



Software within the medical device regulatory framework in the EU

**DITTA WORKSHOP ON MEDICAL SOFTWARE
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Outline – software within the medical device regulatory framework in the EU

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1. Legal background

Safety and performance requirements for software falling under the definition of a medical device (MDs) or an in-vitro diagnostic medical device (IVDs) are regulated by the respective directives:

- Directive 93/42/EEC (MDs)
- Directive 98/79/EC (IVDs)

The "Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices" (MEDDEV 2.1/6, January 2012) provide practical advice to determine when a software falls under the definition of a medical device or of an IVD medical device as well as its class.

The MEDDEV Guidance 2.1/6 applies to standalone software being defined as follows:

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

and introduces the set of qualification criteria as MD and IVD.

2. Latest developments & next steps

A. Proposal for the revision of MEDDEV Guidance 2.1/6 has been prepared by the EU Software Working Group with a view to clarifying:

a) certain software-related definitions

- *definitions have been introduced of software, input and output data, as well as of software as a medical device according to the document IMDRF/SaMD WG/N10FINAL:2013*

b) the distinction between different types of medical software

- *namely medical software that is part of MD, accessory, standalone software, not a MD*

c) the qualification steps described in the decision diagram

d) the regulation of mobile applications

B. New proposals for Regulations on MDs and IVDs

- ✓ New Regulations on MDs and IVDs to replace the existing Directives.
- ✓ The ongoing trilogue since 13 October 2015 and envisaged adoption of the new Regulations in the course of this year.
- ✓ New specific safety and performance requirements for software incorporated in medical devices, standalone software and medical software to be specifically used in combination with mobile computing platforms.

General safety and performance requirements under discussion

- ✓ repeatability, reliability and performance according to the intended use
- ✓ the principles of development life cycle, risk management, verification and validation
- ✓ the use of software in combination with mobile computing platforms
- ✓ IT security measures, including protection against unauthorised access

C. Manual on Borderline and Classification

- In the context of borderline cases, the European Commission introduced a new section 9. on medical standalone software and mobile applications in the Manual on Borderline and Classification.
- In the course of the last year, two new entries to the Manual on Borderline and Classification on mobile applications were approved regarding mobile apps for managing pictures and the assessment of moles.

3. Other initiatives in the field of mHealth

- Stakeholders consultation in 2014 on existing barriers and other issues related to mobile health deployment – publication of a *Green Paper on mHealth* and a *Staff Working Document on the existing EU legal framework applicable to lifestyle and wellbeing apps*.
- Possible follow-up policy actions regarding quality and reliability of mobile health apps to respond to the main challenges identified, in particular as regards data protection, safety and transparency of information, and the clarity of the legal framework.

- Legal clarity: developing a legal framework aimed at clarifying a legal status of mHealth apps as consumer products and defining legal means addressing safety and liability of mHealth apps (which do not qualify as MDs, so-called ***lifestyle and wellbeing apps***).
- Safety and transparency of information: establishment of a working group, consisted of civil society, research and industry representatives, to develop guidelines for assessing validity and reliability of mHealth apps data.
- Data protection: developing the code of conduct on privacy for mHealth applications aimed at providing guidance for apps manufacturers on compliance with data protection rules at EU level and at promoting good practices in this field.

4. IMDRF angle

- In the meantime, EU has been involved in the ongoing work of the **IMDRF Software as a Medical Device Working Group** for SaMD clinical evaluation.
- EU mirror group for regulators to the IMDRF WG has been created in December 2015 due to growing interest of the EU Member States.



***Thank you
for your attention!***