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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 004968 0002 Rev. 00

Manufacturer

Tianchang Ganor Medical Device Co., Ltd.

Shuangliu Village, Datong Town
239361 Tianchang City, Anhui
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Prolinx GmbH
Brehmstr. 56, 40239 Duesseldorf, GERMANY

Product

Urine Drainage Bag

Category(ies):

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.:

SH18137501

Valid from:

2018-12-13

Valid until:

2023-12-12

Date,

2018-12-13

Stefan Preiß



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Facility(ies):

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