

# Certificate



**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 2159138-1

Organization: Changzhou Huankang Medical  
Device Co., Ltd.  
22 Changhe Road, Sanhekou, Zhenglu,  
213116 Changzhou,  
Jiangsu  
P.R. China

Scope: Manufacture and Distribution of Disposable Vaginal Speculums, Disposable Drainage Bags, Disposable Colostomy Bags, Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Nelaton Catheters, Rectal Tubes, Endotracheal Tubes, Disposable Vaginal Irrigation Sets, Medical Brush, Oxygen Masks, Irrigation Syringes, Enema Bags, Vomit Bags, Mucus Extractors, Suction Connecting Tubes with Yankauer, Umbilical Cord Clamps, Disposable Endoscopic Retrieval Bags, Disposable Trocars, Disposable Gynecological Kits, Disposable Biopsy Forceps, Disposable Veress Needles, Disposable Waste Liquid Suction Bags

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.

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