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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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Product Service

# EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

**No. G2S 005225 0004 Rev. 01**

## Manufacturer

**Hangzhou Primecare Medical Co., Ltd.**

Room 408-409, Zancheng Center West

Shangcheng District

310008 Hangzhou

PEOPLE'S REPUBLIC OF CHINA

## Facility(ies):

Hangzhou Primecare Medical Co., Ltd.

Room 408-409, Zancheng Center West, Shangcheng District,

310008 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

## Product

### Category(ies):

**Urine Bag (with and without Gloves Pack/  
with and without straps), Suction Canister,  
Irrigation Tray, Pre-filled Syringe,  
Tracheostomy Care/Cleaning Kits,  
Specimen Container, Dressing Change Tray,  
Catheter Valve, Suture Remove Kits,  
Suction Liner, Ear/Ulcer Syringe**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned 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.:** SH191320CN01

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**Valid until:** 2023-12-03

**Date,** 2019-10-25

Stefan Preiß

Head of Certification/Notified Body