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THE MDR TRANSFER PROJECT

Swedish Medtech Regulatory Summit - Stockholm Feb 20, 2020

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MDR TRANSFER PROCESS

OVERVIEW OF THE MDR TRANSFER PROCESS

QUALIFICATION AND CLASSIFICATION

Qualify your device according to MDR based on Intended Use, Claims and Mode of Action. Classify according to MDR Annex VIII.

TIME PLAN

Develop the plan of your MDR transfer process. Decision regarding critical milestones and time plan.

GAP ANALYSIS

Identify applicable requirements and perform GAP-analysis of the technical file (including GSPR, Clinical Data and QMS) to identify actions.

TRANSFER STRATEGY

Develop the Strategy for your MDR transfer eg. including priority, Notified Body, re-certification, economic operator control and internal responsibilities.

IMPLEMENTATION

Perform planned activities and update Technical File, Clinical Evaluation and QMS.

PORTFOLIO ANALYSIS

Review of the impact on the implementing acts on the devices in your device portfolio. Decide priority and discontinuance.

MOCK AUDIT

Perform Mock audit of QMS and review Technical File to confirm MDR compliance. Report result to Management Review.

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QUALIFICATION BASED ON INTENDED USE, CLAIMS AND MODE OF ACTION

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

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

— devices for the control or support of conception;

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

Ref: MDR, article 2

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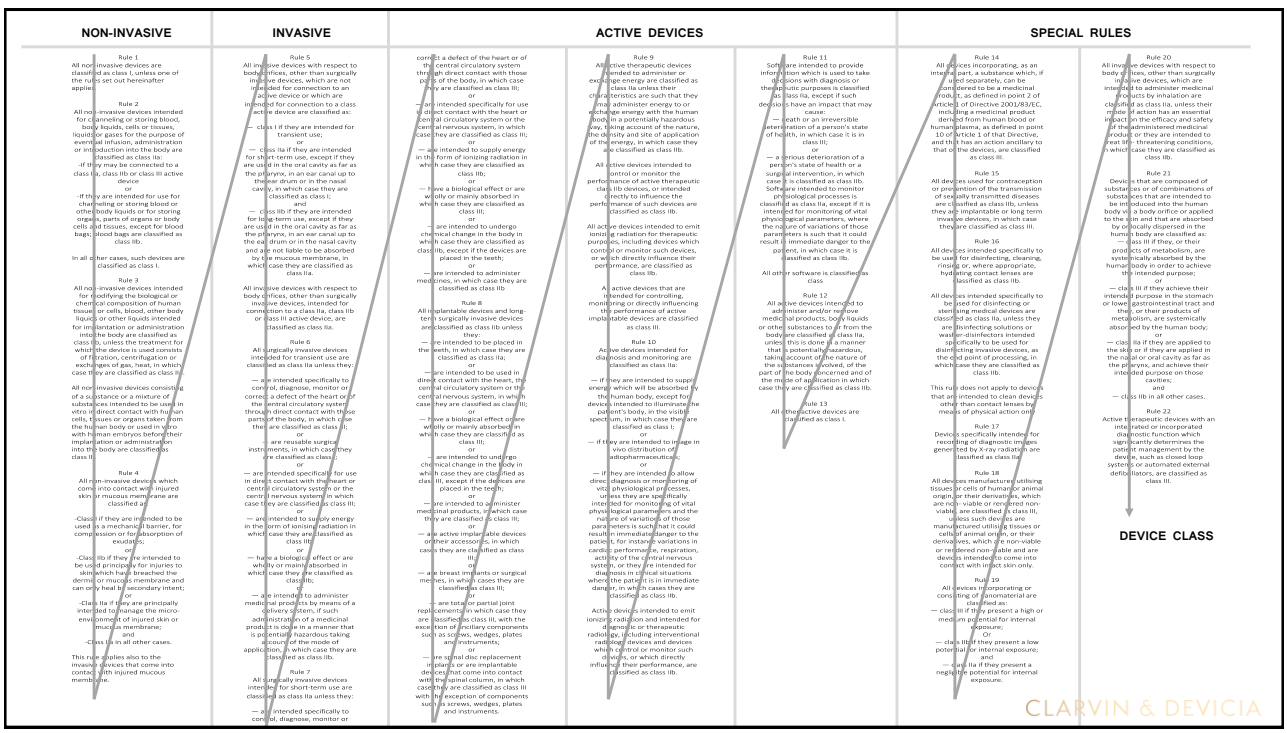

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2020-02-20

Classification of Medical Device Software

Mats Artursson
Inspector – Swedish Medical Products Agency

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

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Agenda

- What does the regulations say
- Qualification of MDSW
- Classification of MDSW
- Useful links

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What does the regulations say?

- In the medical device regulations, requirements on software are generic and independent of technology
- In MDD almost all software are CE class I
- In MDR most software will become CE class IIa or higher (IIb, III)
- MDR ”fully” applies 2020-05-26
- Prolonged transition period for MDD CE class I software until 2024-05-26

Corrigendum II

- MDR Article 120(3).

By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2020 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2020 it continues …

Corrigendum II

- MDR Article 120(3) cont.

… 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.

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Definitions

- **MDR Art 2 (1) … software … intended by the manufacturer … for human beings for …**

- **diagnosis, prevention, monitoring, prediction, prognosis, treatment of disease**
- **diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,**
- **Investigation ... of the anatomy or of a physiological or pathological process …**
- **control or support of conception**

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Definitions

MDCG 2019-11

- **Software is defined as a set of instructions that processes input data and creates output data.**
- **Medical device software (MDSW) is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the medical devices regulation or *in vitro* diagnostic medical devices regulation.**

Qualification

- MDR (19) … software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device
- … software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device
- … qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

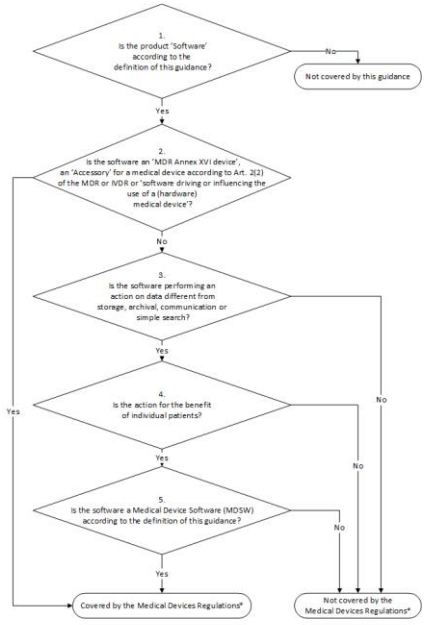

Figure 1 – Decision steps to assist qualification of MDSW

Medical Devices Regulations* refers to the two applicable regulations: Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices (IVDR)

Classification

MDR Annex VIII Rule 3.3 and 3.5

3.3. Software, which drives a device or influences the use of a device, shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right.

3.5. If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply.

Classification

MDR Annex VIII Rule 11

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.

MDCG 2019-11

- 1. Scope and purpose of this document
- 2. Definitions and abbreviations
- 3. Qualification
- 4. Classification of MDSW per MDR 2017/745
- 5. Classification and implementing rules per IVDR 2017/746
- 6. Considerations on placing on the market and conformity assessment of MDSW
- 7. Modules
- 8. Consideration of changes to an MDSW
- 9. Annex I: Illustrative examples of qualification of software used in the healthcare environment
- 10. Annex II - Qualification examples of Medical Device Software (MDSW)
- 11. Annex III - Usability of the IMDRF risk classification framework in the context of the MDR
- 12. Annex IV – Classification examples

EU guidance

Qualification and classification of software – MDCG 2019-11, Oct 2019

Guidance on cybersecurity for medical devices - MDCG 2019-16, Dec 2019

Clinical / Performance Evaluation of MDSW – MDCG 2020-XX, Mar 2020

Artificial Intelligence under MDR/IVDR framework - TBD

Useful links.

EU Guidance

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

Läkemedelsverket

https://lakemedelsverket.se/malgrupp/Foretag/Medicinteknik---ny-lagstiftning/

https://lakemedelsverket.se/overgripande/Publikationer/Nyhetsbrev/Medicinteknik/

MDR TRANSFER PROCESS

OVERVIEW OF THE MDR TRANSFER PROCESS

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GENERAL SAFETY & PERFORMANCE REQUIREMENTS

ANNEX I

- Identify new compliance requirements and develop an action plan for how to deal with them
- Devices in conformity with applicable Common Specifications and Harmonized Standards are presumed to be in conformity with the relevant requirements of the MDR
- Will current MDD harmonized standards be harmonized with the MDR?

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MDCG GUIDES ASSISTING STAKEHOLDERS IN IMPLEMENTING MDR

- Legally non-binding guidance documents provided by the European Commission, adopted by MDGC
- MDGC Overview list include the following topics:
  - Notified Bodies oversight
  - Standards
  - Clinical Investigations and Evaluations
  - Post Market Surveillance and Vigilance
  - Borderline & Classification
  - Market Surveillance
  - New Technologies
  - EUDAMED
  - UDI
  - International Matters
  - IVD
  - Nomenclature
  - Annex XVI

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GAP-ANALYSIS
GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

MDR GSPR	Appl	Fulfilled	Action	Compliance Reference	Harmonized standard, CS, other guidance
1	Y	Y		Doc ABC	
2	Y	Y		Doc ABC	
3	Y	N	Update Risk Management procedure and …		SS EN ISO 14971:2020
4	Y	Y		Doc ABC	
…					

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INCREASED REQUIREMENTS FOR CLINICAL EVIDENCE

"Ensure a high level of health and safety protection for EU citizens. Making clinical investigation & evaluation requirements more stringent is aimed at improving health and safety through transparency and traceability".

- MDR 2017/745

GAP analysis of clinical data:

- Re-certification
- Up-classification
- New products under MDR

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CLINICAL EVIDENCE REQUIREMENTS - CONSIDERATIONS

- PMCF data: Internal audits vs. ISO 14155
- Use of foreign data: Justify EU relevance
- Clinical Development plan – when robust and clear, avoid misunderstandings with the NB
- PMS and PMCF plans;
  - Carefully considering MDR guidance
  - Consult with medical specialists
  - Include biostatisticians early
- GDPR

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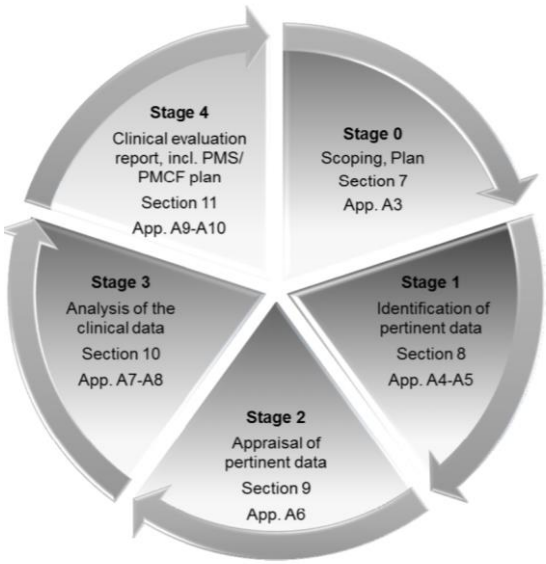
CLINICAL EVALUATION

MEDDEV 2.7/1 REV 4

Clinical evaluation means a systematic and planned process to continuously generate, collect, analyze 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.
- MDR Annex XIV, Part A



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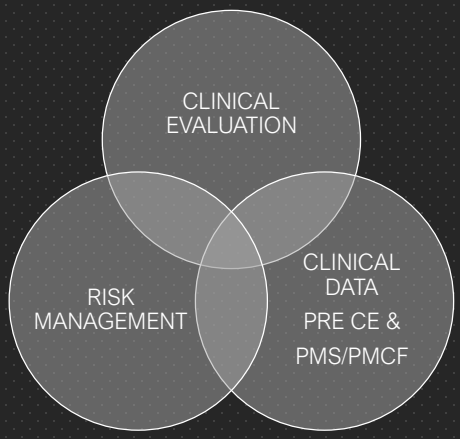
GAP ANALYSIS CLINICAL EVIDENCE



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NEW CONFORMITY ASSESSMENT PROCEDURE WILL HAVE IMPLICATION ON THE QMS

- Assessment of the conformity of the device
  - In accordance with the applicable conformity assessment procedures set out in Annexes IX to XI
- A strategy for regulatory compliance
- Person responsible for Regulatory Compliance
- Reporting EUDAMED
  - QMS shall ensure compliance with MDR in the most effective manner and in a manner that is proportionate to the risk class and the type of device
- The quality management system shall address at least the following aspects …

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GENERAL OBLIGATIONS OF THE MANUFACTURER ARTICLE 10

a)	A strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;
b)	Identification of applicable general safety and performance requirements and exploration of options to address those requirements;
c)	Responsibility of the management;
d)	Resource management, including selection and control of suppliers and sub-contractors;
e)	Risk management as set out in in Section 3 of Annex I;
f)	Clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;
g)	Product realization, including planning, design, development, production and service provision;
h)	Verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29;
i)	Setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83;
j)	Handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;
k)	Processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;
l)	Management of corrective and preventive actions and verification of their effectiveness;
m)	Processes for monitoring and measurement of output, data analysis and product improvement.

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GAP-ANALYSIS TO GET THE TO-DOS FOR THE QMS UPDATE

CHAPTER II Making available on the market and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement				
	Requirement	Fulfilled in current QMS	Reference to current SOP	Recommended QMS update
…				
Article 10				
1.	When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.	N	SOP 123 Design Control SOP 456 Manufacturing SOP 789 Control of Suppliers	Update SOP 123 with MDR New Procedure for Regulatory Compliance
2.	Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.	N	SOP 101 Risk Management	Update SOP 101 Risk Management. Use EN ISO 14971:2020
3.	Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.	N	-	Establish procedure for Clinical Evaluation.

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MDR TRANSFER PROCESS

OVERVIEW OF THE MDR TRANSFER PROCESS

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ANALYSIS TO ASSESS MDR´S IMPACT ON PORTFOLIO

- "Survival of the most adaptable"
- Resources required to update and maintain Technical Files and design Dossiers - cost of keeping product on the market
- Borderline products that will be medical devices under MDR
- Products classified in higher class under MDR
- Impact if extended definitions
- Can previously claimed equivalence still be made?
- Will additional clinical investigations be required?
- Clinical investigations conducted according to the MDR
- Notified Body Availability
- Documentation requirement - significantly increase workload – are the required resources available? Realistic? Additional funding required?

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MDR TRANSFER PROCESS

OVERVIEW OF THE MDR TRANSFER PROCESS

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TRANSFER STRATEGY

- Based on outcome of GAP-analysis and Portfolio Analysis
- Expiry date of current CE certificate – recertification?
- Corrigendum – what does it mean for your device(s)?
- Notified Body readiness
- V&V data sufficient for compliance with GSPR (and Harmonized Standards, CS and MDCG guidance)
- Additional Clinical Data required (PMCF?)
- Conformity Assessment route
- Economic operator control

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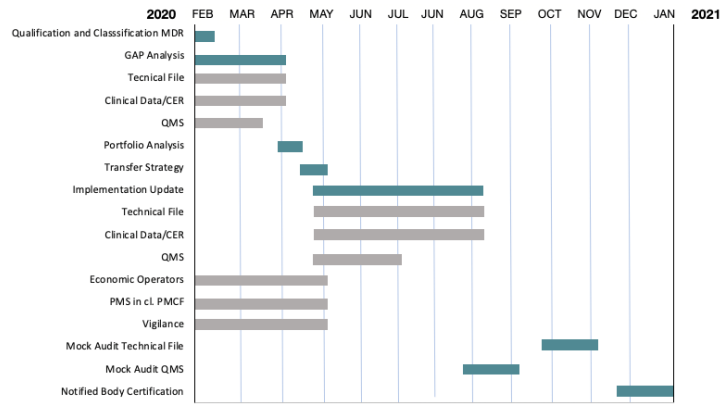
MDR TRANSFER PLAN



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MAY 2020 - REQUIRED IMPLEMENTATION

- Vigilance
- Post Market Surveillance
- Economic Operators

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MIR – Manufacturer Incident Report

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MIR – Manufacturer Incident Report

- Revised form for reporting of incidents
  - Adaption of the MIR to the Vigilance module in Eudamed to enable *e.g.* automatic upload of incident reports
- MDD/AIMDD/IVDD and MDR/IVDR
  - The new MIR is suitable for incidents with devices in conformity to the directives or the regulations
- Implementation
  - Latest version published on the website of the EU commission in December 2018 https://ec.europa.eu/docsroom/documents/37348
  - To be used from 1 January 2020
- Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8
  - Kap 4; "*The updated version of the MIR Form V 7.2 will become mandatory from January 2020"* https://ec.europa.eu/docsroom/documents/36292

MIR – Manufacturer Incident Report

- **Some of the news with the revised MIR**
  - Revised form sections
  - Final (Non-reportable incident)
  - Similar incidents
    - Expanded section and a more defined description of the assessment of similar incidents
  - Usage of IMDRF codes for:
    - The incident
    - The investigation of the incident
    - Harm/effect on the patient
  - Reduced number of data fields with free text
  - Implementation of UDI and other data fields related to Eudamed

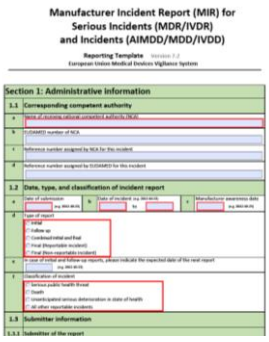
IMDRF codes

- Purpose of using codes in the MIR
  - Increased precision
  - Reduced ambiguity – enables an efficient evaluation process
  - Enables trend analysis and signal detection
  - Multilingual (or ”language neutral”)
- The codes are grouped in different annexes:
  - Medical device problem (Annex A)
  - Cause investigation:
    - Type of Investigation (Annex B),
    - Investigations Findings (Annex C),
    - Investigation Conclusion (Annex D)
  - Patient problem:
    - Clinical signs, symptoms and conditions (Annex E)
    - Health impact (Annex F)
  - Component (Annex G)
- Guidance document: IMDRF/AE WG/N43FINAL:2017
  http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-aer-n43-r3.pdf

Mandatory!

MIR – Manufacturer Incident Report

- Until EUDAMED is up and running the completed MIR:s shall be submitted to the CA in the member state where the incident took place. When EUDAMED is completed and in production mode, incidents shall be reported there.


Manufacturer Incident Report (MIR) for
Serious Incidents (MDR/IVDR)
and Incidents (AIMDD/MDD/IVDD)

Reporting Template

Section 1: Administrative information

1.1 Corresponding competent authority

1.2 Date, type, and classification of incident report

1.3 Submitter information

ECONOMIC OPERATORS

EU Authorized Representative | Importer | Distributor(s)

Identify

New Agreement

Procedures to handle obligations

Audit

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OVER 30 LEGALLY BINDING PMS REQUIREMENTS

All activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

MDR Article 2 (60)

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DETERMINE PMS METHODOLOGY

- Identify PMS data needed to get required PMS output
- Identify PMS Sources to get data
- Identify methods for data collection and analysis technique
- Active & Reactive PMS data collection

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PMS vs. PMCF

Same lifecycle phase, but different focus

PMS	PMCF
• All activities carried out by the manufacturer in cooperation with other economic operators to …	• Part of PMS and shall be addressed in the PMS Plan
• Institute and keep up to date a systematic procedure to …	• A continuous process to update the Clinical Evaluation
• Proactively collect and review experience gained from the device they place on the market, make available on the market or put into service …	• "Proactively collect and evaluate clinical data from the use in or on humans of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in its relevant conformity assessment procedure."
• For the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.	

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PMCF INVESTIGATION

"A **systematic approach** to obtain additional information on **performance** and **safety** of already CE certified medical devices when used in **clinical practice**"

- MDR; Article XIV, part B

Intended to

- Confirm safety and clinical performance
- Ensure continued acceptability of identified risks
- Detect emerging risks based on factual evidence

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PMCF INVESTIGATION

- CE marking was based on equivalence
- Address questions on long-term safety/performance or risks identified for similar devices
- PMS surveillance have raised concerns
- Risk classification of device has increased
- Requested by NB/CA
- …

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MDR TRANSFER PROCESS

OVERVIEW OF THE MDR TRANSFER PROCESS

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TECHNICAL FILE

1. Device Description
2. Information to be supplied
3. Design and Manufacturing information
4. General Safety and Performance Requirements
5. Benefit Risk Analysis and Risk Management
6. Product Verification and Validation

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SUSTAINABLE CER STRATEGY

- Suitable CER process in the QMS
- System based on your product portfolio
- Updates
  - Calendar and Event based
  - Identify key stakeholders, and allocate sufficient resources

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SUSTAINABLE CER STRATEGY

- Suitable CER process in the QMS
- System based on your product portfolio
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  - Identify key stakeholders, and allocate sufficient resources

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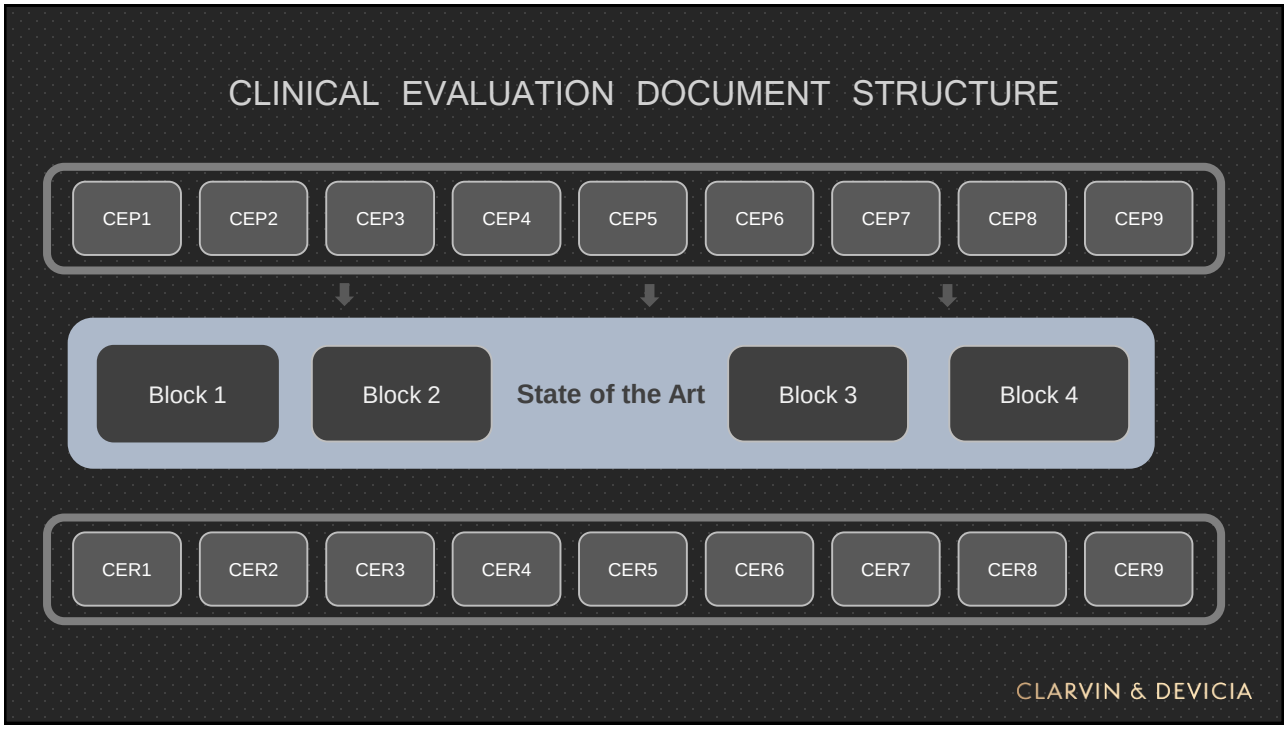
CLINICAL EVALUATION DOCUMENT STRUCTURE
CEP1
CEP2
CEP3
CEP4
CEP5
CEP6
CEP7
CEP8
CEP9
Block 1
Block 2
State of the Art
Block 3
Block 4
CER1
CER2
CER3
CER4
CER5
CER6
CER7
CER8
CER9
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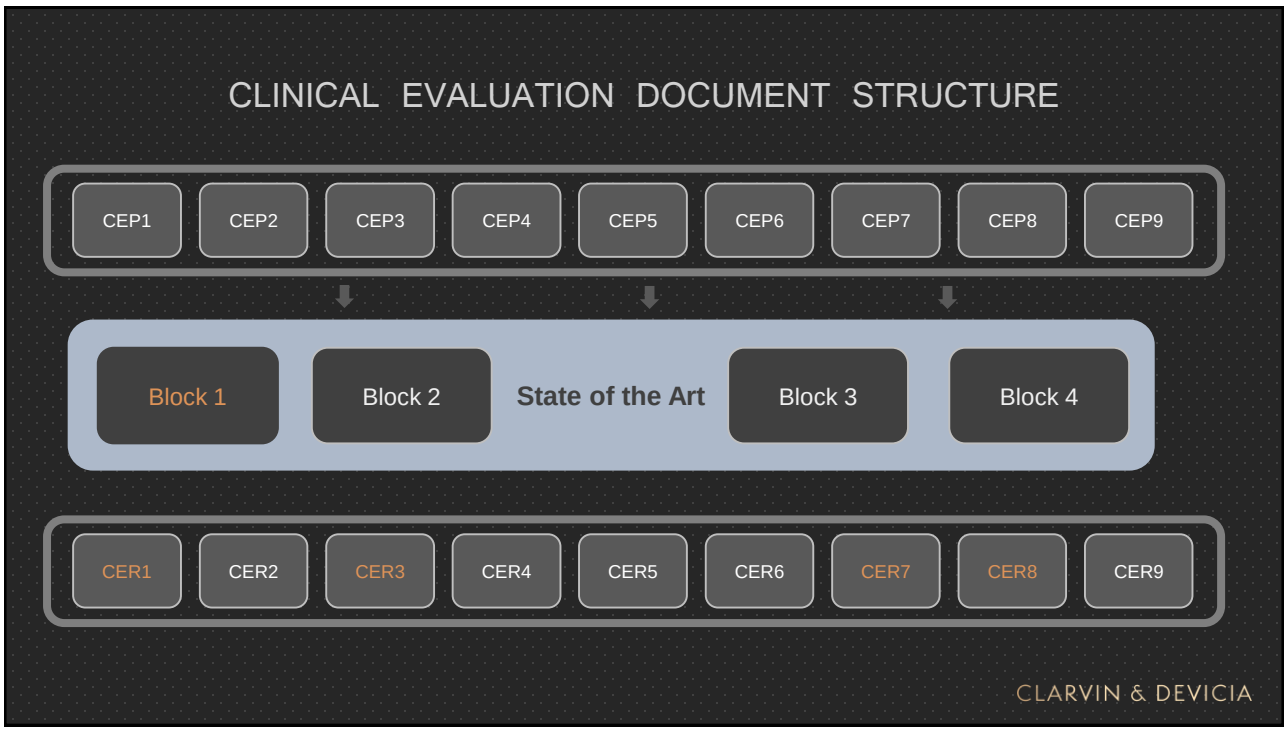
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Block 3
Block 4
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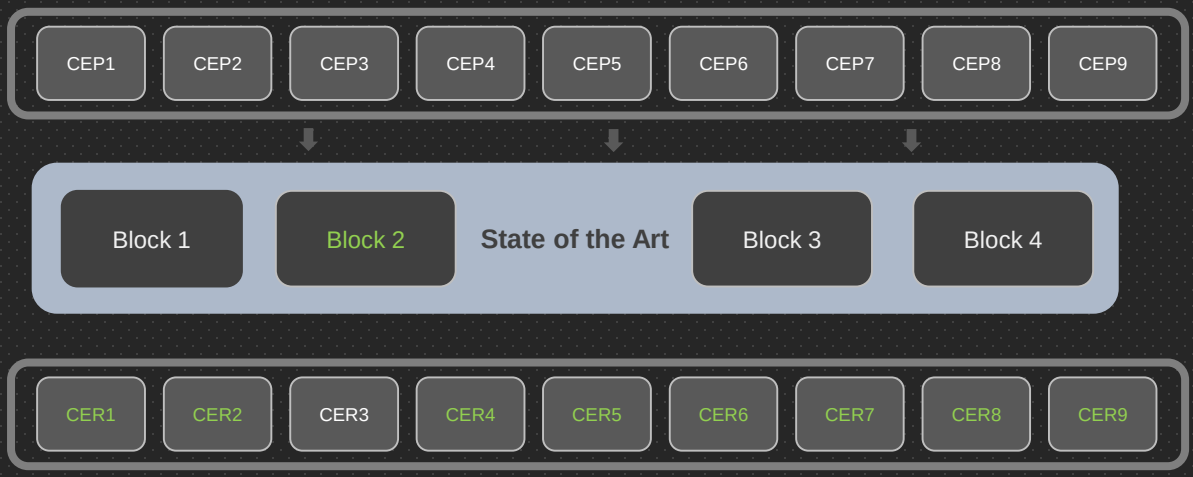
CLINICAL EVALUATION DOCUMENT STRUCTURE



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SUSTAINABLE CER STRATEGY

- Suitable CER process in the QMS
- System based on your product portfolio
- Updates
  - Calendar and Event based
  - Identify key stakeholders and allocate sufficient resources

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- 2020-02-20

Software Clinical Evaluation

Mats Artursson
Inspector – Swedish Medical Products Agency

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SWEDISH MEDICAL PRODUCTS AGENCY

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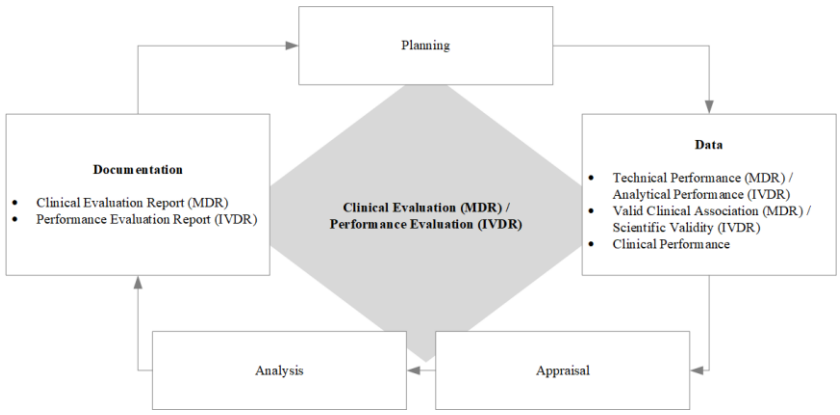
EU guidance

- **Clinical / Performance Evaluation of MDSW – MDCG 2020-XX, Mar 2020**



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MDCG 2020-xx

- 1. Purpose
- 2. Scope
- 3. Background
- 4. General principles of the MDSW CLINICAL EVALUATION (MDR) / PERFORMANCE EVALUATION (IVDR) process
- 4.1. Introduction
- 4.2. Determination of the valid clinical association / scientific validity
- 4.3. Technical/Analytical Performance
- 4.4. Clinical Performance
- 4.4.1. Clinical investigations and clinical performance studies
- 4.4.2. Where demonstration of conformity based on clinical data is not deemed appropriate
- 4.5. Final analysis and conclusion of the clinical evaluation (MDR) / performance evaluation (IVDR)
- 4.6. Continuous update of the clinical evaluation (MDR) / performance evaluation (IVDR)
- Annex I – Methodological principle for generation of CLINICAL EVIDENCE
- Annex II – Examples of CLINICAL EVALUATION (MDR) / PERFORMANCE EVALUATION (IVDR) strategies

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MDCG 2020-xx

- Annex II – Examples
- a) MDSW intended to analyse sleep quality data
- b) MDSW intended for image segmentation
- c) MDSW intended to detect inflammatory bowel diseases (IBD)
- d) Active devices containing MDSW to enable their intended purpose
- e) MDSW which provides an additional user-interface to control an insulin pump
- f) MDSW intended to analyse exhaled CO2 in a life-sustaining device in order to control ventilator settings

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MDR READINESS CHECK

- The technical file is updated according to the MDR requirements.
- Clinical Evaluation updated and is in accordance with MDR (and available applicable MDGG guide or MEDDEV 2.7.1 Rev 4).
- Risk management is according to EN ISO 14971 and your Risk Management activities (plan, analysis and report) are aligned with your PMS and PMCF activities.
- Labelling of the device is updated to be in compliance with MDR.
- Your Medical Device have an UDI-DI and UDI-PI (submitted and transferred to the UDI database).
- Post Market Surveillance system is implemented, and you have established a PMS Plan. Procedure specifies establishment of PMS report or Periodic Safety Update Report.
- Post Market Clinical Follow-up is planned and collected data will support the device´s clinical benefit.
- QMS updated with MDR requirements and a procedure/strategy for Regulatory Compliance with MDR is established and implemented.
- Person Responsible for Regulatory Compliance appointed.
- Control of Economic Operator´s implemented.
- Agreements with key suppliers updated with MDR.
- Procedures in place to continuously monitor publication of Common Specifications, Harmonized Standards, and MDCG guidance.
- Mock audit of QMS and Technical File performed. Correction and Corrective actions implemented for all NCs. Result reported during Management Review.
- EUDAMED registration (when available).

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MDR TRANSFER PROCESS

OVERVIEW OF THE MDR TRANSFER PROCESS

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MDR TRANSFER PROCESS

OVERVIEW OF THE MDR TRANSFER PROCESS

QUALIFICATION AND CLASSIFICATION

Qualify your device according to MDR based on Intended Use, Claims and Mode of Action. Classify according to MDR Annex VIII.

TIME PLAN

Develop the plan of your MDR transfer process. Decision regarding critical milestones and time plan.

GAP ANALYSIS

Identify applicable requirements and perform GAP-analysis of the technical file (including GSPR, Clinical Data and QMS) to identify actions.

TRANSFER STRATEGY

Develop the Strategy for your MDR transfer eg. including priority, Notified Body, re-certification, economic operator control and internal responsibilities.

IMPLEMENTATION

Perform planned activities and update Technical File, Clinical Evaluation and QMS.

PORTFOLIO ANALYSIS

Review of the impact on the implementing acts on the devices in your device portfolio. Decide priority and discontinuance.

MOCK AUDIT

Perform Mock audit of QMS and review Technical File to confirm MDR compliance. Report result to Management Review.

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Call to action & Thank you!

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