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)

Article 1

The Annex to Decision 2002/364/EC is amended in accordance with the Annex to this Decision.

Article 2

1 This Decision shall apply from 2 March 2021.

2 Notwithstanding paragraph 1, from 2 March 2020 until 1 July 2020 Member States shall apply the presumption of compliance laid down in Article 5(3) of Directive 98/79/EC for all in vitro diagnostic medical devices that comply with any of the following:

a the common technical specifications laid down in Decision 2002/364/EC as amended by Commission Decision 2011/869/EU[(1)];

b the common technical specifications laid down in Decision 2002/364/EC as amended by Commission Implementing Decision (EU) 2019/1244[(2)];

c the common technical specifications laid down in Decision 2002/364/EC as amended by this Decision.

3 Notwithstanding paragraph 1, from 2 July 2020 until 1 March 2021 Member States shall apply the presumption of compliance laid down in Article 5(3) of Directive 98/79/EC for all in vitro diagnostic medical devices that comply with either of the following:

a the common technical specifications laid down in Decision 2002/364/EC as amended by Implementing Decision (EU) 2019/1244;

b the common technical specifications laid down in Decision 2002/364/EC as amended by this Decision.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 28 February 2020.

For the Commission

Stella KYRIAKIDES

Member of the Commission

(**1**) Commission Decision 2011/869/EU of 20 December 2011 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices (OJ L 341, 22.12.2011, p. 63).

(**2**) Commission Implementing Decision (EU) 2019/1244 of 1 July 2019 amending Decision 2002/364/EC as regards requirements for HIV and HCV antigen and antibody combined tests and as regards requirements for nucleic acid amplification techniques with respect to reference materials and qualitative HIV assays (OJ L 193, 19.07.2019, p.1).

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