EUROPEAN
COMMISSION

Brussels, XXX
[…](2024) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulation (EU) 2022/1107 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) Common specifications for certain *in vitro* diagnostic medical devices are laid down in Commission Implementing Regulation (EU) 2022/1107[2].

(2) For class D devices intended for detection of hepatitis E virus, *Toxoplasma gondii*, *Plasmodium spp*., as well as four types of arboviruses (Chikungunya virus, dengue virus, West Nile virus and Zika virus), harmonised standards do not exist as regards certain requirements of Annex I to Regulation (EU) 2017/746, 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 add common specifications for those devices in respect of those requirements.

(3) The experience with the use of common specifications laid down in Implementing Regulation (EU) 2022/1107, has demonstrated that there is a need to clarify some of those specifications or, where necessary, update them to reflect the state of the art.

(4) To allow manufacturers, other economic operators, notified bodies and other relevant actors to adapt to the new and updated specifications laid down in this Regulation, and to ensure their proper application, it is appropriate to set an adequate transition period. However, in the interest of public health and patient safety, manufacturers should be allowed to comply with these specifications on a voluntary basis before the date of application of this Regulation.

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

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

(7) Implementing Regulation (EU) 2022/1107 should therefore be amended accordingly,

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[1] OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj.

[2] Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 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, (OJ L 178, 5.7.2022, p. 3, ELI: http://data.europa.eu/eli/reg_impl/2022/1107/oj).

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2022/1107 is amended as follows:

(1) Article 1 is replaced by the following:

‘*Article 1*

Common specifications

This Regulation lays down common specifications for certain *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 XX, as specified in that Annex.

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

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

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

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

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

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

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

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

Annex XI lays down common specifications for class D devices intended for detection of markers of *Treponema pallidum* (*T. pallidum*) infection.

Annex XII lays down common specifications for class D devices intended for detection or quantification of markers of *Trypanosoma cruzi* (*T.cruzi*) infection.

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

Annex XIV lays down common specifications for class D devices intended for detection or quantification of markers of hepatitis E virus (HEV) infection.

Annex XV lays down common specifications for class D devices intended for detection or quantification of markers of *Toxoplasma gondii* infection.

Annex XVI lays down common specifications for class D devices intended for detection of markers of *Plasmodium* infection.

Annex XVII lays down common specifications for class D devices intended for detection or quantification of markers of Chikungunya virus (CHIKV) infection.

Annex XVIII lays down common specifications for class D devices intended for detection or quantification of markers of dengue virus (DENV) infection.

Annex XIX lays down common specifications for class D devices intended for detection or quantification of markers of West Nile virus (WNV) infection.

Annex XX lays down common specifications for class D devices intended for detection or quantification of markers of Zika virus (ZIKV) infection.';

(2) in Article 2, point (15) is replaced by the following:

'(15) 'virus typing device' means a device used for typing with already known positive specimens, not used for primary diagnosis of infection or for screening;';

(3) Annexes I to XIII are amended in accordance with Annex I to this Regulation;

(4) the text of Annex II to this Regulation is added as Annexes XIV to XX.

Article 3

Transitional provisions

From [*OP: please insert the date of entry into force of this amending Regulation*] until [*OP: please insert the date of application of this amending Regulation*] devices that are in conformity with the common specifications set out in 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 enter the date – 2 years from date of entry into force of this amending 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