

# Blood Purification Products



## Standard Kits include:

1. Hemodialysis Catheter
2. Vessel Dilator
3. Introducer Needle
4. Syringe
5. Guide-wire
6. Adhesive Wound Dressings
7. Heparin Caps
8. Scalpel
9. Needle with Suture

## Optional Compound Kits include:

1. Hemodialysis Catheter Standard Kit Accessories
2. 5ml Syringe
3. Surgical Gloves
4. Surgical Pledget
5. Surgery Sheet
6. Surgery Towel
7. Sterile Brush
8. Gauze Pad

# Hemodialysis Catheter



**Soft Tip**  
Tapered tip facilitates ease of insertion without use of peel-away sheath. Reduces vessel trauma during insertion.



**Side Holes**  
2.5cm far from end hole reduces recirculating and wall-suction. Minimizes risk of clot formation.



**Radiopaque**  
Radiopaque, facilitates quick visualization under X-Ray.



**Rotatable Suture Wing**  
Facilitates skin inspection. Avoid blood vessel wall-suction. Minimizes risk of exit infections. No tube-kinking occurred.



**Silicone Extension Tube**  
Increases patient comfort, will not crimp over time, able to visualize fluids.



**Multi-lumen available**  
Single, double, triple lumen.



**Compound-packaging Tray**  
Various Accessories for choice.



**Made from PU (medical grade)**  
Better flexibility and anti-kinking performance.

**Pre-curved Type**  
More comfortable on patients.

## Order Information



Product Code	Lumen	Catheter Size	Catheter Length(cm)	Dilator	Guidewire	Shape of Extension Tube
FH-1721	Single Lumen	7Fr	5	8F×10cm	0.035"×50cm	Straight
FH-1721W						Curved
FH-1722	Single Lumen	7Fr	8	8F×10cm	0.035"×50cm	Straight
FH-1722W						Curved
FH-1723	Single Lumen	7Fr	10	8F×10cm	0.035"×50cm	Straight
FH-1723W						Curved
FH-1724	Single Lumen	7Fr	13	8F×10cm	0.035"×50cm	Straight
FH-1724W						Curved
FH-1725	Single Lumen	7Fr	16	8F×10cm	0.035"×50cm	Straight
FH-1725W						Curved
FH-1726	Single Lumen	7Fr	20	8F×10cm	0.035"×60cm	Straight
FH-1726W						Curved
FH-1821	Single Lumen	8Fr	5	9F×10cm	0.038"×50cm	Straight
FH-1821W						Curved
FH-1822	Single Lumen	8Fr	8	9F×10cm	0.038"×50cm	Straight
FH-1822W						Curved
FH-1823	Single Lumen	8Fr	10	9F×10cm	0.038"×50cm	Straight
FH-1823W						Curved
FH-1824	Single Lumen	8Fr	13	9F×10cm	0.038"×50cm	Straight
FH-1824W						Curved
FH-1825	Single Lumen	8Fr	16	9F×10cm	0.038"×50cm	Straight
FH-1825W						Curved
FH-1826	Single Lumen	8Fr	20	9F×10cm	0.038"×60cm	Straight
FH-1826W						Curved
FR/FH-2622	Double Lumen	6.5Fr	8	7F×10cm	0.021"×50cm	Straight
FR/FH-2622W						Curved
FR/FH-2623	Double Lumen	6.5Fr	10	7F×10cm	0.021"×50cm	Straight
FR/FH-2623W						Curved
FR/FH-2624	Double Lumen	6.5Fr	13	7F×10cm	0.021"×50cm	Straight
FR/FH-2624W						Curved
FR/FH-2625	Double Lumen	6.5Fr	16	7F×10cm	0.021"×50cm	Straight
FR/FH-2625W						Curved
FR/FH-2626	Double Lumen	6.5Fr	20	7F×10cm	0.021"×60cm	Straight
FR/FH-2626W						Curved

# Order Information

Product Code	Lumen	Catheter Size	Catheter Length(cm)	Dilator	Guidewire	Shape of Extension Tube
FR/FH-2921	Double Lumen	8.5Fr	5	9F×10cm	0.025"×50cm	Straight
FR/FH-2921W						Curved
FR/FH-2922	Double Lumen	8.5Fr	8	9F×10cm	0.025"×50cm	Straight
FR/FH-2922W						Curved
FR/FH-2923	Double Lumen	8.5Fr	10	9F×10cm	0.025"×50cm	Straight
FR/FH-2923W						Curved
FR/FH-2924	Double Lumen	8.5Fr	13	9F×10cm	0.025"×50cm	Straight
FR/FH-2924W						Curved
FR/FH-2925	Double Lumen	8.5Fr	16	9F×10cm	0.025"×50cm	Straight
FR/FH-2925W						Curved
FR/FH-2926	Double Lumen	8.5Fr	20	9F×10cm	0.025"×60cm	Straight
FR/FH-2926W						Curved
FR/FH-2323	Double Lumen	10F	10	9F×10cm	0.038"×50cm	Straight
FR/FH-2323W				10F×15cm		Curved
FR/FH-2324	Double Lumen	10F	13	9F×10cm	0.038"×50cm	Straight
FR/FH-2324W				10F×15cm		Curved
FR/FH-232915	Double Lumen	10F	15	9F×10cm	0.038"×50cm	Straight
FR/FH232915W				10F×15cm		Curved
FR/FH-2325	Double Lumen	10F	16	9F×10cm	0.038"×50cm	Straight
FR/FH-2325W				10F×15cm		Curved
FR/FH-2326	Double Lumen	10F	20	9F×10cm	0.038"×60cm	Straight
FR/FH-2326W				10F×15cm		Curved
FR/FH-2124	Double Lumen	11.5Fr	13	12F×15cm	0.038"×50cm	Straight
FR/FH-2124W				10F×15cm		Curved
FR/FH-2125	Double Lumen	11.5Fr	16	12F×15cm	0.038"×50cm	Straight
FR/FH-2125W				10F×15cm		Curved
FR/FH-2126	Double Lumen	11.5Fr	20	12F×15cm	0.038"×60cm	Straight
FR/FH-2126W				10F×15cm		Curved
FR/FH-2127	Double Lumen	11.5Fr	25	12F×15cm	0.038"×60cm	Straight
FR/FH-2127W				10F×15cm		Curved

Product Code	Lumen	Catheter Size	Catheter Length(cm)	Dilator	Guidewire	Shape of Extension Tube
FR/FH-2224	Double Lumen	12Fr	13	12Fx15cm	0.038"×50cm	Straight
FR/FH-2224W				10Fx15cm		Curved
FR/FH-2225	Double Lumen	12Fr	16	12Fx15cm	0.038"×50cm	Straight
FR/FH-2225W				10Fx15cm		Curved
FR/FH-2226	Double Lumen	12Fr	20	12Fx15cm	0.038"×60cm	Straight
FR/FH-2226W				10Fx15cm		Curved
FR/FH-2524	Double Lumen	14Fr	13	14Fx15cm	0.038"×50cm	Straight
FR/FH-2524W				12Fx15cm		Curved
FR/FH-2525	Double Lumen	14Fr	16	14Fx15cm	0.038"×60cm	Straight
FR/FH-2525W				12Fx15cm		Curved
FR/FH-2526	Double Lumen	14Fr	20	14Fx15cm	0.038"×70cm	Straight
FR/FH-2526W				12Fx15cm		Curved
FR/FH-3224	Triple Lumen	12Fr	13	12Fx15cm	0.038"×50cm	Straight
FR/FH-3224W				10Fx15cm		Curved
FR/FH-3225	Triple Lumen	12Fr	16	12Fx15cm	0.038"×50cm	Straight
FR/FH-3225W				10Fx15cm		Curved
FR/FH-3226	Triple Lumen	12Fr	20	12Fx15cm	0.038"×60cm	Straight
FR/FH-3226W				10Fx15cm		Curved

### Remarks:

1. The product codes in this chart are for HC kits with straight introducer needle configuration.
2. HC kits with Y-shaped introducer needle configuration are also available upon discussion. The product code of HC kit with Y-shaped introducer needle configuration is different from the product code of HC kit with straight introducer needle configuration. Before you order, please clarify which configuration you request, either straight or Y-shaped introducer needle.
3. Pediatric types of HC include double lumen 6.5Fr and 8.5Fr.
4. Adult types of HC include single lumen 7Fr, 8Fr ; double lumen 10Fr, 11.5Fr, 12Fr, 14Fr and triple lumen 12Fr.
5. "FR" in the product code means with soft tip.
6. "FH" in the product code means without soft tip (i. e. with relatively harder tip).
7. Pre-curved catheter is available for adult type in double lumen 11.5Fr, 12Fr, 14Fr.

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
9729-2017-CE-RGC-NA-PS Rev. 1.0

Project No.:  
PRJC-127103-2009-PRC-CHN

Valid Until:  
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**



For:  
**DNV GL PRESAFE AS**  
Notified Body No.: 2460

**Cathrine Wisbech**

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



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**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 <b>(in bold)</b>	2019-12-16

Products covered by this Certificate:

Product Description	Product Name	Class
Central Venous Catheter Kit	<b>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-252912, 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,</b>	III*



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	<p><b>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</b></p>	
<p>Haemodialysis Catheter Kit</p>	<p><b>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-</b></p>	<p>III*</p>

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	<p><b>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</b></p>	
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\* 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**

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