EUROPEAN
COMMISSION

Brussels, XXX
[…](2015) XXX draft

COMMISSION IMPLEMENTING DECISION (EU) …/…

of XXX

on qualification of the group of products whose principal intended action, depending on proanthocyanidins (PAC) present in cranberry (Vaccinium Macrocarpon), is to prevent or treat cystitis

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THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[1], and in particular Article 13 (1) thereof,

Having regard to the request submitted by France in accordance with Article 13 (1) (d) of this Directive,

Whereas:

(1) According to Article 13(1) (d) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, a Member State shall submit a duly substantiated request to the Commission and ask to take necessary measures when this Member State considers that a decision is required as to whether a particular product or product group falls within one of the definitions in Article 1(2) (a) to (e).

(2) France has requested that a decision should be taken with the effect that the group of products whose principal intended action, depending on proanthocyanidins (PAC) present in cranberry (Vaccinium Macrocarpon) extract, is to prevent or treat cystitis, should not be qualified as medical devices.

(3) Article 1 (2) (a) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices defines a 'medical device' as any instrument, apparatus, appliance, software, material or other article [..] intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- (…)
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

(4) The principal intended action of the group of products described under point (2) is achieved by pharmacological, immunological or metabolic means, notably by inhibiting adhesion between P-fimbriated E. Coli and mucous membrane cells in the urinary tract.

(5) The present decision does not concern the question whether the intended action can be achieved by the group of products described under (2) as these do not fall under the definition of a 'medical device' in Article 1 (2) (a) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

[1] OJ L [169], [12.7.1993], p. [1].

(6) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 7 (1) of Council Directive 93/42/EEC.

HAS ADOPTED THIS DECISION:

Article 1

The group of products whose principal intended action, depending on proanthocyanidins (PAC) present in cranberry (Vaccinium Macrocarpon) extract, is to prevent or treat cystitis, are not medical devices in the meaning of Article 1 (2) (a) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices,

Article 2

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

Article 3

This Decision is addressed to the Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude Juncker