Commission Implementing Decision (EU) 2020/350 of 28 February 2020 amending Decision 2002/364/EC as regards definitions of first–line assays and confirmatory assays, requirements for devices for self-testing and requirements for HIV and HCV rapid tests, confirmatory and supplementary assays (notified under document C(2020) 1086) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2020/350

of 28 February 2020

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(notified under document C(2020) 1086)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices[(1)], and in particular the second subparagraph of Article 5(3) thereof,

Whereas:

(1) Pursuant to the first subparagraph of Article 5(3) of Directive 98/79/EC, Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of devices designed and manufactured in conformity with common technical specifications. The common technical specifications for in vitro diagnostic medical devices are laid down in Commission Decision 2002/364/EC[(2)].

(2) In the interest of public health and patient safety and in order to reflect scientific and technological progress, including the evolution in the intended use, performance, and analytical sensitivity of certain devices, it is appropriate to update the common technical specifications laid down in Decision 2002/364/EC.

(3) The definitions of first-line assays and confirmatory assays, requirements for devices for self-testing and requirements for HIV and HCV rapid tests, confirmatory and supplementary assays should be amended in order to take into account the evolved state of the art, the changes in clinical needs, new scientific knowledge available and the new types of devices present on the market.

(4) The manufacturers should be allowed time to adapt to the changes in common technical specifications. The date of application of this Decision should therefore be deferred. However, in the interest of public health and patient safety, manufacturers should be allowed to comply with the common technical specifications as amended by this Decision before its date of application on a voluntary basis.

(5) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 6(2) of Council Directive 90/385/EEC[(3)],

HAS ADOPTED THIS DECISION:

(**1**) OJ L 331, 7.12.1998, p. 1.

(**2**) Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (OJ L 131, 16.5.2002, p. 17).

(**3**) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2020/350, Introductory Text.