



REGISTRATION NO. 04721Q10000530

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Zener Medtec (Changzhou) Co., Ltd.

Registered Address: 9D, Jinton International Industrial Zone, No.8 Xihu Road, Wujin Hi-Tech Industrial Zone

Manufacturing Address: Site 1: 1st Floor, 9D, Jinton International Industrial Zone, No.8 Xihu Road, Wujin Hi-Tech Industrial Zone, Jiangsu Province Site 2: 201, Bldg 13, No.9 Xihu Road, Wujin Hi-Tech Industrial Zone, Jiangsu Province

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

Design and development, manufacturing, distribution and service of Single Use Negative Pressure Wound Therapy Kit, Surgical Masks.

Design and development of Disposable Medical Face Masks, Disposable Endoscopic Cutter Stapler and Reload , Disposable Endoscopic Cutter Stapler and Cartridge, Disposable Circular Stapler, Disposable Trocar, Kyphoplasty Took Kit, Disposable Balloon Inflator and Kyphoplasty Balloon Catheter.

Date of issue: September 29, 2021

Date of expiry: September 28, 2024

General Manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**

