriptive with respect to:
  – What data should be gathered
  – How it should be gathered
  – How it should be used
  – Timescales for updates, review and validation

• New requirements for publicly available information and sharing of information across Member States

PMCF - Annex XIV Part B:
• Clinical data from use in / on humans on the device
• Within its intended purpose as referred to in the relevant conformity assessment procedure
• Specific methods and procedures, including rationale for appropriateness
• Specific objectives
• Reference to CS, harmonised standards and relevant guidance
• Comparison to equivalent or similar devices
• Detailed and adequately justified time schedule
PMS – What’s changing from MDD/AIMDD to MDR?

• Requirements are more explicit and prescriptive with respect to:
  – What data should be gathered
  – How it should be gathered
  – How it should be used
  – Timescales for updates, review and validation

• New requirements for publicly available information and sharing of information across Member States

PMS - Article 83(3):
PMS data shall be used to:
• Update the benefit-risk determination, technical documentation, IFU, labelling, clinical evaluation, SSCP
• Improve risk management
• Identify needs for CAPAs or FSCA;
• Identify options to improve the usability, performance and safety of the device
• Contribute to the post-market surveillance of other devices (where relevant)
• Detect and report trends
PMS – What’s changing from MDD/AIMDD to MDR?

• Requirements are more explicit and prescriptive with respect to:
  – What data should be gathered
  – How it should be gathered
  – How it should be used
  – Timescales for updates, review and validation

• New requirements for publicly available information and sharing of information across Member States

PMCF - Annex XIV Part B:
• Confirm safety, performance and benefit-risk throughout device lifetime
• Identify requirements for corrective action

Article 61(11):
• Update clinical evaluation, PSUR and (if indicated) SSCP
PMS – What’s changing from MDD/AIMDD to MDR?

• Requirements are more explicit and prescriptive with respect to:
  – What data should be gathered
  – How it should be gathered
  – How it should be used
  – Timescales for updates, review and validation

• New requirements for publicly available information and sharing of information across Member States

PMS is linked to PSUR (Article 86) and SSCP (Article 32)
• PSUR updated annually for Class III and IIb, every two years for Class IIa
• SSCP updated if outputs of PMS impact on it
• For Class III and implantable devices, NB must validate these documents and upload to EUDAMED
PMS – What’s changing from MDD/AIMDD to MDR?

• Requirements are more explicit and prescriptive with respect to:
  – What data should be gathered
  – How it should be gathered
  – How it should be used
  – Timescales for updates, review and validation

• New requirements for publicly available information and sharing of information across Member States

For Class III and implantable devices, PMCF report is updated at least annually (Article 61(11))
PMS – What’s changing from MDD/AIMDD to MDR?

• Requirements are more explicit and prescriptive with respect to:
  – What data should be gathered
  – How it should be gathered
  – How it should be used
  – Timescales for updates, review and validation

• New requirements for publicly available information and sharing of information across Member States

PSUR requirement applies to all Directive certificates

PSUR due no later than 2021 for all IIb and III devices

PSUR due no later than 2022 for all Class IIa

If Directive DOC follow MDD, If Regulation DOC follow MDR

NB will review in surveillance audits

e.g. PSUR, SSCP, vigilance, status of clinical studies ...

4. Vigilance
Manufacturer Incident Report Form

- **Section 1 = Administrative Information**
- **Red Boxes = mandatory fields**
- **EUDAMED – Reference Number, Competent Authority, Manufacturer’s Single Registration Number, Periodic Summary Report Number, PMCF/PMPF Reference Number, EU AR SRN = NOT mandatory yet**

### Section 1: Administrative Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EUDAMED number of IME</td>
<td>IME's EUDAMED number</td>
</tr>
<tr>
<td>Reference number assigned by EMA for this incident</td>
<td></td>
</tr>
<tr>
<td>Reference number assigned by EUDAMED for this incident</td>
<td></td>
</tr>
</tbody>
</table>

### Date, type, and classification of incident report

<table>
<thead>
<tr>
<th>Type of incident</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Contraindicated test</td>
<td></td>
</tr>
<tr>
<td>PIC</td>
<td></td>
</tr>
<tr>
<td>PIC followed by incident</td>
<td></td>
</tr>
</tbody>
</table>

### Qualification of incident

- Serious public health risk
- Death
- Unintended serious deterioration in state of health
- All other reportable incidents

### Submitter information

- Manufacturer or Authorized Representative
- Other, please specify

*V7.1 can be used until end Mar 2020*
MIR – Section 2 – Medical Device Information

- **UDI, UDI-DI, UDI-PI, Basic UDI-DI, Unit of Use UDI-DI** = NOT mandatory yet
- **GMDN, UMDNS, GIVD, EDMS, Other** = NOT mandatory yet
- **CND (EMDN)** could be entered in free text nomenclature field
- **NB Number, Certificate** = NOT mandatory yet
MIR – Section 3 – Incident Information

- Free text field = mandatory

- IMDRF Medical Device Problem Code (Annex A) = mandatory

- Option to pick multiple Annex A codes

**Mission:** Development of a harmonized terminology for reporting adverse events related to medical devices including in-vitro diagnostics

**Purpose:** To improve the efficiency of the adverse event management systems for faster response by both industry and regulatory agencies, with the use of a single, appropriate adverse event terminology and coding system.

- What happened to the device?
- Which components were involved?
- What happened to the patient?
- What were the probable causes of the problem?

**Medical Device Problem (Annex A)**

**Components (Annex G)**

**Cause Investigation (Annex B, C & D)**

**Health Effects (Annex E & F)**
**IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes (Edition 4) - Annex A (Edition 3), G**

<table>
<thead>
<tr>
<th>Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes - PDF (468kb)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes - DOC (265kb)</td>
</tr>
<tr>
<td>Annex A: IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes - XLSX (60kb)</td>
</tr>
<tr>
<td>N43 Annex A Reference Mapping - XLSX (41kb)</td>
</tr>
<tr>
<td>Annex B: IMDRF terminologies for categorized Adverse Event Reporting (AER): Type of investigation - XLSX (14kb)</td>
</tr>
<tr>
<td>N43 Annex B Reference Mapping - XLSX (10kb)</td>
</tr>
<tr>
<td>Annex C: IMDRF terminologies for categorized Adverse Event Reporting (AER): Investigation Findings (what were the findings?) - XLSX (30kb)</td>
</tr>
<tr>
<td>N43 Annex C Reference Mapping - XLSX (20kb)</td>
</tr>
<tr>
<td>Annex D: IMDRF terminologies for categorized Adverse Event Reporting (AER): Investigation Conclusion - XLSX (18kb)</td>
</tr>
<tr>
<td>Annex E: IMDRF terminologies for categorized Adverse Event Reporting (AER) Health Effect – Clinical Signs, Symptoms and Conditions - XLSX (218kb)</td>
</tr>
<tr>
<td>N43 Annex D Reference Mapping - XLSX (11kb)</td>
</tr>
</tbody>
</table>


**IMDRF Archive**

**GHTF Archive**
IMDRF N43 Annex A – Medical Device Problem

- Patient Device Interaction Problem
- Manufacturing, Packaging, Shipping Problem
- Chemical Problem
- Material Integrity Problem
- Mechanical Problem
- Optical Problem
- Electrical / Electronic Problem
- Calibration Problem
- Output Problem
- Temperature Problem
- Software Problem
- Connection Problem
- Infusion / Flow Problem
- Activation / Positioning / Separation Problem
- Protective Measures Problem
- Compatibility Problem
- Contamination / Decontamination Problem
- Environmental Compatibility Problem
- Installation Related Problem
- Labelling / IFU / Training Problem
- Human Interface Problem
- Use of Device Problem
- Adverse event without identified device or use problem
- No apparent adverse event
- Insufficient information
- Appropriate Term / Code not available

Level 1: 27
Level 2: 167
Level 3: 267

What happened to the device?
# IMDRF N43 Annex A – Medical Device Problem

<table>
<thead>
<tr>
<th>Compatibility Problem</th>
<th>Component or Accessory Incompatibility</th>
<th>Problem associated with the incompatibility of any device while being operated in the same use environment thereby leading to a dysfunction between the devices.</th>
<th>Accessory Incompatible</th>
<th>An accessory required for the intended purpose of the device appears incompatible with device, thus compromising the intended function of the device.</th>
<th>Component Incompatible</th>
<th>A component required for the proper functioning of the device is not compatible with other components or subassemblies of the device, thus compromising the intended function of the device.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device-Device Incompatibility</td>
<td>Problem associated with the incompatibility of two or more devices while being operated in the same use environment thereby leading to a dysfunction of more than one device.</td>
<td>A1702</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Measurement System Incompatibility</td>
<td>Problem associated with the incompatibility of the measurement systems between and/or within device systems that are inherent to the individual device thereby leading to miscalculated or mismatched measurements from those devices, e.g., international metric system versus U.S. measurement system.</td>
<td>A1703</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unintended Compatibility</td>
<td>Problem associated with the ability of two or more devices which are intended to be incompatible but are able to work or fit together.</td>
<td>A1704</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
MIR – Code Summary of Report

- Last page pulls from other pages:
  - Device Name
  - Basic UDI-DI / UDI-DI / UDI-PI
  - Annex E1612 – Inadequate osseointegration
  - Annex F1905 – Device revision or replacement
  - Annex A010202 – Problem associated with weakened integration of the device at the bone-implant interface i.e. loosening/lysis
  - Annex G – Bearing Materials
  - Annex B15 – Analysis of data provided by user
  - Annex C070606 – Wear problem
  - Annex D1101 – User not following manufacturer’s instructions

Need to use MIR form – January 2020
5. Registration of Economic Operators
Registration of Economic Operators

Select one of the options below

NEW ACCESS REQUEST
My organisation is already registered. I need to get access to Eudamed for my organisation.

ACTOR REGISTRATION
No actor exists for my organisation. I want to proceed with the registration of my organisation.
Registration of Economic Operators
Registration of Economic Operators

Actor registration

1. Actor identification
2. Actor address
3. Contact Details
4. Regulatory persons
5. Registering Local Actor Administrator
6. Competent Authority

Actor identification
* Role
Manufacturer

* Country
Sweden

Actor/Organisation name:

Organisation name

Abbreviated name:
Org name

VAT information:
Yes ☐ No ☑

ECPI
National Trade region:

Organisation identification document

Browse

1 file uploaded successfully

Organisation identification document.doc

Actor address

Street:
Orande Place

Address complement:

PO box Information:

GPS coordinates (format not final):

* City name:
Stockholm

* Country:
Sweden

Street number:
1

Postal code:
1000
Registration of Economic Operators

PRRC – Article 15

(a) conformity of the devices is checked, in accordance with the QMS, before a device is released
(b) technical documentation and EU DOC are drawn up and kept up-to-date
(c) PMS obligations are complied with in accordance with Article 10(10)
(d) reporting obligations in Articles 87 to 91 are fulfilled
(e) in the case of investigational devices, “investigational device that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation”
Registration of Economic Operators

Actor registration

Registering Local actor administrator

EU LOGIN personal data
First Name: TestEudamed
Email: testEudamed@mailinator.com

EUDAMED personal data
* First Name: TestEudamed

EUDAMED email of the user for the actor
* Email: testEudamed@mailinator.com

* Signed agreement annex

The agreement annex has to be signed before to...
Registration of Economic Operators

Actor registration

Competent Authority

* Select the Competent Authority which will validate this actor:

Medical Products Agency

Organisation
Medical Products Agency

Email
meddev.central@mnpa.se

Tel.
+46 18 17 46 00

Address
Box 28 -
SE-751 03 Uppsala

Any other information of significance for the Competent Authority

Additional information:
Single Registration Number (SRN)

• From our current understanding there will only be one SRN number for a manufacturer for both IVDR and MDR (Article 52)
• There will be a separate SRN Number for Article 22 (3) Systems and Procedure Pack Producers
• BSI will provide CE certificates to manufacturers without an SRN until EUDAMED is functional
• BSI will populate certificates with “Not Available” until EUDAMED is in a position to be able to provide Manufacturers with SRN
• BSI will get six months to update EUDAMED once it is functional
6. Registration of Devices
Registration of Devices

Article 33 MD/30 IVD - Electronic Systems included in Eudamed

- 1st module set:
  - Actors
  - UDI
  - Device 2
  - NB
  - Certificate

- 2nd module set:
  - Vigilance
  - Market Surveillance

- Clinical Investigation / Performance Studies

- MDR EUDAMED Public Site

Device placed on the market
1st release
MDR Transition *Rolling Plan as of November 2019

Date of Application
(26 May 2020)

MDD/AIMD certificate validity
(4 years)

MDGCG & Subgroup Set-up
Implementing Act – Designation of UDI
Issuing Entities (GS1, HIBCC, ICCBBA, IFA)
EU) 2019-939 Q2 2019

Standardisation Mandate

SCHER report – phthalates
Designation of EU Nomenclature (CND = EMDN)

Implementing Act – Reprocessing of single use devices
Implementing Act – Fees for Expert Panels
Implementing Act – set up of EUDAMED
Implementing Act – Class D Scrutiny 2019
Implementing Act – Devices with no Medical Purpose
Implementing Act – Expert Laboratories
Implementing Act – EU Reference Labs & Fees
Functional Specifications - EUDAMED 2020

EUDAMED Go Live
EUDAMED Help Desk
March 2022

MDD/AIMD certificates (max 5-year expiry from issue/renewal date)

BSI designation under MDR
(21 Jan 2019)

(EU) 2017-2185
MDR & IVDR
Codes

Communication Campaign


27 May 2025
No more « placing on the market » of devices covered by MDD/AIMD/IVD certificates

Last MDD/AIMD/IVD certificates expire
(27 May 2024)

27 May 2022

No more « placing on the market » of devices covered by MDD/AIMD/IVD certificates

(EU) 2019-939 Q2 2019

“A UDI-DI shall be associated with one and only one Basic UDI-DI.”

“The association between different Basic UDI-DIs, where applicable, shall be identified through the technical documentation.”

“... a new UDI-DI shall be required in the case of any change of ... name or trade name, device version or model ...”

Annex VI Part C 3.9

MDCG Guidance identifies additional attributes (SRN, risk, class, type (implantable, measuring ...)) that would require new UDI-DI

Basic-UDI-DI is the main key in the database to connect devices the same intended purpose, risk class and essential design and manufacturing characteristics.
EUDAMED will require Basic UDI-DI for all devices.

“Certificates shall identify and cover all devices associated with the same Basic UDI-DI, that is referred to in that certificate.”

“Any Basic UDI-DI shall identify the devices (group) covered by that Basic UDI-DI in a unique manner.”
Basic UDI-DI

“The Basic UDI-DI shall identify systems or procedure packs having the same group of components and the same intended purpose, regardless of the original components manufacturers.”

“For software a new UDI-DI shall be required whenever there is a modification that changes - original performance, safety or the intended use of the software or interpretation of data” Annex VI Part C 6.5.2

‘configurable device’ allows one Basic UDI-DI

‘system’ means a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose

‘system’ allows one Basic UDI-DI

Each device, if placed on the market individually, would also be assigned a UDI-DI and linked to different Basic UDI-DI(s)
<table>
<thead>
<tr>
<th>Document number</th>
<th>Title</th>
<th>Information</th>
<th>Published Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDCG 2018_1 V2</td>
<td>Guidance on basic UDI-DI and changes to UDI-DI</td>
<td>Essential reading, explains the basics</td>
<td>February 2019</td>
</tr>
<tr>
<td>MDCG 2018_2</td>
<td>Future EU medical device nomenclature – Description of requirements</td>
<td>States future nomenclature will be free of charge to users and informs about what is needed in a nomenclature</td>
<td>March 2018</td>
</tr>
<tr>
<td>MDCG 2018_3</td>
<td>Guidance on UDI for systems and procedure packs</td>
<td>Need their own UDI-DI and UDI-PI</td>
<td>October 2018</td>
</tr>
<tr>
<td>MDCG 2018_4</td>
<td>Annex on UDI data elements for systems and procedure packs</td>
<td>Definitions, descriptions and formats</td>
<td>October 2018</td>
</tr>
<tr>
<td>MDCG 2018_5</td>
<td>UDI Assignment and placement criteria to Medical Device Software</td>
<td>Change of Basic, UDI-DI or UDI-PI</td>
<td>October 2018</td>
</tr>
<tr>
<td>MDCG 2018_6</td>
<td>Clarifications of UDI related responsibilities in relation to Article 16</td>
<td>Focuses on distributor and importers responsibilities</td>
<td>October 2018</td>
</tr>
<tr>
<td>MDCG 2018_7</td>
<td>Considerations on use of language issues associated with the UDI database</td>
<td>To ensure information is written in information accessible to the public</td>
<td>October 2018</td>
</tr>
<tr>
<td>MDCG 2019_1</td>
<td>Rules on Basic UDI-DI for issuing entities</td>
<td>EU UDI to be similar to IMDRF UDI</td>
<td>January 2019</td>
</tr>
<tr>
<td>MDCG 2019_2</td>
<td>Application of UDI to Human Blood, Medicines, Human Tissues</td>
<td>May not need to meet MDR UDI requirements</td>
<td>February 2019</td>
</tr>
</tbody>
</table>
Registration of Devices

Legacy Devices

MDCG 2019-4 – Timelines for registration of device data elements in EUDAMED – April 2019

MDCG 2019-5 – Registration of legacy devices in EUDAMED – April 2019

New Devices under MDR

Summary of Safety and Clinical Performance – Article 32 + GSPR 23.4 d)

Clinical Evaluation Consultation Procedure – Article 54

Periodic Safety Update Report – Article 86

...?
Questions & Answers