

# Kalitest

NOTIFIED BODY NO : 2179

## CERTIFICATE OF CONFORMITY

This certificate has been awarded to the company

### **BEIJING SAFE HEART TECHNOLOGY LTD.**

**2F Tower-1, 25 Yongxing Road, Zhongguancun  
Science Park in Daxing Biomedicine Industry Base,  
Beijing, CHINA**

To certify that the implemented full quality assurance system to ensure the listed products below conform to the provisions of

### **93/42/EEC Medical Devices Directive Annex II**

for products described below according to report

**11/MD-MDD/BEIJING SAFEHEART/B01 – 20-21.10.2011**

**ELECTROCARDIOGRAPH (Annex IX, Rule 11)  
FINGER PULSE OXIMETER (Annex IX, Rule 10)  
Class IIa**

Kalitest Certification and Training Services Inc. :



Signed

Certificate No **K-MDD-1039**  
First Registration Date **07.12.2011**  
Period of registration : **5 years**  
Certificate Date **07.12.2011**  
Expiry Date **07.12.2016**

Please verify the validity of this certificate with the serial number of 4227422 from the web site of [www.kalitest.com.tr](http://www.kalitest.com.tr)

**KALİTEST BELGELENDİRME VE EĞİTİM HİZMETLERİ LİMİTED ŞİRKETİ**

Akatlar Mahallesi Hare Sokak 2. Söлтаş Evleri G-10 No:9 1.Levent / İSTANBUL Tel: 0212 269 37 41 - 42 - 43 Faks: 0212 269 37 44

The validity of this certificate depends on the company's conformity with KALİTEST Certificate Regulations and the result of the surveillance audits which will be carried out at least once in a year.

# Kalitest

ANNEX to TO CERTIFICATE OF CONFORMITY K-MDD-1039  
FOR BEIJING SAFE HEART TECHNOLOGY LTD.

## FINGER PULSE OXYMETER MODELS

SHO-1001,  
SHO-1002,  
SHO-2001,  
SHO-2002,  
SHO-3001,  
SHO-3002,  
SHO-4001,  
SHO-4002,  
SHO-5001,  
SHO-5002

## ELECTROCARDIOGRAPH MODELS

SHC-6A,  
SHC-7A

SIGNED:.....



Attachment to the Certificate No :K-MDD-1039, First Registration Date: 07.12.2011 Period of registration 5 years.  
The validity of this certificate depends on the company's conformity with KALİTEST Certificate Regulations and the result of the surveillance audits which will be carried out at least once in a year. This attachment is only valid with the date of issue and with the serial number of the original certificate. In case of change or update of the products the list should be updated also to reflect the valid status. Please verify the validity of the main original certificate with the serial number of 4227422 from the web site of [www.kalitest.com.tr](http://www.kalitest.com.tr)

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### **93/42/EEC Medical Devices Directive Annex II**

for products described below according to report

**11/MD-MDD/BEIJING SAFEHEART/B01 – 20-21.10.2011**

**ANESTHESIA MACHINE  
EMERGENCY VENTILATOR  
FETAL DOPPLER  
ICU VENTILATOR  
PATIENT MONITOR**

**Class IIb (Annex IX, Rule 10)**

Kalitest Certification and Training Services Inc. :



Signed

Certificate No **K-MDD-1036**

First Registration Date **07.12.2011**

Period of registration : 5 years

Certificate Date **07.12.2011**

Expiry Date **07.12.2016**

Please verify the validity of this certificate with the serial number of 5534728 from the web site of [www.kalitest.com.tr](http://www.kalitest.com.tr)

**KALİTEST BELGELENDİRME VE EĞİTİM HİZMETLERİ LİMİTED ŞİRKETİ**

Akatlar Mahallesi Hare Sokak 2. Söлтаş Evleri G-10 No:9 1.Levent / İSTANBUL Tel: 0212 269 37 41 - 42 - 43 Faks: 0212 269 37 44

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ANNEX to TO CERTIFICATE OF CONFORMITY K-MDD-1036  
FOR BEIJING SAFE HEART TECHNOLOGY LTD.

## PATIENT MONITOR MODELS

SHM-3012, SHM-3010,  
SHM-3008, SHM 3007

## ANESTHESIA MACHINE MODELS

SHA-5000, SHA-3000,  
SHA-1000

## ICU VENTILATOR MODELS

SHB-2000C, SHB-1000C

## EMERGENCY VENTILATOR MODELS

SHB-2000E, SHB-1000E

## FETAL DOPPLER MODELS

SHD-3001, SHD-3002,  
SHD-5001, SHD-5002

SIGNED.....



Attachment to the Certificate No :K-MDD-1036, First Registration Date: 07.12.2011 Period of registration 5 years.  
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Akattar Mahallesi Hare Sokak 2. Söğüt Evleri G-10 No:9 1.Levent / İSTANBUL Tel: 0212 269 37 41 - 42 - 43 Faks: 0212 269 37 44