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:	Pregnancy test for self-testing
Valid until:	25th March 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-1550-02-1086-270-07-P0.

Tampere, 23rd March 2007

Kaarle Kylmälä

Markku Helminen

Certificate no.
VTT-C-1550-02-1086-270-07

Notified Body no. 0537:
VTT Technical Research Centre of Finland
P.O. Box 1300 (Tekniikankatu 1)
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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-1550-02-1086-270-07-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:	20.2.2007
Product category:	Pregnancy test for self-testing.
Decision:	EC design-examination certificate will be issued for the manufacturer. The certificate covers the following products: - One Step hCG Urine Test containing • Cat. No. W1-S, W1-S (10mIU) and W1-S (20mIU) Strip • Cat. No. W1-C, W1-C (10mIU) and W1-C (20mIU) Cassette • Cat. No. W1-M, W1-M (10mIU) and W1-M (20mIU) Midstream • Cat. No. W1-MI, W1-MI (10mIU) and W1-MI (20mIU) Midstream • Cat. No. W1-MII and W1-MIII Midstream
Justification:	The manufacturer's certificate no. TUO 1086-162 expires 25.3.2007. 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-A3. The company has signed the undertaking to follow the obligations of Annex III of the Directive.
Certificate related to decision:	VTT-C-1550-02-1086-270-07
Valid until:	This decision is valid until 25th March, 2010 unless the validity of the related certificate is changed.
Date:	Tampere 23rd March, 2007 Kaarle Kylmälä Markku Helminen

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

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