

# EC Certificate



## 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

Effective date: 2021-01-21

Expiry date: 2024-05-26



# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 2139971-1

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

Scope: Design and Development, Manufacture and Distribution of Disposable pressure transducers, Introducer sets, Hemostasis valve sets, Guidewires, Percutaneous nephrostomy sets, Injection caps, Balloon inflation devices, Manifolds, Radial Artery Closure Band, Dose control syringes, Three-way stopcocks, Connecting tubes, Hemodialysis Catheters, High Pressure Angiographic Syringes, I.V. Cannulas, Ureteral Stent Sets, Nasogastric Feeding Tubes, Closed Suction Catheters, Drainage Catheters, Cervical Ripening Balloons, Guidewire Syringes, Manifold Sets, Puncture Needles

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 17062740 008

Effective date: 2021-01-21

Expiry date: 2023-11-17

