EUROPEAN
COMMISSION

Brussels, XXX
[…](2016) XXX draft

COMMISSION DECISION

of XXX

[…]

amending Decision 2002/364/EC as regards requirements for HCV antigen/antibody combined tests and Nucleic Acid Amplification techniques in qualitative HIV assays

(Text with EEA relevance)

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amending Decision 2002/364/EC as regards requirements for HCV antigen/antibody combined tests and Nucleic Acid Amplification techniques in qualitative HIV assays

(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) 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 in order to reflect scientific and technological progress, including the evolution in the performance and analytical sensitivity of certain devices, it is appropriate to revise the common technical specifications laid down in Decision 2002/364/EC.

(3) Taking into account the state of the art and the current scientific knowledge, the common technical specifications should be amended, as regards the requirements for HCV antigen/antibody combined tests and Nucleic Acid Amplification techniques assays in particular for qualitative HIV assays.

(4) In order to allow the manufacturers, whose devices are already on the market and which are not compliant with the new common technical specifications, to adapt to the requirements of the new common technical specifications, the application of this Decision should be deferred.

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

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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).

HAS ADOPTED THIS DECISION:

Article 1

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

Article 2

This Decision is addressed to the Member States.

It shall apply from six months after taking effect.

Done at Brussels,

For the Commission
Elzbieta Bienkowska
Member of the Commission