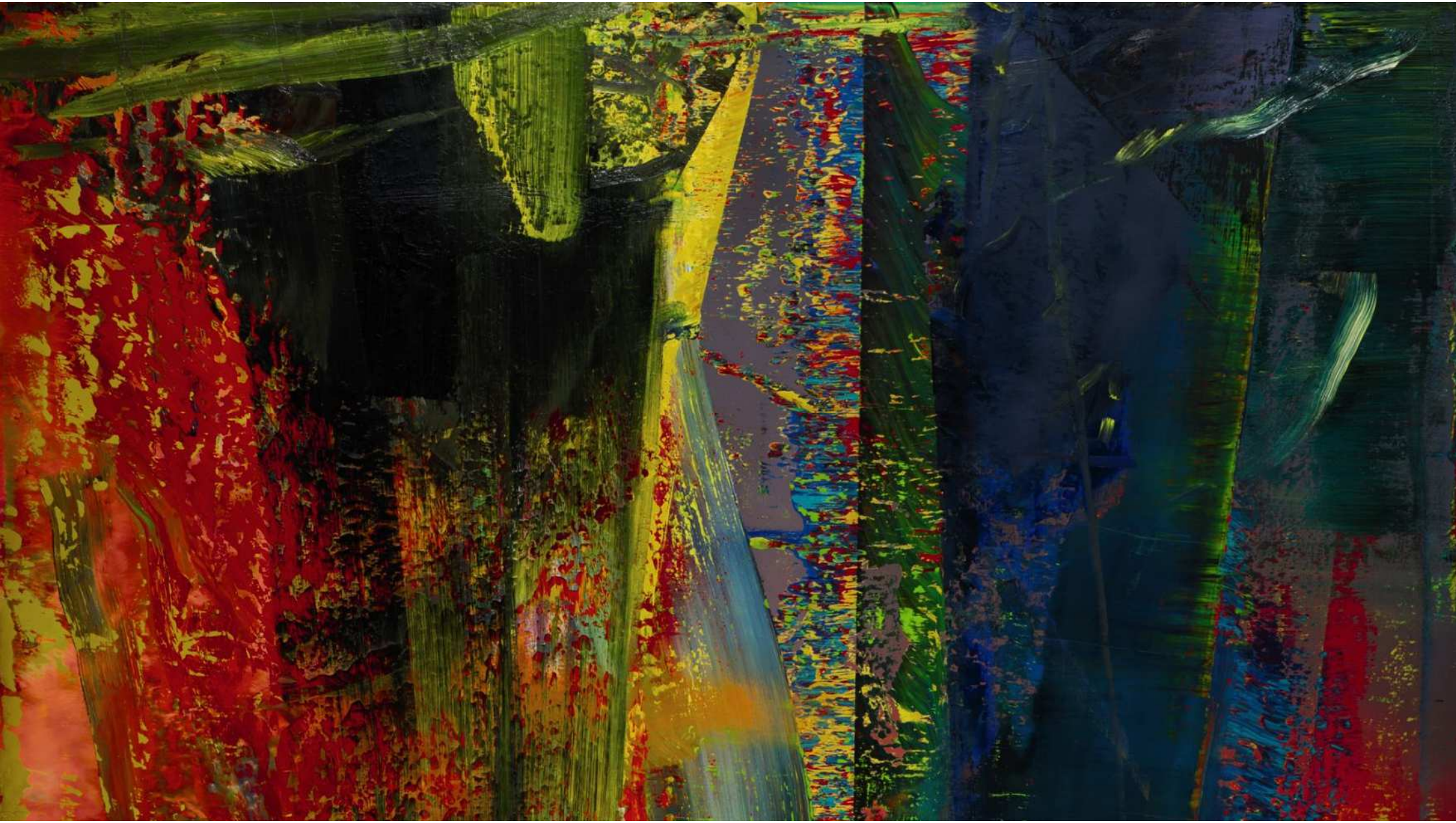
COCIR

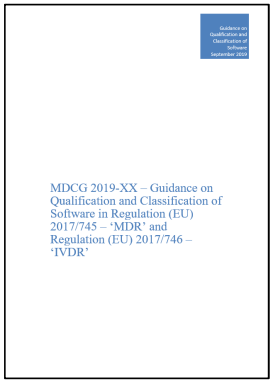
Sustainable Competence
in Advancing Healthcare

Classification of Medical Device Software

Koen Cobbaert

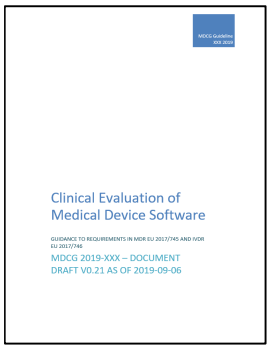
2019-11-29





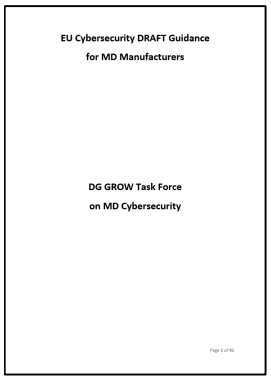
MDSW Guideline – Guidance on the Qualification and Classification of Software in MDR 2017/745 and IVDR 2017/746

Adopted Oct 2019



Clinical Evaluation of Medical Device Software

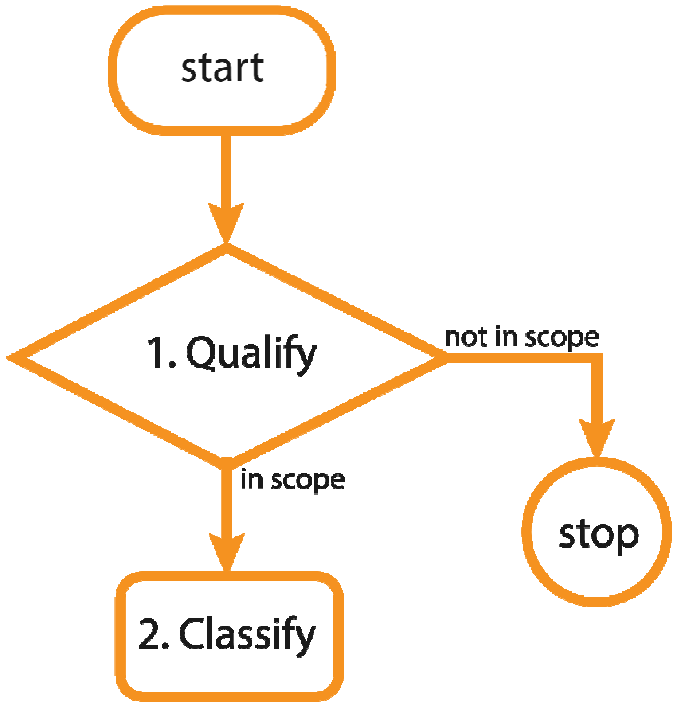
Adoption expected Dec 2019



Cybersecurity Guidance for Medical Device Manufacturers

Adoption expected Dec 2019

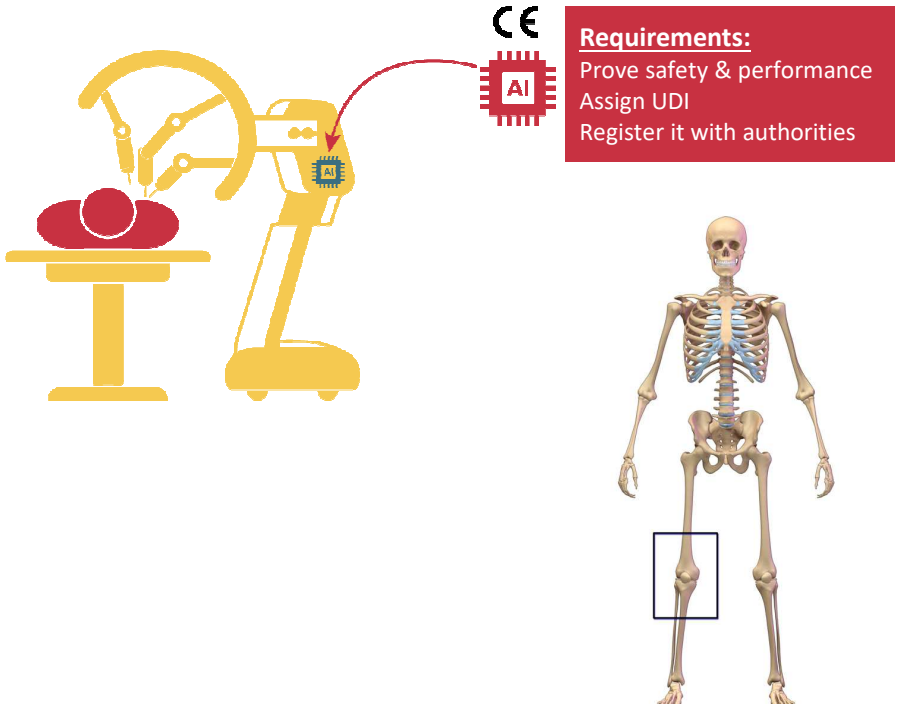
CLASSIFY WHAT FALLS IN SCOPE



In scope

a) Medical device, in vitro diagnostic medical device and Annex XVI device
b) Accessory of a MD or IVDD
c) CE-marked part or component of a MD/IVD or of an Annex XVI device

SOFTWARE UPGRADE EXTENDING THE ORIGINAL INTENDED PURPOSE



Manufacturer A places a surgical **robot** on the market.

Manufacturer B places a **software** upgrade on the market intended to execute a new surgical script so that the **robot can now also be used for total knee arthroplasty** (new specific medical purpose).

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software ≠ MD: the software in itself it does not fulfill a specific medical purpose (it solely drives the robot; by itself it does not create information for medical purposes)

software ≠ accessory: the software is not an accessory because it is not necessary for the robot to fulfill its (original) specific medical purpose.

software = CE-marked part or component: the software is intended to significantly change the intended purpose, safety and performance characteristics of the robot, i.e. the software requires a CE-mark.

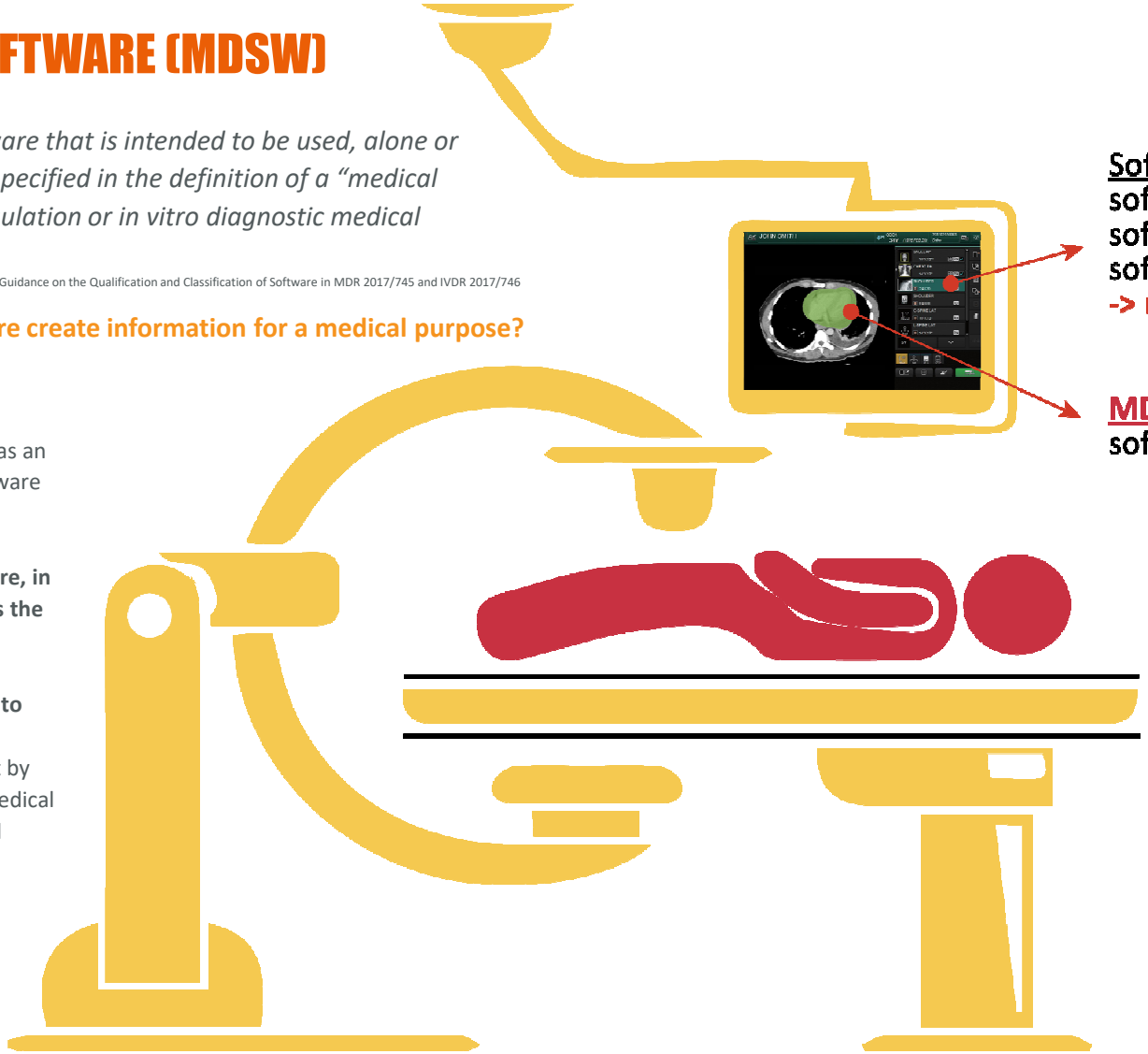
MEDICAL DEVICE SOFTWARE (MDSW)

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 medical devices regulation or in vitro diagnostic medical devices regulation*

Source: MDSW Guideline – Guidance on the Qualification and Classification of Software in MDR 2017/745 and IVDR 2017/746

In other words: does the software create information for a medical purpose?

- **regardless of its location**
  e.g. operating in the cloud, on a computer, on a mobile phone, or as an additional functionality on a hardware medical device
- **regardless of whether the software, in addition, also drives or influences the use of a (hardware) device.**
- **If the software is solely intended to drive or influence the use o**f a hardware medical device, without by itself creating information for a medical purpose, **then it is not considered MDSW,** but still covered by the regulation



MDR ANNEX VIII: 22 CLASSIFICATION RULES

Non-invasive

Rule 1	default to class I
Rule 2	storage, content enters body
Rule 3	processing, content enters body
Rule 4	contact with injured skin or mucous membrane

Invasive

Rule 5	via body orifices
Rule 6	via surgery transient
Rule 7	via surgery short term
Rule 8	via surgery long term

Active

Rule 9	therapy or related to implantable
Rule 10	diagnosis or monitoring
Rule 11	software
Rule 12	add or remove substances to or from body
Rule 13	all other defaults to class I

Special Rules

Rule 14	contains medicinal product that has ancillary action
Rule 15	contraception or prevention of transmission of sexually transmitted diseases
Rule 16	disinfecting, cleaning, rinsing or hydrating contract lenses
Rule 17	record diagnostic x-ray images
Rule 18	contacts intact skin and contains human or animal cells
Rule 19	contains nanomaterial
Rule 20	inhalers
Rule 21	via body orifice or skin contact disperse substances or get them absorbed
Rule 22	therapeutic with closed-loop diagnostic function

applicable to
software-only devices

AN ACCESSORY THAT DRIVES OR INFLUENCES THE USE

Implementing Rule 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.

an accessory . . . . . that drives or influences

Implementing Rule 3.2
[…] Accessories for a medical device shall be classified in their own right separately from the device with which they are used.

contradictory Instruction

Implementing Rule 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.

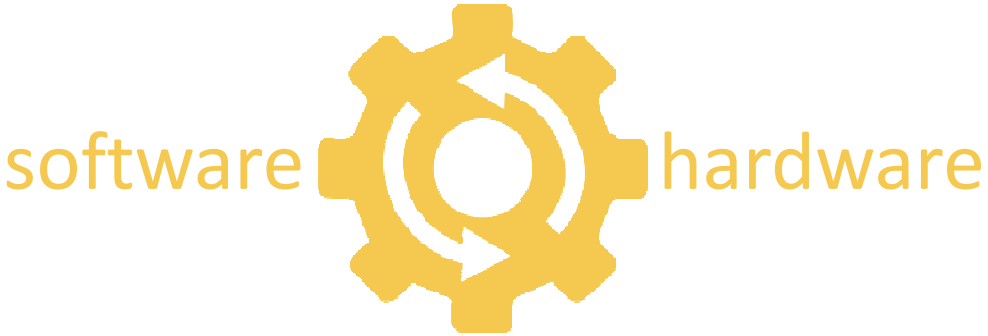
Interpret as "at least in the same class" (because of Impl. Rule 3.5)

Accessory for a medical device
An article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) **to specifically enable** the medical device(s) to be used in accordance with its/their intended purpose(s) or **to specifically and directly assist** the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

Software accessories may be driving or influencing the use of a (hardware) medical device.

Corresponding implementing rules in IVDR: 3.2 = 1.2 + 1.3; 3.3=1.4)

SOFTWARE THAT DRIVES OR INFLUENCES THE USE



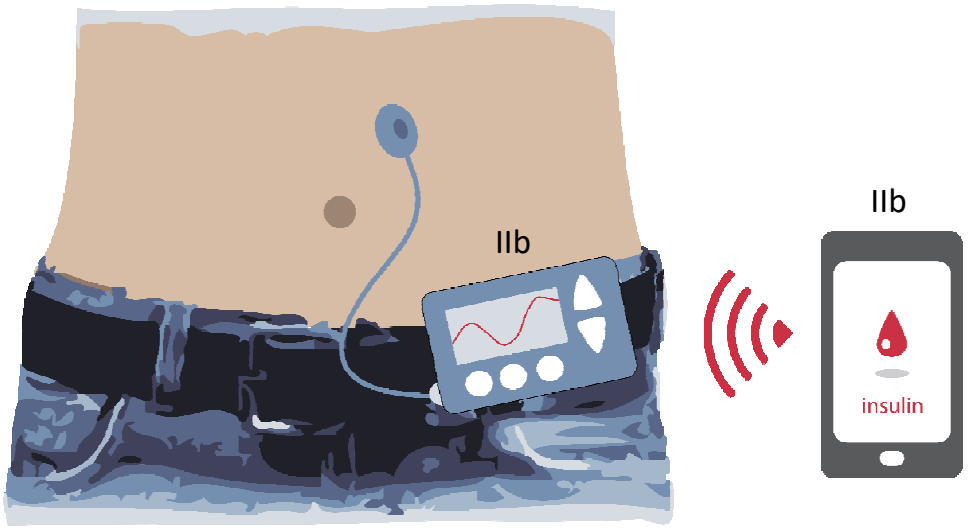
Definition

Software which is intended to drive or influence the use of a (**hardware**) medical device but does not have or perform a medical purpose *on its own, nor* does it create information *on its own* for one or more of the medical purposes described in the definition of a medical device or an in vitro diagnostic medical device. This software can, but is not limited to:

- operate, modify the state of, or control the device either through an interface (e.g., software, hardware) or via the operator of this device
- or supply output related to the (hardware) functioning of that device

Source: MDSW Guideline – Guidance on the Qualification and Classification of Software in MDR 2017/745 and IVDR 2017/746

SOFTWARE THAT DRIVES OR INFLUENCES THE USE



Insulin dose calculator performs a medical purpose on Its own, i.e. it is MDSW.
The app also is intended to drive or influence the use of the insulin pump.

Definition

Software which is intended to drive or influence the use of a (hardware) medical device but **does not have or perform a medical purpose *on its own, nor* does it create information *on its own* for one or more of the medical purposes** described in the definition of a medical device or an in vitro diagnostic medical device.

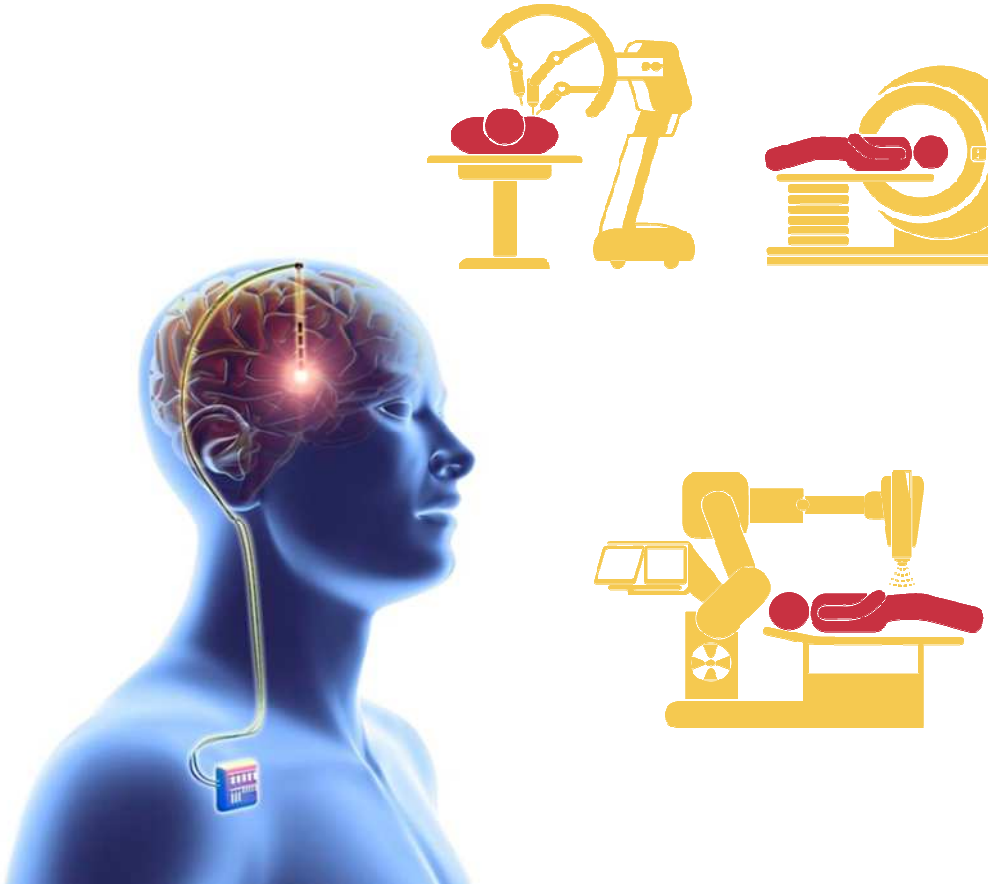
This software can, but is not limited to:

- operate, modify the state of, or control the device either through an interface (e.g., software, hardware) or via the operator of this device
- or supply output related to the (hardware) functioning of that device

Don't let this part of the definition mislead you. If the software drives or influences the use of a (hardware) medical device AND also has a medical purpose, then it is qualified as a MDSW, but would still need to consider the class of the device it is driving or influencing.

Source: MDSW Guideline – Guidance on the Qualification and Classification of Software in MDR 2017/745 and IVDR 2017/746

SOFTWARE THAT DRIVES OR INFLUENCES THE USE



Definition

Software which is intended to drive or influence the use of a (hardware) medical device but does not have or perform a medical purpose on its own, nor does it create information on its own for one or more of the medical purposes described in the definition of a medical device or an in vitro diagnostic medical device.

This software can, but is not limited to:

- **operate, modify the state of, or control the device** either **through an interface** (e.g., software, hardware) or **via the operator** of this device
- or supply output related to the (hardware) functioning of that device

Example (through an interface)

Software consoles or firmware intended to drive or provide the output of medical equipment. E.g. CT console, Remote (cloud-based) console for robotic surgery, software for neuromodulation….

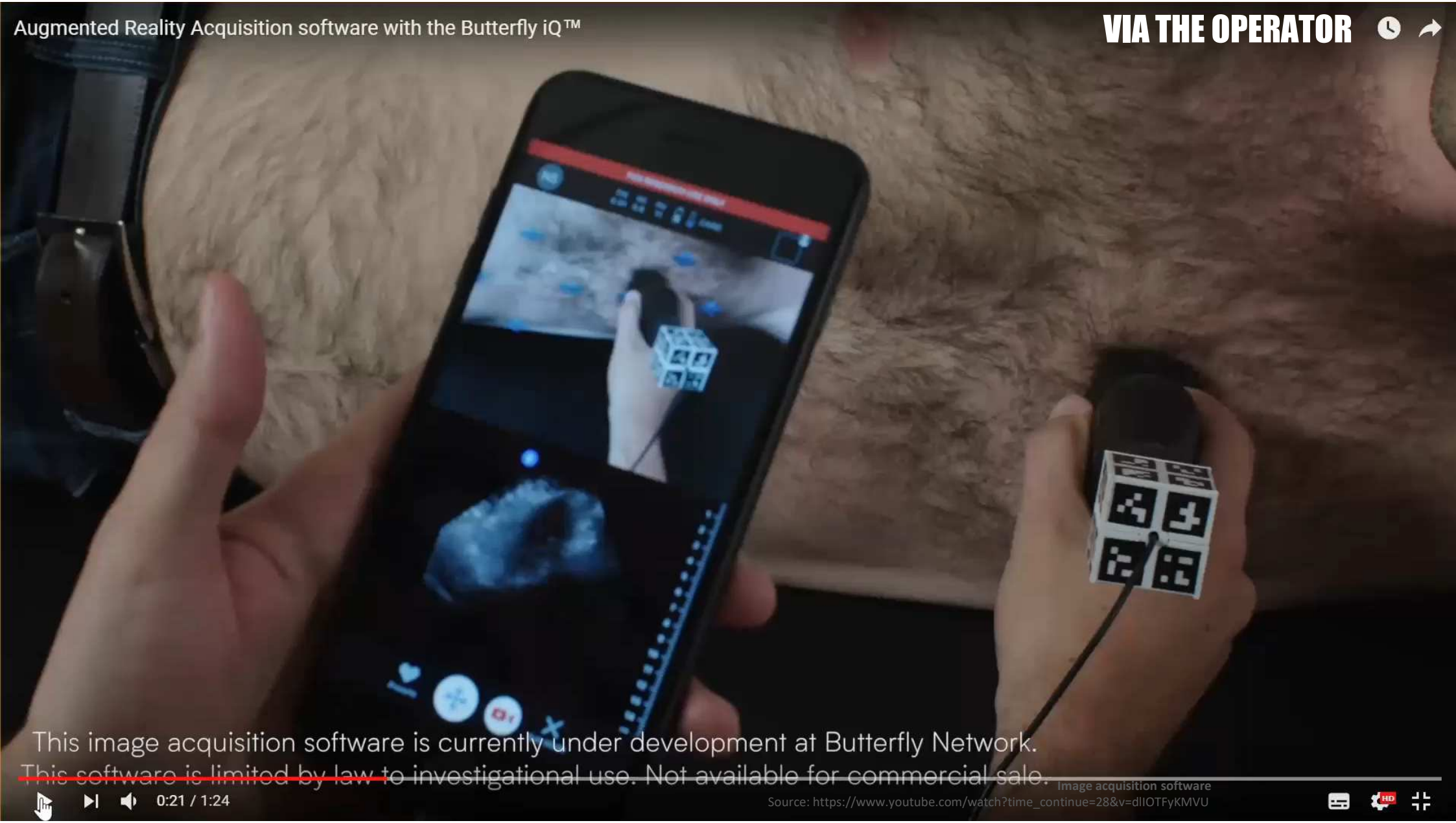
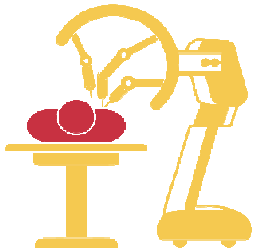


Image acquisition software

Source: https://www.youtube.com/watch?time_continue=28&v=dlIOTFyKMVU

TO SUPPLY OUTPUT RELATED TO THE (HARDWARE) FUNCTIONING



firmware or integrated circuits used to only supply output to move the patient positioning tables, electric wheelchairs or surgical robots

firmware or integrated circuits used to only extract the temperature from a thermometer, the image from an ultrasound probe or x-ray device

Definition

Software which is intended to drive or influence the use of a (hardware) medical device but does not have or perform a medical purpose *on its own, nor* does it create information *on its own* for one or more of the medical purposes described in the definition of a medical device or an in vitro diagnostic medical device.

This software can, but is not limited to:

- operate, modify the state of, or control the device either through an interface (e.g., software, hardware) or via the operator of this device
- **or supply output related to the (hardware) functioning of that device**

INDEPENDENT

Implementing Rule 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.

Medical Device definition
"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 […]

Independent = software having its own intended medical purpose (**i.e. alone**)

Not independent = software intended to be used **in combination** with a hardware medical device to specifically enable or specifically an directly assist that hardware medical device to fullfill its intended purpose

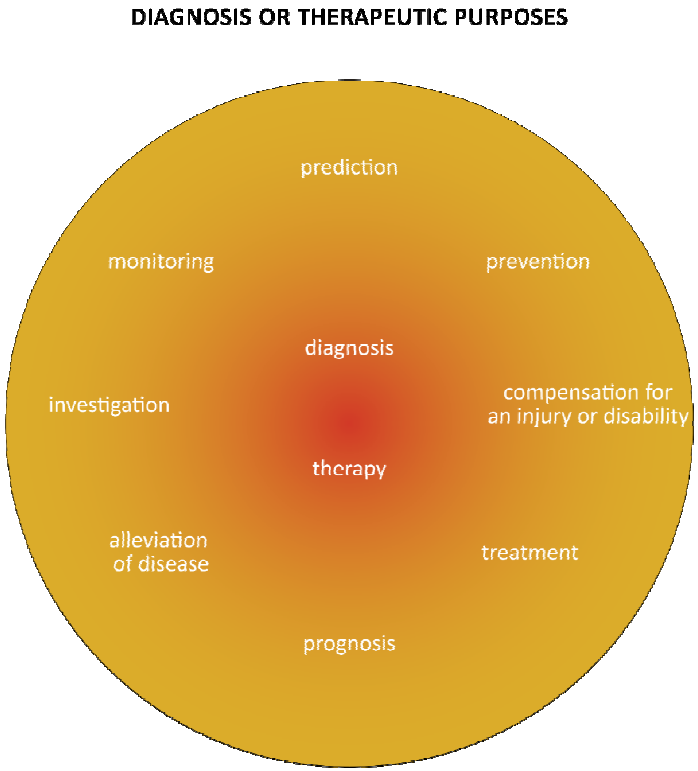
Software being independent is **irrespective of how the software is placed on the market**, i.e. as an integral component/part of a device or as a medical device in its own right.

RULE 11 COVERS ALL CLASSES

a **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**

b **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**.

c All other **software** are classified as class **I**.



RULE 11

a 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

b 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.

c **All other software** are classified as class I.

MDSW

with medical purpose
subject to Rule 11a

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.

MDSW

without medical purpose
subject to both Rule 11c

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

- Devices for the control or support of conception
- Products specifically intended for cleaning, disinfection or sterilization of medical devices, accessories of medical devices and products listed in Annex XVI

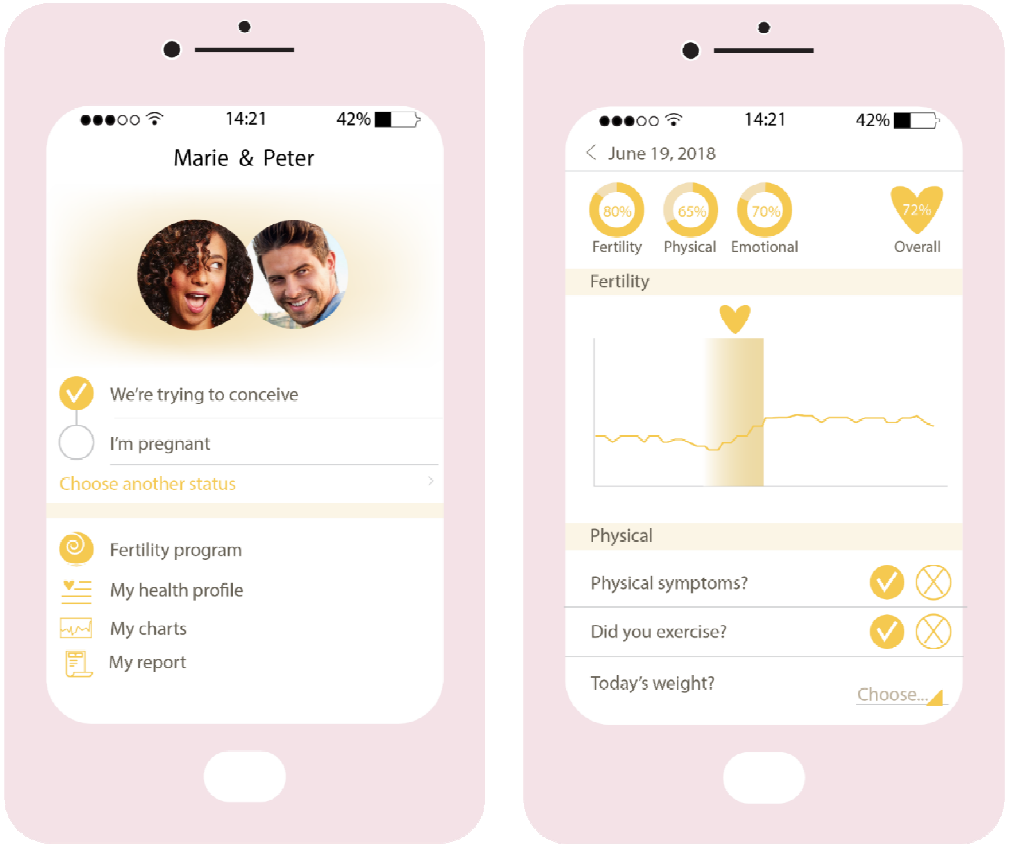
FERTILITY APPS

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.**



RULE 11

a 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**

b 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**.

c All other software are classified as class **I**.

Software for monitoring of physiological processes (not just vital processes):

- **monitoring over time**
- **verifying whether a signal is within range, i.e. checking against limits**

MDSW

subject to Rule 11a and Rule 11b

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.

- Devices for the control or support of conception
- Products specifically intended for cleaning, disinfection or sterilization of medical devices, accessories of medical devices and products listed in Annex XVI

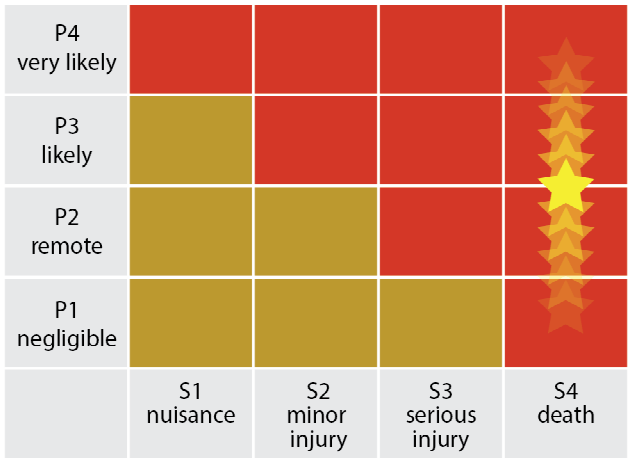
RULE 11 §1

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.



None of the classification rules contain a probability term as that would make the class dependent on who and how one performs risks assessment.

As only severity can be considered, **a literal interpretation of rule 11 always leads to class III**, because there is always someone that can think of a situation where, even though extremely unlikely, multiple conditions coincide and the information provided by the software contributes to a death.

To avoid the related legal uncertainty the IMDRF risk framework is suggested to assist with the interpretation.

EU MDR Classification Rule 11a

Disease Type Patient Condition	Intervention Type		Significance of Information: Treat or Diagnose • Treat • Provide therapy to a human body • Diagnose • Detect • Screen	Significance of Information: Drive Clinical Management • Aid in treatment • Provide enhanced support for safe and effective use of medicinal products or medical device • Aid to make a definitive diagnosis • Triage or identify early signs of a disease or condition	Significance of Information: Inform Clinical Management • Inform of options for - treatment - diagnosis - prevention • Aggregate relevant clinical information
• Life-threatening	• Requires major therapeutic interventions • Sometimes time critical • Accurate and/or timely diagnosis vital to: avoid death; serious deterioration of health or to mitigate public health risk	Critical	III Type IV.I	IIb Type III.I	IIa Type II.I
• Moderate in progression • Often curable	• Does not require major therapeutic interventions • Not expected to be time critical • Vital to avoiding unnecessary interventions	Serious	IIb Type III.ii	IIa Type II.ii	IIa Type I.ii
• Slow with predictable progression of disease state • Minor chronic illnesses or states • May not be curable	• Can be managed effectively	Non-Serious	IIa Type II.iii	IIa Type I.iii	IIa Type I.i

IMDRF SaMD Risk Framework

			Significance of Information		
			• Treat • Provide therapy to a human body • Diagnose • Detect • Screen	• Aid in treatment • Provide enhanced support for safe and effective use of medicinal products or medical device • Aid to make signs of a disease or condition	• Inform of options for - treatment - diagnosis - prevention • Aggregate relevant clinical information
Disease Type Patient Condition	Intervention Type		Treat or Diagnose	Drive Clinical Management	Inform Clinical Management
• Life threatening	• Requires major therapeutic intervention • Sometim… critical • Accur… diagnosis vit… ious deteric… lth or to miti… calth risk	Critical	Type IV.i	Type III.i	Type II.i
• Moderate in progression • Often curable	• Does n… ajor therap… ntions • Not ex… time cr… • Vital to… necessary interv…	Serious	Type III.ii	Type II.ii	Type I.ii
• Slow with predictable progression of disease state • Minor chronic illnesses or states • May not be curable	• Can be… fectively	Non-Serious	Type II.iii	Type I.iii	Type I.i

Significance of information

Healthcare situation or condition

Examples

Source:
IMDRF N12 SaMD risk framework
FDA draft guidance on clinical decision support software

			Significance of Information		
			• Treat • Provide therapy to a human body • Diagnose • Detect • Screen	• Aid in treatment • Provide enhanced support for safe and effective use of medicinal products or medical device • Aid to make a definitive diagnosis • Triage or identify early signs of a disease or condition	• Inform of options for - treatment - diagnosis - prevention • Aggregate relevant clinical information
Disease Type Patient Condition	Intervention Type		Treat or Diagnose	Drive Clinical Management	Inform Clinical Management
• Life-threatening	• Requires major therapeutic interventions • Sometimes time critical • Accurate and/or timely diagnosis vital to: avoid death; serious deterioration of health or to mitigate public health risk	Critical	- image-based stroke detection - melanoma detection - paediatric meningitis detection - screening of mutable pathogen	- virtual colonoscopy - melanoma tracking - bolus calculator to achieve preset peak blood concentration of a medication	- stroke prediction - identifying genetic predisposition to develop sepsis in general population
• Moderate in progression • Often curable	• Does not require major therapeutic interventions • Not expected to be time critical • Vital to avoiding unnecessary interventions	Serious	- sleep apnoea detection - tinnitus sound therapy - diagnoses Parkinson's disease based on data captured by vibration/position sensors	- heart arrhythmia detection - cardiovascular surgical planning - guide for diagnosis of kidney function disorders and cardiac risk - Insulin dose calculator	- data collection to guide exercise-based treatment of cardiac rehabilitation patients - prediction of asthma episode
• Slow with predictable progression of disease state • Minor chronic illnesses or states • May not be curable	• Can be managed effectively	Non-Serious	- skin lesion tracking to diagnose or rule out eczema - migraine risk prediction	- Nystagus and other eye movement disorder detection	- provides options for diagnosing seasonal allergic rhinitis vs. common cold - alert doctor of potential triggers indicative of cholesterol management issues - advise on eff seasonal allergy drug

Mistakes

IMDRF N12 contains numbering discrepancies in the section on criteria for category II and in the category III examples

This diagram reflects the mistakes.

Disease Type Patient Condition	Intervention Type		Significance of Information: Treat or Diagnose • Treat • Provide therapy to a human body • Diagnose • Detect • Screen	Significance of Information: Drive Clinical Management • Aid in treatment • Provide enhanced support for safe and effective use of medicinal products or medical device • Aid to make a definitive diagnosis • Triage or identify early signs of a disease or condition	Significance of Information: Inform Clinical Management • Inform of options for - treatment - diagnosis - prevention • Aggregate relevant clinical information
• Life-threatening	• Requires major therapeutic interventions • Sometimes time critical • Accurate and/or timely diagnosis vital to: avoid death; serious deterioration of health or to mitigate public health risk	Critical	Type IV.i	Type III.ii	Type II.iii
• 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.i	Type II.ii	Type I.ii
• Slow with predictable progression of disease state • Minor chronic illnesses or states • May not be curable	• Can be managed effectively	Non-Serious	Type II.i	Type I.iii	Type I.i

Industry interpretation

Disease Type Patient Condition	Intervention Type		Significance of Information: Treat or Diagnose	Significance of Information: Drive Clinical Management	Significance of Information: Inform Clinical Management
• Life threatening • Could result in temporary impairment of body function or structure of body requiring professional intervention	• Requires major therapeutic interventions • Sometimes time critical • Accurate and/or timely diagnosis vital to: avoid death; serious deterioration of health or to mitigate public health risk	Critical	SaMD output is intended to be used to: - Definitively diagnose a disease or condition - Provide direct treatment or definitive treatment information for a disease or condition; SaMD output is the sole determinant for clinical action and requires no further steps or confirmatory testing. SaMD output is intended for immediate or near-term clinical action.	SaMD output intended to be: - One of several inputs used for clinical action and/or decision-making; and - Necessary for clinical action or decision-making by the health care professional or patient, i.e. determinative. SaMD output intended for immediate or near-term clinical action.	SaMD output is intended to be: - One of several inputs used for clinical action and/or decision-making; and - Not necessary for clinical action or decision-making by the health care professional or patient and may or may not lead to direct clinical action, i.e. informative or adjunctive.
• Moderate in progression • Often curable • Could result in temporary impairment of body function or structure of body requiring professional intervention	• Does not require major therapeutic interventions • Not expected to be time critical • Vital to avoiding unnecessary interventions	Serious			
• Slow with predictable progression of disease state • Minor chronic illnesses or states • May not be curable • Not likely to result in temporary impairment of body function or in the structure of the body	• Can be managed effectively	Non-Serious			

Definitions

Blue text represents industry additions/corrections to the definitions

To treat or to diagnose

Treating and diagnosing infers that the information provided by the SaMD will be used to take an immediate or near term action:

- To treat/prevent or mitigate by connecting to other medical devices, medicinal products, general purpose actuators or other means of providing therapy to a human body
- To diagnose/screen/detect a disease or condition (i.e., using sensors, data, or other information from other hardware or software devices, pertaining to a disease or condition)

Output of the SaMD is intended to be used to:
- Definitively diagnose a disease or condition;
- Provide direct treatment or definitive treatment information for a disease or condition;

Output of the SaMD is the sole determinant for clinical action and requires no further steps or confirmatory testing.
Output of the SaMD is intended for immediate or near-term clinical action.

To drive clinical management

Driving clinical management infers that the information provided by the SaMD will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition will be used to guide next diagnostics or next treatment interventions:

- To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device.
- To aid in diagnosis by analyzing relevant information to help predict risk of a disease or condition or as an aid to making a definitive diagnosis.
- To triage or identify early signs of a disease or conditions.

Output of the SaMD is intended to be:
- One of several inputs used for clinical action and/or decision-making; and
- Necessary for clinical action or decision-making by the health care professional or patient, i.e. determinative.

Output of the SaMD is intended for immediate or near-term clinical action.

To inform clinical management

Informing clinical management infers that the information provided by the SaMD will not trigger an immediate or near term action:

- To inform of options for treating, diagnosing, preventing, or mitigating a disease or condition.
- To provide clinical information by aggregating relevant information (e.g., disease, condition, drugs, medical devices, population, etc.)

Output of the SaMD is intended to be:
- One of several inputs used for clinical action and/or decision-making; and
- Not necessary for clinical action or decision-making by the health care professional or patient and

may or may not lead to direct clinical action, i.e. informative or adjunctive.

Critical situation or condition

Situations or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health. SaMD is considered to be used in a critical situation or condition where:

- The type of disease or condition is:
  - Life-threatening state of health, including incurable states,
  - Requires major therapeutic interventions,
  - Sometimes time critical, depending on the progression of the disease or condition that could affect the user's ability to reflect on the output information.

~~Intended target population is fragile with respect to the disease or condition (e.g., pediatrics, high-risk population, etc.)~~
~~Intended for specialized trained users.~~
Could result in permanent impairment of body function or in the structure of the body,

Serious situation or condition

Situations or conditions where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions (e.g., biopsy) or timely interventions are important to mitigate long term irreversible consequences on an individual patient's health condition or public health. SaMD is considered to be used in a serious situation or condition when:

- The type of disease or condition is:
  - Moderate in progression, often curable,
  - Does not require major therapeutic interventions,
  - Intervention is normally not expected to be time critical in order to avoid death, longterm disability or other serious deterioration of health, whereby providing the user an ability to detect erroneous recommendations.

~~Intended target population is NOT fragile with respect to the disease or condition.~~
~~Intended for either specialized trained users or lay users.~~
Could result in temporary impairment of body function or in the structure of the body

Note: SaMD intended to be used by lay users in a "serious situation or condition" as described here, without the support from specialized professionals, should be considered as SaMD used in a "critical situation or condition".

Non-serious situation or condition

Situations or conditions where an accurate diagnosis and treatment is important but not critical for interventions to mitigate long term irreversible consequences on an individual patient's health condition or public health. SaMD is considered to be used in a non-serious situation or condition when:

- The type of disease or condition is:
  - Slow with predictable progression of disease state (may include minor chronic illnesses or states),
  - May not be curable; can be managed effectively,
  - Requires only minor therapeutic interventions, and
- Interventions are normally noninvasive in nature, providing the user the ability to detect erroneous recommendations.

~~Intended target population is individuals who may not always be patients.~~
~~Intended for use by either specialized trained users or lay users.~~
Is not likely to result in temporary impairment of body function or in the structure of the body

Note:
The fragile nature of the target population and the type of user were striked out as COCIR believes these were intended as indications of where most software for professional users or fragile populations is situated, rather than as discriminatory conditions. The fragile nature of the patient population would impact the type of controls (or risk mitigations) that are necessary, but it would not impact the risk classification. This is consistent with prior GHTF guidance. The nature of the user could impact the type or amount of evidence/information required, but not the classification itself. In addition, we believe that simply because the software is intended to be used only by a specialized user should not increase the risk to patients. Conversely, use by a specialized user should reduce the risk of the software..

SaMD ≠ MDSW

Not all SaMD is MDSW and vice versa:
Contrary to SaMD, MDSW also includes software without specific medical purpose (e.g. control and support of conception, ...)

Contrary to SaMD, MDSW does not include software intended for population studies

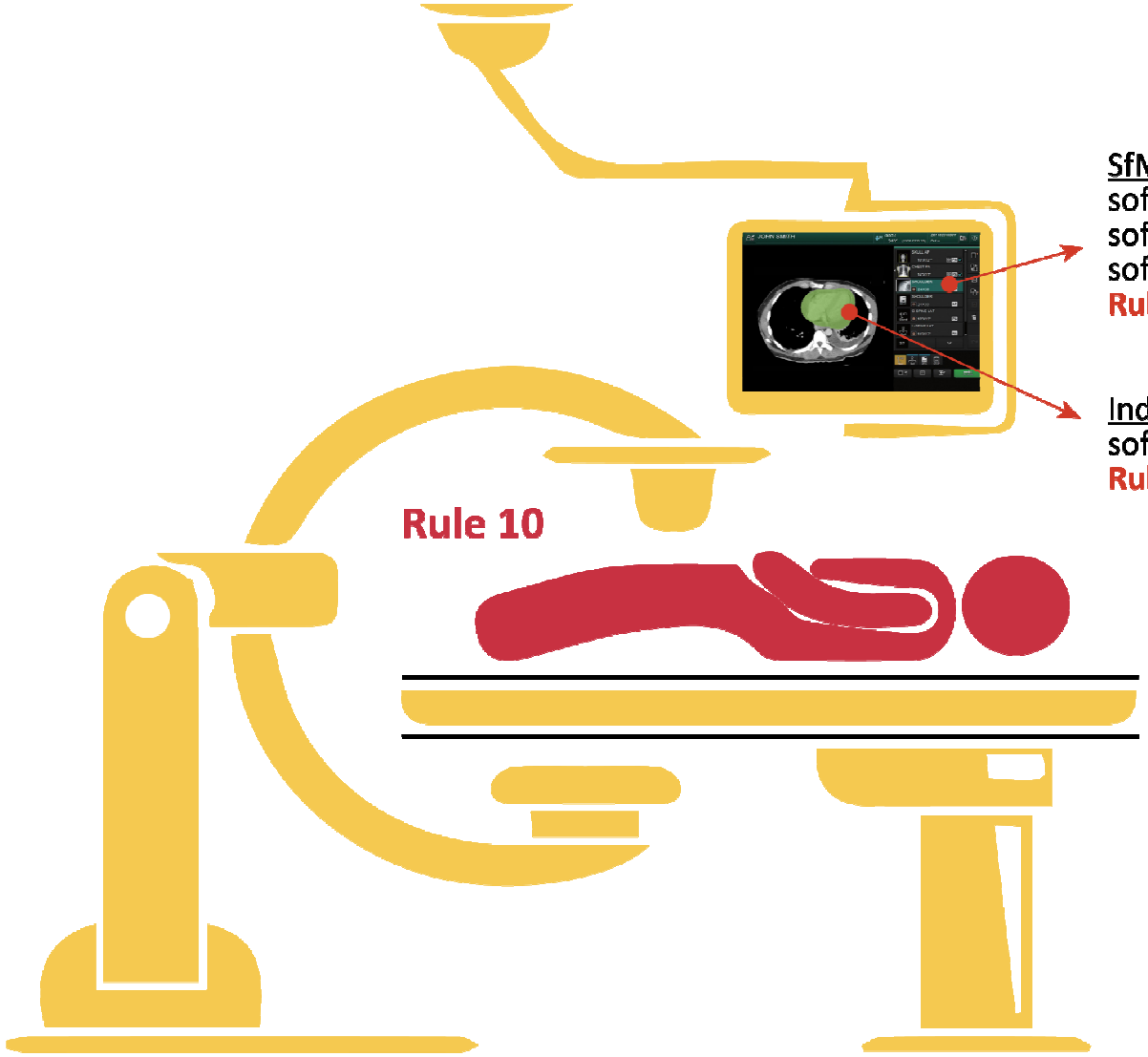
Contrary to SaMD, MDSW can also be intended to drive or influence the use of a hardware medical device. Such software is also known as SfMD or SiMD.

Both SaMD and MDSW can run on the computing platform of a hardware medical device.

SaMD and MDSW:

- fulfill a medical purpose on their own
- can run on the computing platform of a hardware medical device or be placed on the market as part of that hardware medical device

			Significance of Information		
			• Treat • Provide therapy to a human body • Diagnose • Detect • Screen	• Aid in treatment • Provide enhanced support for safe and effective use of medicinal products or medical device • Aid to make a definitive diagnosis • Triage or identify early signs of a disease or condition	• Inform of options for - treatment - diagnosis - prevention • Aggregate relevant clinical information
Disease Type Patient Condition	Intervention Type		Treat or Diagnose	Drive Clinical Management	Inform Clinical Management
• Life-threatening	• Requires major therapeutic interventions • Sometimes time critical • Accurate and/or timely diagnosis vital to: avoid death; serious deterioration of health or to mitigate public health risk	Critical	Type IV.i	Type III.i	EU regulates software to inform clinical management except if such software only stores, archives, communicates or provides simple searches
• 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	Type II.ii	
• Slow with predictable progression of disease state • Minor chronic illnesses or states • May not be curable	• Can be managed effectively	Non-Serious	Type II.III	Type I.III	



SfMD
software to position table
software to drive x-ray tube
software to read detector output
Rule 10 via impl. rule 3.3

Independent MDSW
software to detect lung lesion
Rule 11 §1

Questions?

Koen Cobbaert