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

TÜV SÜD 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 002901 0002 Rev. 00

Manufacturer:

JIANGSU JIANZHIYUAN MEDICAL INSTRUMENTS TECHNOLOGY CO., LTD.
Floor 2, Building102
No.198, East Wuzhou Road
Development Zone
225000 Yangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

JIANGSU JIANZHIYUAN MEDICAL INSTRUMENTS TECHNOLOGY CO., LTD.
Floor 2, Building102, No.198, East Wuzhou Road, Development Zone, 225000 Yangzhou, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Chest Drainage Catheter for Single Use, Closed Wound Drainage Catheter for Single Use, Three Cavities Stomach Tube for Single Use, Nasal Biliary Drainage Catheter for Single Use, Irrigation and Suction Catheter in Endoscopic Surgery for Single Use, Nasal Feeding Tube for Single Use, Urethra Single J and Double J Catheter for Single Use, Medical Laparoscopic Instrument Trocar Suite for Single Use

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.: SH19123202

Valid from: 2019-10-21
Valid until: 2024-05-26

Date, 2019-10-21

Stefan Preiß
Head of Certification/Notified Body

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

Digitally signed by Mocanu Marin
Date: 2023.09.08 10:51:09 EEST
Reason: MoldSign Signature
Location: Moldova

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