

'medical device'

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

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

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

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

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

Article 2(1), MDR

'accessory'

for a medical device' means 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);

Article 2(2), MDR

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.

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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:

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

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software may run on different operating systems or in virtual environments. These operating systems or virtual environments do not impact the qualification criteria.

the risk of harm to patients, users of the software, or any other person, related to the use of the software within healthcare, including a possible malfunction is not a criterion on whether the software qualifies as a medical device

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Medical Purpose

- has a medical purpose or is qualified as an accessory for a medical device
- Directly controls a medical device
- Provides immediate decision-triggering information
- Provides support for healthcare professionals
- SW does process, create or modify medical information if that is governed by a medical purpose.
- SW alters the representation of data for a medical purpose
- Searching image for findings that support a clinical hypothesis as to the diagnosis or evaluation of therapy
- the software does perform an action on data, or performs an action beyond storage, archival, communication, simple search, lossless compression
- action for the benefit of individual patients
- Decision support software using patient specific data
- Computer Aided Detection systems that are intended to provide information that may suggest or exclude medical conditions

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Example

- ECG interpretation software
- SW 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
- 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
- MDSW that is intended to operate a point of care test from a remote location
- 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.
- 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.
- Radiotherapy treatment planning systems are intended to calculate the dosage of ionizing irradiation to be applied to a specific patient.
- Drug planning systems (e.g. chemotherapy) are intended to calculate the drug dosage to be administered to a specific patient
- systems that would be able to automatically analyse x-ray images or interpret ECGs.
- An image viewer with functionality for diagnosis based on digital images;
- A medication module
- A software module generating alarms based on the monitoring and analysis of patient specific physiological parameters
- web system for monitoring of active implants such as pacemakers or Intra Cardiac Defibrillators (ICDs)

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No Medical Purpose

- Search: retrieval of records by matching record metadata against record search criteria or to the retrieval of information
- SW intended to be used for non medical purposes but used in health care facilities
- Pure e-mailing, web or voice messaging, data parsing, word processing, back up is not considered a medical purpose by itself
- 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
- Hospital Information Systems, that support the process of patient management.
- Information Systems that are intended only to transfer, store, convert, format, archive data
- software intended to modify the representation of available in vitro diagnostic medical device results

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Example

- Library functions
- SW for invoicing or staff planning
- compression procedure that allows the exact reconstruction of the original data
- Patient admission, scheduling patient appointments, insurance and billing purposes
- Electronic patient record systems
- A CIS/PDMS intended to store and transfer patient information generated in association with the patient's intensive care treatment that does not provide additional information that contributes to diagnosis, therapy and follow-up
- Communication systems
- Software for the monitoring of medical devices in hospital systems for the purpose of maintenance and repair
- 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
- Laboratory Information Systems (LIS) and Work Area Managers (WAM)

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