IVDR requirements for Software

Software fulfilling the definition of an in vitro diagnostic medical device falls under the in vitro diagnostic medical devices regulation (EU) 2017/746 (IVDR). In the past, several of these are self-certified or not covered under IVDD. 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.

Classification and implementing rules as per IVDR 2017/746

Implementing Rules:
All implementing rules, Annex VIII of Regulation (EU) 2017/746 shall be considered.

Special considerations on Implementing Rule 1.4 and 1.9:
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 classification of software which is placed on the market in combination with a hardware medical device.

According to implementing rule 1.4, if the software is independent of any other device, it shall be classified in its own right. Implementing rule 1.9 states that if several classification rules apply to the same device based on the devices intended purpose, the rule resulting in higher classification will apply.

Examples for applying this implementing rule under the in vitro diagnostic medical devices regulation:

- 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.
- 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 a 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.

Classification Rules

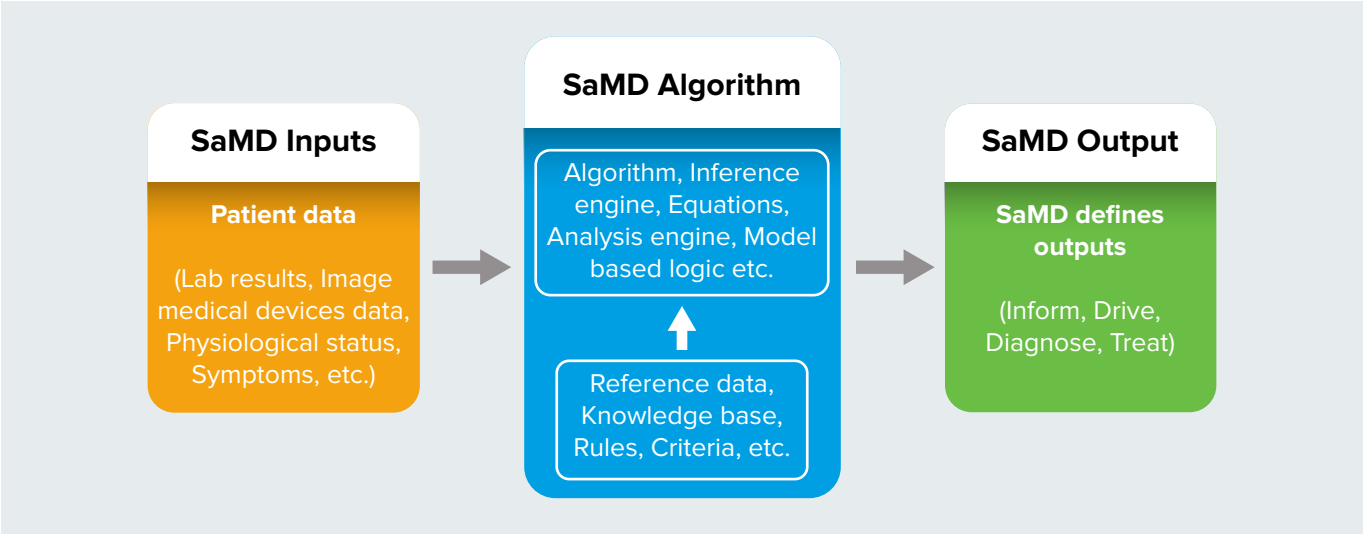
In determining the proper classification of MDSW under the IVDR, the manufacturer shall consider all classification and implementing rules of Annex VIII of the IVD Regulation (EU) 2017/746. As spelled out by Implementing Rule 1.1 of Annex VIII of Regulation (EU) 2017/746, the application of the classification rules shall be governed by the intended purpose of the MDSW.

Examples for the classification of MDSW under the IVDR:

- 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, and should be in class C perRule 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). 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.

General Principles and Context of SaMD Clinical Evaluation Process

SaMD can best be described as software that utilizes an algorithm (logic, set of rules, or model) that operates on data input (digitized content) to produce an output that is intended for medical purposes as defined by the SaMD manufacturer. The risks and benefits posed by SaMD outputs are largely related to the risk of inaccurate or incorrect output of the SaMD, which may impact the clinical management of a patient.



Software verification and validation

Documentation shall contain evidence of the validation of the software, as it is used in the finished device. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

Include IVD software life-cycle documentation and related procedures (e.g. software development plan, software requirements specification, software architecture, software detailed design, software unit testing procedures/reports, software integration testing procedures/reports, software system testing, software maintenance, software risk management, configuration management, problem resolution).

A manufacturer must have a technical file that demonstrates the conformity of their standalone software with the respective provisions of the applicable regulations.

Harmonised standards

- IEC 62304: Software lifecycle processes for medical devices
- IEC 62366: Application of usability engineering for medical devices
- ISO 14971: Application of risk management for medical devices
- IEC 61010: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- ISO 13485: Medical devices - Quality management systems - Requirements for regulatory purposes.

Conformity assessment

The new Medical Device software validation method (life cycle process model) developed is known as IEC 62304 or ISO 62304. The new standard covers software development & maintenance, risk management according to ISO 14971, partitioning and safety classification of software items, and software process management.

Functions of In vitro diagnostic medical device software

Software normally support 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 the ordering clinic's patient record.
- Analytical instruments can be interfaced with Hospital Information Systems (HIS), Electronic Patient Record Systems, Infectious control databases, etc

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