

Management System Certificate

Certificate No.: 243519-2017-AQ-RGC-NA-PS Rev. 1.0

Project No.: PRJC-80007-2008-MSC-CHN

Initial Certification Date: **26 October 2017**

Valid Until: **26 February 2022**

This is to certify that the management system of:

Changshu Taining Medical Equipment Co., Ltd.

Nan Shou, Yangyuan Town, Changshu City, Jiangsu Province, P. R. China (Unicode: 913205817855793498)

Complies with the requirements of:

ISO 13485:2016/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Manufacture, Sales and Distribution of Sterile or Non-Sterile Umbilical Cord Clamp, Suction Catheter, Feeding Tube, Stomach Tube, Nelaton Catheter, Rectal Tube, Urine Bag, Vaginal Speculum, Nasal Oxygen Cannula, Mucus Extractor, Oxygen Mask, Endotracheal Tube, Urine Meter, Feeding Bag, and Enema Bag. Perform EO Sterilization as per EN ISO 11135-1.

Place and Date: Høvik, 28 February 2019





For: DNV GL PRESAFE AS

Tone Elise Kolpus

The Certificate has been digitally signed. See $\underline{\text{www.presafe.com/digital_signatures}} \quad \text{for more info}$

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.