MedTech Europe
from diagnosis to cure

Medical Device Software (MDSW): qualification & classification

Regulatory approval under MDR

Swiss MedTech MDR ONLINE CONFERENCE ON «SAMD»

25 March 2021

Jana Moravcova, Manager

MedTech Europe: Industrial Policies

Agenda:

1. MDCG Guidance 2019-11 on MDSW qualification & classification

2.1. Qualification

2.2. Classification

2.3. Placing on the market

2. MedTech Europe's involvement

3. Resources

About MedTech Europe

The European trade association for the medical technology industry including diagnostics, medical devices and digital health.

MedTech Europe
from diagnosis to cure

OUR MEMBERS

130+ multinational corporations*

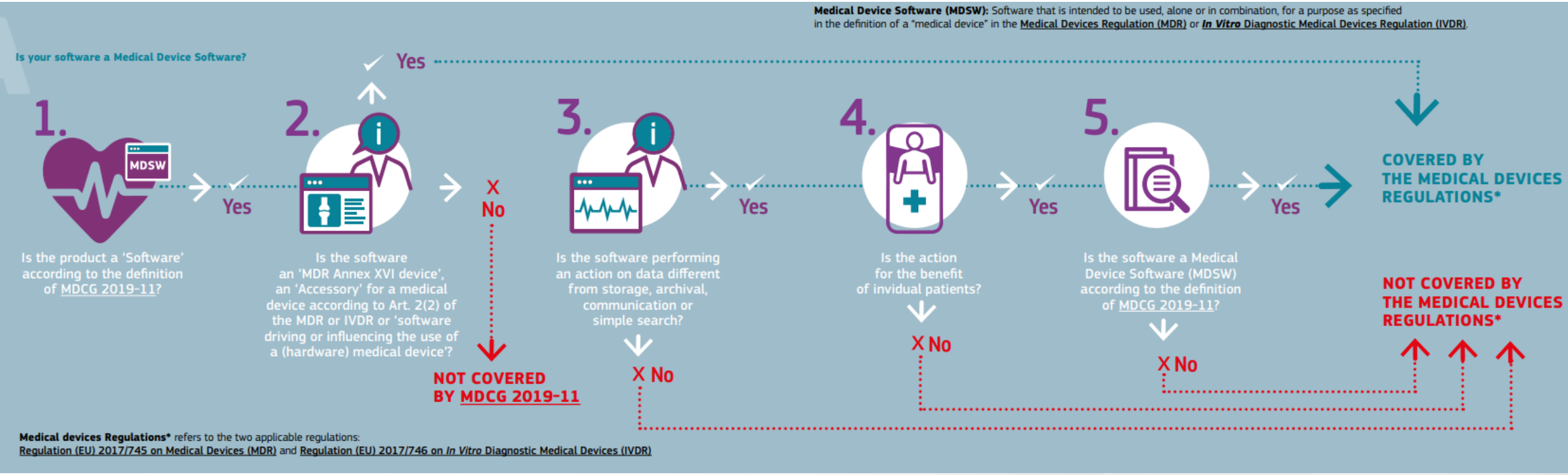
50+ medical technology associations

*medical devices, diagnostics and digital health

Software Qualification

Medical device software 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 MDR or IVDR, regardless of whether the software is independent or driving or influencing the use of a device. MDSW as per MDCG 2019-11

To qualify as MDSW the software must have a medical intended purpose & all MDSW must be supported by Clinical Evidence (lifecycle).



Link to visual on European Commission website
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2021_mdsw_en.pdf

MedTech Europe
from diagnosis to cure

MDR application

1) Independent software with a medical purpose of its own MDSW

2) Software drives/influences a hardware MD and **has a medical purpose**

or is intended as an **accessory/component/Annex 16 product** by the manufacturer MDSW

MDR does not apply to:

- *Software without a medical intended purpose*
- *Software not intended by the manufacturer to be an accessory/part or component/Annex 16 product*
- *Software that is capable of driving/influencing a medical device but it is not intended to*

Systems & Modules

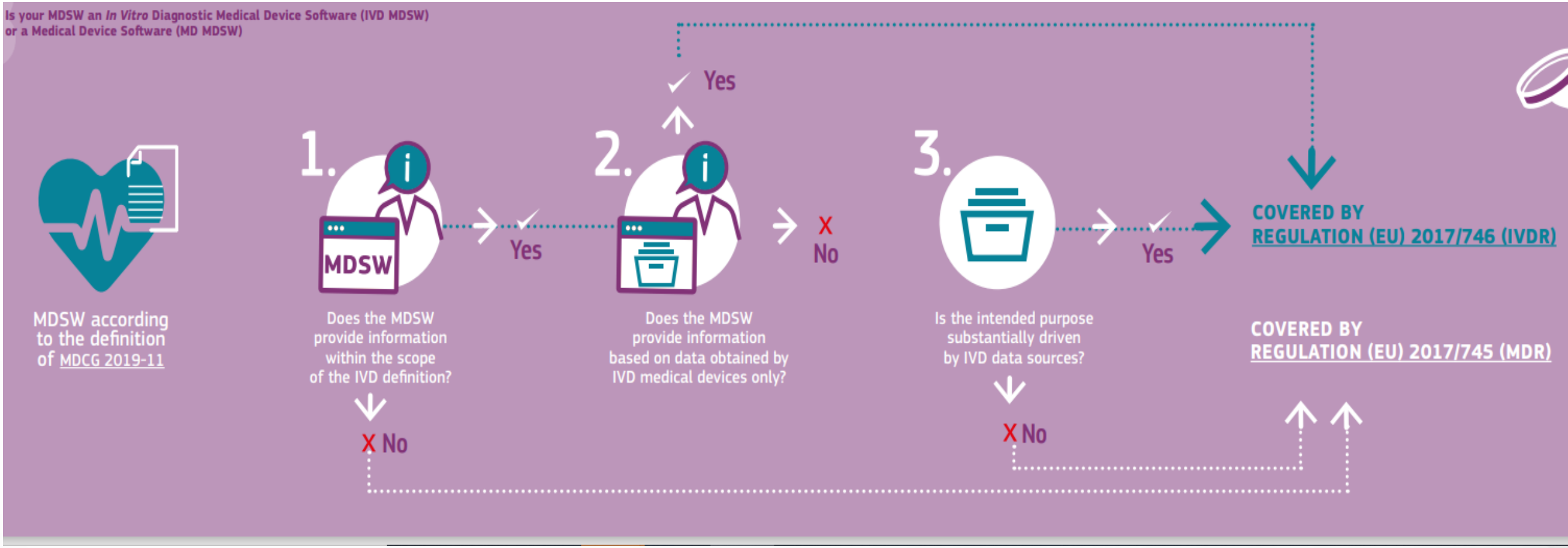
Hospital information systems, healthcare communications systems patient record systems (store, transfer, archive..)-> not MDSW

- Patient medication module
- An image viewer allowing for diagnosis

Decision support software: Radiotherapy treatment planning – system will combine general medical information & patient specific data

Modules with/without medical purpose – only modules with medical purpose to follow MDR Manufacturer to identify these based on intended purpose**.**

Qualification as MD MDSW or IVD MDSW



Link to visual on European Commission website
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2021_mdsw_en.pdf

Case studies

1) A software generating a risk score to reduce ICU transfers, readmissions etc. will include blood pressure, heart rate, respiratory rate but may also include IVD derived results.

- Conclusion: qualifies as MD MDSW since the MD derived data is decisive: intended purpose driven mainly by MD data sources.

2) A software algorithm for predisposition to Down Syndrome during pregnancy. Data obtained from ultrasound & data from IVD assays.

- Conclusion: qualifies as IVD MDSW since the IVD derived data is decisive

Classification

- Consider: Intended purpose, intended population (conditions to treat/diagnose), context of use (e.g. intensive care, home..) & possible decisions to be taken
- Consider all the rules
- Some may be applicable directly/indirectly: 9, 10, 12, 13, 15 or 22..

Complex classification cases may be referred to the MDCG Borderline and Classification: 'Manual' update

Implementing rules

MDR Annex VIII

Rule 3.3. - software:

- Independent MDSW -> its own classification
- MDSW driving or influencing (component, accessory..) the use of a MD-> same class as the device. If MDSW also has its own intended purpose -> its own classification possible

Rule 3.5.

- in case of multiple rules or sub-rules applicable the strictest one takes precedence

Classification: Rule 11

Rule 11 a	MDSW providing information on which basis diagnostic or therapeutic decisions are made	Class IIa	Generally applicable to all MDSW
	EXCEPTIONS: Incorrect information provided by MDSW may lead to: a) death/irreversible deterioration b) Serious deterioration/surgical intervention	a) Class III a) Class IIb	
Rule 11 b	Only monitoring; all physiological processes (not jut VITAL)	software with the same intended purpose as hardware of rule 10; 3rd indent, to be in the same risk class	
Rule 11 c	All other MDSW	Class I	

Placing on the market

1. **Medical Device in its own right**
    - Appropriate conformity assessment for MDSW; independent
2. **Part of a device configuration**
    - Conformity assessment as part of the hardware device
    - Driving/influencing MDSW most likely placed together with the (hardware) device
    - Could also be independent software

Changes to function, design, intended purpose (significant change)

➡ may have an impact on qualification & classification

➡ manufacturer responsibility to evaluate impact on qualification & classification

MedTech Europe's involvement

Regulatory:

1) Regulatory joint working group MD & IVD, mirroring work at the MDCG level

2) Representation at European Commission working groups:

    - MDCG NET (New & Emerging Technologies)
    - MDCG Borderline & Classification (Classification guidance expected in 2021; Borderline guidance expected by MDR Date of Application).

Non regulatory work:

Digital Health Committee (AI, cybersecurity..)

Resources

- https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_11_guidance_qualification_classification_software_en.pdf
- MDCG 2020-1 Guidance on Clinical Evaluation/Performance Evaluation: framework for the level of clinical evidence needed for MDSW
- md_mdcg_2021_mdsw_en.pdf (europa.eu)
- md_cybersecurity_en.pdf (europa.eu)

Thank you!

Jana Moravcova

j.moravcova@medtecheurope.org

www.medtecheurope.org

MedTech Europe
from diagnosis to cure