

# Certificate



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

Registration No.: SX 2183016-1

Organization: Changzhou Medical Appliances General  
Factory Co., Ltd.  
Hengshanqiao Town, Wujin District,  
Changzhou  
213119 Jiangsu  
P.R. China

Scope: Design and Development, Manufacture and Distribution of Hernia Surgical  
Meshes;  
Manufacture and Distribution of Infusion Sets, Transfusion Sets, Syringes  
for Single Use, Hypodermic Needles, Scalp Vein Sets, Oxygen Masks,  
Sterile Nasal Oxygen Tubes, Nebulizer Masks, Re-usable Oral  
Syringes(with or without Adaptors), Sterile Urine Bags, Sterile Latex  
Examination Gloves, Sterile Vaginal Speculum, Sterile Urine Cups for  
single use, Oral/Enteral Syringes for single use

TÜVRheinland

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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