

APPROVAL

EC Directive 98/79/EC Annex IV, Article 3
Full Quality Assurance System
In vitro diagnostic medical devices

Registration No.: HL 60022834 0001

Report No.: 15025854 001

Manufacturer: Core Technology Co., Ltd.
Room 100, C Building
No. 29 Life Park Road
Changping District

Beijing 102206
China

Scope: Design/development and manufacture of
HCG Pregnancy Tests and LH Ovulation Tests for self-testing
Production facility: see attachment

Date of Expiry: 11.09.2013

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex IV, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex IV, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 02.12.2008



Notified Body


Dr. H. Lüdemann

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.



The CE marking may be used if all relevant and effective EC Directives are complied with.

