



POLICY BRIEF

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**MDCG 2019-11 GUIDANCE ON QUALIFICATION AND
CLASSIFICATION OF SOFTWARE IN REGULATION (EU)
2017/745 – MDR AND REGULATION (EU) 2017/746 –
IVDR OCTOBER 2019**

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MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR October 2019 ¹	
BACKGROUND OF THE POLICY ACT	Article 2 of the Medical Devices Regulation (MDR ²) expressly includes software as a medical device. It is the same for the In Vitro Devices Regulation (IVDR ³) at Article 2(1) IVDR. The issue this policy legislation intended to solve is when to consider software as a medical device. In 2019, This question was addressed by the Medical Devices Coordination Group ⁴ , which is an EU expert pool on medical devices, divided into sub-groups, whose function is to clarify ambiguities and to solve interpretative issues concerning MDR and IVDR. At the root of this policy brief is the manufacturers' need to have clear rules on differentiating software as a service or a medical device . This might seem a trivial decision, but it is not as the amount of compliance duties under the MDR or IVDR is much higher and complex than when software is not a medical device or an in vitro medical device.
HIGHLIGHTS	<ul style="list-style-type: none"> • The first part lists all the relevant definitions of the MDR, especially the one of intended purpose. It is <i>'the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation'</i>⁵. • Section 3(2) explains more clearly when software is a medical device. It is defined as Medical Device Software and could be used alone or in combination. Useful examples can be found at Notes 1, 2, 3,4. In particular, Note 1 makes examples of MDSW which are in themselves medical devices such as the one that uses maternal parameters such as age, the concentration of serum markers and information obtained through fetal ultrasound examination for evaluating the risk of trisomy 21⁶. Note 2 makes examples of MDSW which operates on hardware or influences it. An example is <i>'melanoma image analysis software intended to drive a near-infrared laser light scanner'</i>⁷. Note 3 instead explains that an MSDW could also be operating in the cloud, computer and mobile phone. Note

¹ Available at <https://ec.europa.eu/docsroom/documents/37581>.

² Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC *OJ L 117, 5.5.2017*, p. 1–175.

³ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU *OJ L 117, 5.5.2017*, p. 176–332.

⁴ More at https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en.

⁵ Article 2(12) MDR

⁶ p.7

⁷ p.7



	<p>4 describes the case as MSDW as software that can be used by both healthcare professionals but also patients and care-givers such as a software providing insulin dose recommendations⁸.</p> <ul style="list-style-type: none"> Section 3(3) provides also a step by step guide on how to understand with a clear decision tree. The steps to follow are these <i>Decision step 1: if the product is software according to Section 2 (Definitions and Abbreviations) of this guidance, then it may be a medical device software, proceed to decision step 2; if the product is not software according to the definition of this guidance, then it is not covered by this guidance but may still be covered by the Medical Devices Regulations.</i> <p><i>Decision step 2: if the product is an MDR Annex XVI device, or is an accessory for a medical device, or is software driving or influencing the use of a medical device, then it must be considered as part of that device in its regulatory process or independently if it is an accessory. If it is not, proceed to decision step 3.</i></p> <p><i>Decision step 3: if the software does perform an action on data, or performs an action beyond storage, archival, communication, simple search, lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) then it may be a medical device software (Refer to section 3.1 for more guidance on these software functions) proceed to step 4.</i></p> <p><i>Decision step 4: is the action for the benefit of individual patients? Examples of software which are not considered as being for the benefit of individual patients are those which are intended only to aggregate population data, provide generic diagnostic or treatment pathways (not directed to individual patients), scientific literature, medical atlases, models and templates as well as software intended only for epidemiological studies or registers.</i></p> <p><i>Decision step 5: Is the software medical device software (MDSW) according to the definition of this guidance?"</i></p>
IMPACT	<p>Potentially relevant scenarios</p> <p>This policy guide is relevant for manufacturers as the application of the MDR imposes the respect of health and safety requirements coupled with lengthy conformity procedures in order to obtain the CE marking. It is relevant as most biorobotic applications are software driven and one needs to know if the software part is actually a medical device as they will need to combine the MDR compliance and the AI act one at the same time.</p>
	<p>Interdependencies with other policy areas</p> <p>The most direct interdependencies are with:</p> <ul style="list-style-type: none"> GDPR integration: there will be the necessity of a DPIA AI act AI act → if the software is an AI system which is also a safety component then all the conformity obligations of the AI act will need to be applied together with the MDR ones concerning the medical software.

⁸ P.7

⁹ P. 8-9.



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| | <ul style="list-style-type: none">• The product liability directive (PLD)¹⁰ and its update PLDU will be applicable whenever the medical software is not a high-risk AI system. |
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¹⁰ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

OJ L 210, 7.8.1985, p. 29–33