



Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

Director General

Our Ref.: FD/FD 30.120

Paris, 6 June 2013

Dr Yun-long Tsai
Research Manager
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No. 19, Keyuan 2nd Road, Central Taiwan Science Park
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Taiwan

Dear Dr Tsai,

OIE Procedure for Registration of Diagnostic Kits

Official inclusion in the OIE register

Further to the adoption of Resolution No. 26 by the World Assembly of Delegates during the 81st General Session, I am pleased to inform you that the "IQ Plus™ WSSV Kit with POKKIT System" (Approval number 20130108) is officially included in the OIE register (available on the OIE website at <http://www.oie.int/en/our-scientific-expertise/certification-of-diagnostic-tests/the-register-of-diagnostic-tests/>) for the fitness for purposes mentioned in this Resolution (see enclosed).

I kindly remind you that the new mock-ups or specimens of the final outer and immediate packaging and the package insert, mentioning this new status, must be submitted to the OIE before being placed on the market with the kit. I also kindly refer you to Section 7 of the Standard Operating Procedure, here enclosed, for the use of the OIE logo.

The annual review and annual fee should be provided every year between 1 and 15 January (please see the point 2.7., section 2, p. 11 and section 6, p. 20 of the Standard Operating Procedure).

I also remind you that no changes may be made to the components or configuration of the kit without prior notification to the OIE, and providing evidence that the changes will not affect the performance characteristics of the kit.

If you have any questions or need some additional information, do not hesitate to contact the OIE Secretariat for Registration of Diagnostic Kits (Dr François Diaz, f.diaz@oie.int, 01 44 15 19 69).

Best regards

Yours sincerely

Dr Bernard Vallat

Enclosure: Copy of the Resolution No. 26 (three official languages)
Standard Operating Procedure

cc: M. Eloit, E. Erlacher-Vindel, S. Linnane, F. Diaz
F. Berthe (President of the AAHSC)

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