



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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ZLG-BS-244.10.08



Product Service

# EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical devices (MDD), Annex V  
(Devices in Class I with measuring function and in sterile condition)

**No. G2MS 045879 0017 Rev. 01**

## Manufacturer

**Jiangsu Kanghua Medical Equipment  
Co., Ltd.**

Sanhekou  
213115 Changzhou  
PEOPLE'S REPUBLIC OF CHINA

## Facility(ies):

Jiangsu Kanghua Medical Equipment Co., Ltd.  
Sanhekou, 213115 Changzhou, PEOPLE'S REPUBLIC OF  
CHINA

## Product Category(ies):

**Disposable Catheter Tip Syringes,  
Disposable Syringes without Needle,  
Disposable Tuberculin Syringes without Needle,  
Disposable Insulin Syringes without Needle**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements and with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

## Report No.:

SH19165EXT01

## Valid from:

2019-09-30

## Valid until:

2024-05-26

## Date,

2019-09-30

Stefan Preiß  
Head of Certification/Notified Body