Confidential: Strictly personal -		The recipient may not share with anyone, including his/her direct colleagues.
Confidential: For your staff only -		The recipient may share with his/her direct colleagues but not anyone outside the organisation (including members, in the case of national associations)
Confidential: For industry use only -	**X**	**The recipient may share with his/her staff and with other medtech companies/organisations (including members, in the case of national associations)**
Appropriate for external use-		The recipient may share with anyone, including individuals not from medtech companies/organisations, if he/she has a need to do so

Best Practice Guidance
How to Label IVD and Medical Device Software (MDSW)?

9 October 2020

Contents

Introduction

This document provides best practice guidance on how manufacturers may label Medical Device Software (MDSW) as defined in the *MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR,* This guidance focuses on the requirements of the *Regulation (EU) 2017/745* (MDR) and the *Regulation (EU) 2017/746* (IVDR). In addition, it provides a mapping between the requirements of the *Directive 93/42/EEC* (MDD), *Directive 98/79/EC* (IVDD) and *Directive 90/385/EEC* (AIMDD) and the Regulations.

The guidance should be considered to all MDSW, irrespective of the computing platform on which it runs, e.g., a general-purpose computer, in the cloud, or on specialised hardware like fitness products or independent software that runs on the computing platform of medical devices (e.g. Computer Aided Detection (CADe) plugin for a bedside monitor. However, there may be different application of labelling requirements for MDSW, depending on if the software is independent or drive/influences. As noted in *MDCG 2019-11*, MDSW, including accessory software, can be placed on the market in one of two ways:

- as a device in its own right (Independent), or
- as an integral component/part of a (hardware) device (drives/influences).

The guidance is specific to the device label aspect of labelling and does not include in its scope the requirements of the Regulations as regards the instructions for use, nor regarding other regulatory documents apart from the device label. Label requirements which are unlikely to be part of the device label for MDSW are not covered in this document, for example, label requirements regarding hazardous substances.

As a general rule, independent MDSW, as a device in its own right, shall fulfil all the device labelling requirements listed in the IVDR or MDR. Drives/influences MDSW, as an integral part/component of a hardware device, should generally be incorporated as part of the device label for the hardware on which it runs.

While there are specific requirements for software under Annex I of the respective Regulations, the label requirements are not specific to software and questions may arise as to where, how, and when to label software. A mapping of the label requirements of Annex I in the five legal documents which apply for MDSW is provided in the Appendix to this document. General guidance on the format, placement, and language requirements of the label are provided below.

The MDR applies from 26 May 2021 and the IVDR applies from 26 May 2022. IVD and MD software that seeks compliance under the Regulations (even if they do so before the dates of application) shall comply with all applicable requirements of the Regulations, including those relating to the device label.

At the time of writing, it is considered good practice for manufacturers to follow ISO standards on device labelling. For IVDR, the ISO 18113:1-5 series is relevant; it is being revised for possible publication in 2021. For MDR, the relevant ISO 20417 standard will replace EN 1041 regarding information to be supplied by the manufacturer; at the time of writing, ISO 20417 is in the final stage of development. This guidance document may be updated from time to time to take account of updates to these referenced standards.

General Provisions

Definitions

Label

Label means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices, according to the IVDR/MDR.

Medical Device Software (MDSW)

The *MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR* defines *medical device software as ''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"*. The guidance notes that the definition is "*regardless of whether the MDSW is independent or driving or influencing the use of a device".* For further considerations around defining software, its qualification and classification please consult the aforementioned MDCG guidance. For the purpose of this document, the terms:

- **Shall** means a requirement is mandatory based on the (applicable) regulation.
- **Should** means that the requirement is recommended but is not mandatory for compliance with the applicable regulation.
- **May** is used to describing permission (e.g. a permissible way to achieve conformance with a requirement of the applicable regulation).
- **Can** is used to describe a possibility or capability.

When does MDSW need a label?

The short answer is that any software which qualifies as MDSW requires a label according to the IVDR or MDR, as appropriate. In addition, software which is an accessory qualifies as a 'device' and therefore shall also require a label under the IVDR or MDR, as applicable. However, independent MDSW requires its own label; drives/influences MDSW labelling requirements may be incorporated into the hardware device label.

It should be noted that for software which is specifically intended to replace a part or component of a device and that significantly changes the performance and safety characteristics or the intended purpose of the device shall be considered a device and meet the requirements of the IVDR or MDR, as appropriate [Article 20(2) (IVDR), Article 23(2) (MDR)].

MDSW lacking user interfaces

The Regulations mention middleware for image conversion as an example of independent MDSW lacking a user interface.[1] This means that the required elements of the label may be conveyed in another manner. With respect to Unique Device Identification (UDI), the Regulations require in Annex VI, Part C, section 6.2.4c (IVDR) and section 6.5.4 (MDR), that independent MDSW lacking a user interface be capable of transmitting the UDI through an application programming interface (API).

Modular MDSW

Since MDSW often comprises a multitude of functions for different purposes, manufacturers may group these into separate modules. Some of these modules will not be a medical device, such as email, word processing, voice transcription, or accounting, while others will be MDSW. The Directives and Regulations only apply to MDSW modules.

The extent to which manufacturers can group functionality into a separate module depends on the MDSW architecture. Some level of functional and logical segregation is expected. This should be clear from architectural diagrams. To facilitate the conformity assessment the manufacturer should ideally also have technical documentation for each module that demonstrates configuration management is under control and compatibility between the different modules was tested.

Whereas from a regulatory perspective, a manufacturer may consider a product to consist of multiple medical devices and general purpose products, this does not prohibit the manufacturer from presenting the whole to the user as if it were one integrated product with a uniform user interface as this may improve the usability of the device. Therefore, one product from a user perspective may equal several medical devices and general-purpose products from a regulatory perspective. The additional benefit is that this modular approach allows the manufacturer to tightly integrate modules from third party manufacturers and identify the manufacturer's responsibility for their own medical device products.

[1] See Regulation (EU) 2017/746, Annex VI 6.2.4 and Regulation (EU) 2017/745, Annex VI 6.5.4. UDI placement criteria for software

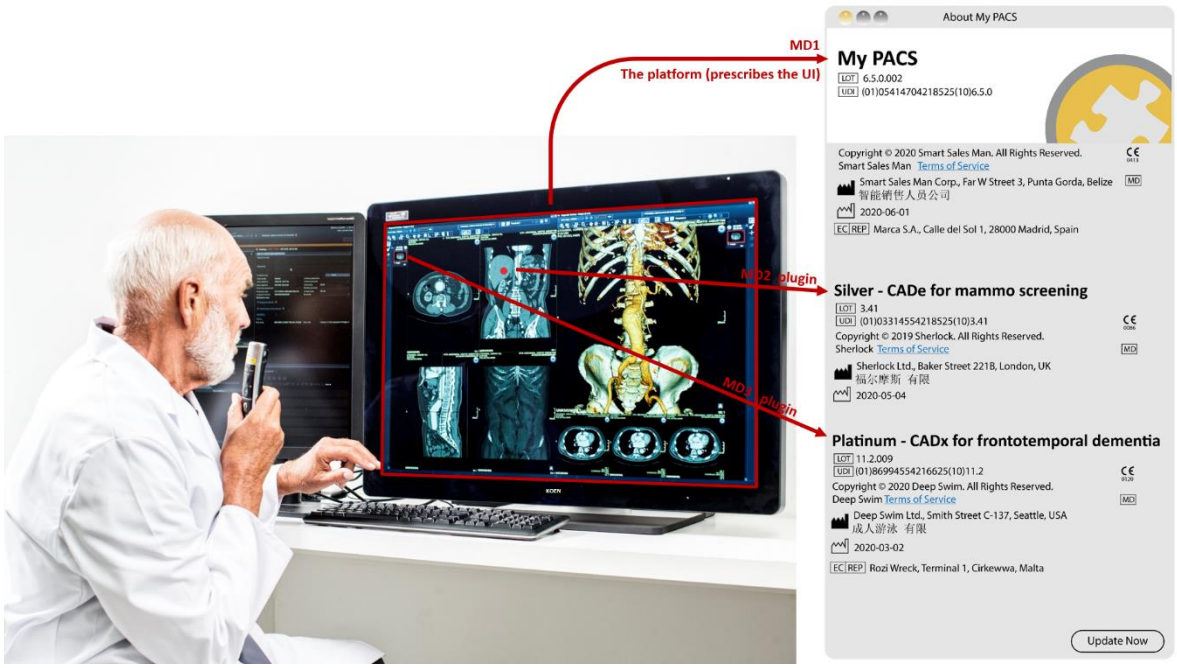


Figure 1 Label example of modular MDSW. It consists of a Picture Archiving and Communication System (PACS) and two additional MDSWs; one Computer Aided Detection (CADe) module and one Computer Aided Diagnosis (CADx) module. Whereas to a user it may look like one product, the three medical devices are placed on the market by three different manufacturers. The PACS is a medical device and is the platform and user interface of the other medical devices. Because the other medical devices do not have their own user interface, they only receive information as inputs (in this case radiological images), perform analysis to e.g. detect tumours in the images, and provide the new information to the PACS which in turn displays the new information to the user. The product information of the other medical devices is provided through the user interface of the PACS.

Placement and format

The Regulations state that the medium, format, content, legibility, and location of the label shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s) [Annex I, section 20.1a (IVDR) and section 23.1a (MDR)].

The information required on the label shall be provided on the device itself, unless this is not practicable or appropriate, in which case some or all of the information may appear on the packaging for each unit [Annex I, section 20.1b (IVDR) and section 23.1b (MDR)]. As such, independent MDSW label shall be provided on e.g., the splash screen of the software interface and MDSW provided as an integral part may be covered by the hardware device label.

For drives/influences MDSW it is considered practical and appropriate to provide some minimum elements of the device label on the user interface of the software. The label elements may appear in e.g. an about-box or the start-up screen of the software. The hardware device label remains the primary device label source. The elements of the label are described later in this guidance document.

If the independent MDSW is placed on the market on a physical medium, like a USB-stick or a CD-ROM, the applicable label elements should primarily still be provided on the user interface of the software and replicated

on the physical medium containing the MDSW should also be labelled in accordance with the requirements of the Regulations. MedTech Europe cannot provide additional specific guidance on this – it is ultimately the manufacturer's responsibility to decide, case by case, the specific approach to take for its MDSW.

Language requirements and symbols

The EU Member States in which a device is placed on the market can specify the languages required for information accompanying the MDSW, including the language of the label [Article 4(4) (AIMDD), Article 4(4) (IVDD), Article 10(10) (IVDR), Article 4(4) (MDD), Article 10(11) (MDR)]. To date, there are few national legal requirements for label language requirements under the Regulations, however, MedTech Europe's labelling working groups monitor the situation on an ongoing basis.

The language of the remainder of the user-interface, such as built-in instructions, is out of scope of the Regulations, but falls under the responsibility of the EU Member States, whose national regulations shall be adhered to. It is recommended to verify Member States legislation on this topic.

To reduce the need for translation and provide information swiftly to the user, it is recommended as far as possible to use internationally recognised symbols on the label as a means of conveying information in a visual and language neutral way. Where used, these symbols shall conform to any applicable harmonised standards or common specifications that exist. Where these do not exist, the symbols shall be described in the documentation supplied with the device [Annex I, section 14 (AIMDD), section 8.2 (IVDD), section 20.1h (IVDR), section 13.2 (MDD), section 23.1h (MDR)].

* *Under the Regulations, the manufacturer should use its risk management system to determine when it is necessary to update the product label because of the information gathered under the PMS system.*

Technical documentation

The label(s) shall be included as part of the technical documentation of the MDSW [Annex III, 3 (IVDD); Annex II, 2 (IVDR); Annex VII, 3 (MDD); Annex II, 2 (MDR)].

Under the Regulations, all the labels in the languages accepted in the Member States where the device is envisioned to be sold shall be included in the technical documentation [Annex II, 2 (IVDR and MDR)].

Elements of the label

The following section lists the individual label elements which are required by the Directives and Regulations. Some of the elements apply to all MDSW, some only apply to certain types of devices.

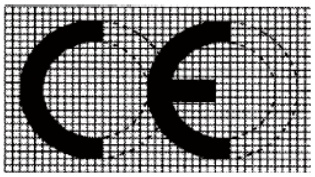
CE Marking and Notified Body Number

The CE marking within the device interface is required for all independent MDSW to be placed on the market, with the exclusion of IVD-MDSW intended for performance evaluation and MD-MDSW intended for clinical investigations. MDSW intended only for performance evaluation or only for clinical investigation cannot bear the CE marking, unless the MDSW already bears the CE marking and therefore falls under the provisions of Article 70(1) of the IVDR ('PMPF study') or Article 74(1) of the MDR ('PMCF investigation').

MDSW placed on the market as an integral component of a hardware medical device is covered by the CE marking on the hardware device label, as this MDSW will have been part of the conformity assessment with the hardware device.

The form of the CE marking is presented in the Annexes of the Directives and Regulations [Annex 9 (AIMDD), Annex X (IVDD), Annex V (IVDR), Annex XII (MDD), Annex V (MDR)]. The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. Therefore, when creating the label that will bear the CE marking, where applicable the manufacturer might consider the relative size and resolution of the screens of the devices (e.g. computer, tablet or smartphone) intended to display the MDSW when providing minimum requirements necessary to run the software [e.g. Annex I; sections 16.3 and 16.4 (IVDR), sections 17.3 and 17.4 (MDR)]. See Appendix, Table 1.

Simply writing the letters "CE" is not a correct representation of the CE marking. This means, that the Graphical User Interface of the MDSW cannot rely on alphanumerical data alone but should also be capable of displaying graphics in order to correctly represent the CE-marking of conformity.



If a notified body has been involved in the conformity assessment of the MDSW, the notified body identification number (four digits) shall follow the CE marking (e.g., the number may be placed next to or underneath the CE marking).

Name or trade name of the MDSW

Under the Regulations, the label of independent MDSW shall bear the name or trade name of the MDSW. This is not a requirement under the Directives. See Appendix, Table 2.

MDSW placed on the market as an integral component of the hardware device is covered by the name or trade name of the hardware device label.

Details strictly necessary to identify the device

The Directives and Regulations require the details strictly necessary for the user to uniquely identify the device to appear on the label of the standalone/independent MDSW. If the name of the independent MDSW does not uniquely identify the device, labelling standards [ISO 18113-1-5, ISO 20417, EN 1041] propose that an additional means of identification be given, e.g. catalogue number or model number manufacturer may provide both a name and an additional means of identification, such as the version, revision level or date of build/release/issue. For MDR the contents of the packaging should also be identified, where independent software is provided within packaging. See Appendix, Table 3.

This requirement is not necessary for MDSW placed on the market as an integral part of a (hardware) device, as this requirement may apply to the device as a whole, and not just the MDSW on its own.

Intended purpose

The manufacturer is required to add the name or trade name of the device as well as the details strictly necessary for a user to identify the device. Where it is not obvious for the user, the intended purpose of the device shall be included on the label. The manufacturer needs to determine who the user is and if it can reasonably be expected that the user will understand the purpose of independent MDSW. A restatement of the intended use is not what is required: what is required is to have an idea of what the device is used for [Annex I, section 20.2b (IVDR); section 23.2b (MDR)]. An extended version of intended purpose is required to be included under the instructions for use [Annex I, section 20.4.1c (IVDR); section 23.4b (MDR)]. The extended version is not required to be included on the device label. Rather, the requirement calls for the details strictly necessary for the user to identify the intended purpose (if not already obvious), to be included. See Appendix, Table 4.

MDSW placed on the market as an integral part of a (hardware) device (and therefore not Independent MDSW) does not need a separate statement regarding the intended use of the software, as the intended use of the device as a whole includes the use of the software.

Name and address of the Manufacturer

The label shall always bear the name, trade name or trademark of the manufacturer and the address of the manufacturer's registered place of business. The manufacturer symbol as defined in [ISO 15223-1:2016, ref no: 5.1.1] can be used to indicate that the referred-to legal entity is the independent MDSW manufacturer. See Appendix, Table 5.

For MDSW placed on the market as an integral part of a hardware device, the hardware device label covers this requirement.

Name and address of the Authorised Representative

If the manufacturer is based outside the Union, the label shall also bear the name and address of the authorised representative. The authorised representative symbol as defined in [ISO 15223-1:2016, ref no: 5.1.2] can be used to indicate that the referred-to legal entity is the independent MDSW authorised representative. See Appendix, Table 6.

For MDSW placed on the market as an integral part of a hardware device, the hardware device label covers this requirement.

Indication of medical device or "exclusively for clinical investigations" (MD only)

The MDR requires the device label to contain an indication that independent MDSW is a medical device. An MD symbol has been proposed to indicate this fact [ISO 15223-1:20XX and MedTech Europe guidance on Use of Symbols to Indicate Compliance with the MDR]. If independent MDSW is intended by the manufacturer to be used exclusively in clinical investigation, and not placed on the market for medical use, the words "Exclusively for clinical investigation" shall appear on the label. If independent MDSW is already CE-marked, and the clinical investigation is within the intended use of the MDSW and therefore falls under the provisions of Article 74 of the MDR ('Clinical investigations regarding devices bearing the CE marking), the CE marking shall be clearly indicated on the label. See Appendix, Table 7.

For MDSW placed on the market as an integral part of a hardware device, the hardware device label covers this requirement.

Indication of IVD-device or "device for performance study" (IVD only)

The IVDD and the IVDR require the *in vitro* diagnostic use of a MDSW to be indicated, either with the statement: 'For *in vitro* diagnostic use' or (to avoid translation) the graphical symbol '*in vitro* diagnostic medical device' [ISO 15223-1:2016, ref no: 5.5.1]. If the MDSW is intended by the manufacturer to be used in or for a performance study, and not placed on the market for medical use, the words 'For performance

evaluation only' [Annex I, section 8.4f (IVDD)] or 'Device for performance study' [Annex I, section 20.2e (IVDR)] shall appear on the label. The symbol as defined in [ISO 15223-1:2016, ref no: 5.5.6] may be used in place of this text. See Appendix, Table 8.

Version number

The Directives, except AIMDD, and Regulations require the label to bear the lot or the serial number of the device. Annex VI, Part C, Section 3.5 of the IVDR and MDR, states that the lot number or serial number shall appear on the label and shall be part of the UDI-PI. For independent MDSW, it is understood that the equivalent of the lot or the serial number is the version number, though the standard used to generate UDI may allow for a specific software version [as per, for instance, IMDRF/GRRP WG/N52 FINAL:2019 Principles of Labelling for Medical Devices and IVD Medical Devices and ISO 18113-1-5]. This is supported by Annex VI, Part C, Section 6.2.1 of the IVDR and section 6.5.1 of the MDR which state that MDSW identification "*shall be considered to be the manufacturing control mechanism*."

For MDSW to be installed on a hardware medical device, manufacturers should consider whether it may be necessary to distinguish between the MDSW and the lot or the serial number of a physical configuration. This may be especially important in cases where the MDSW is capable of being upgraded after it is placed on the market, even though the physical hardware originally provided (and labelled) by the manufacturer continues to be used. The version number of MDSW may be indicated on the label using the lot or serial number symbol [ISO 15223-1:2016, ref no: 5.1.5] or provided as part of the UDI string. See Appendix, Table 9.

UDI Carrier

The Regulations require the device label, and all higher packaging levels (excluding shipping containers) to bear the UDI carrier. The UDI carrier is the means of conveying the UDI by using an AIDC (Automatic Data Capture and Interpretation) and, if applicable an HRI (Human Readable Interpretation of the AIDC content). "*The UDI carrier (AIDC and HRI representation of the UDI) shall be placed on the label and on all higher levels of device packaging"* [Annex VI, Part C, section 4.1 (IVDR and MDR)] and "*If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be required to appear on the label. For devices intended to be used outside healthcare facilities, such as devices for home care, the HRI shall however appear on the label even if this results in there being no space for the AIDC"* [Annex VI, Part C, section 4.7 (IVDR and MDR)]. See Appendix, Table 10.

The European Commission has provided specific guidance on the placement of the UDI carrier on MDSW in the *MDCG 2018-5 UDI Assignment to Medical Device Software*. However, the guidance document mainly points back to the actual text of Annex VI, Part C, section 6.2.4 in the IVDR and section 6.5.4 in the MDR, which applies to independent MDSW, as software that is placed on the market in its own right:

UDI placement criteria for software:

a) *where the software is delivered on a physical medium, for example via a CD or DVD, each packaging level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the software and its packaging shall be identical to the UDI assigned to the system level software;*
b) *the UDI shall be provided on a readily accessible screen for the user in an easily-readable plain-text format such as an 'about' file, or included on the start-up screen;*
c) *software lacking a user interface such as middleware for image conversion, shall be capable of transmitting the UDI through an application programming interface (API);*
d) *only the human readable portion of the UDI shall be required in electronic displays of the software. The marking of UDI using AIDC shall not be required in the electronic displays such as 'about' menu, splash screen, etc.;*
e) *the human readable format of the UDI for the software shall include the application identifiers (AI) for the standard used by the issuing entities, so as to assist the user in identifying the UDI and determining which standard is being used to create the UDI*

For MDSW that is placed on the market as an integral part to a (hardware) device (also known as software intended to drive or influence the use of a hardware device), the UDI is assigned at the system level (i.e. the hardware device of which it is part) [Annex VI, Part C, section 6.2.1 (IVDR) and section 6.5.1 (MDR)] such that the MDSW does not receive a separate UDI.

Warnings/Precaution/reference to IFU

The Directives and the Regulations require that warnings and/or precautions are stated on the device label if applicable. Similarly, the Regulations require that *residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer*. [Annex I, section 20.1g (IVDR); section 23.1g (MDR)]. The manufacturer should, taking the intended user into consideration, use their risk management procedure to identify any relevant warnings or precautions. The ISO 14971:2019 standard cover the risk management process, including determination and communication of residual risk, and may be a useful tool for manufacturers to follow in this regard. The information which is displayed on the label may be kept to a minimum (for example, warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device) with more detailed information appearing in the instructions for use. [MedTech Europe guidance on Requirements under IVD Regulation 2017/746/EU which drive labelling changes].

'Residual risk' is the risk remaining after risk control measures have been implemented. The method for the evaluation of the overall residual risk and the criteria for its acceptability must be defined in the risk management plan. If following an evaluation, the overall residual risk is assessed as acceptable, the manufacturer shall decide which residual risks to disclose and what information is necessary to include in the accompanying documentation to disclose those residual risks. These residual risks should be included as

limitations, contra-indications, precautions, or warnings. 'Accompanying documentation' can be considered to include the label, the instructions for use and the summary of safety and performance/summary of safety and clinical performance. Applicable warnings and precautions may take the form of symbols, either harmonised or explained in the IFU. Standardised symbols must be still explained in the IFU as long as they remain non harmonised. For more information on warnings and precautions, please see ISO 18113-1:2009 and ISO 20417: 20XX. See Appendix, Table 11.

For MDSW placed on the market as an integral part of a hardware device, the hardware device label covers this requirement.

Reference to the accessibility of IFU

If the manufacturer has electronic IFUs, the manufacturer can use the symbol [ISO DIS 15223-1, ref no: 5.4.3], followed by an URL linking to the relevant electronic IFU, to indicate where it can be accessed. If the IFU is not provided in paper form, the manufacturer shall provide information on where the IFU can be accessed, e.g. website or contact information. At the time of writing this guidance, the Commission Regulation (EU) 2012/207 on electronic instructions for use of medical devices is under revision and may lay down provisions on when IFUs may be provided in non-paper form. See Appendix, Table 12.

Particular/special operating instructions

Where applicable the label must bear any special or particular operating instructions. E.g. for independent MDSW intended to display medical images, it could be relevant to inform about restrictions regarding the lighting of the environment in which the MDSW is intended to be used. Internationally recognised or accepted symbols may be used to convey these instructions. In the above example the "keep away from sunlight" symbol might be applicable [ISO 15223-1:2016, ref no: 5.3.2]. See Appendix, Table 13.

For MDSW placed on the market as an integral part of a hardware device, the hardware device label covers this requirement.

Indication of self-testing or near-patient testing (IVD only)

Annex I, section 8.4k (IVDD) and section 20.2q (IVDR) require that the label informs the user, if the MDSW is intended for self-testing. Annex I, section 20.2q (IVDR) additionally requires that the label of the device intended for near-patient testing indicates that fact. Definitions for 'device for self-testing' and 'device for near-patient testing' can be found under Article 2 of the IVDR:

(5) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services;

(6) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional;

MedTech Europe recommends symbols to indicate where the device is intended for self-testing or near-patient testing. See these symbols below and in the MTE *Regulatory Update* *Symbols for self-testing and near-patient testing under the IVD Regulation (EU) 2017/746*, which are also available in *high quality formats* under the Regulatory E-Library of MedTech Europe. See Appendix, Table 14.

Exclusion of self-testing or near-patient testing for rapid assays (IVD only)

The IVDR requires that the label of rapid assays, that are not intended for self-testing or near-patient testing, bears the explicit exclusion of self-testing or near-patient testing. Rapid assays do not generally require an analyser system and could be partly based on IVD MDSW run on a mobile device. In appearance, they can be very similar to those tests that could be used in a self-testing or near-patient environment. *Decision 2002/364/EC on Common Technical Specifications for IVDs* *on Common Technical Specifications for IVDs* provides a definition of rapid test:

"Rapid test" means qualitative or semi-quantitative in vitro diagnostic medical devices, used singly or in a small series, which involve non-automated procedures and have been designed to give a fast result.

MedTech Europe recommends negation symbols to indicate when a rapid test is not intended for self-testing or near-patient testing. See symbols below and in the *MTE Regulatory Update - Symbols for self-testing and near-patient testing under the IVD Regulation (EU) 2017/746*. Please note that these are also available in *high quality formats* under the Regulatory E-Library of MedTech Europe. The indication of when a device is not for self-testing or near-patient testing is only required in the case of rapid assays. See Appendix, Table 15.

Device not for self-testing

Device not for near-patient testing

Components of IVD kits (IVD only)

The IVDR specifies that for device kits which include individual reagents and articles that are made available as separate devices, each of those devices shall comply with the requirements for labels contained in Annex I, section 20.2 and with the other requirements of the IVDR. Article 2(11) provides a definition: 'kit' means a set of components that are packaged together and intended to be used to perform a specific *in vitro* diagnostic examination, or a part thereof." This requirement only applies to components, which are CE-marked in their own right. For IVD MDSW it would apply in the situation where a CE-marked MDSW or mobile application was made available via a QR-code packaged together with a hardware device and reagents or test strips. There is no equivalent requirement under the MDR for procedure packs and systems. See Appendix, Table 16 and also MedTech Europe *Q&A no 7 on CE-marking components*.

Particulars for self-testing IVDs (IVD only)

In the case of IVD MDSW intended for self-testing the IVDR requires a set of particulars to appear on the device label. This includes where applicable, e.g. the type of specimen(s) required to perform the test, information on any additional materials needed for the test to function properly and contact details for further advice and assistance. Given the amount of information newly required to be added to the label of the device for self-testing, their design may be expected to be significantly affected. An example of MDSW intended for self-testing could be a mobile application which is used in combination with a hardware device and test strips to measure blood glucose levels, that display and analyse the measurements. The label for devices for self-testing shall bear the following particulars [MedTech Europe guidance on Requirements under IVD Regulation 2017/746/EU which drive labelling changes]:

- the type of specimen(s) required to perform the test (e.g. faecal or stool sample). However, if the type of specimen is already mentioned in the identification or description of the device (e.g. 'faecal bowel cancer test' and or its test strips), then it is not necessary to repeat this information.
- materials or a particular system or component are needed for the test to function as intended, but are not provided with the device sold, then they should be listed on the device label (e.g. blood glucose meter, test strips or lancet).
- contact details for further advice and assistance. The requirement could refer to a website or phone numbers and be very device specific.

See Appendix, Table 17.

Summary of safety and performance/Summary of safety and clinical performance

According to the IVDR, a Summary of Safety and Performance must be drawn up for class C and D devices and, likewise, according to the MDR a Summary of Safety and Clinical Performance must be drawn up for

class III and implantable devices. The regulations further state that the label or the instructions for use shall mention where this summary is available. The *MDCG 2019-9 Summary of safety and clinical performance: A guide for manufacturers and notified bodies* was published in September 2019. At the time of writing, the IVD equivalent guidance is being discussed, but there is no draft yet available. See Appendix, Table 18.

Date of manufacture

"Where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable" [Annex I, section 20.2i (IVDR); section 23.2j (MDR)]. This is one of the labelling requirements which may not have been written with software in mind, as the following questions arise, when is software manufactured and when is this requirement applicable?

As per IVDR and MDR, Articles 10(8b) and 10(9b), respectively, manufacturers shall identify which general safety performance requirements are applicable to their devices.

In cases where this requirement is considered applicable to the MDSW, the manufacturer can use the date of manufacture symbol ISO 15223-1:2016, ref no: 5.1.3 or the manufacturer symbol as defined in ISO 15223-1:2016, ref no: 5.1.1 to identify the manufacture date of the physical configuration. See Appendix, Table 19.

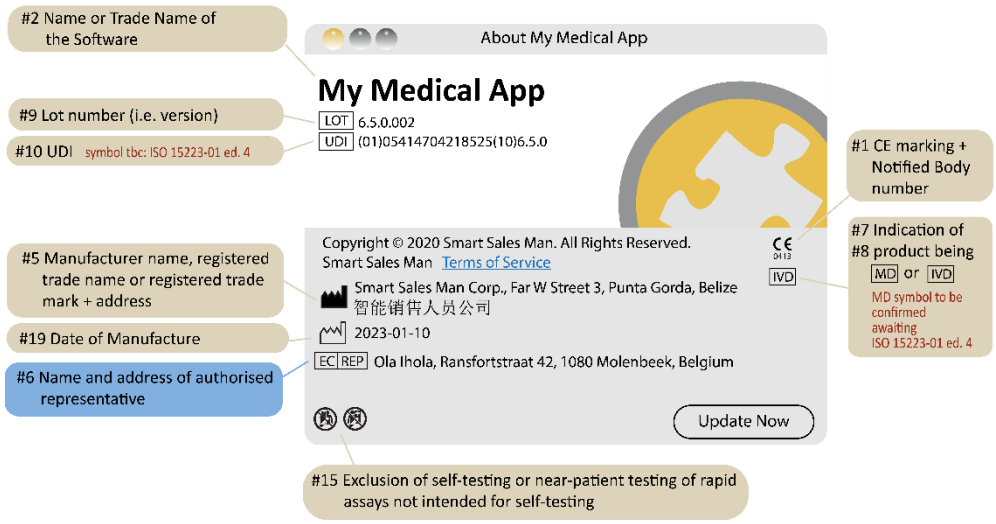
For MDSW placed on the market as an integral part of a hardware device, the hardware device label covers this requirement.

Examples

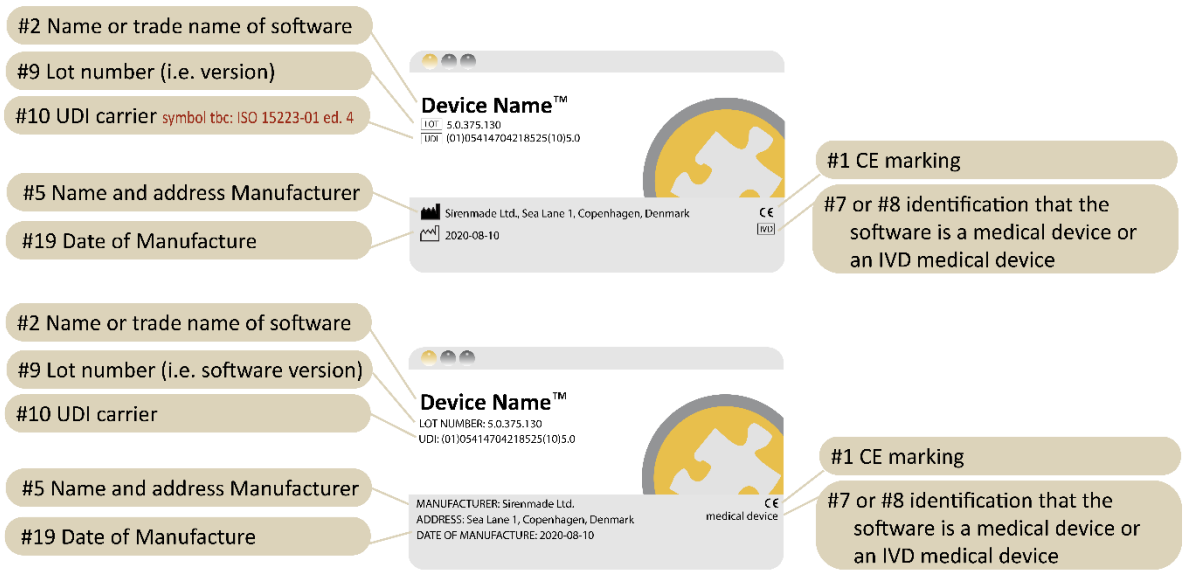
Below is a collection of examples of independent MDSW labels. The number of each of the label elements corresponds to the number of the corresponding label element in above list.

Minimum requirements

Below is an illustration of the minimum label requirements for a CE marked MDSW (in this case IVD):



Other examples



References*

Legislation

Regulation (EU) 2017/746 (IVDR)

Regulation (EU) 2017/745 (MDR)

Directive 90/385/EEC (AIMDD)

Directive 98/79/EC (IVDD)

Directive 93/42/EC (MDD)

Regulation (EU) 207/2012 of 9 March 2012 on electronic instructions for use of medical devices: *Currently under revision*

Decision 2002/364/EC on Common Technical Specifications for IVDs*: Currently under revision*

Standards

EN 1041:2008+A1:2013 *to be replaced by ISO 20417*

ISO/ 20417: 20XX: Medical devices — Information to be supplied by the manufacturer

ISO 18113 (5-part series), *In vitro* diagnostic medical devices — Information supplied by the manufacturer (labelling): *Currently under revision*

MEDDEV 2.14/3 rev.1 (Supply of IFU and other information for IVDs)

ISO 15223-1:2016 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

ISO 15223-1: 20XX – expected publication by end 2020

ISO 14971:2019 Medical devices — Application of risk management to medical devices

Guidance documents

MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

MDCG 2018-5 Guidance on UDI Assignment to Medical Device Software

MEDDEV 2.2/3 rev.3 (use by date)

IMDRF/GRRP WG/N52 FINAL:2019 Guidance on "Principles of Labelling for Medical Devices and IVD Medical Devices"

MRHA Guidance on "Medical device independent software including apps (including IVD MDs)"

BSI Guidance on "General Safety and Performance Requirements (Annex I) in the New Medical Device Regulation"

MedTech Europe Q&A 7 on CE-marking of components

MedTech Europe Guidance on Requirements under IVD Regulation (EU) 2017/746 which drive labelling changes

MedTech Europe Regulatory Update on "Symbols for self-testing and near-patient testing under the IVD Regulation (EU) 2017/746" (and zip file with high definition versions of the symbols)

MedTech Europe Guidance on "Use of Symbols to Indicate Compliance with the MDR"

Appendix – Mapping of the labelling requirements under the medical devices' directives and regulations

Table 1. **CE Marking and Notified Body Number**

IVDD (Article 16)	IVDR (Article 18)	AIMDD (Article 12)	MDD (Article 17)	MDR (Article 20)
1. Devices, other than devices for performance evaluation, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market. 2. **The CE marking of conformity**, as shown in Annex X, must appear in a **visible, legible and indelible form** on **the device**, where practicable and appropriate, and on the instructions for use. The CE marking of conformity **must also appear on the sales packaging**. The CE marking shall be accompanied by the identification number of the notified body responsible for implementation of the	1. Devices, other than devices for performance studies, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex V. 2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008. 3. The **CE marking** shall be affixed **visibly**, **legibly** and **indelibly** to the **device** or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking **shall also appear** in any instructions for use and **on any sales packaging**.	1. Devices other than those which are custom made or intended for clinical investigations considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity. 2. The CE marking of conformity, as shown in Annex 9, must appear in a visible, legible and indelible form on the sterile pack and, where appropriate, It must be followed by the identification number of the notified body responsible for implementation of the procedures set out in Annexes 2, 4 and 5.	1. Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market. 2. **The CE marking of conformity**, as shown in Annex XII, must appear in a **visible**, **legible** and **indelible** form on the **device** or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable, the CE marking **must also appear on the sales packaging**. It shall be accompanied by the identification number of the notified body responsible for	1. Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex V. 2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008. 3. The **CE marking** shall be affixed **visibly**, **legibly** and **indelibly** to the **device** or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any

procedures set out in Annexes III, IV, VI and VII. 3. It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking. Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not thereby reduced.	4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use. 5. **Where applicable**, the **CE marking shall be followed by the identification number of the notified body** responsible for the conformity assessment procedures set out in Article 48. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking. 6. Where devices are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the requirements of that other legislation.		implementation of the procedures set out in Annexes II, IV, V and VI. 3. It is prohibited to affix marks or inscriptions which are likely to mislead third parties with regard to the meaning or the graphics of the CE marking. Any other mark may be affixed to the device, to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not thereby reduced. VI.	instructions for use and **on any sales packaging**. 4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use. 5. **Where applicable**, the **CE marking shall be followed by the identification number of the notified body** responsible for the conformity assessment procedures set out in Article 52. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking. 6. Where devices are subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the requirements of that other legislation.

Table 2. **Name or Trade Name of the MDSW**

IVDD (Annex I)	IVDR (Annex I)	AIMDD (Annex 1)	MDD (Annex I)	MDR (Annex I)
8.4. The label must bear the following particulars which may take the form of symbols as appropriate:	**20.2. Information on the label** The label shall bear all of the following particulars:	14. Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:	**13.3** The label must bear the following particulars:	**23.2 Information on the label** The label shall bear all of the following particulars:
	(a) the **name** or **trade name** of the device;	14.2 On the sales packaging: - the name and address of the manufacturer and the name and address of the authorised representative, where the manufacturer does not have a registered place of business in the Community,	(a) the name or trade name and address of the manufacturer.	(a) the **name** or **trade name** of the device;

Table 3. **Details strictly necessary to identify the device**

AIMDD (Annex 1)	IVDD (Annex I)	IVDR (Annex I)	MDD (Annex I)	MDR (Annex I)
14. Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:	**8.4.** The label must bear the following particulars which may take the form of symbols as appropriate:	**20.2. Information on the label** The label shall bear all of the following particulars:	**13.3** The label must bear the following particulars:	**23.2 Information on the label** The label shall bear all of the following particulars:

14.2 On the sales packaging: - a description of the device, -the relevant characteristics for its use,	(b) the **details strictly necessary** for the user to uniquely **identify** the device and the contents of the packaging;	(b) the **details strictly necessary** for a user to **identify** the device and, where it is not obvious for the user, the intended purpose of the device;	(b) the **details strictly necessary** to **identify** the device and the contents of the packaging especially for the users;	(b) the **details strictly necessary** for a user to **identify** the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;

Table 4. **Intended purpose**

IVDD (Annex I)	**IVDR (Annex I)**	**AIMDD**	**MDD (Annex I)**	**MDR (Annex I)**
8.5. If the **intended purpose** of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the **label**.	**20.2. Information on the label** The label shall bear all of the following particulars: (b) the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the **intended purpose** of the device;	N/A	13.4. If the **intended purpose** of the device is not obvious to the user, the manufacturer must clearly state it on the **label** and in the instructions for use.	**23.2 Information on the label** The label shall bear all of the following particulars: (b) the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the **intended purpose** of the device;

Table 5. **Name and address of Manufacturer**

IVDD (Annex I)	IVDR (Annex I)	AIMDD (Annex 1)	MDD (Annex I)	MDR (Annex I)
8.4. The label must bear the following particulars which may take the form of symbols as appropriate:	**20.2. Information on the label** The label shall bear all of the following particulars:	14. Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:	**13.3** The label must bear the following particulars:	**23.2 Information on the label** The label shall bear all of the following particulars:
(a) the **name** or **trade name** and **address** of the **manufacturer**. For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative of the manufacturer;	(c) the **name**, registered **trade name** or registered **trade mark** of the **manufacturer** and the **address** of its registered place of business;	14.2. On the sales packaging: - the name and address of the manufacturer and the name and address of the authorised representative, where the manufacturer does not have a registered place of business in the Community,	(a) the **name** or **trade name** and **address** of the **manufacturer**. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community;	(c) the **name**, registered **trade name** or registered **trade mark** of the **manufacturer** and the **address** of its registered place of business;

Table 6. **Name and address of authorised representative**

IVDD (Annex I)	IVDR (Annex I)	AIMDD	MDD (Annex I)	MDR (Annex I)
8.4. The label must bear the following particulars which may take the form of symbols as appropriate:	**20.2. Information on the label** The label shall bear all of the following particulars:		**13.3** The label must bear the following particulars:	**23.2 Information on the label** The label shall bear all of the following particulars:
(a) the name or trade name and address of the manufacturer. For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the **name** and **address** of the **authorised representative** of the manufacturer;	(d) if the manufacturer has its registered place of business outside the Union, the **name** of its **authorised representative** and the **address** of the registered place of business of the authorised representative;	N/A	(a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the **name** and **address** of the **authorised representative** where the manufacturer does not have a registered place of business in the Community;	(d) if the manufacturer has its registered place of business outside the Union, the **name** of the **authorised representative** and **address** of the registered place of business of the authorised representative;

Table 7. **Indication of medical device or "exclusively for clinical investigations"**

IVDD	IVDR	AIMDD (Annex I)	MDD (Annex I)	MDR (Annex I)
N/A	N/A	**14.** Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:	**13.3** The label must bear the following particulars:	**23.2 Information on the label** The label shall bear all of the following particulars:
		14.2. On the sales packaging: - if the device is intended for clinical investigations, the words: **'exclusively for clinical investigations'**	(h) if the device is intended for clinical investigations, the words **'exclusively for clinical investigations'**;	(e) an **indication** that the device is a **medical device**. If the device is intended for clinical investigation only, the words **"Exclusively for clinical investigation"**

Table 8. **Indication of IVD-device or "device for performance study"**

IVDD (Annex I)	IVDR (Annex I)	AIMDD	MDD	MDR
8.4. The label must bear the following particulars which may take the form of symbols as appropriate:	**20.2. Information on the label** The label shall bear all of the following particulars:	N/A	N/A	N/A
(f) in case of devices for performance evaluation, the words **'for performance evaluation only'**; (g) where appropriate, a **statement indicating** the **in vitro use** of the device;	(e) an **indication** that the device is an **in vitro diagnostic medical device**, or if the device is a '**device for performance study**', an indication of that fact;			

Table 9. **Version number**

IVDD (Annex I)	IVDR (Annex I)	AIMDD	MDD (Annex I)	MDR (Annex I)
8.4. The label must bear the following particulars which may take the form of symbols as appropriate:	**20.2. Information on the label** The label shall bear all of the following particulars:	N/A	**13.3** The label must bear the following particulars:	**23.2 Information on the label** The label shall bear all of the following particulars:
(d) the batch code, preceded by the word 'LOT', or the serial number;	(f) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;		(d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number;	(g) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;

Table 10. **UDI Carrier**

IVDD	IVDR (Annex I)	AIMDD	MDD	MDR (Annex I)
N/A	**20.2. Information on the label** The label shall bear all of the following particulars:	N/A	N/A	**23.2 Information on the label** The label shall bear all of the following particulars:
	(g) the **UDI carrier** as referred to in Article 24 and Part C of Annex VI;			(h) the **UDI carrier** as referred to in Article 27 and Part C of Annex VI;

Table 11. **Warnings/Precaution/reference to IFU**

IVDD (Annex I)	IVDR (Annex I)	AIMDD (Annex 1)	MDD (Annex I)	MDR (Annex I)
8.4. The label must bear the following particulars which may take the form of symbols as appropriate:	**20.2. Information on the label** The label shall bear all of the following particulars:	**14.** Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:	**13.3** The label must bear the following particulars:	**23.2 Information on the label** The label shall bear all of the following particulars:
(j) appropriate **warnings** and/or **precautions** to take;	(m) **warnings** or **precautions** to be taken that need to be brought to the immediate attention of the user of the device or to any other person. This information may be kept to a minimum in which case more **detailed information** shall appear in the **instructions for use**, taking into account the intended users;	14.2. On the sales packaging: - the relevant characteristics for its use,	(k) any **warnings** and/or **precautions** to take;	(m) **warnings** or **precautions** to be taken that need to be brought to the immediate attention of the user of the device or to any other person. This information may be kept to a minimum in which case more **detailed information** shall appear in the **instructions for use**, taking into account the intended users;

Table 12. **Reference to accessibility of IFU**

IVDD	IVDR (Annex I)	AIMDD	MDD	MDR
MEDDEV. 2.14/3 rev.1 IVD GUIDANCES: Supply of Instructions For Use (IFU) and other information for *In-Vitro* Diagnostic (IVD) Medical Devices	**20.2. Information on the label** The label shall bear all of the following particulars:	**Regulation (EU) 207/2012 on electronic instructions for use of medical devices**		
Various references	(n) if the **instructions for use** are not provided in paper form in accordance with point (f) of Section 20.1, a reference to their **accessibility** (or availability), and where applicable the website address where they can be consulted;	**Article 6** 1. Manufacturers shall clearly indicate that the instructions for use of the device are supplied in electronic form instead of in paper form. That information shall be provided on the packaging for each unit or, where appropriate, on the sales packaging. In the case of fixed installed medical devices, that information shall also be provided on the device itself. 2. Manufacturers shall provide information on how to access the instructions for use in electronic form. That information shall be provided as set out in the second subparagraph of paragraph 1 or, if not practicable, in a paper document supplied with each device. 3. The information on how to access the instructions for use in electronic form shall contain the following: (a) any information needed to view the instructions for use; (b) a unique reference, giving direct access, and any other information needed by the user to identify and access the appropriate instructions for use; (c) relevant manufacturer contact details; (d) where, how and within which time instructions for use in paper form can be requested and shall be obtained at no additional cost in conformity with Article 5.		

		4. Where a part of the instructions for use is intended to be provided to the patient, that part shall not be provided in electronic form. 5. The instructions for use in electronic form shall be available entirely as text which may contain symbols and graphics with at least the same information as the instructions for use in paper form. Video or audio files may be offered in addition to the text.

Table 13. **Particular/ special operating instructions**

IVDD (Annex I)	**IVDR (Annex I)**	**AIMDD (Annex 1)**	**MDD (Annex I)**	**MDR (Annex I)**
8.4 The label must bear the following particulars which may take the form of symbols as appropriate:	**20.2. Information on the label** The label shall bear all of the following particulars:	**14.** Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:	**13.3** The label must bear the following particulars:	**23.2 Information on the label** The label shall bear all of the following particulars:
(i) where applicable, any **particular operating instructions**;	(o) where applicable, any **particular operating instructions**;	14.2. On the sales packaging: - the relevant characteristics for its use,	(j) any **special operating instructions**;	N/A

Table 14. **Indication of self-testing or near-patient testing**

IVDD (Annex I)	IVDR (Annex I)	AIMDD	MDD	MDR
8.4. The label must bear the following particulars which may take the form of symbols as appropriate:	**20.2. Information on the label** The label shall bear the following particulars:	N/A	N/A	N/A
(k) if the device is intended for self-testing, that fact must be clearly stated.	(q) if the device is intended for **self-testing** or **near-patient** testing, an **indication** of that fact;			

Table 15. **Exclusion of self-testing or near-patient testing for rapid assays**

IVDD	IVDR Annex I	AIMDD	MDD	MDR
N/A	**20.2. Information on the label** The label shall bear all of the following particulars:	N/A	N/A	N/A
	(r) where **rapid assays** are **not intended** for **self-testing** or **near-patient testing**, the explicit **exclusion** hereof;			

Table 16. **Components of IVD kits (not applicable for MD)**

IVDD	IVDR (Annex I)	AIMDD	MDD	MDR
N/A	**20.2. Information on the label** The label shall bear all of the following particulars:	N/A	N/A	N/A

	(s) where device **kits** include **individual reagents and articles that are made available as separate devices,** each of those devices **shall comply** with the labelling requirements contained in this Section and with the requirements of this Regulation;			

Table 17. **Particulars for self-testing IVDs**

IVDD	IVDR (Annex I)	AIMDD	MDD	MDR
N/A	**20.2. Information on the label** The label shall bear all of the following particulars: (u) the label for devices for **self-testing** shall bear the following **particulars**: (i) the type of specimen(s) required to perform the test (e.g. blood, urine or saliva); (ii) the need for additional materials for the test to function properly; (iii) contact details for further advice and assistance. The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.	N/A	N/A	N/A

Table 18. **Summary of safety and performance/Summary of safety and clinical performance**

IVDD	IVDR	AIMDD	MDD	MDR
N/A	**Article 29 - Summary of safety and performance** 1. For class C and D devices, other than devices for performance studies, the manufacturer shall draw up a summary of safety and performance. The summary of safety and performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed.	N/A	N/A	**Article 32 - Summary of safety and clinical performance** 1. For implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance. The summary of safety and clinical performance shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via Eudamed.

	The draft of the summary of safety and performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 48 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The **manufacturer** shall mention on the **label or instructions for use** where the **summary** is **available**.			The draft of the summary of safety and clinical performance shall be part of the documentation to be submitted to the notified body involved in the conformity assessment pursuant to Article 52 and shall be validated by that body. After its validation, the notified body shall upload the summary to Eudamed. The **manufacturer** shall mention on the **label or instructions for use** where the **summary** is **available**.

Table 19. **Date of manufacture**

IVDD	IVDR (Annex I)	AIMDD (Annex 1)	MDD (Annex I)	MDR (Annex I)
N/A	**20.2. Information on the label** The label shall bear all of the following particulars:	14. Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:	**13.3** The label must bear the following particulars:	**23.2 Information on the label** The label shall bear all of the following particulars:
	(i) where there is no indication of the date until when it may be used safely, the **date of manufacture**. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;	14.2. On the sales packaging: - the month and year of manufacture	(l) **year of manufacture** for active devices other than those covered by (e). This indication may be included in the batch or serial number;	(j) where there is no indication of the date until when it may be used safely, the **date** of **manufacture**. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.

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MedTech Europe Software Working Group
MedTech Europe Labelling Working Groups (IVD and MD)

***For EU legislation please see latest consolidated version. For MedTech Europe documents, in case any links are broken, please consult the latest version under the Regulatory E-Library.**

The *In Vitro* Diagnostic Medical Devices Regulation and Medical Devices Regulation contain several provisions that are capable of being given more than one interpretation. In the preparation of this Guidance, MedTech Europe has used its best efforts to ensure that the opinions and advice expressed are sound. However, the Association makes no assertion that those opinions and advice are correct, and it accepts no legal responsibility for them. Specific legal advice should be sought before acting on any of the topics covered. MedTech Europe reserves the right to change or amend this document at any time without notice in order to keep the information up to date.

Members are reminded that, while competent authorities and notified bodies may be helpful in providing views as to the meaning of EU Regulations, it is ultimately for the courts to interpret legislation.