Regulatory Summit 2019

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Guidance for Medical Device Software

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Agenda

- Guidance on Classification for Software in MDR and IVDR
- Guidance on Clinical Evaluation of Medical Device Software
- Reglering av Nationella medicinska informationssystem

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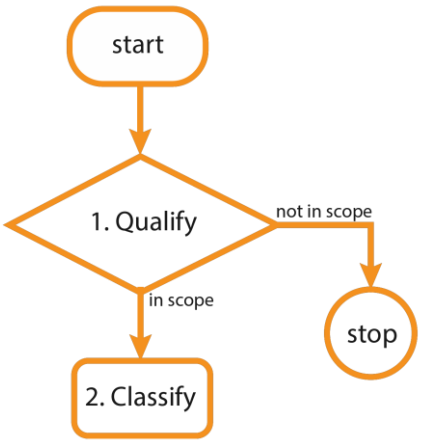
Software classification Taskforce - Overview

- Aim of Taskforce is to provide guidance relating to definitions and classification rules of MDR and IVDR relevant to software
- Taskforce team consists of:
  - Member states (BE, DE, FR, IE, PT)
  - Industry (COCIR, Medtech Europe, AESGP, ESIP, NBs)
- Work to date progressed through teleconferences and face to face meetings with start July 2017.
- Goal to complete work by June 2019.

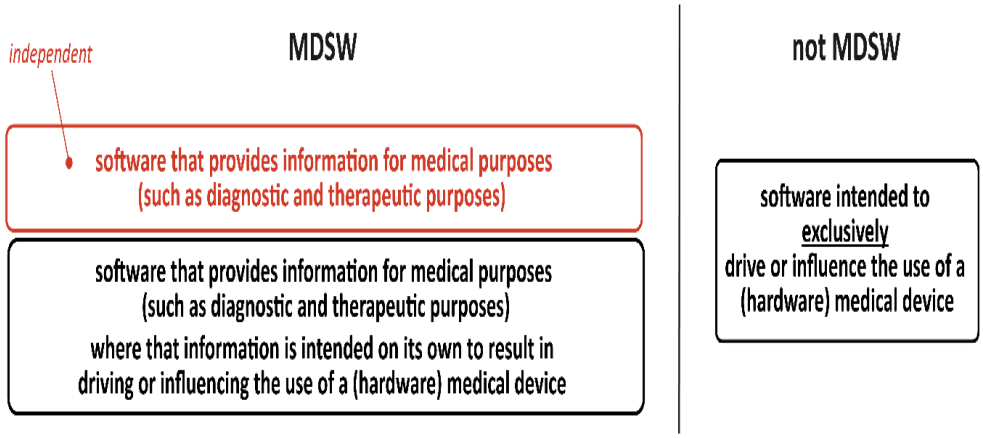
Classify what falls in scope



In scope

a) Medical device, in vitro diagnostic medical device and Annex XVI product
b) Accessory of a MD or IVDD
c) CE-marked part or component of a MD/IVDD or Annex XVI product (MDR art. 23/IVDR art. 20)

Medical Device Software



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Rule 11 §1 uses severity of impact, without consideration of probability

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 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 variation 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 are classified as class I.

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Rule 11 §1 mapped on IMDRF SaMD scheme

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.

Disease Type / Patient Condition	Intervention Type		Significance of Information: Treat or Diagnose	Significance of Information: Drive Clinical Management	Significance of Information: Inform Clinical Management
			• Treat • Provide therapy to a human body using other means • Diagnose • Detect • Screen • Prevent • Mitigate • Lead to an immediate or near term action	• Aid in treatment • Provide enhanced support for safe and effective use of medicinal products • Help predict risk of a disease or condition • Aid in diagnosis • Aid to make a definitive diagnosis • Triage early signs of a disease or condition	• Inform of options for - treatment - diagnosis - prevention • Aggregate relevant clinical information • Will not trigger an immediate or near term action
• Life-threatening	• Requires major therapeutic interventions • Sometimes time critical • Vital to: avoid death; serious deterioration of health; mitigating public health situations or conditions	Critical	Type IV.i **III**	Type III.i **IIb**	Type II.i **IIa**
• Moderate in progression • Often curable	• Does not require major therapeutic interventions • Not expected to be time critical • Vital to avoiding unnecessary interventions	Serious	Type III.ii **IIb**	Type II.ii **IIa**	Type I.ii **IIa**
• Slow with predictable progression of disease state • Minor chronic illnesses or states • May not be curable • Individuals who may not always be patients • Can be managed effectively		Non-Serious	Type II.iii **IIa**	Type I.iii **IIa**	Type I.i **IIa**

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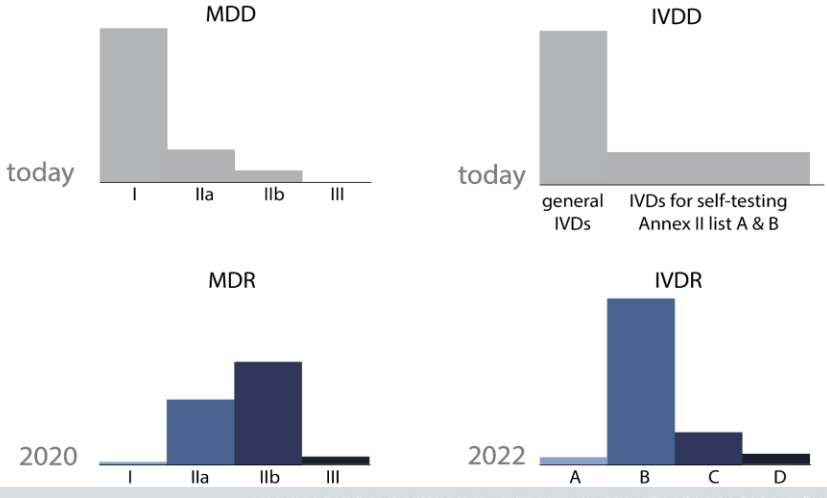
Class distribution



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Classification conclusions

- A dedicated classification rule for software was needed
- Regulators wanted more scrutiny for software
  (cf. insulin dose calculator study, unwanted pregnancies contraception apps)
- No more class I medical device software under MDR
- All medical device software manufacturers require a notified body
- Rule 11 text is still discussed for further clarification
- Guidance to support implementation and avoid legal uncertainty and uneven playing
- Guidance still has some loose ends, might even still be simplified a bit
- IMDRF SaMD risk framework needs fine tuning

MDSW Clinical Evaluation Taskforce - Overview

- Aim of Taskforce is to provide guidance relating to the level of clinical evidence required for MDSW to fulfill the requirements in MDR and IVDR. The guidance also describes methodologies by which clinical evidence may be provided.
- Taskforce team consists of:
  - Member states (SE, BE, FI, UK)
  - Industry (COCIR, Medtech Europe, NBs)
- Work to date progressed through teleconferences and Face to face meetings with start March 2018.
- Goal to complete work by Sept 2019.

MDSW Regulatory landscape

- MEDICAL DEVICE SOFTWARE (MDSW) is all software that is intended to be used, alone or in combination, for one or more medical purpose as specified in the definition of a 'Medical Device' in Article 2 (1) of the MDR or Article 2(2) of the IVDR, regardless of whether the software is independent or is driving or influencing the use of a device.
- In order to promote global convergence, this guidance will take into account concepts outlined in International Medical Device Regulators Forum (IMDRF) guidance documents (such as N41).

Requirements for clinical evidence

- For MDSW, the specification and justification of the level of clinical evidence should consider where applicable:
  - intended purpose
  - indications for use and contraindications
  - risk categorization
  - claimed clinical benefits
  - data input and output
  - the applied algorithms
  - the analytical and clinical performance
  - associated clinical risks
  - grade of innovation of the technology
  - device history on the market
  - type of interconnection

Principles for evaluating MDSW

- The same principles of clinical evidence apply to all MDSW.
- Independent MDSW (claims a clinical benefit by fulfilling its own medical intended purpose) requires clinical evidence within its own conformity assessment.
- MDSW that is an integral component/part of a device or is driving or influencing the use of a device requires clinical evidence provided in the context of the devices that it is a component/part of, or driving or influencing.

Principles for evaluating MDSW

- Software and its level of connectivity encourages more frequent capture of real-world performance data:
  - to understand user interactions
  - to conduct ongoing monitoring of clinical performance
  - to allow for promt detection of issues
  - to improve effectiveness
  - or to inform future claims

Overview of the stages of clinical evaluation

Stage 1 - Valid Clinical Association	•Appraisal and analysis of scientific validity information
Stage 2 - Analytical Validation	•Generation and appraisal of analytical / technical performance data
Stage 3 - Clinical Validation	•Generation, appraisal and analysis of clinical usability/user interface test data •Identification, generation and appraisal of clinical performance data
Stage 4 - Compilation of Clinical Evidence	•Preparation of the report
Stage 5 - Continuous Clinical / Performance Evalution	•Product monitoring through Real World Evidence / Performance •Expansion of claimed clinical benefits

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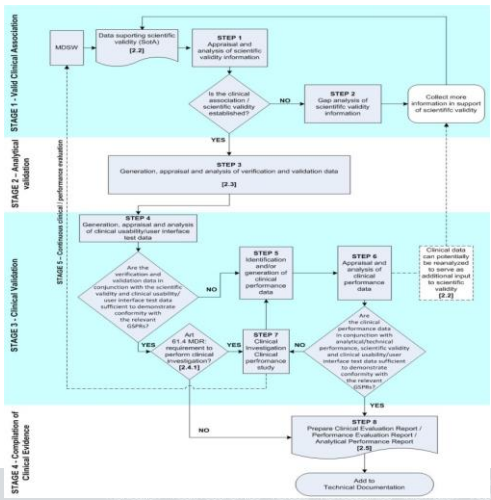
Methods for generation of clinical evidence



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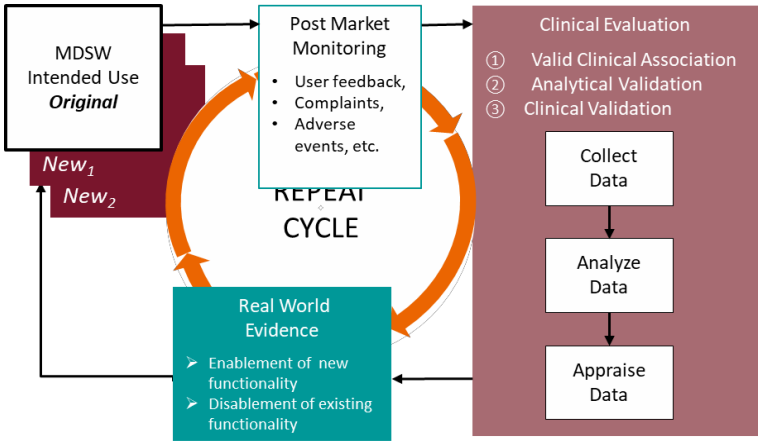
Continuos development



MDSW References

- MDR 2017/745
- IVDR 2017/746
- IMDRF N12 2014 – SaMD Framework for risk categorization
- IMDRF N41 2017 – SaMD Clinical Evaluation
- MEDDEV 2.1/6 - Qualification and Classification of stand alone software
- MEDDEV 2.7/1 rev. 4 – Clinical Evaluation
- MDCG 2019-XX – Guidance on classification for SW in MDR and IVDR
- MDCG 2019-XXX – Guidance on Clinical Evaluation of Medical Device Software

Nationella medicinska informationssystem (NMI)

- LV önskar ha kvar reglering av NMI
- Hur länge gäller LVFS 2014:7?
- Arbete med att se över nuvarande föreskrifter pågår.
- Övergångsregler för NMI finns ej på samma sätt som för MDD/MDR reglerade produkter
- Behöver regleras nationellt.
- Föreskrift och vägledning behöver revideras och harmoniseras med MDR.
  - Bemyndigande i lagstiftning är under beredning hos Regeringskansliet

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Thank you!

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