



Product Service

# Certificate

No. Q5 073403 0026 Rev. 01

**Holder of Certificate:**    **Henan Tuoren Medical Device Co., Ltd.**  
 Weiyuan Industrial Zone  
 Menggang, Changyuan County  
 453400 Henan  
 PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**    Design, Development, Production and Distribution of Infusion Pump, I.V. Cannula, Endotracheal Tube, Reinforced Endotracheal Tube, Tracheotomy Tube, Endobronchial Tube, Laryngeal Mask Airway, Connecting Tube, Foley Catheter Kit, Suction Catheter, Breathing Circuit, Oxygen Mask, Anesthesia Mask, Guedel Airway, Endotracheal Intubation Kit, Disposable central venous catheter kit, Anesthesia Kit and Anesthesia Needle, Manual resuscitator, Disposable Infusion Connection Tube, Suction Drainage Bag, Disposable Suction Drainage Bag, Nasal Oxygen Tube, Suction Handle, Heat and moisture exchanger, Disposable pressure transducer, Electronic infusion pump, LOR Indicator Syringe.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

<b>Report No.:</b>	BJ1973704
<b>Valid from:</b>	2019-11-29
<b>Valid until:</b>	2022-11-28

**Date,**                    2019-11-21

Christoph Dicks  
 Head of Certification/Notified Body





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- Applied Standard(s):** EN ISO 13485:2016  
 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)  
 DIN EN ISO 13485:2016
- Facility(ies):**
- Henan Tuoren Medical Device Co., Ltd.  
 Weiyuan Industrial Zone, Menggang, Changyuan County, 453400  
 Henan, PEOPLE'S REPUBLIC OF CHINA
  
  - Henan Tuoren Medical Device Co., Ltd.  
 Middle of Weft 7 Road, Nanpu District, 453400 Changyuan  
 County, Henan, PEOPLE'S REPUBLIC OF CHINA
  
  - Henan Tuoren Medical Device Co., Ltd.  
 Mancun Industrial Zone, Changyuan County, 453400 Henan,  
 PEOPLE'S REPUBLIC OF CHINA