OFFICE OF HEALTH
AUTHORISATION AND ADMINISTRATIVE PROCEDURES
DEPARTMENT OF MEDICAL DEVICES

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Subject: Certificate
Reference: 37072-005/2013/OTIG
Registration No.: **HU/CA01/37072/13**
Admin.ref.: Ádám Eszter

The Department of Medical Devices of the Office of Health Authorisation and Administrative Procedures according to the Article 7, point (3) of the Decree No. 8/2003.(III.13.) EszCsM on „In vitro diagnostic medical devices" (in the following IVD-decree) harmonizing the 98/79/EC Directive on In vitro diagnostic medical devices

c e r t i f i e s

that the Vitrolife Kft. (H-6722 Szeged, Gogol u. 9/B) has notified the following IVD-devices according to points (1) of Article 7 of the IVD-decree.

Device category (due to ISO 15225:2000): In vitro diagnostic medical devices
Name of the device(s):
Primo Vision WOW microwell embryo culture-dish

Name of manufacturer: Vitrolife Kft.
Code of manufacturer: HU/23068003-2-06

This certificate has been issued to the manufacturer in the procedure launched on the request presented on 29 May 2013, on the basis of documents available, in order to certify that notification according to Article 7 of the IVD-decree has been done.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of „in vitro medical device", and that you have classified it/them as falling within the IVD-decree. In accepting your registration, I should make clear that the Department of Medical Devices does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the Hungarian Competent Authority.

This Certificate has been issued instead of the Certificate Ref. Number HU/CA01/29403/12 because of change of name of the manufacturer. From this time the Certificate HU/CA01/29403/12 is no longer valid.

Budapest, 20 June 2013

on behalf of President dr. Rita Paphalmi acting
within the task and competence of the Office:

Péter Bunyitai
/ Head of Department /

Receivers are as follows:
1. Vitrolife Kft. (H-6722 Szeged, Gogol u. 9/B)
2. Archives