



National Testing Center for Digital Electronic Product (TDE)
Shenzhen Academy of Metrology and Quality Inspection (SMQ)

Certificate

Of

Compliance

No: WT083002733

The applicant

SHENZHEN PROCAN ELECTRONICS INC.

5th Floor, Block D, Changyuan New Material Port, Gaoxin Central 1st Road, Nanshan,
Shenzhen, Guangdong, China

has successfully demonstrated that its product

FULLY AUTO HEMATOLOGY ANALYZER

PE-6000 Plus, PE-6300 Plus, PE-6000, PE-6300, PE-6100, PE-6800

is compliant with

EN61010-1: 2001

EN61010-2-101: 2002

The certificate of compliance shows that the tested sample technically complies with safety requirement of the European Union IVDD 98/79/EC directive and its latest amended version. The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production.



Authorized Signer :



Issued

Date :

Sep. 12, 2008



Canada





Product Service

CERTIFICATE

No. Q1N 07 02 61132 001

Holder of Certificate: Shenzhen Procan Electronics Inc.

5th Floor, Block D
 Changyuan New Material Port
 Gaoxin Central Road 1th
 Nanshan
 518057 Shenzhen
 PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shenzhen Procan Electronics Inc.
 5th Floor, Block D, Changyuan New Material Port, Gaoxin Central
 Road 1th, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC
 OF CHINA

Certification Mark:



Scope of Certificate: Design and Development,
 Production and Distribution of
 Hematology Analyzer and Reagent,
 Chemistry Analyzer and Reagent

Applied Standard(s): ISO 13485:2003
 Medical Devices - Quality Management Systems -
 Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 64200600301

Valid until: 2010-04-30



Date, 2007-05-23

Reiner Krumme

Page 1 of 1

TÜV SÜD Product Service GmbH
 Zertifizierstelle
 Ridlerstr. 65 · 80339 München
 Germany



Akkreditiert durch
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln
 und Medizinprodukten
 ZLG-ZQ-999.98.12-46