The European Association of Medical devices Notified Bodies

Team-NB Position Paper

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Software classification under the IVDR

1. Background

Regulation (EU) 2017/746 on in vitro diagnostic medical devices came into force on May 26, 2022. Among the novelties introduced by this regulation, the classification system has been modified to be based on the risks related to the destination of the device, and the notified bodies' role has been strengthened.

Indeed, while most in vitro diagnostic medical devices did not require the intervention of a Notified Body under Directive 98/79/EC, it is estimated that with the application of the new classification rules, 80% of in vitro diagnostic medical devices are subjected to an assessment by a notified body before being placed on the market under Regulation (EU) 2017/746. This includes several types of software used in in vitro diagnostics.

Although the Medical Device Coordination Group (MDCG) has issued a Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR (MDCG 2019-11), there is still a great deal of uncertainty on the manufacturer's side regarding the qualification and classification of their software.

Hence, this Position Paper is intended to provide clarification on the expectations of the Notified Bodies regarding qualification of software in the in vitro diagnostic medical devices (IVD MD) field, as well as actionable examples to help manufacturers decide whether they should submit their software to a Notified Body.

2. Definitions

Medical Device Software (MDSW) (from the MDCG 2019-11):
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 in vitro diagnostic medical devices regulation, regardless of whether the software is independent or driving or influencing the use of a device.
Note 1: MDSW may be independent, by having its own intended medical purpose and thus meeting the definition of an in vitro diagnostic medical device on its own.
Note 2: 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).
Note 3: The type of interconnection between the MDSW and the device (e.g. embedded systems, wires, Wi-Fi, Bluetooth) does not affect the qualification of the software as a device under the IVDR (whether the software is incorporated in a device or not).

Software driving or influencing the use of a device (from the MDCG 2019-11):

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

Accessory (from the 2017/746 Regulation):

"Accessory for an in vitro diagnostic medical device" means 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).

Modules (from MDCG 2019-11)

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

The modules which are subject to the Medical Devices Regulations 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.

Expert system (from MDCG 2019-11)

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).

3. Market placement

Medical device software can be placed on the market in two different ways.

Option 1: The manufacturer can place the MDSW or component on the market as an IVD MD on its own right.

According to the MDCG 2019-11, in this case, the MDSW shall undergo an appropriate regulatory process that shall take into consideration the qualification, classification and intended purpose of the MDSW.

- A cloud-based histopathology slide image analysis software that incorporates functions to support the post-processing of images for diagnostics purposes, e.g., AI-support functionality for labelling cancer cells to aid in diagnosis.

- A software performing NGS sequence analysis installed on a desktop computer.

Option 2: The manufacturer can place an IVD MDSW on the market solely as an integral component / part of an IVD MD,

In this case, the MDSW shall be assessed through the regulatory process applied to the device as a whole.

- An analyser placed in the market with its controlling software. The analyser and software are considered together as an integrated system.
- An analyser with IVD intended purpose placed in the market with its installed operating software and an additional data conversion module. The analyser and its operating software are considered together as an integrated system.
- A kit composed of targeted PCR primers and software intended for the NGS sequence analysis. The manufacturer can place the kit on the market with software together as the entire IVD medical device system. Please note in this case, the software may be considered as either as an integral part of the IVDR device, or independently, depending on its intended purpose and how it is put on the market by manufacturer.

Note: Regardless of how the software is presented (whether as Option 1 or Option 2), a MDSW could be considered as independent. Careful consideration of the intended purpose of the MDSW is hence required for its qualification and classification.

4. Non-IVD Medical Device Software (Non-IVD MDSW)

Some software can be associated to IVD medical devices but don't have a medical purpose, such as Excel, Word or pdf, or modules intended solely for communication, storage, or performing a simple search.

Examples for software that are not considered to be MDSW:

- Laboratory Information Management Systems (LIMS), that is used to manage laboratory operations, including sample tracking, workflow automation, and data management, and does not perform a diagnostic or analyse patient data to make/drive clinical decisions that would qualify the software to be a device under the regulation.
- Inventory Management Software, that is used to track and manage laboratory inventory, including reagents, consumables, and instruments.
- General Data Storage or Backup Solutions, cloud-based or on-premises data storage systems that archive patient test data or laboratory results without modifying or impairing the information being stored.
- Non-Diagnostic Data Visualization Tool, that visualizes lab data, such as graphs or charts, to aid in administrative decision-making without providing any clinical interpretation or diagnostic recommendation.
- Software that generates synthetic or simulated data for training, validation, or verification purposes, such as software for creating realistic images of specimens with different

characteristics, software for simulating the performance of an IVD device under various conditions, or software for generating reference data sets for comparison with actual results.

- Software that adjusts the calibration or quality control parameters of an IVD instruments as part of the device, such as a blood glucose meter, a coagulation analyzer, or a hematology analyzer.

Some software can also analyse data obtained from a combination of in vitro diagnostic medical devices and medical devices. When the software meets the definitions of both an IVD and a MD, a weighting of the data sources based on the significance of the information in relation to fulfilling the intended purpose should be conducted to determine if the intended purpose is substantially driven by data sources coming from in vitro diagnostic medical devices, then it is an IVD MDSW.

5. Decision steps for the qualification of a software

The decisions steps are described below:

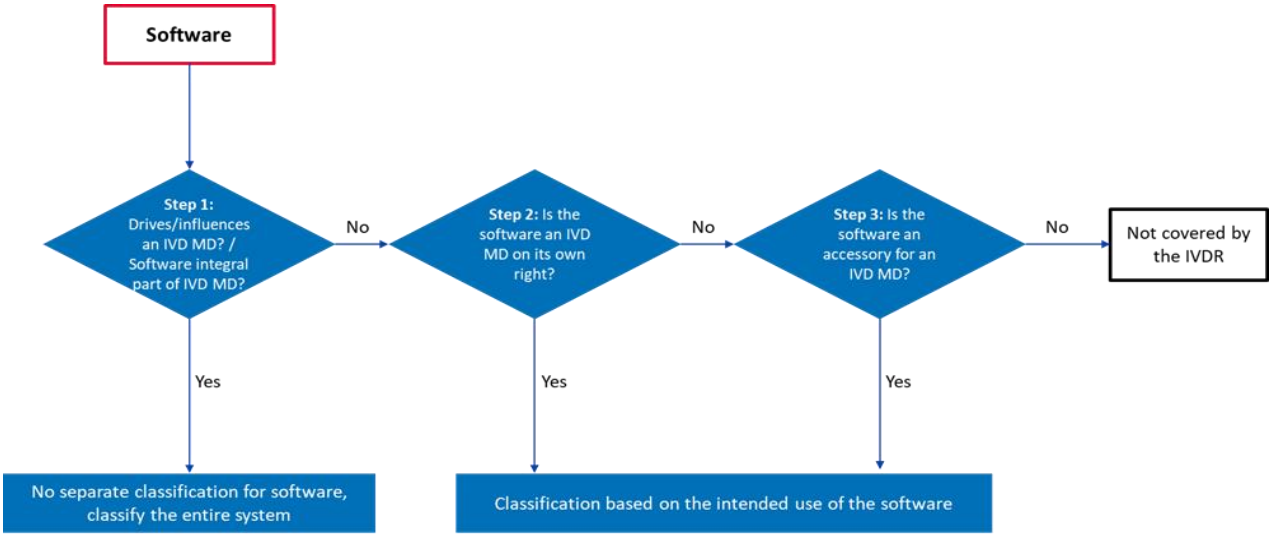

Figure 1. Reference representation of decision steps flow-chart

- **Decision step 1. Is the software driving or influencing the use of an IVD medical device, or is the software an integral part of an IVD Medical Device?**

Scenario 1: Software driving or influencing the use of an IVD medical device

MDCG 2019-11 defines 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.
Software driving or influencing a device 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

Depending on its intended use, and in accordance with MDCG 2019-11, such software may be considered an accessory to an IVD medical device. This means software does not have a medical intended purpose on its own. Instead, it functions as part of another IVD device and contributes to achieving the intended purpose with the IVD medical device together. In this case, the accessory should fall within the same classification as the associated device.

Note: By contrast, Step 3 treats the accessory as an independent software product, which must be classified in its own right.

Example:

- A software does not have a medical intended purpose on its own but is used to drive or control the motors of a medical digital microscope, thereby enabling the medical digital microscope to fulfill its intended purpose. In this case, software is considered part/component of the (hardware) medical device and falls within the same class as the device.
- A Hemoglobin A1c software is designed to control an analyzer that measures HbA1c levels in blood for self-testing and near-patient testing.

Scenario 2: Software that is an integral part of an IVD Medical Device

Software that is an integral part of an IVD Medical Device is essential for the functioning and operation of the diagnostic device. The device is intended to function exclusively with its specific integrated software.
It is to be noted that the type of interconnection between the MDSW and the device (e.g. embedded systems, wires, Wi-Fi, Bluetooth) does not affect the qualification of the software as a device under the IVDR (e.g. whether the software is incorporated in a device or is at a different location).

Examples that are integral part of the IVD MD:

- Firmware for IVD Instrument Control: Operating software, such as software controlling the temperature, timing, or movement of an IVD device (thermal cycler, centrifuge, spectrophotometer, hematology analyzer, blood glucose meter).
- A software intended to predict cancer reoccurrence risk from a gene signature, after amplification of a patient sample using targeted PCR primers to capture the signature sequences. The device is composed of the PCR primers and analysis software.

- Software embedded in a self-testing analyzer (Blood Glucose Monitoring System for insulin dosage adjustments)
- Software installed on a blood gas analyzer and performing the interpretation of the readings from the measuring cell.

In both cases whether the software is driving or influencing an IVD MD or an integral part of the IVD MD, the IVD MD and its associated software should be categorized and assessed as a system. The intended purpose of the device will drive the classification of the system.

It is to be noted that some software associated to an IVD MD can have a modular organization, with modules having a medical purpose on their own and/or falling into the definition of an expert system. These modules should be classified and assessed on their own.

Examples:

- Additional software module embedded in an automated platform and aggregating the results of a microbial identification assay and Minimal Inhibitory Concentration results for several antibiotics to provide a sensitivity profile.
- Additional module embedded in a biochemistry analyzer and aggregating results of several allergy assays to provide a patient allergy profile.

- **Decision step 2. Does the software meet the definition of an IVD MD on its own?**

This refers to software that is itself an *in vitro* diagnostic medical device according to IVDR article 2(2).

This software is intended for use in diagnosis or aid to diagnosis, screening, monitoring, prognosis or prediction and is considered as an IVD MD on its own.

Software is classified based on its intended use and is subject to its own technical documentation assessment.

Examples of devices used by professional users:

- Software used in non-invasive prenatal testing to screen samples for genome-wide fetal genetic anomalies using whole genome sequencing.
- NGS Sequence Analysis for diagnosis of hereditary diseases or disease predispositions, such as breast cancer or ovarian cancer.
- NGS Sequence Analysis software associated to specific reagents allowing DNA capture: the software does not influence the reagent, but the entry data of the software are influenced by the reagent.
- Software used to analyze pap test slide images for assisting in cervical cancer screening.
- Image analysis application MDSW which targets the liver fibrosis stage or for metastasis detection.

- Software which carries out the analysis of digital urine cytology slides and associated patient data and produces a result report in JSON format.
- Software that uses Artificial Intelligence or Machine-Learning algorithms to analyze images, signals, or patterns from specimens and provide diagnostic (detection of cancer cells in histopathology slides, identification of bacteria in blood cultures)
- Software that provides clinical decision support/recommendations based on the integration and analysis of data from multiple sources, for example software predicting the risk of sepsis from vital signs, laboratory results, and medical history or software for suggesting the optimal antibiotic therapy based on the patient's condition and microbiological data.

Examples of devices used for self-testing or near-patient applications:

- Software or mobile applications that uses algorithms to analyze trends, provide clinical recommendations or send alerts for high/low glucose levels. (e.g., Blood Glucose Monitoring System for insulin dosage adjustments).
- Mobile application integrating patient's bloodwork results, used by emergency care clinicians to aid sepsis management.

- **Decision step 3. Is the software an accessory software for an IVD device?**

The accessory software does not have medical purpose and, therefore, does not fulfill the definition from article 2(1) and 2(2) in the 2017/746 Regulation. Instead, it is intended to be used alongside an IVD device, and it is determined by the manufacturer if they must be considered as "accessory" or not. Accessories are regulated within the IVDR framework and must meet the associated requirements.

In this situation, accessories are considered as separate devices on the market by the manufacturer and shall be classified in their own right separately from the device with which they are used.

If the main purpose of the software is not the examination of a specimen, but collecting results obtained from one or several IVD devices (directly and/or manually) or archiving patient results, and transmitting without modification this information to a centralized database (e.g. LIMS) or to healthcare providers, it is not considered as an IVD-MD.

Examples:

- Software applications associated to an IVD MDSW that are intended to assist the user in interpreting or reporting the results of an IVD device, and it is intended to be used along with the IVD MDSW as an accessory by manufacturer.
- Middleware or software module performing image format conversion to enable analysis of a biopsy slide by an Artificial Intelligence.