EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

laying down common specifications for certain class D *in vitro* diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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[1], and in particular Article 9(1) thereof,

Whereas:

(1) For certain class D *in vitro* diagnostic medical devices falling within the scope of Regulation (EU) 2017/746, harmonised standards do not exist as regards certain requirements of Annex I to that Regulation, and there is a need to address public health concerns as the risk associated with the use of those devices is significant for public health and patient safety. It is therefore appropriate to adopt common specifications for those devices in respect of those requirements.

(2) Regulation (EU) 2017/746 replaces Directive 98/79/EC of the European Parliament and of the Council[2]. The common technical specifications set out in Commission Decision 2002/364/EC[3] for certain devices covered by Directive 98/79/EC remain relevant. Those common technical specifications have therefore been taken into account and where necessary updated to reflect the state of the art.

(3) To allow manufacturers, other economic operators, notified bodies and other actors to adapt to this Regulation, and to ensure its proper application, it is appropriate to defer its application. However, in the interest of public health and patient safety, manufacturers should be allowed to comply with the common specifications laid down in this Regulation on a voluntary basis before its date of application.

(4) To ensure a continuous high level of safety and performance of devices, as a transitional measure it should be provided that devices that are in conformity with Decision 2002/364/EC are to be presumed to be in conformity with the requirements for certain performance characteristics set out in Annex I to Regulation (EU) 2017/746 until the date of application of this Regulation.

(5) The Medical Device Coordination Group has been consulted.

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1 OJ L 117, 5.5.2017, p. 176.

2 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

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

(6) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices,

HAS ADOPTED THIS REGULATION:

Article 1

Common specifications

This Regulation lays down common specifications for certain class D in vitro diagnostic medical devices in respect of the requirements regarding the performance characteristics set out in Section 9.1, points (a) and (b), Section 9.3 and Section 9.4, point (a), of Annex I to Regulation (EU) 2017/746.

Annex I lays down common specifications for devices covered by Annexes II to XIII, as specified in that Annex.

Annex II lays down common specifications for devices intended for detection of blood group antigens in the ABO, Rh, Kell, Duffy and Kidd blood group systems.

Annex III lays down common specifications for devices intended for detection or quantification of markers of human immunodeficiency virus (HIV) infection.

Annex IV lays down common specifications for devices intended for detection or quantification of markers of human T-cell lymphotropic virus (HTLV) infection.

Annex V lays down common specifications for devices intended for detection or quantification of markers of hepatitis C virus (HCV) infection.

Annex VI lays down common specifications for devices intended for detection or quantification of markers of hepatitis B virus (HBV) infection.

Annex VII lays down common specifications for devices intended for detection or quantification of markers of hepatitis D virus (HDV) infection.

Annex VIII lays down common specifications for devices intended for detection of markers of variant Creutzfeldt-Jakob disease (vCJD).

Annex IX lays down common specifications for devices intended for detection or quantification of markers of cytomegalovirus (CMV) infection.

Annex X lays down common specifications for devices intended for detection or quantification of markers of Epstein-Barr virus infection (EBV).

Annex XI lays down common specifications for devices intended for detection of markers of *Treponema pallidum* infection.

Annex XII lays down common specifications for devices intended for detection of markers of *Trypanosoma cruzi* infection.

Annex XIII lays down common specifications for devices intended for detection or quantification of markers of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) ‘true positive’ means a specimen known to be positive for the target marker and correctly classified by the device;

(2) ‘false negative’ means a specimen known to be positive for the target marker and misclassified by the device;

(3) ‘false positive’ means a specimen known to be negative for the target marker and misclassified by the device;

(4) ‘the limit of detection’ (‘LOD’) means the smallest amount of the target marker that can be detected;

(5) ‘nucleic acid amplification techniques’ (‘NAT’) means methods of detection and/or quantification of nucleic acids by either amplification of a target sequence, by amplification of a signal or by hybridisation;

(6) ‘rapid test’ means a qualitative or semi-quantitative *in vitro* diagnostic medical device, used singly or in a small series, which involves non-automated procedures (except the reading of results) and has been designed to give a fast result;

(7) ‘robustness’ means the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage;

(8) ‘cross-reactivity’ means the ability of non-target analytes or markers to cause false positive results in an assay because of similarity, e.g. the ability of non-specific antibodies binding to a test antigen of an antibody assay, or the ability of non-target nucleic acids to be reactive in a NAT assay;

(9) ‘interference’ means the ability of unrelated substances to affect the results in an assay;

(10) ‘whole system failure rate’ means the frequency of failures when the entire process is performed as prescribed by the manufacturer;

(11) ‘first-line assay’ means a device used to detect a marker or analyte, and which may be followed by a confirmatory assay; devices intended solely to be used to monitor a previously determined marker or analyte are not considered first line assays;

(12) ‘confirmatory assay’ means a device used for the confirmation of a reactive result from a first line assay;

(13) ‘supplemental assay’ means a device that is used to provide further information for the interpretation of the test result of another assay;

(14) ‘virus typing device’ means a device used for typing with already known positive samples, not used for primary diagnosis of infection or for screening;

(15) ‘95% positive cut-off value’ means the analyte concentration where 95% of test runs give positive results following serial dilutions of an international reference material, where available, e.g. a World Health Organisation (WHO) International Standard or reference material calibrated against the WHO International Standard.

Article 3

Transitional provisions

1. From … [OP: please insert the date of entry into force of this Regulation] until … [OP: please insert the date – 2 years after the date of entry into force of this

Regulation], devices that are in conformity with the common technical specifications set out in Decision 2002/364/EC shall be presumed to be in conformity with the requirements regarding the performance characteristics set out in Section 9.1, points (a) and (b), Section 9.3 and Section 9.4, point (a), of Annex I to Regulation (EU) 2017/746.

During that period manufacturers of devices that are not in conformity with the common technical specifications set out in Decision 2002/364/EC shall duly justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent thereto.

2. From … [*OP: please insert the date of entry into force of this Regulation]* until *... [OP: please insert the date – 2 years after the date of entry into force of this Regulation*] devices that are in conformity with the common specifications laid down by this Regulation shall be presumed to be in conformity with the requirements regarding the performance characteristics set out in Section 9.1, points (a) and (b), Section 9.3 and Section 9.4, point (a), of Annex I to Regulation (EU) 2017/746.

Article 4

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from … [*OP: please insert the date – 2 years after the date of entry into force of this Regulation*].

However, Article 3 shall apply from … [*OP: please insert the date of entry into force of this Regulation*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN