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MEDICAL DEVICES: Guidance document
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Qualification and Classification of stand alone software

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GUIDELINES ON THE QUALIFICATION AND CLASSIFICATION OF STAND ALONE SOFTWARE USED IN HEALTHCARE WITHIN THE REGULATORY FRAMEWORK OF MEDICAL DEVICES

Foreword

The present guidelines are part of a set of guidelines relating to questions of application of the EU legislation on medical devices. They are legally not binding.

The guidelines have been carefully drafted through a process of consultation of the various interested parties (Competent Authorities, Commission services, industry and Notified Bodies in the medical device sector) during which intermediate drafts were circulated and comments were taken up in the document where appropriate.

Therefore this document reflects positions taken in particular by the aforementioned interested parties.

Due to the participation of the aforementioned interested parties, it is anticipated that these guidelines will be followed within the Member States and, therefore, ensure uniform application of relevant Directive provisions.

Content

Introduction

The purpose of this document is to define the criteria for the qualification of stand alone software, when used in healthcare setting, as a medical device and the application of the classification criteria to such software.

This document only deals with stand alone software and provides some illustrative examples.

Software incorporated in medical devices is outside the scope of this guideline.

Directive 2007/47/EC[1] amended the definition of the term "medical device" used in Directives 90/385/EEC[2] and 93/42/EEC[3].

Recital 6 of Directive 2007/47/EC states that "it is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Stand alone software for general purposes when used in a healthcare setting is not a medical device."

Stand alone software shall be qualified as an *in vitro* diagnostic (IVD) medical device or as an accessory to an IVD provided that it satisfies the definition of an IVD or of an accessory to an IVD as set out in Directive 98/79/EC[4].

[1] OJ L 247, 5.9.2007, p. 21
[2] OJ L 189, 20.7.1990, p. 17
[3] OJ L 169, 12.7.1993, p. 1
[4] OJ L 331, 7.12.1998, p. 1

1. Definitions and abbreviations

- **Intended purpose:**

  'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the *labelling*, in the *instructions* and/or in *promotional materials*.[5]

- **Accessory:**

  'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device[6].

- **Placing on the market:**

  'placing on the market' means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished[7].

- **Putting into service:**

  'putting into service' means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose[8].

- **Medical Device:**

[5] Article 1(2)g of Directive 93/42/EEC
[6] Article 1(2)b of Directive 93/42/EEC
[7] Article 1(2)h of Directive 93/42/EEC
[8] Article 1(2)i of Directive 93/42/EEC

‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
— investigation, replacement or modification of the anatomy or of a physiological process,
— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means[9];

- ***In Vitro* diagnostic medical device:**

  ‘in vitro diagnostic medical device’ means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

— concerning a physiological or pathological state, or
— concerning a congenital abnormality, or
— to determine the safety and compatibility with potential recipients, or
— to monitor therapeutic measures[10].

- **Active medical device:**

  any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient without any significant change, are not considered to be active medical devices. **Stand alone software is considered to be an active medical device[11]**.

- **Active implantable medical device:**

[9] Article 1(2)a of Directive 93/42/EEC
[10] Article 1(2)b of Directive 98/79/EC

‘active implantable medical device’ means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure[12].

- **Active therapeutical device:**

  Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap[13].

- **Active device for diagnosis:**

  Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities[14].

- **Stand alone software:**

  For the purpose of this guideline ‘stand alone software’ means software which is not incorporated in a medical device at the time of its placing on the market or its making available.

- **Expert function software:**

  For the purpose of this document, the ‘expert function software’ means software which is able to analyse existing information to generate new specific information according to the intended use of the software.

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[11] Annex IX, section 1.4, of Directive 93/42/EEC
[12] Article 1(2)c of Directive 90/385/EEC
[13] Annex IX, section 1.5, of Directive 93/42/EEC
[14] Annex IX, section 1.6, of Directive 93/42/EEC

2. Qualification

2.1 Introduction to criteria for qualification

Stand alone software must have a medical purpose to be qualified as medical device. It should be noted that only the intended purpose as described by the manufacturer of the product is relevant for the qualification and classification of any device and not by virtue of the way it may be called.
Stand alone software that does not meet the definition of a medical device or of an IVD medical device but is intended by the manufacturer to be an accessory to a medical device, or an IVD medical device, falls respectively under the scope of Directive 93/42/EEC or Directive 98/79/EC.
It is to be noted that to be qualified as an IVD medical device, stand alone software must first fulfil the definition of a medical device.
Where a given product does not fall under the definition of medical device, or is excluded by the scope of the Directives, other Community and/or national legislation may be applicable.

2.1.1 Qualification criteria as medical device

Software can be used for a large variety of medical purposes[15]. In that respect the arguments do not differ from those used for other medical devices.
Stand alone software can directly control an apparatus (e.g. radiotherapy treatment), can provide immediate decision triggering information (e.g. blood glucose meters), or can provide support for healthcare professionals (e.g. ECG interpretation).
Not all stand alone software used within healthcare can be qualified as a medical device.
Stand alone software may run on different operating systems or in virtual environments.
These operating systems or virtual environments do not impact the qualification criteria.
Stand alone software might also be an accessory of a medical device.
The risk related to a malfunction of the stand alone software used within healthcare is in itself not a criterion for its qualification or not as a medical device.

[15] MEDDEV 2.1/1: Definitions of "medical devices", "accessory" and "manufacturer"

It is, therefore, necessary to clarify some criteria for the qualification of stand alone software as medical devices.

The decision diagram (Figure 1) gives some guidance regarding the necessary steps to qualify stand alone software as medical device.

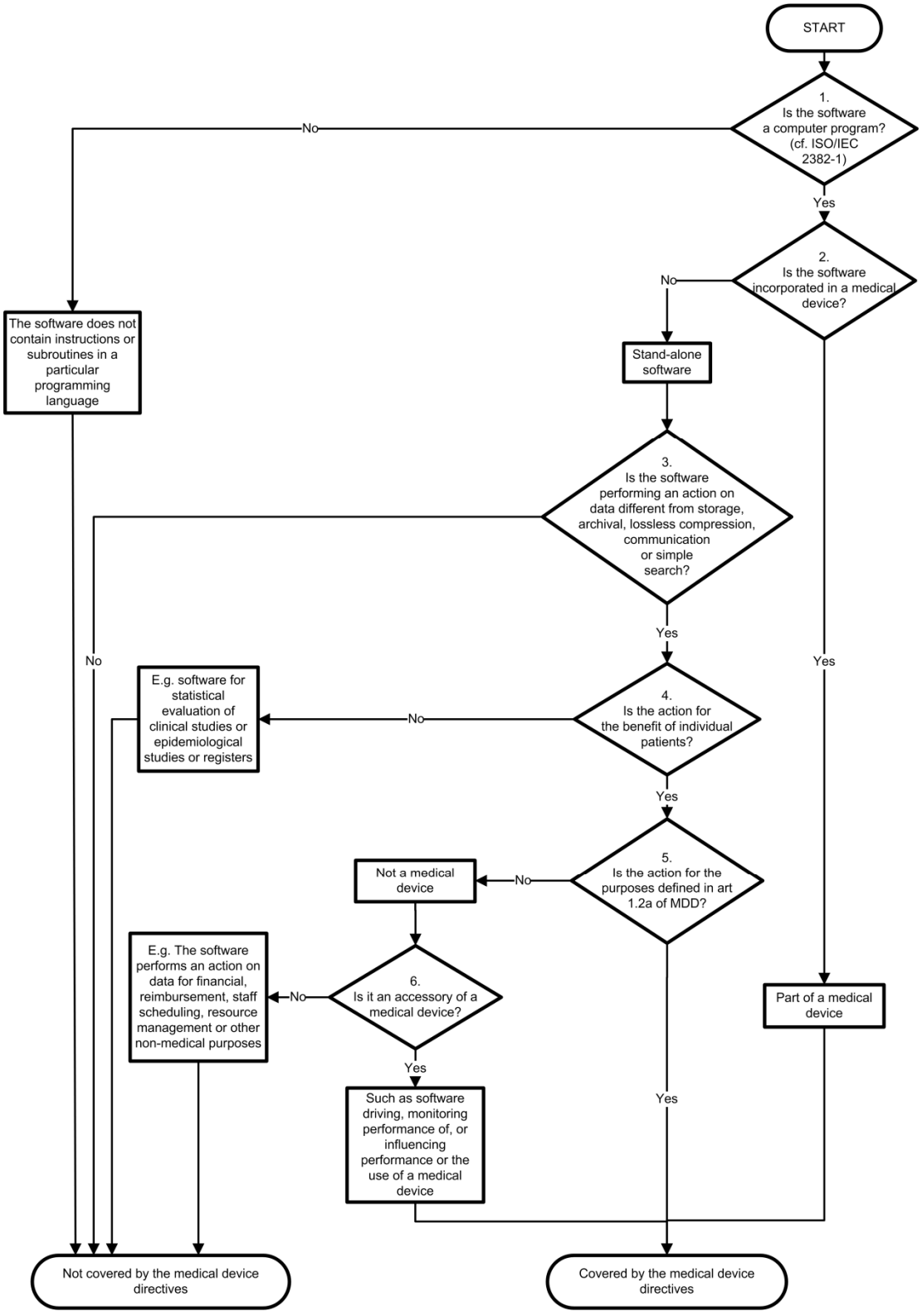

Figure 1: A decision diagram to assist qualification of software as medical device.

Decision step 1: if the stand alone software is a computer program[16], then it may be a medical device. If the software is not a computer program, then it is a digital document and therefore not a medical device.

Examples of computer programs are software applications, macros, scripts, dynamically linked libraries, batch files, style sheets and any document containing active formatting or filtering instructions. Examples of digital documents are image files, DICOM files, digital ECG recordings, numerical results from tests and electronic health records (EHR).

> ***Note*:** While the EHR is usually not a computer program, the EHR system, *i.e.* the software writing, retrieving, representing, etc. the information in the EHR, is a computer program. This is similar as for DICOM files vs. a PACS.

Decision step 2: if the software is incorporated into a medical device rather than stand alone software, it must be considered as part of that medical device in the regulatory process of that device. If it is stand alone software[17], proceed to decision step 3.

Decision step 3: if the software does not perform an action on data, or performs an action limited to storage, archival, communication[18], 'simple search' or lossless compression (*i.e.* using a compression procedure that allows the exact reconstruction of the original data) it is not a medical device.
Altering the representation of data for embellishment purposes does not make the software a medical device. In other cases, including where the software alters the representation of data for a medical purpose, it could be a medical device.

'Simple search' refers to the retrieval of records by matching record metadata against record search criteria, *e.g.* library functions. Simple search does not include software which provides interpretative search results, *e.g.* to identify medical findings in health records or on medical images.

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[16] A computer program is defined as syntactic unit that conforms to the rules of a particular programming language and that is composed of declarations and statements or instructions needed to solve a certain function, task, or problem. Source: ISO/IEC 2382-1:1993 (01.05.01) Information technology -- Vocabulary -- Part 1: Fundamental terms.
[17] See chapter 2 - Definitions and Abbreviations for a definition of stand alone software.
[18] Communication: The flow of information from one point, known as the source, to another, the receiver; Source: IEEE 610.10-1994.

Software which is intended to create or modify medical information might be qualified as a medical device. If such alterations are made to facilitate the perceptual and/or interpretative tasks performed by the healthcare professionals when reviewing medical information, (*e.g.* when searching the image for findings that support a clinical hypothesis as to the diagnosis or evolution of therapy) the software could be a medical device.

> ***Note***: the display of images usually involves alterations to the representation because techniques are used such as contrast stretching, edge enhancement, gray scale manipulation, smoothing, sharpening, zooming and re-sizing. Alterations may include reconstruction, lossy compression, filtering, pattern recognition, modelling, interpolation, transformation, classification (*e.g.* scoring of tumors against specific criteria), segmentation, registration (*e.g.* mapping a data set to a model or atlas or to another data set, *e.g.* registering an MRI image on a CT image), calculations, quantification, qualification (*e.g.* comparison of data against references), rendering, visualisation, interpretation, etc..

Decision step 4: an example of software for the benefit of individual patients is software intended to be used for the evaluation of patient data to support or influence the medical care provided to that patient. Examples of software which are not considered as being for the benefit of individual patients are those which aggregate population data, provide generic diagnostic or treatment pathways, scientific literature, medical atlases, models and templates as well as software for epidemiologic studies or registers.

Decision step 5: if the manufacturer specifically intends the software to be used for any of the purposes listed in Article 1(2)a of Directive 93/42/EEC, then the software shall be qualified as a medical device.
However, if only a non-medical purpose is intended by the manufacturer, such as invoicing or staff planning, it is not a medical device.

> ***Note***: A task such as e-mailing, web or voice messaging, data parsing, word processing, and back-up is by itself not considered as being a medical purpose, according to Directive 93/42/EEC.

Decision step 6: if the software is an accessory to a medical device, it is not a medical device, but it falls under Directive 93/42/EEC.
The legal definition of 'putting into service' requires that a device is made available to the final user/operator as being ready for use on the Community market. Software made available to the user over the internet (directly or via download) or via *in vitro* diagnostic commercial services, which is qualified as a medical device, is subject to the medical devices directives.

2.1.2 Qualification criteria as IVD medical device

Stand alone software fulfilling the definition of medical device and intended to be used for the purpose of providing information derived from *in vitro* examination of a specimen derived from the human body falls under Directive 98/79/EC.

Provided that stand alone software is intended specifically by its manufacturer to be used together with an IVD medical device to enable that device to be used in accordance with its intended purpose, this stand alone falls under the scope of the IVD Directive and shall be treated as an IVD device in its own right.

Example: analysis and interpretation of the optical density delivered by an ELISA reader, line or spot pattern of a blot.

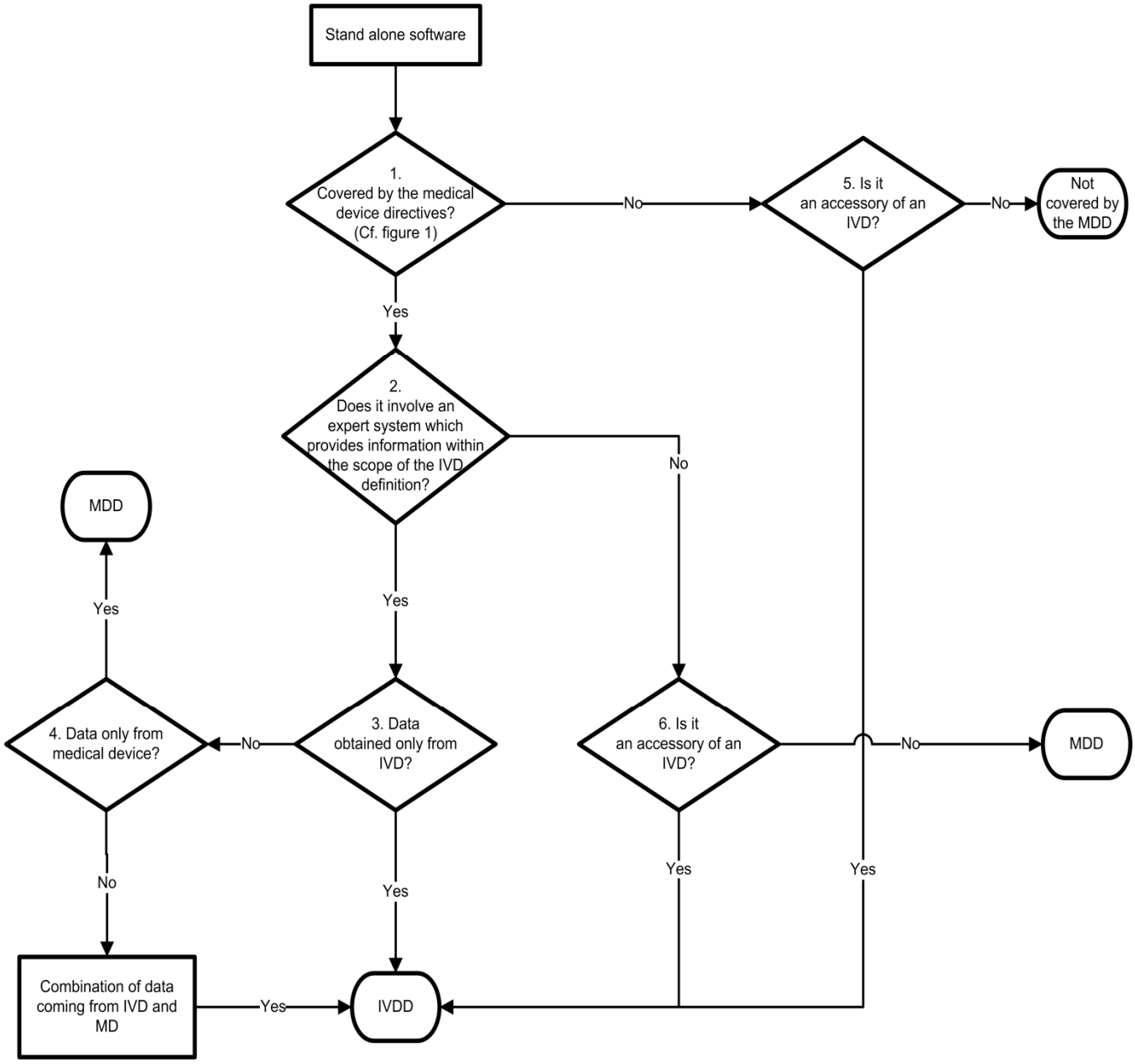

Figure 2: Decision diagram to assist qualification of stand alone software as IVD device.

Decision step 1: please, start by making reference to figure 1.

Decision step 2: Stand alone software with expert function:
This stand alone software might provide information on *e.g.* differential diagnosis, prediction of the risks of developing a disease, prediction of the percentage of efficiency or failure (*e.g.* of a treatment), identifying species of bacteria.

It may qualify differently based on the fact that the existing information is obtained from either IVD medical devices, other medical devices or both.

Decision step 3:
if the information provided by the software is based on data obtained from IVD medical devices only, the software is an IVD medical device or an accessory of an IVD medical device.

If data are obtained from both IVD medical devices and from medical devices are analysed together for the purpose of providing information according to the definition of an IVD medical device, this software is an IVD medical device (*e.g.* evaluation of the risk of Trisomy 21).

As described in Annex I B 3.1, for stand alone software that is intended for use in combination with other devices or equipment, the whole combination must be safe and must not impair the specified performances of the devices. As a concretization of these general requirements of the IVDD; the clinical evidence of this combined intended use of medical devices shall be performed for each of the medical devices from which the data is obtained.

Decision step 4: if the information provided by the software is based on data obtained from medical devices only, the software would be a medical device.

> ***Note 1***: Stand alone software that only collects results obtained from one or several IVD devices (directly and/or manually), and transmits without modification this information to a centralised database (*e.g.* Laboratory Information Management System, LIMS) or to healthcare providers is not an IVD medical device.

Note 2: Stand alone software (*e.g.* LIMS) managing the feed-back to an IVD (*e.g.* retesting of samples) based on collected IVD results is not an IVD medical device as per decision step 5 of **figure 1**.

Note 3: Software intended to modify the representation of available IVD results is not considered as an IVD medical device as per decision step 5 of **Figure 1**, *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.

Note 4: Stand alone software intended for archiving patient results or for transferring results from the home environment to the healthcare provider is not an IVD device.

3. Classification of stand alone software

Stand alone software that meets the definition of a medical device shall be considered as an **active medical device.**[19] This means that rules 9, 10, 11 and 12 of Annex IX to Directive 93/42/EEC may apply.

Clause 2.3 of the implementing rules in Annex IX states that software 'which drives a medical device or influences the use of a device, falls automatically into the same class[20], as the device it drives.

3.1 Software as active therapeutic medical devices

According to rule 9 of Annex IX to Directive 93/42/EEC, all active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb.

[19] Annex IX, section 1.4, of Directive 93/42/EEC
[20] Annex IX, section 2.3, of Directive 93/42/EEC

All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb according to implementing rule 2.3.

Example: radiotherapy planning system used to calculate the dose of ionizing radiation to be administered to the patient, insulin dosage planning stand alone software.

3.1.1 Software intended for diagnosis or therapy

According to rule 10 of Annex IX to Directive 93/42/EEC, active devices intended for diagnosis are in Class IIa:

- if they are intended to image in vivo distribution of radiopharmaceuticals.

Example: Clinical application of registration of PET datasets on CT datasets for follow-up tumour treatment.

- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb.

Examples: - Software for the presentation of the heart rate or other physiological parameters during routine checkups (Class IIa);
- Software for the presentation of the heart rate or other physiological parameters for intensive care monitoring (Class IIb).

Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.

Rule 11 of Annex IX to Directive 93/42/EEC states that all active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa, unless this is done in a manner:

- that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class IIb.

Stand alone software which drives such medical device or influences the use of such device falls automatically into the same class as the device it drives (implementing rule 2.3).

Rule 12 of Annex IX to Directive 93/42/EEC states that all other active devices are in Class I. Class I stand alone software can also come with a measuring function.

Example: orthopaedic planning software to measure interpedicular distance or sagittal diameter of the spinal canal.

3.2 IVDD and software in conjunction with in-vitro diagnostic devices

Stand alone software qualified as *in vitro* diagnostic medical devices should be regulated according to Directive 98/79/EC.

When intended for evaluating the risk of trisomy 21, such software are specifically mentioned in Annex II List B of Directive 98/79/EC and shall therefore follow the conformity assessment procedure described in Article 9 of this Directive.

4. Modules

Some stand alone software may break down into a significant number of applications for the user where each of these applications is correlated with a module. Some of these modules have a medical purpose, some not.

Such software may be intended to cover many needs, *e.g.*:

- Collect and maintain administrative patient details;
- 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).

This raises the issue as to whether the whole product can be CE marked when not all applications have a medical purpose.

Computer programmes used in healthcare mostly have applications which consist of both medical device and non-medical device modules.

The modules which are subject to the medical device Directives (Figures 1 and 2) must comply with the requirements of the medical device Directives 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.

The boundaries of the modules which are subject to the medical device Directives should be clearly identified by the manufacturer and based on the intended use.

If the modules which are subject to the medical device Directives 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 Directives[21].

[21] *i.e.* essential requirements 3.1 of Directive 98/79/EC and essential requirements 9.1 of Directive 93/42/EEC

Annex 1: Illustrative examples of qualification for software used in the healthcare environment

The sector of software pursuing a medical purpose is rapidly evolving.

The list of examples provided below is not exhaustive.

The examples have been drafted in the light of today's state of the art, in order to give the reader a better understanding of the application of the principles set out in the guideline.

In the light of the technological progress, further examples will be regularly added into the Manual on borderline and classification in the Community regulatory framework for medical devices[22].

a) Hospital Information Systems

Hospital Information Systems mean, in this context, systems that support the process of patient management. Typically they are intended for patient admission, for scheduling patient appointments, for insurance and billing purposes.

These Hospital Information Systems are not qualified as medical devices. However they may be used with additional modules, as described hereafter.

These modules might be qualified in their own right as medical devices.

b) Decision Support Software

[22] http://ec.europa.eu/health/medical-devices/files/wg_minutes_member_lists/borderline_manual_ol_en.pdf

In general, they are computer based tools which combine medical knowledge databases and algorithms with patient specific data. They are intended to provide healthcare professionals and/or users with recommendations for diagnosis, prognosis, monitoring and treatment of individual patients.

Based on steps 3, 4, and 5 of Figure 1, they are qualified as medical devices.

- Radiotherapy treatment planning systems[23] 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 (*e.g.:* Chemotherapy) planning systems 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 and, therefore, qualified as medical devices. For example, such systems would be able to automatically read x-ray images or interpret ECGs.

c) Information Systems

Information systems that are intended only to store, archive and transfer data are not qualified as medical devices in themselves.

However they may be used with additional modules. These modules might be qualified in their own right as medical devices.

c.1) Electronic Patient Record Systems

Electronic patient record systems are intended to store and transfer electronic patient records. They archive all kinds of documents and data related to a specific patient. The electronic patient records themselves are not computer programs, therefore, they should not be

[23] See EN 62083 « Requirements for the safety of radiotherapy treatment planning systems »

qualified as a medical device *i.e.* an electronic patient record that simply replaces a patient's paper file does not meet the definition of a medical device. The modules used with electronic patient record system modules that might be qualified in their own right as medical devices are for example:

- an image viewer with functionality for diagnosis based on digital images;

- a medication module.

c.1.1) Clinical Information Systems – CIS / Patient Data Management Systems - PDMS

A CIS/PDMS is a software based system primarily intended for *e.g.* intensive care units to store and transfer patient information generated in association with the patient's intensive care treatment.

Usually the system contains information such as patient identification, vital intensive care parameters and other documented clinical observations.

These CIS/PDMS are not qualified as medical devices.

Modules that are intended to provide additional information that contributes to diagnosis, therapy and follow-up (*e.g.* generate alarms) are qualified as medical devices.

c.1.2) Pre-hospital Electrocardiograph (ECG) System

A system for managing pre-hospital ECG is a software based system intended for ambulance services to store and transfer information from patients, which are connected to an ECG monitor, to a doctor at remote location. Usually the system contains information about patient identification, vital parameters and other documented clinical observations. These Pre-hospital Electrocardiograph (ECG) Systems are not qualified as medical devices.

Modules that provide patient's treatment information to the paramedics in the ambulance to start the patient's treatment while the patient is being transported are qualified as Medical Devices.

c.1.3) Radiological Information System (RIS)

A RIS is a software based database used in radiology departments to store and transfer radiological images and patient information. The system normally includes functions for patient identification, scheduling, examination results and imaging identification details.

These Radiological Information Systems are not qualified as medical devices.

However, if such a system includes additional modules they might qualify as medical devices according to step 3 of of **Figure 1**.

c.1.4) Picture Archive Communication System (PACS)

The Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices[24], already addresses the issue.

d) Communication Systems

The healthcare sector uses communication systems (*e.g.* email systems, mobile telecommunication systems, video communication systems, paging etc.) to transfer electronic information. Different types of messages are being sent such as prescriptions, referrals, images, patient records, etc.

Most of the communication systems handle other 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.

Communication systems are normally based on software for general purposes, and do not fall within the definition of a medical device.

Communication system modules might be used with other modules that might be qualified in their own right as medical devices.

Example: software generating alarms based on the monitoring and analysis of patient specific physiological parameters.

d.1) Telemedicine Systems

[24] http://ec.europa.eu/health/medical-devices/files/wg_minutes_member_lists/borderline_manual_ol_en.pdf

Telemedicine Systems are intended to allow monitoring and/or delivery of healthcare to patients at locations remote from where the healthcare professional is located.

d.1.1) Telesurgery

Telesurgery is intended to 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.

Telesurgery systems should be qualified as medical devices according to steps 3, 4, and 5 of **Figure 1**.

Remote control software used in combination with telesurgery robots is qualified as a medical device. Communication modules themselves are not medical devices.

Other modules that are intended to influence the surgery procedure are qualified as medical devices.

d.1.2) Video appointment software

Video appointment software is intended to perform remote consultations between clinics and patients. It does not fall under the Medical Devices Directives.

d.1.3) Home care monitoring, wired or mobile

The telecommunication system (mobile, wireless, wire, etc…) is not as such a medical device.

e) Web systems for monitoring of data

A web system for the 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:

Modules that are intended to monitor the medical performance of medical devices fall under the Medical Devices Directives.

This includes the clinical performance and failures that could affect medical performance of the device. One example of such product is a web system for monitoring of active implants such as pacemakers or Intra cardiac defibrillators (ICDs).

- Monitoring of non medical performance of medical devices:

Modules that are intended to monitor non medical performance of medical devices do not fall under the scope of Medical Devices Directives.

Example: software for the monitoring of medical devices in hospital systems for the purpose of maintenance and repair.

Software modules on server(s) might be qualified in their own right as medical devices depending on their intended purpose.

f) *In vitro* diagnostic (IVD) software: LIS & WAM

f.1) Laboratory Information Systems (LIS) and Work Area Managers (WAM)

Laboratory Information Systems (LIS) and Work Area Managers (WAM) mean, in this context, systems that support the process from patient sample to patient result. Typically they have pre-analytical functions for ordering, sorting and distribution of test samples.

The main task is the management and validation of incoming information obtained from IVD 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).

Finally the post analytical process takes care of communication of laboratory results, statistics and optional reporting to external databases.

The software normally supports the following functions:

- 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.

***Note*:** Software intended to modify the representation of available IVD results is not considered an IVD 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.

The results are available, readable and understandable without the intervention of the software.

Laboratory Information Systems (LIS) and Work Area Managers (WAM) are not qualified as medical devices in themselves.

However they may be used with additional modules. These modules might be qualified in their own right as medical devices.

f.2) Expert system

Where software is intended to capture and analyze together several results obtained for one patient by one or more IVD devices by means of *in vitro* examination of body samples (possibly combined with information from medical devices) to provide information falling within the definition of an IVD medical device, *e.g.* differential diagnosis, this software is considered as an IVD in itself.

Examples: - software that integrates genotype of multiple genes to predict risk of developing a disease or medical condition;

- software that uses an algorithm to characterize 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;

- software intended to be used in microbiology for the identification of clinical isolates and/or the detection antimicrobial resistances.

The information provided by the software is based on data obtained with IVD medical devices only or possibly combined with

information from medical devices.

The software is an IVD medical device or an accessory of an IVD medical device.

f.3) Interpretation of raw data

In the case where software is necessary to render raw data, obtained from an IVD by means of *in vitro* examination of body samples, readable for the user, this software is to be considered as an accessory to an IVD when it is specifically intended to be used together with this IVD to enable it to be used in accordance with its intended purpose.

Example: software intended for the analysis and interpretation of ELISA reader optical density results, line patterns or spot patterns of a blot.

f.4) Home care monitoring, wired or mobile

Stand alone software intended for archiving patient results or for transferring results from the home environment to the healthcare provider is not an IVD device. The results are available, readable and understandable by the user without the intervention of the software.