Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 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

Valid from: 2019-10-25

Valid until: 2023-12-03

Date, 2019-10-25

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany