



Ministerie van Volksgezondheid,
Welzijn en Sport

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Software

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Programma

Welkom en kennismaking

Door Luc Knaven - FHI

Software guidance: Welke software is een medisch hulpmiddel en in welke risicoklasse valt het?

Door Joël Buiten – IGJ

Europese en andere ontwikkelingen: Welke informatie is relevant en waar vindt u het?

Door Claire Hostmann – ministerie van VWS

Discussie

Discussieleider Luc Knaven – FHI



Inhoud

- Wie beslist over kwalificatie en classificatie?
- Gevolgen van wijzigingen classificatieregels
- Ingangsdata nieuwe regels
- Regels voor software als medisch hulpmiddel
- Vindplaatsen informatie



Wie beslist over kwalificatie en classificatie?

- Fabrikant / softwareontwikkelaar zelf verantwoordelijk
- Check door notified body (vanaf risicoklasse IIa)
- Toezicht door IGJ
- Meningsverschil met notified body? > Naar IGJ
- Meningsverschil met IGJ? > Naar rechter



Gevolgen wijziging classificatieregels

- Meer software naar hogere risicoklasse
- Meer software langs notified body



Ingangsdatum nieuwe regels software

- Software met een CE-certificaat van notified body?
 - > Overgangstermijn tot certificaat afloopt
 - > Alle certificaten die nog gelden verlopen 26 mei 2024
 - > Software bij distributeur? – verkoop tot 26 mei 2025
- Risicoklasse I software met *declaration of conformance*?
 - > Blijft klasse I? – Vanaf 26 mei 2020 voldoen aan MDR
 - > Naar hogere risicoklasse? - Mogelijk overgangsbepaling
- Software als medisch hulpmiddel dat niet aan MDD voldoet?
 - > Nu al illegaal op Europese markt



Zelfde regels als andere hulpmiddelen en voor software o.a.:

- Goed en betrouwbaar bij gebruik samen met andere producten (bijlage I, 14.5 [MDR](#)).
- Prestaties, herhaalbaarheid en betrouwbaarheid gewaarborgd (bijlage I, 17.1 [MDR](#))
- Ontwikkeld volgens state of the art, o.a. informatiebeveiliging (bijlage I, 17.2/4 [MDR](#))
- Bij het ontwerpen rekening houden met de gebruiker, en diens kennis en vaardigheden (bijlage I, 22.1/2 [MDR](#))
- Eisen aan gegevens op het etiket en gebruiksaanwijzing (bijlage I, 23.2/4 [MDR](#))
- Gedetailleerde informatie over het testontwerp en methode waarop gegevens worden geanalyseerd (bijlage II,6.1(b) [MDR](#))
- Hou rekening met specifieke eigenschappen mobiele comp.platform (bijlage I, 17.3 [MDR](#))



Software updates

- Ook significante veranderingen van hulpmiddel na de markttoelating moeten langs notified body.
- Dit kan effecten hebben voor de manier waarop updates en upgrades van software plaatsvinden.
- Bij acute risico's via field actions snel te handelen
- Er is nog onduidelijkheid welke updates of upgrades goedgekeurd moeten worden door notified body.



Medische hulpmiddelen binnen een zorginstelling gemaakt

- Andere/minder strenge eisen, mits aan voorwaarden voldaan (art. 5.5. MDR)
- Als niet aan voorwaarden wordt voldaan wordt de zorginstelling gezien als fabrikant en moeten zij aan dezelfde regels voldoen als een fabrikant

Bijvoorbeeld:

- de hulpmiddelen niet overdragen aan een andere rechtspersoon;
- de hulpmiddelen maken en gebruiken met inachtneming van een passend kwaliteitsmanagementsysteem;
- rechtvaardigen in documentatie dat er op de markt geen gelijkwaardig alternatief beschikbaar is;
- opstellen (openbare) verklaring waaruit blijkt dat aan de veiligheids- en prestatie-eisen is voldaan.



Modificatie

- Als zorgverlener door modificatie of reparatie het beoogde doel van een medisch hulpmiddel aantast of zodanig wijzigt dat de CE markering vervalt:

= zorginstelling fabrikant of *'in house'*-regels



Relevante guidance documenten

- [Guidance UDI assignment to medical device software](#)
- [Guidance Qualification and classification of software](#)
- Guidance Clinical Evaluation of Software
- Guidance Cybersecurity of Software
- Borderline & Classification-manual



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



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Guidance

The European Commission provides a range of guidance documents to assist stakeholders in implementing the medical devices regulations.

Legally non-binding guidance documents, adopted by the medical device coordination group (MDCG) in accordance with Article 105 of Regulation 745/2017, pursue the objective of ensuring uniform application of the relevant provisions of the regulations within the EU.



<https://www.rijksoverheid.nl/onderwerpen/medische-hulpmiddelen/nieuwe-wetgeving-medische-hulpmiddelen>

Nieuwe wetgeving medische hulpmiddelen

Er zijn nieuwe Europese regels voor medische hulpmiddelen (MDR) en medische hulpmiddelen voor in-vitro diagnostiek (IVDR). Door de nieuwe regels stellen alle landen in de Europese Unie dezelfde eisen. Bijvoorbeeld aan fabrikanten van medische hulpmiddelen. Zo vergroten de nieuwe regels de veiligheid van patiënten. Ook zorgen zij ervoor dat vernieuwende medische hulpmiddelen beschikbaar blijven voor de patiënt.

> Gevolgen voor fabrikanten

> Gevolgen voor gemachtigden, importeurs en distributeurs

> Gevolgen voor zorginstellingen

> Meer informatie

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Discussie

- Wat moeten softwareontwikkelaars weten?
- Hoe kunt u uw achterban hierover informeren?
- Wat is daarvoor nodig?



Software guidance

MDCG 2019-11

*Welke software is een medisch hulpmiddel
en in welke risicoklasse valt het?*

Den Haag - 12 november 2019

Introductie

Software guidance

Doel

- Vertrekpunt conformiteitsroutes Medical Device Software (MDSW)
- Beperkte juridische status
- Dient als richtsnoer
- Geeft kwalificatie- en classificatievoorbeelden

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Disclaimer:

- Deze presentatie is een visuele weergave van de inhoud van de guidance, bij afwijkingen met MDCG 2019-11 is de guidance leidend.
- Een uitgebreidere versie wordt gedistribueerd.

Software guidance

Totstandkoming

- > Tijdslijnen:
 - Opstellen door taskforce (2018-2019)
 - Review door werkgroepen (NT, B&C, CIE) (2019)
 - Finalisatie (juli–september 2019)
 - Goedkeuring MDCG (september 2019)
 - Gepubliceerd (oktober 2019)

Inhoud guidance

Medical Device

Medical Device Coordination Group Document

MDCG 2019-11

MDCG 2019-11

**Guidance on Qualification and Classification
of Software in Regulation (EU) 2017/745 – MDR
and Regulation (EU) 2017/746 – IVDR**

October 2019

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Inhoud van de guidance

Algemeen & Definities

- Scope en doel
- Verduidelijking van MDR/IVDR-terminologie en definities
- Introductie aantal nieuwe termen (bijvoorbeeld MDSW)

Kwalificatie van MDSW

- Kwalificatiecriteria
- Flowcharts kwalificatie MDSW en IVD MDSW
- Voorbeelden kwalificatie

Classificatie van MDSW

- Implementing rules
- Relevante classificatieregels voor MDSW
- Regel 11 en het IMDRF raamwerk
- Voorbeelden classificatie

Overig

- Placing on the market en conformiteitsassessments
- Modules
- Changes aan een MDSW

Algemeen & Definities

Term

Relevant part of guidance

Implications for MDSW/Examples

Software

For the purpose of this guidance, “software” is defined as a set of instructions that processes **input data** and creates **output data**.

- Data given through the use of a human data-input device such as a keyboard, mouse, stylus, or touch screen.
- Data given through speech recognition.
- Digital document: formatted for general purpose such as Word file or pdf file or jpeg image, formatted for medical purpose such as DICOM file or ECG records or Electronic Health.
- Record, unformatted document. Note that digital documents have to be differentiated from software able to read such documents;
- Data received from/transmitted by devices.

Input data

Any data provided to software in order to obtain output data after computation of this data can be considered as input data.

Output data

Any data produced by a software can be considered as an output data.

- Screen display data (such as layout with number, characters, picture, graphics, etc.).
- Print data (such as layout with number, characters, picture, graphics, etc.).
- Audio data.
- Digital document (formatted for a general purpose such as Word file or pdf file or jpeg image, or formatted for medical purpose such as DICOM file or ECG records or Electronic Health
- Record, unformatted document).
- Haptic buzzing as an alternative to audio sound.

Accessory

From MDR: 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).
From IVDR: an article which, whilst not being itself an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or several particular in vitro diagnostic medical device(s) to specifically enable the in vitro diagnostic 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 in vitro diagnostic medical device(s) in terms of its/their intended purpose(s).

Software accessory may be driving or influencing the use of a medical device.

 Manufacturers must describe in the technical documentation accessories of a medical device or an in vitro diagnostic medical device which are intended to be used in combination with it; and in case of medical devices they must include in the instructions for use information allowing the selection of the corresponding software and accessories.

Term

Software driving or influencing the use of a device

Medical Device Software (MDSW)

Relevant part of guidance

Software which is intended to drive or influence the use of a (hardware) medical device and 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:

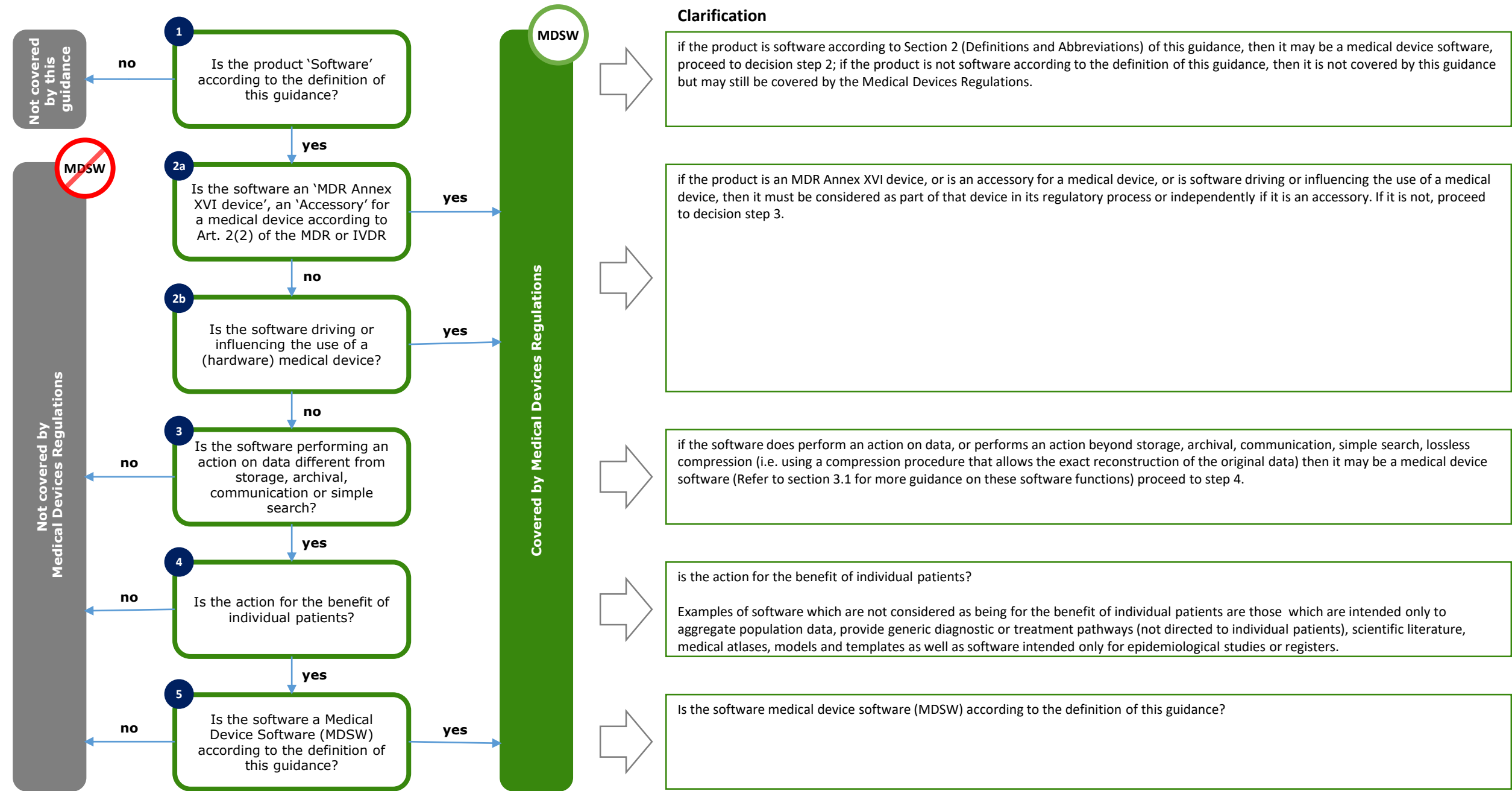
- operate, modify the state of, or control the device either through an interface (e.g., software, hardware) or via the operator of this device.
- or supply output related to the (hardware) functioning of that device.

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 regulation¹⁵ or in vitro diagnostic medical devices regulation.

Implications for MDSW/Examples

Software driving or influencing the use of a (hardware) medical device may be qualified as an accessory for a (hardware) medical device.

Kwalificatie van MDSW



Clarification
 if the product is software according to Section 2 (Definitions and Abbreviations) of this guidance, then it may be a medical device software, proceed to decision step 2; if the product is not software according to the definition of this guidance, then it is not covered by this guidance but may still be covered by the Medical Devices Regulations.








if the product is an MDR Annex XVI device, or is an accessory for a medical device, or is software driving or influencing the use of a medical device, then it must be considered as part of that device in its regulatory process or independently if it is an accessory. If it is not, proceed to decision step 3.






if the software does perform an action on data, or performs an action beyond storage, archival, communication, simple search, lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) then it may be a medical device software (Refer to section 3.1 for more guidance on these software functions) proceed to step 4.






is the action for the benefit of individual patients?
 Examples of software which are not considered as being for the benefit of individual patients are those which are intended only to aggregate population data, provide generic diagnostic or treatment pathways (not directed to individual patients), scientific literature, medical atlases, models and templates as well as software intended only for epidemiological studies or registers.

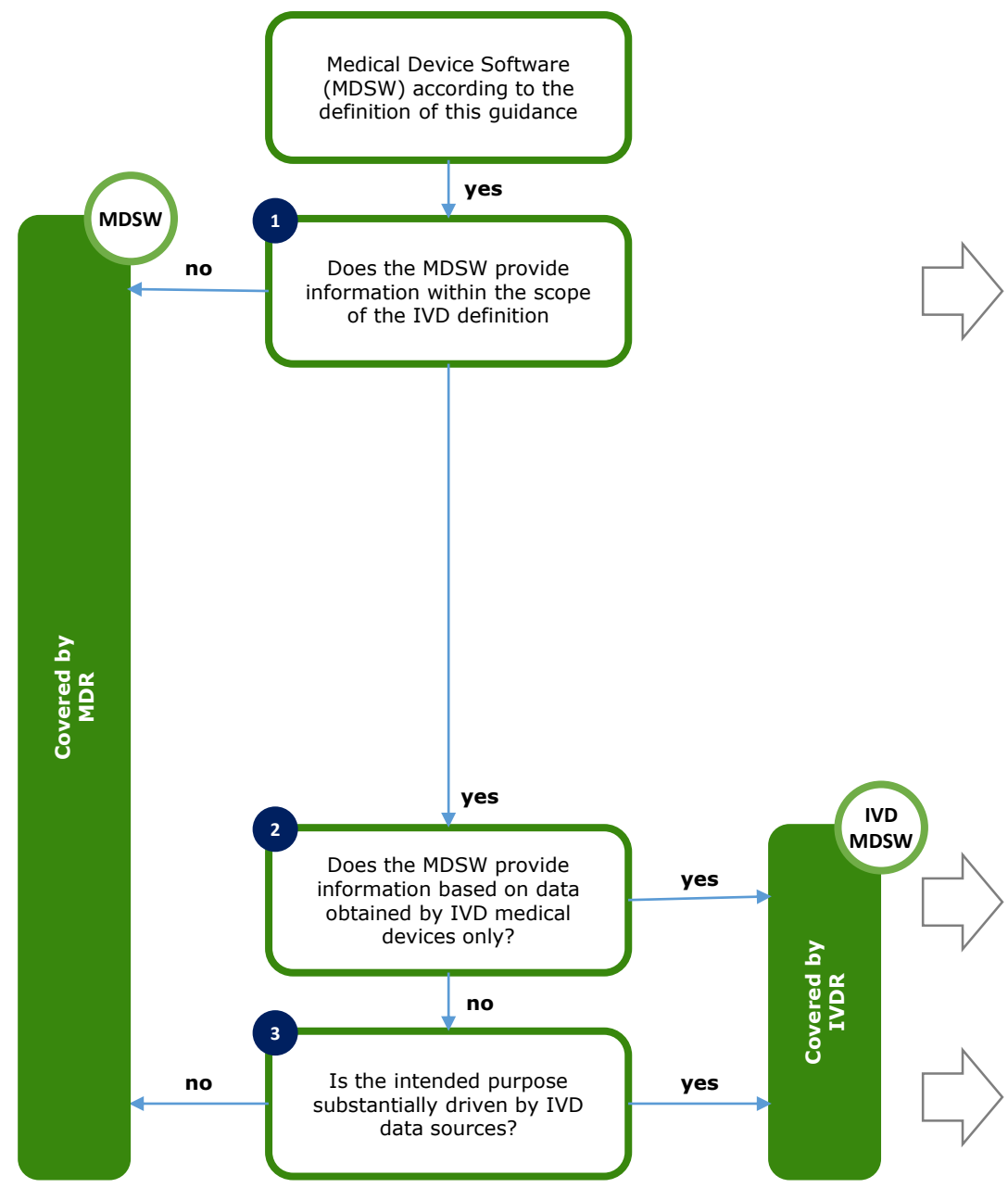
Is the software medical device software (MDSW) according to the definition of this guidance?

Type of software	Description		Rationale / (Counter)examples
(Hospital) Information Systems	<ul style="list-style-type: none"> Systems that support the process of patient management. Typically intended for patient admission, for scheduling patient appointments, for insurance and billing purposes. 		
Electronic Patient Record Systems	<ul style="list-style-type: none"> Store and transfer electronic patient records. Archive all kinds of documents and data related to a specific patient. I.e. an electronic patient record that simply replaces a patient's paper file. 		<ul style="list-style-type: none"> An image viewer with functionality for diagnosis based on digital images. A medication module.
Clinical Information Systems – CIS / Patient Data Management Systems – PDMS	<ul style="list-style-type: none"> Primarily intended to store and transfer patient information generated in association with the patient's intensive care treatment (e.g. intensive care units). Contains information such as patient identification, vital intensive care parameters and other documented clinical observations. 		<ul style="list-style-type: none"> Modules that are intended to provide additional information that contributes to diagnosis, therapy and follow-up (e.g. generate alarms).
Pre-hospital Electrocardiograph (ECG) System	<ul style="list-style-type: none"> Intended for ambulance services to store and transfer information from patients to a doctor at remote location. Usually the system contains information about patient identification, vital parameters and other documented clinical observations. 		<ul style="list-style-type: none"> Modules that create and provide new patient treatment information to the paramedics or to the doctor at a remote location to start the patient's treatment while the patient is being transported.
Picture Archive Communication System (PACS)	<p>The Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices addresses the qualification of PACS.</p>		
Decision Support Software	<ul style="list-style-type: none"> Computer based tools which combine general medical information databases and algorithms with patient-specific data. Intended to provide healthcare professionals and/or users with recommendations for diagnosis, prognosis, monitoring and treatment of individual patients. 		<ul style="list-style-type: none"> Radiotherapy treatment planning systems are intended to calculate the dosage of ionizing irradiation to be applied to a specific patient. They are considered to control, monitor or directly influence the source of ionizing radiation and are qualified as medical devices. Drug planning systems (e.g. chemotherapy) are intended to calculate the drug dosage to be administered to a specific patient and therefore are qualified as medical devices. Computer Aided Detection systems are intended to provide information that may suggest or exclude medical conditions are qualified as medical devices (MDSW). For example, such systems would be able to automatically analyse x-ray images or interpret ECGs.

Type of software	Description		Rationale / (Counter)examples
Communication Systems	<ul style="list-style-type: none"> Communication systems (e.g. email systems, mobile telecommunication systems, video communication systems, paging, etc.) to transfer electronic information. Different types of messages are sent such as prescription, referrals, images, patient records, etc. Handle types of messages other than medical information. This communication system is intended for general purposes, and is used for transferring both medical and non-medical information. 		<ul style="list-style-type: none"> A software module generating alarms based on the monitoring and analysis of patient specific physiological parameters. 
Telemedicine / Telesurgery	<ul style="list-style-type: none"> Allow monitoring and/or delivery of healthcare to patients at locations remote from where the healthcare professional is located. Conduct a surgical procedure from a remote location. Virtual reality technology may be used to support a remote surgeon to control a surgical robot performing the surgical procedure. 		<ul style="list-style-type: none"> Remote control software used in combination with telesurgery robots.  Other modules that are intended to influence the surgery procedure. 
Web systems for monitoring of data	<ul style="list-style-type: none"> Monitoring of clinical data typically interacts with a medical device (e.g. implanted devices or homecare devices), and uses a transmitter to send the information over the internet, a landline telephone or a mobile network. The information is collected and stored on a web server usually run by an external party who is generally the manufacturer of the system. The information can be reached by authorized health professionals or the patient through an internet connection. 		
Monitoring of performance of medical devices	<ul style="list-style-type: none"> Monitor the medical performance of medical devices. This includes the clinical performance and failures that could affect medical performance of the device. 		<ul style="list-style-type: none"> Web system for monitoring of active implants such as pacemakers or Intra Cardiac Defibrillators (ICDs).
Monitoring of non-medical performance of medical devices	<ul style="list-style-type: none"> Perform administrative monitoring of non-medical performance of medical devices. 		<ul style="list-style-type: none"> Software for the monitoring of medical devices in hospital systems for the purpose of maintenance and repair.

Criterion	Relevant part of guidance		Examples / Notes
<p>Altering representation of data</p>	<p>Software which alters the representation of data for a medical purpose would qualify as a medical device software.</p>		<ul style="list-style-type: none"> • Searching image for findings that support a clinical hypothesis as to the diagnosis or evolution of therapy. • Software which locally amplifies the contrast of the finding on an image display so that it serves as a decision support or suggests an action to be taken by the user.
	<p>altering the representation of data for embellishment/cosmetic or compatibility purposes.</p>		
<p>Simple search</p>	<p>“Simple search” refers to the retrieval of records by matching record metadata against record search criteria or to the retrieval of information does not qualify as medical device software (e.g. library functions).</p>		
<p>Non-medical purposes</p>	<p>Software intended for non-medical purposes (excluding MDR Annex XVI devices), does not qualify as a medical device software. These software do not fall under the Medical Devices Regulations.</p>		<ul style="list-style-type: none"> • Such as invoicing or staff planning. • A task such as e-mailing, web or voice messaging, data parsing, word processing, and back-up is by itself not considered as having a medical purpose.
<p>Software driving or influencing the use of a medical device</p>	<p>Is software intended to drive or influence the use of a (hardware) medical device and 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.</p> <p>This software can, but is not limited to:</p> <ol style="list-style-type: none"> 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 <p>Note: Software that is driving or influencing the use of a medical device is covered by the medical devices regulations either as a part/component of a device or as an accessory for a medical device.</p>		<ul style="list-style-type: none"> • Software that is intended to be used to operate a clinical chemistry analyser. • Software with built-in electronic controls for IVD quality control procedures. These quality control procedures are intended to provide users with assurance that the device is performing within specifications.

Criterion	Relevant part of guidance		Examples / Notes
Medical purpose	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.		
Independent MDSW	MDSW may be independent, by having its own intended medical purpose and thus meeting the definition of a medical device or in vitro diagnostic medical device on its own (i.e. alone).		<ul style="list-style-type: none"> • MDSW that uses maternal parameters such as age, concentration of serum markers and information obtained through foetal ultrasound examination for evaluating the risk of trisomy 21. • MDSW that receives measurements from transrectal ultrasound findings, age, and in vitro diagnostic instruments and calculates a patient’s risk of developing prostate cancer. • Mass Spectrometry MDSW intended to analyse LC-MS/MS data to be used for microorganism identification and detection of antibiotic resistance. • MDSW smartwatch app, which is intended to send alarm notifications to the user and/or health practitioner when it recognises irregular heartbeats for the purpose of detecting cardiac arrhythmia.
Software driving or influencing the use of a medical device with medical purpose	If the software drives or influences a (hardware) medical device and also has a medical purpose, then it is qualified as a MDSW.		<ul style="list-style-type: none"> • Melanoma image analysis software intended to drive a near-infrared laser light scanner. • MDSW intended to measure and transmit blood glucose levels, calculate insulin dose required and drive the insulin pump to administer the calculated dosage (closed loop insulin delivery system).
Location of software	Software may be qualified as MDSW 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).		<ul style="list-style-type: none"> • MDSW that is intended to operate a point of care test from a remote location.
Intended users	MDSW may be intended to be used by healthcare professionals or laypersons (e.g. patients or other users).		<ul style="list-style-type: none"> • MDSW that provides insulin dose recommendations to a patient regardless of the method of delivery of the prescribed dose, whether via an insulin pump, insulin pen or insulin syringe.



Clarification

MDSW which provides information according to Regulation (EU) 2017/746 – IVDR Article 2(2) (a) to (f) should qualify as In Vitro Diagnostic Medical Device Software (IVD MDSW)






- (a) concerning a physiological or pathological process or state (by investigation of this process or state); or
- (b) concerning congenital physical or mental impairments
- (c) concerning the predisposition to a medical condition or a disease;
- (d) to determine the safety and compatibility with potential recipients;
- (e) to predict treatment response or reactions;
- (f) to define or monitoring therapeutic measures.

A MDSW which falls under the definition set out in EU Article 2 (1) of Regulation (EU) 2017/745 – MDR should qualify as Medical Device Software (MD MDSW). In specific, the following considerations should apply on the provision of information by software on:

- (g) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
- (h) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- (i) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- (j) control or support of conception;
- (k) products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and Annex XVI products.

If the information provided is based on data obtained solely from in vitro diagnostic medical devices, then the software is an in vitro diagnostic medical device and is therefore an IVD MDSW.
 If the data analysed is obtained from a combination of both in vitro diagnostic medical devices and medical devices, proceed to step 3.

In the condition where the intended purpose of the MDSW output data fulfils both the medical device and in vitro diagnostic medical device definitions set out in the MDR and IVDR (refer to Decision Step 2), a weighting of the data sources based on the significance of the information in relation to fulfilling the intended purpose should be conducted to aid the manufacturer in determining which regulation to apply.
 Annex II of this guidance offers some prescriptive examples of how such a weighting may be performed.

Type of software	Description		Rationale / (Counter)examples
Laboratory Information Systems (LIS) and Work Area Managers (WAM)	<ul style="list-style-type: none"> Support the process from patient sample to patient result. Typically, they have preanalytical functions for ordering, sorting and distribution of test samples. The main task is the management and validation of incoming information obtained from in vitro diagnostic medical device analysers connected to the system, such as calibration, quality control, product expiry and feedback (e.g. retesting of samples needed) through interconnections with various analytical instruments (technical and clinical validation). The post-analytical process allows communication of laboratory results, statistics and optional reporting to external databases. <p>Note: software intended to modify the representation of available in vitro diagnostic medical device results is not considered an in vitro diagnostic medical device, e.g. basic operations of arithmetic (e.g. mean, conversion of units) and/or plotting of results in function of time, and/or a comparison of the result to the limits of acceptance set by the user.</p>		<p>The software normally supports the following functions:</p> <ul style="list-style-type: none"> Ordering of laboratory tests, samples with labels and sorting. Technical and clinical validation, connection to analytic instruments. Laboratory results and reports on paper, fax or electronic records that can be directly returned to e.g. the ordering clinic's patient record. Analytical instruments can be interfaced with Hospital Information Systems (HIS), Electronic Patient Record Systems, Infectious control databases, etc. <p>The results are available, readable and understandable without the intervention of the software.</p> <p>Counterexample:</p> <ul style="list-style-type: none"> A module whose intended purpose is to assess the criticality of tests required and to perform automatic reprioritisation of the order based on patient data.
Expert system	<ul style="list-style-type: none"> MDSW which is intended to provide information within the scope of the in vitro diagnostic medical devices definition by capturing and analysing together one or multiple results obtained for one patient by means of in vitro examination of body samples (possibly combined with information from medical devices and non-medical devices). 		<ul style="list-style-type: none"> MDSW that integrates genotype of multiple genes to predict risk a disease or medical condition developing or recurring. MDSW that uses an algorithm to characterise viral resistances to various drugs, based on a nucleotide sequence generated by genotyping assays. This software serves to generate new information (virus resistance profile) from available information on the genotype of the virus. MDSW intended to be used in microbiology for the identification of clinical isolates and/or the detection of antimicrobial resistances.
Interpretation of raw data	<ul style="list-style-type: none"> In the case where MDSW is necessary to render raw data, readable for the user, obtained from an in vitro diagnostic medical device by means of in vitro examination of body samples, this MDSW is to be considered driving or influencing the use of the in vitro diagnostic medical device. Specifically intended to be used together with this in vitro diagnostic medical device to enable it to be used in accordance with its intended purpose. 		<ul style="list-style-type: none"> MDSW intended for the analysis and interpretation of enzyme-linked immunosorbent assay (ELISA) reader optical density results, line patterns or spot patterns of a blot.
Home care monitoring, wired or mobile	<ul style="list-style-type: none"> Software intended for archiving patient results or for transferring results obtained from in vitro diagnostic medical devices from the home environment to the healthcare provider. The results are available, readable and understandable by the user without the intervention of the software. 		
Image Management System (IMS)	<ul style="list-style-type: none"> Primarily intended to be networked with digital pathology systems, e.g., whole slide scanners, scanning microscopes, as well as LIS. Does not contain controls for the direct operation of the digital pathology systems. Intended to access, display, annotate, manage, store, archive and share collections of digitised patient images. IMS may be configured to provide limited or extensive capabilities to further visualise or analyse patient images acquired from networked digital pathology systems. 		<ul style="list-style-type: none"> An IMS only used for viewing, archiving and transmitting images. IMS that incorporate functions to support post-processing of images for diagnostics purposes, e.g., image processing functions which alter image data or complex quantitative functions to aid in diagnosis.

Criterion

Relevant part of guidance

Examples / Notes

MDSW intended to be used with an IVD

Medical Device Software (MDSW) fulfilling the definition of an in vitro diagnostic medical device falls under the in vitro diagnostic medical devices Regulation (EU) 2017/746. Provided that MDSW is intended specifically by its manufacturer to be used together with an in vitro diagnostic medical device to enable it to be used in accordance with its intended purpose, this MDSW falls under the scope of the in vitro diagnostic medical devices regulation and shall be treated as an In Vitro Diagnostic MDSW (IVD MDSW) in its own right.



- Software that analyses and interprets the optical density delivered by an ELISA reader, line or spot pattern of a blot. Such software takes raw data outputs and use clinical algorithms for diagnostic and/or prognostic purposes.

Software driving or influencing the use of a (hardware) device

In cases when software is driving or influencing the use of a (hardware) device, the software should be considered as falling under the respective regulation of the driven or influenced (hardware) device.



Type of software

Description

**Example 1;
Laboratory Information System**

A software module which runs on an in vitro diagnostic medical device instrument and tracks how the laboratory is performing in real-time on key operational metrics such as test volumes, turnaround times, pending tests, and quality control.

Its intent is to improve a laboratory's operations by providing real-time monitoring of performance metrics that can drive change management and continuous improvement initiatives within the lab. The software is configurable so that customers can choose the metrics on which they would like to focus.

Type of software

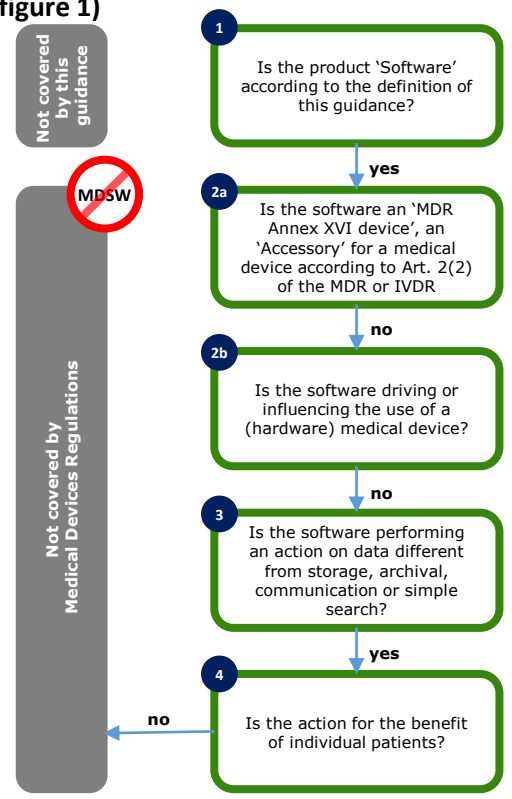
Description

**Example 2;
MDSW generating risk scores to trigger care processes**

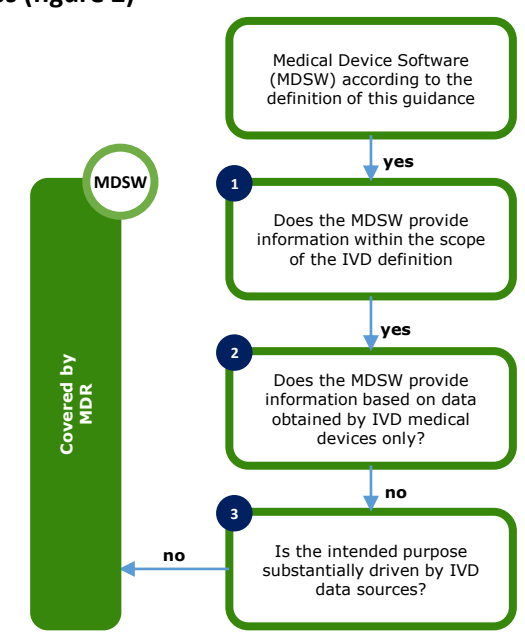
MDSW intended to generate a risk score in order to trigger care processes to help reduce ICU transfers, readmissions, adverse events and length of stay.

The risk score by default includes respiratory rate, heart rate, blood pressure and SpO2, but a user can configure it to include other parameters, including in vitro diagnostic medical device results.

Qualification steps (figure 1)



Qualification steps (figure 2)



Type of software

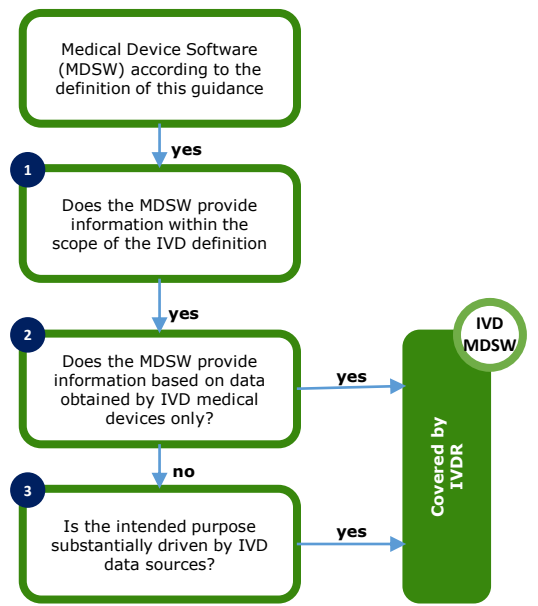
Description

**Example 3;
MDSW providing information on statistical predisposition for Down and Edwards syndrome**

A MDSW algorithm intended to provide information on the statistical predisposition for Down syndrome (Trisomy 21) and Edwards syndrome (Trisomy 18) in the first and second trimesters of pregnancy. The MDSW analyses input data from various in vitro diagnostic medical device assays as well as, ultrasound measurements of the nasal bone or neck fold.

The MDSW provides clinicians/obstetricians with a risk factor score for a foetus's likelihood of having genetic mutations in the first or second trimester of pregnancy. The risk score suggests whether or not additional diagnostic testing is needed to confirm the genetic mutations of Trisomy 21, Trisomy 18.

Qualification steps (figure 2)



Type of software

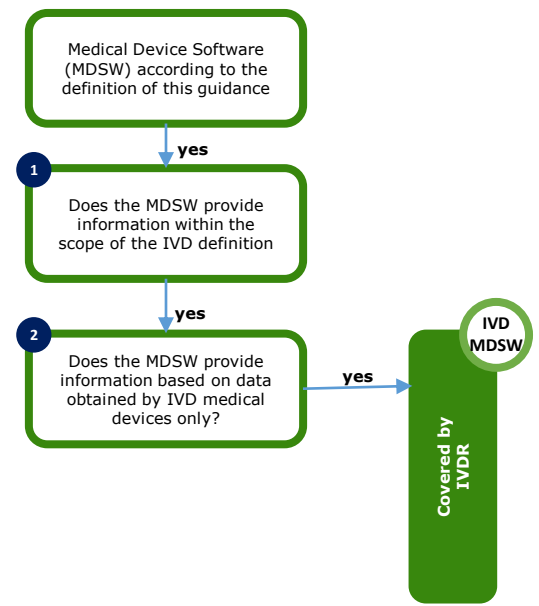
Description

**Example 4;
MDSW analysing digital NGS raw data**

A bioinformatics MDSW intended to analyse digital Next Generation Sequencing (NGS) raw data coming from sequenced patient's cancer genomes. It allows the detection and visualisation of somatic genome alterations (such as substitutions, small insertions and deletions (indels), copy number alterations, and genomic rearrangements) across a selected number of genes.

Additionally, it is also capable of determining genomic signatures* (such as microsatellite instability [MSI] and/or tumour mutational burden [TMB]). The types of somatic genome alterations and genomic signatures detected depend on the test chosen. The MDSW assists the user in identifying and visualising genomic alterations and is intended to identify somatic genome alterations to support diagnosis and treatment decisions.

Qualification steps (figure 2)



Classificatie van MDSW

Rule 11 was introduced into the MDR and is intended to address the risks related to the information provided by an active device, such as MDSW.



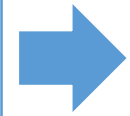
Rule 11

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:

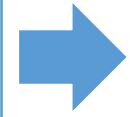
- death or an irreversible deterioration of a person's state of health, in which case it is in **class III**; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as **class IIb**.

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**.

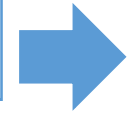
All other software is classified as **class I**.



Subrule 11a)



Subrule 11b)



Subrule 11c)

Criterion

Subrule 11a)
Diagnostic or therapeutic purposes

Relevant part of guidance

The wording “intended to provide information which is used to take decisions with diagnosis or therapeutic purposes” describes, in very general terms, the “mode of action” which is characteristic of all MDSW. Therefore, **this sub-rule is generally applicable to all MDSW** (excluding those MDSW that have no medical purpose).

Sub-rule 11a), states that MDSW (which is intended to provide information which is used to take decisions with diagnosis or therapeutic purposes) is classified as **class IIa**.

There are two exceptions from sub-rule 11a) that are mainly intended to apply a risk classification based on the significance of the provided information and the potential impact of an (incorrect) decision made using information from the MDSW. Accordingly, MDSW that is intended to provide information which is used to take decisions with diagnosis and therapeutic purposes, is at a higher risk class where such decisions, if based on incorrect information from the MDSW, are reasonably likely to have an impact that may cause:

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

Examples / Notes

IMDRF risk categorization of software as a medical device

		Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy		
		High Treat or diagnose ~ <i>IMDRF 5.1.1</i>	Medium Drives clinical management ~ <i>IMDRF 5.1.2</i>	Low Informs clinical management (<i>everything else</i>)
State of Healthcare situation or patient condition	Critical situation or patient condition ~ <i>IMDRF 5.2.1</i>	Class III Category IV.i	Class IIb Category III.i	Class IIa Category II.i
	Serious situation or patient condition ~ <i>IMDRF 5.2.2</i>	Class IIb Category III.ii	Class IIa Category II.ii	Class IIa Category I.ii
	Non-serious situation or patient condition (<i>everything else</i>)	Class IIa Category II.iii	Class IIa Category I.iii	Class IIa Category I.i

Option	Description* (intended use)	Relevant rule	Rationale	Proposed classification
Image analysis & diagnosis	<ul style="list-style-type: none"> Performs diagnosis. Image analysis for making treatment decisions in patients with acute stroke. 	Rule 11(a)	IMDRF Risk Category IV.i as the healthcare situation (stroke) is critical and the significance of the information is “treat or diagnose”.	III
Anaysis of heartbeat & detection	<ul style="list-style-type: none"> A mobile app. Analyse a user’s heartbeat, detect abnormalities and inform a physician accordingly. Intended to guide the physician in the diagnosis. 	Rule 11(a)	IMDRF Risk Category III.i as the information drives clinical management.	IIb
Scoring depression	<ul style="list-style-type: none"> Diagnostic MDSW intended for scoring depression. Based on inputted data on a patient’s symptoms (e.g. mood, anxiety). 	Rule 11(a)	IMDRF Risk Category III.ii as the healthcare situation (depression) is serious and the significance of the information is “diagnosis”.	IIb
Ranking of therapeutic suggestions	<ul style="list-style-type: none"> Rank therapeutic suggestions for a health care professional. Based on patient history, imaging test results, and patient characteristics. MDSW that ranks all available chemotherapy options for BRCA-positive individuals. 	Rule 11(a)	IMDRF Risk Category II.i as it informs clinical management for cancer, a critical disease.	IIa
Cognitive therapy MDSW (without feedback loop)	<ul style="list-style-type: none"> A specialist determines the necessary cognitive therapy. Based on the outcome provided by the MDSW. 	Rule 11(a)	IMDRF Risk Category II.ii as the healthcare situation is serious and the significance of the information is to “drive clinical management”.	IIa

* Descriptions in guidance are more comprehensive.

		Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy		
		High Treat or diagnose ~ IMDRF 5.1.1	Medium Drive clinical management ~ IMDRF 5.1.2	Low Informs clinical management (everything else)
State of Healthcare situation or patient condition	Critical situation or patient condition ~ IMDRF 5.2.1	Class III Category IV.i	Class IIb Category III.i	Class IIa Category II.i
	Serious situation or patient condition ~ IMDRF 5.2.2	Class IIb Category III.ii	Class IIa Category II.ii	Class IIa Category I.ii
	Non-serious situation or patient condition (everything else)	Class IIa Category II.iii	Class IIa Category I.iii	Class IIa Category I.i

NOTE: Classification examples in Annex IV are provided for guidance purposes and aim to illustrate how a particular rule may be applied to a device. The indicated classification in the example is not a confirmation of the final classification of the device, as other rules must also be considered.

Criterium	Relevant part of guidance	Examples / Notes
<p>Subrule 11b) <i>Monitor physiological processes</i></p>	<p>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.</p> <p>MDSW that is intended to monitor physiological processes will, under most circumstances, provide “information which is used to take decisions with diagnosis or therapeutic purposes and hence fall under sub-rule 11a.</p> <p>Sub-rule 11b) should therefore be considered as a specific rule for MDSW intended only for monitoring purposes. Sub-rule 11b) was introduced to ensure that MDSW which has the same intended purpose as (hardware) devices which would fall under rule 10, third indent, are in the same risk class.</p> <p>However, this sub rule applies to MDSW intended to be used for monitoring any/all physiological processes and not just vital physiological processes (equivalent to rule 10, third indent).</p>	<p>Vital physiological processes and parameters include, for example,</p> <ul style="list-style-type: none"> • respiration, • heart rate, • cerebral functions, • blood gases, • blood pressure, • body temperature.
<p>Subrule 11c) <i>All other MDSW</i></p>	<p>Sub-rule 11c) implies that all other MDSW is classified as class I.</p>	

Option	Description (intended use)	Relevant rule	Proposed classification
Monitoring of vital physiological processes	<ul style="list-style-type: none"> Used for continuous surveillance of vital physiological processes. In anaesthesia, intensive care or emergency care. 	Rule 11(b)	IIb
Monitoring of non-vital physiological processes	<ul style="list-style-type: none"> Monitor physiological processes that are not considered to be vital. Obtain readings of vital physiological signals in routine check-ups including monitoring at home. 	Rule 11(b)	IIa
Support of conception	<ul style="list-style-type: none"> Support conception by calculating the user's fertility status. Based on a validated statistical algorithm. User inputs health data including basal body temperature (BBT) and menstruation days to track and predict ovulation. The fertility status of the current day is reflected by one of three indicator lights: red (fertile), green (infertile) or yellow (learning phase/cycle fluctuation). 	Rule 11(c)	I

* Descriptions in guidance are more comprehensive.

NOTE: Classification examples in Annex IV are provided for guidance purposes and aim to illustrate how a particular rule may be applied to a device. The indicated classification in the example is not a confirmation of the final classification of the device, as other rules must also be considered.

Criterion

Relevant part of guidance

Examples / Notes

Rule 12

Active devices intended to administer and/or remove substances

As software devices cannot physically administer and/or remove substances, please refer to the implementation rule 3.3 of Annex VIII for MDSW covered by this rule.

Rule 13

All other active devices

Taking into consideration all implementing and classification rules applicable to active devices, if no other rule applies, all other active devices are **class I**.

Specific implementation or classification rules for active Annex XVI devices (which might also include software) are expected to be provided together with the relevant Common Specifications for those devices.

Rule 15

Devices used for contraception

Rule 15 applies to devices used for contraception or prevention of the transmission of sexually transmitted diseases. Software used for contraception will be classified as **class IIb**.

Rule 22

Closed loop systems

Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device are classified as **class III**.

See also implementing rule 3.3 for MDSW covered by this rule.

Examples:

- Closed loop systems
- Automated external defibrillators

Option	Description (intended use)	Relevant rule	Rationale	Proposed classification
Ambulatory respiratory systems	<ul style="list-style-type: none"> Ambulatory respiratory ventilation systems MDSW. Intended for long-term use (e.g. at home). Alerts the user/operator to any disconnection or deviation to the programmed respiratory volume. 	Rule 9		IIb
Electronic thermometers / stethoscopes	<ul style="list-style-type: none"> Active devices, such as electronic thermometers and stethoscopes. Which include MDSW intended for direct diagnosis. 	Rule 10, third indent	Body temperature and heart rate are considered decisive information for diagnosis (implementing rule 3.7), where the nature of the variations of these parameters would not result in immediate danger to the patient.	IIa
Cognitive therapy MDSW (feedback loop)	<ul style="list-style-type: none"> Cognitive therapy MDSW. Includes a diagnostic function which is intended to feed back to the software to determine follow-up therapy, e.g. software adapts treatment of depression based on diagnostic feedback. 	Rule 22		III

* Descriptions in guidance are more comprehensive.

NOTE: Classification examples in Annex IV are provided for guidance purposes and aim to illustrate how a particular rule may be applied to a device. The indicated classification in the example is not a confirmation of the final classification of the device, as other rules must also be considered.

Rule	Relevant part of guidance	Examples / Notes
Software, which drives or influences the use of a device	Annex VIII, rule 3.3: Software, which drives or influences the use of a device, shall fall within the same class as the device	This rule should also be considered at least as an orientation for finding the correct (minimum) classification of software which is placed on the market in combination with a (hardware) medical device. Therefore, Medical Device Software that both achieves its own intended purpose and also drives or influences the use of a (hardware) device for a medical purpose is classified on its own, based on the intended purpose achieved. In such a case, however, the risk class shall not be lower than the risk class of the hardware medical device.
Software independent of any other device	Annex VIII, rule 3.3: If software is independent of any other device, it shall be classified in its own right	
Several (sub)rules	Annex VIII, 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 higher classification will apply'	<ul style="list-style-type: none"> • Melanoma image analysis software intended to be used with a near-infrared laser light scanner, which is considered class IIa per Rule 10. The software “drives or influences the use of” the nearinfrared laser light scanner as it is intended to take control of the scanner by letting it execute proprietary multi-exposure programs for the detection of melanoma. As such, implementing rule 3.3 applies. However, Rule 11 would also apply based on the intended medical purpose of the software e.g. cancer diagnosis. The MDSW would be classified as class III based on Rule 11 (see section Classification Rules) and per implementing rule 3.5 of Annex VIII.
Rules to be considered for MDSW	As software is defined as an active device, for the classification of active (hardware) devices, which also includes MDSW providing information for patient management, Rules 9, 10, 11, 12, 13, 15 and 22 of Annex VIII MDR 2017/745 should be considered. In line with implementation rule 3.5, the strictest rule or sub-rule should hence apply. MDSW should be classified in the same way, regardless of the software's location or the type of interconnection between the software and a (hardware) device.	

Rule

Relevant part of guidance

Examples / Notes

Rule 1.4
Software, which drives or influences the use of a device

Annex VIII, rule 1.4: Software, which drives or influences the use of a device, shall fall within the same class as the device.

Implementing rule 1.4 is only applicable for software which drives or influences the use of an in vitro diagnostic medical device. This rule should also be considered at least as an orientation for finding the right (minimum) classification of software which is placed on the market in combination with a (hardware) medical device.

Examples:

- Software that is exclusively intended to drive or influence the use of an instrument intended by the manufacturer specifically to be used for in vitro diagnostic procedures is classified in the same class as the instrument.
- A software that is intended to operate (driving) a C-reactive protein (CRP) measuring analyser from a remote location is classified in the same class as the analyser i.e. if the analyser is classified as class A then the software operating the analyser falls into Class A.
- MDSW that integrates genotype of multiple genes to predict risk a disease or medical condition developing or recurring; this is an independent IVD MDSW and is classified on its own.

Rule 1.4
Software independent of any other device

Annex VIII, rule 1.4: If software is independent of any other device, it shall be classified in its own right.

Rule 1.9
Several classification rules

Annex VIII, rule 1.9: if several classification rules apply to the same device based on the devices' intended purpose, the rule resulting in higher classification will apply. To classify In Vitro Diagnostic Medical Device Software (IVD MDSW) which is independent of any other device, see the MDCG Guidance on Classification of IVDs when available at: https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en.

Proper classification of MDSW under IVDR

In determining the proper classification of MDSW under the IVDR, the manufacturer shall consider all classification and implementing rules of Annex VIII of the IVD Regulation (EU) 2017/746.

As spelled out by Implementing Rule 1.1 of Annex VIII of Regulation (EU) 2017/746, the application of the classification rules shall be governed by the intended purpose of the MDSW.

Guidance on the application of the IVD classification and implementing rules can be found at https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en.

- Software intended to be installed on a fully automated enzyme-linked immunosorbent assay (ELISA) analyser, and intended to determine the Human HbA1c concentration in serum from the results obtained with a Human HbA1c ELISA, intended to screen for and diagnose diabetes and monitor diabetic patients, should be in class C per Rule 3(k).
- Software within a PAP stain automated cervical cytology screening system, intended to classify the PAP cervical smear as either normal or suspicious, should be in class C per Rule 3(h).
- Software for the interpretation of automated readings of line immunoassay for the confirmation and determination of antibodies to HIV-1, HIV-1 group O and HIV-2 in human serum and plasma, should be in class D per Rule 1.
- Software that uses maternal parameters such as age, concentration of serum markers and information obtained through foetal ultrasound examination for evaluating the risk of trisomy 21, should be in class C per Rule 3(l).

Overig

Option	Relevant part of guidance	Examples / Notes
<p>1) As a medical devices in its own right</p>	<p>MDSW may be placed on the market or put into service in its own right. MDSW placed on the market as a device or put into service in its own right shall undergo an appropriate regulatory process that shall take into consideration the qualification, classification and intended purpose of the MDSW.</p>	<ul style="list-style-type: none"> • MDSW intended to be installed on a fully automated enzyme-linked immunosorbent assay (ELISA) analyser, and intended to determine the Human HbA1c concentration in serum from the results obtained with a Human HbA1c ELISA. • MDSW app that provides a 10-year risk of cardiovascular disease from data input by a lay user. • MDSW app that calculates anticoagulant dosage for patients in oral anticoagulant therapy, from INR test results input by IVD instruments and other manually entered patient data. • MDSW app that analyses digital images of stained HEp-2 cell substrates from a microscope, for detecting antinuclear antibody (ANA) patterns to guide confirmatory testing useful in elucidating a specific clinical diagnosis or prognosis.
<p>2) As an integral component/part of a device</p>	<p>MDSW that is placed on the market or put into service solely as an integral component/part of a (hardware) device may not have to undergo its own regulatory process.²⁶ In this case, the MDSW shall be assessed through the regulatory process applied to the device as a whole, as it is placed on the market.</p> <p>Applying the classification rules to these hardware devices, which is de-facto a combination of the hardware device and the MDSW, requires careful consideration of the intended purpose of the MDSW. This must also be analysed when later changes to the MDSW are done.</p>	<ul style="list-style-type: none"> • MDSW contained within a blood gas analyser that enables a user to run tests on the instrument. • MDSW that is part of a handheld hardware device intended for near-patient testing (POCT: point of care testing) for the determination of the blood glucose concentration. • A fully automated enzyme-linked immunosorbent assay (ELISA) analyser, composed of hardware and MDSW, intended to determine the Human HbA1c concentration in serum from the results obtained with a Human HbA1c ELISA. • MDSW that is part of a pulse oximeter intended to digitally filter the noise from low perfusion performance and motion artefacts, to calculate the ratio of red light/infrared light and to use a lookup table based on Beer-Lambert law to convert the ratio into the oxygen saturation in a person’s blood (SpO2).

NOTE: MDSW could be independent under both scenarios described in 6.1 and 6.2, despite the presentation in which it is placed on the market.

Option	Relevant part of guidance	Examples / Notes
<p>Modules</p>	<p>Some medical device software may be segregated into a number of applications where each of these applications is correlated with a module. Some of these modules have a medical purpose, some not. This raises the issue as to whether the whole product can be CE marked when not all applications have a medical purpose.</p> <p>Computer programmes used in healthcare can have applications which consist of both medical device and non-medical device modules.</p> <p>The modules which are subject to the Medical Devices Regulations (figure 1 and 2) must comply with the requirements of the medical device regulations and must carry the CE marking. The non-medical device modules are not subject to the requirements for medical devices. It is the obligation of the manufacturer to identify the boundaries and the interfaces of the different modules.</p> <p>The boundaries of the modules which are subject to the medical device regulations should be clearly identified by the manufacturer based on the intended use. If the modules which are subject to the medical device regulations are intended for use in combination with other modules of the whole software structure, other devices or equipment, the whole combination, including the connection system, must be safe and must not impair the specified performances of the modules which are subject to the medical device regulations.</p>	<p>Such modules may be intended to cover many needs, e.g.:</p> <ul style="list-style-type: none"> • Collect and maintain administrative patient data; • Keep on file the medical history of the patient; • Invoicing and other accounting functions; • Provide a link to the social security system for reimbursement; • Provide a link to drug prescription systems (with possible link to drug dispensing outlets); • Provide expert system assistance for medical decision making (e.g. radiotherapy dose planner).
<p>Consideration of changes to an MDSW</p>	<p>Manufacturers shall evaluate the potential impact of any changes to the function, intended use, essential design, and manufacturing characteristics on the software’s qualification as MDSW and its classification (including the classification of the combination of the MDSW with another medical device).</p> <p>It is to be noted that a change to or the addition of functionality to a software may lead it to be qualified as MDSW, or a revision of the classification of the MDSW. Similarly, a module that is added to a software might be qualified as a MDSW on its own.</p> <p>When determining the risk class of a combination of a modified MDSW and a medical device, the intended purpose and functionality of that (new) combination must be considered.</p> <p>Note: For all MDSW, the manufacturer shall ensure safety and performance throughout the lifecycle of the software, through a continuous process of clinical and/or performance evaluation and risk management.</p>	

Vragen vorige
veldbijeenkomst

Vragen veldbijeenkomst 6 november 2018

Vraag

- Wat zijn accessoires?
- Gelden de regels (10 en 11) ook voor stand-alone software?
- Vallen EPD's onder de MDR?
- Vallen HIS-en onder de MDR?
- Hoe moet ik regel 11 interpreteren?
- Welke klasse worden: HIS, ZIS, AIS, LIS, EVS-en?
- Is vervanging van papier ook een MH?

Relevante paragraaf in guidance

Hoofdstuk 2 en 3.3

Hoofdstuk 2

Bijlage I, c.1.)

Bijlage I, c.1.)

Hoofdstuk 5

Hoofdstuk 5 en Bijlage I

Hoofdstuk 3.1

