DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
9729-2017-CE-RGC-NA-PS Rev. 1.0	PRJC-127103-2009-PRC-CHN	27 May 2024

This is to certify that the quality system of:

Guangdong Baihe Medical Technology Co., Ltd.

No.89, Taoyuan East Road, Nanhai, Foshan, Guangdong Province, P. R. China

For design, production and final product inspection/testing of:
CENTRAL VENOUS CATHETERS & HAEMODIALYSIS CATHETERS

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 16 December 2019

Digitally signed by Iarovoi Petru
Date: 2022.01.11 14:57:06 EET
Reason: MoldSign Signature
Location: Moldova

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Cathrine Wisbech

Cathrine Wisbech

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the certificate 69190-2009-CE-RGC-NA 4.0 (NB0434) following the transfer of Notified Body functions to DNVGL NEMKO Presafe AS (NB 2460)	2017-10-24
1.0	Recertification and added new models **(in bold)**	2019-12-16

Products covered by this Certificate:

Product Description	Product Name	Class
Central Venous Catheter Kit	**FV-1121**, **FV-11296, FV-1122, FV-1123, FV-1124,** FV-1221**, FV-12296**, FV-1222, FV-1223, FV-1224, **FV-122915**, FV-1225, FV-1226, FV-1321, **FV-13296**, FV-1322, **FV-1323**, FV-1324, **FV-132915**, FV-1325, FV-1326, FV-1421, **FV-14296**, FV-1422, **FV-1423**, FV-1424, **FV-142915**, FV-1425, FV-1426, FV-1428, **FV-1523**, FV-1524, **FV-152915**, FV-1525, FV-1526, FV-1528, **FV-1623**, FV-1624, **FV-162915**, FV-1625, FV-1626, FV-1628, FV-2421, **FV-24296**, FV-2422, **FV-2423**, **FV-242912**, FV-2424, **FV-242915**, FV-2425, FV-2426, **FV-2427**, **FV-2428**, FV-2521, **FV-25296**, FV-2522, **FV-2523**, **FV-2522912**, FV-2524, **FV-252915**, FV-2525, FV-2526, **FV-2527, FV-2528, FV-2721, FV-2722, FV-2723**, FV-2724, **FV-272915**, FV-2725, FV-2726, FV-2727, FV-2728, **FV-272945, FV-272960, FV-2823,** FV-2824, **FV-292915**, FV-2825, FV-2826, FV-2828, FV-2924, FV-2925, FV-2926, FV-2928, FV-3421, **FV-342906**, FV-3422, **FV-3423, FV-342912**, FV-3424, **FV-342915**, FV-3425, FV-3426, **FV-3427, FV-3428,** FV-3521, **FV-35296,** FV-3522, **FV-3523, FV-352912**, FV-3524, **FV-352915**, FV-3525, FV-3526, **FV-3527, FV-3528, FV-3721, FV-3722, FV-3723**, FV-3724, **FV-372915**, FV-3725, FV-3726, FV-3727, FV-3728, **FV-372945, FV-372960, FV-3923, FV-3924, FV-392915, FV-3925, FV-3926, FV-3927, FV-3928, FV-4923, FV-492915,** FV-4924, FV-4925, FV-4926, FV-4928, FC-2421, **FC-24296**, FC-2422,	III*

	FC-2423, **FC-242912**, FC-2424, **FC-242915**, FC-2425, FC-2426, **FC-2427, FC-2428**, FC-2521, **FC-25296**, FC-2522, **FC-2523, FC-2522912**, FC-2524, **FC-252915**, FC-2525, FC-2526, **FC-2527, FC-2528, FC-2721, FC-2722, FC-2723**, FC-2724, **FC-272915**, FC-2725, FC-2726, FC-2727, FC-2728, **FC-272945, FC-272960, FC-2824, FC-2825, FC-2826, FC-2828, FC-3421,** FC-342906, **FC-3422, FC-3423, FC-342912**, FC-3424, **FC-342915, FC-3425, FC-3426, FC-3427, FC-3428,** FC-3521, **FC-35296**, FC-3522, **FC-3523, FC-352912**, FC-3524, **FC-352915**, FC-3525, FC-3526, **FC-3527, FC-3528, FC-3721, FC-3722, FC-3723**, FC-3724, **FC-372915**, FC-3725, FC-3726, FC-3727, FC-3728, **FC-372945, FC-372960, FC-3923, FC-3924, FC-392915, FC-3925, FC-3926, FC-3927, FC-3928**	
Haemodialysis Catheter Kit	**FH-1713**, FH-1714, FH-172913-5, FR-172913-5, **FH-171915**, FH-1715, FH-1716, **FH-1813**, FH-1814, FH-182913-5, FR-182913-5, **FH-181915**, FH-1815, FH-1816, FH-2611, FR-2611, FR-2611W, FH-2612, FR-2612, FR-2612W, **FR-2613, FH-2613, FR-2613W**, FH-2614, FR-2614, FR-2614W, FH-2615, FR-2615, FR-2615W, FH-2911, FR-2911, FR-2911W, FH-2912, FR-2912, FR-2912W, **FH-2913, FR-2913, FR-2913W**, FH-212911, FR-212911, FH-212911W, FR-212911W, **FR-291912, FR-291912W, FH-2914**, FR-2914, FR-2914W, **FR-291915, FR-291915W, FH-2915,** FR-2915, FR-2915W, **FR-291917, FR-291917W**, FR-2926, **FR-2316, FR-2313, FR-2313W, FR-2312, FR-2312W, FR-231912, FR-231912W, FR-231915, FR-231915W, FR-2314, FR-2314W, FR-231917, FR-231917W, FR-2315, FR-2315W, FR-2113, FR-2113W,** FR-212912, **FR-212912W, FR-211912G**, FH-2114, FR-2114, FR-2114W, FH-212913-5, FR-212913-5, FH-212913-5W, FR-212913-5W, FH-211915, FR-211915, FH-211915W, FR-211915W, **FR-211915G,** FH-2115, FR-2115, FR-2115W, FR-2125W, **FH-2116, FR-2116, FR-2116W, FR-2115G, FR-211924, FR-211924W**, FH-2127, FR-2127, **FR-2117W, FR-2213, FR-2213W, FR-221912G, FR-2216G,** FH-2214, FR-2214, FR-2214W, FH-222913-5, FR-222913-5, FH-222913-5W, FR-222913-5W, FH-221915, FR-221915, FH-221915W, FR-221915W, **FR-221915G,** FH-2215, FR-2215, FR-2215W, **FR-**	III*

	2225G, FG-2215, FG-2215W, FH-2216, FR-2216, FR-2216W, FG-2216, FG-2216W, FR-221924, FR-221924W, FR-2217, FR-2217W, FR-2414, FR-241915, FR-241915W, FR-2415, FR-2415W, FR-252919, **FR-2416, FR-2416W, FR-241924, FR-241924W, FR-2417**, FR-3214, FR-3214W, FR-3224, FR-3224W, **FR-321915, FR-321915W**, FR-3215, FR-3215W, **FR-3216, FR-3216W, FR-321924, FR-321924W, FR-3217W, FR-3217**	

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 10615-2017-CE-RGC-NA-PS Rev.1.0 and 10616-2017-CE-RGC-NA-PS Rev.1.0.

Sites covered by this certificate

Site Name	Address
Guangdong Baihe Medical Technology Co., Ltd.	No.89, Taoyuan East Road, Nanhai, Foshan, Guangdong Province, P. R. China

EU Representative

CMC Medical Devices& Drugs S.L., C/ Horacio Lengo No 18, CP 29006, Málaga, Spain

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

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

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Tone Elise Kolpus

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