

TECOM SCIENCE CORPORATION

DECLARATION OF CONFORMITY

Name and Address of Product Owner:

Name: TECOM SCIENCE CORPORATION

Address: No.555 Gaoxin Ave., Nat. Hi-Tech Ind. Development Zone, Nanchang, Jiangxi 330096, P.R. China

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations.

Manufacturing Site:

Name: TECOM SCIENCE CORPORATION

Address: No.555 Gaoxin Ave., Nat. Hi-Tech Ind. Development Zone, Nanchang, Jiangxi 330096, P.R. China

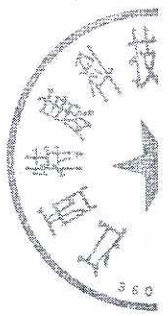
Medical Device(s):

- Automatic Chemistry Analyzer: TC220
- Automatic Chemistry Analyzer: TC6030L
- Automatic Chemistry Analyzer: TC6060L
- Automatic Chemistry Analyzer: TC6090L

- Automatic Chemistry Analyzer: TC6030G
- Automatic Chemistry Analyzer: TC6060G
- Automatic Chemistry Analyzer: TC6090G
- Hematology Analyzer: TEK II MINI
- Hematology Analyzer: TEK 5000
- Hematology Analyzer: TEK 8510
- Reagent Hematology Analyzer

Risk Classification:

Class A (Rule 5)



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GIÁM ĐỐC
Trần Lan Anh

TECOM SCIENCE CORPORATION

Quality Management System Certificate:

EN ISO 13485:2012

Certification Body: TÜV SÜD Product Service GmbH

Certification Register No.: Q1N 16 24 60251 009

Issue / expiry date: 01 April 2016 / 31 March 2019

Standards Applied:

EN ISO 13845:2012 + AC: 2012

ISO 13485:2003 +Cor.1:2009

DIN EN ISO 13845:2012

The declaration of conformity is valid from:

01 July 2017

Authorized Signatory:

Date: 01 July 2017



Zhou Honghua

Director

Tecom Science Corporation

