EC Certificate

TÜVRheinland®

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.: HD 2139971-1

Manufacturer: Tianck Medical Co., Ltd.
Building C, No.16 Yinkui road,
Kuichong town, Dapeng new district
Shenzhen
518119 Guangdong
P.R. China

Products: Disposable pressure transducers, Introducer sets, Guidewires, Percutaneous nephrostomy sets, Hemodialysis Catheters, High Pressure Angiographic Syringes, I.V. Cannulas, Ureteral Stent Sets, Nasogastric Feeding Tubes, Closed suction catheters, Drainage Catheters, Cervical Ripening Balloons, Puncture needles, Hemostasis valve sets, Injection caps, Manifolds, Three-way stopcocks, Connecting tubes, Manifold sets.
Aspects of manufacture concerned with securing and maintaining sterile conditions:
Balloon inflation devices, Radial Artery Closure Bands, Dose control syringes, Guidewire syringes

Replaces Approval, Registration No.: HD 60148984 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 17062740 008

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TÜV Rheinland LGA Products GmbH

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Perminov Andrei
Date: 2022.01.10 13:00:56 EET
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