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.
- 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<sup>(1)</sup>;
  - the common technical specifications laid down in Decision 2002/364/EC as amended by Commission Implementing Decision (EU) 2019/1244<sup>(2)</sup>;
  - the common technical specifications laid down in Decision 2002/364/EC as amended by this Decision.
- 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

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

- (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).

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## **Changes to legislation:**

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