

Management System Certificate

Certificate No.: Project No.: Initial Certification Date: Valid Until:

241634-2017-AQ-RGC-NA-PS Rev. 1.0 PRJC-24025-2007-MSC-RGC 9 August 2004 26 February 2022

This is to certify that the management system of:

Guangdong Baihe Medical Technology Co., Ltd.

No.89, Taoyuan East Road, Nanhai, Foshan, Guangdong Province, P.R. China (Unicode: 91440600721123254C)

Complies with the requirements of:

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

The Certificate is valid for the following scope:

Design, Manufacture, Sales and Service of Sterile & Non-sterile Central Venous Catheter Kit, Central Venous Catheter Set, Haemodialysis Catheter Kit, Haemodialysis Catheter Set.

EO Sterilization Services as per ISO 11135-2014.

Place and Date: Høvik, 28 February 2019



or:

DNV GL PRESAFE AS

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info



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

DNV GL PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA