



EC DESIGN- EXAMINATION CERTIFICATE

Directive 98/79/EC

Manufacturer: Guangzhou Wondfo Biotech Co. Ltd
South China University of Technology, Tianhe
Guangzhou, P.R.China

Designer: Guangzhou Wondfo Biotech Co. Ltd
South China University of Technology, Tianhe
Guangzhou, P.R.China

Product: Ovulation test for self-testing

Valid until: 15th October 2010

The design of the aforesaid product, as specified in decisions related to this certificate, has been examined and meets the relevant provisions of Council Directive 98/79/EC. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex III in Directive 98/79/EC. This certificate is based on decision no. VTT-C-2174-02-1086-301-07-P0.

Tampere, 10th October, 2007

Kaarle Kylmä






Markku Helminen

Certificate no.
VTT-C-2174-02-1086-301-07

Notified Body no. 0537:
VTT Technical Research Centre of Finland
P.O. Box 1300 (Tekniikankatu 1)
FI-33101 TAMPERE
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DECISION

on an in vitro diagnostic medical device, based on Council Directive 98/79/EC concerning in vitro diagnostic medical devices, Annex III.

Decision no.:	VTT-C-2174-02-1086-301-07-P0 Extension of the validity period.
Manufacturer:	Guangzhou Wondfo Biotech Co. Ltd South China University of Technology, Tianhe, Guangzhou, P.R.China
Date of application:	24.8.2007
Product category:	Ovulation test for self-testing.
Decision:	EC design-examination certificate will be issued for the manufacturer. The certificate covers the following products: - One Step Ovulation Urine Test containing <ul style="list-style-type: none"> • Cat. No. W2-S Strip • Cat. No. W2-C Cassette • Cat. No. W2-M and W2-MII Midstream
Justification:	The manufacturer's certificate no. TUO 1086-192 expires 15.10.2007. The design of the product has been reassessed and VTT has found that it meets the requirements of Annex III of In Vitro Diagnostic Medical Device Directive 98/79/EC. The decision is based on the audit report no. NB-1086-A4. The company has signed the undertaking to follow the obligations of Annex III of the Directive.
Certificate related to decision:	VTT-C-2174-02-1086-301-07
Valid until:	This decision is valid until 15 th October, 2010 unless the validity of the related certificate is changed.
Date:	Tampere, 10 th October, 2007 <div style="text-align: center;">  </div> <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">  Kaarle Kylmä </div> <div style="text-align: center;">  Markku Helminen </div> </div>

VTT is Notified Body no 0537 under Council Directive 98/79/EC.

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