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 IIa, IIb or III)

No. G2 005225 0002 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):

**Urethral Catheter,
Suction Connecting Tube with and without Yankauer,
Wound Drainage Systems with and without Trocar,
Enteral Feeding Set(Bag),
Urinary Catheterization/Collection Kits with and without Prefilled Syringe**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. 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

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