Declaration of Conformity

TO COUNCIL DIRECTIVE 93/42/EEC

CONCERNING MEDICAL DEVICES

MANUFACTURER:	Shandong Weigao Blood Purification Products Co., Ltd. No.20 Xingshan Road Weihai Torch Hi-tech Science Park, 264210 Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	Hollow Fiber Dialyzer MODEL: F12, F13, F14, F15, F16, F17, F18, F19, F20 HF10, HF12, HF13, HF14, HF15, HF16, HF17, HF18, HF19, HF20, HF21, HF22, HF23 MF10, MF12, MF13, MF14, MF15, MF16, MF17, MF18, MF19 E15H, E16H, E17H, E18H, E19H, E20H, E21H, E22H, E23H
CLASSIFICATION - *ANNEX IX*:	*. CLASS IIB, RULE 3*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX II .3*

WE, Shandong Weigao Blood Purification Products Co., Ltd., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	**G1 076229 0004 Rev.03**
EC REP	
EUROPEAN REPRESENTATIVE:	***MedNet EC-REP GmbH*** ***Borkstrasse 10, 48163 Muenster, GERMANY.***

Digitally signed by Şarco Alexandru
Date: 2022.02.17 08:17:49 EET
Reason: MoldSign Signature
Location: Moldova

	Tel: +49 251 32266-0 Fax: +49 251 32266-22
START OF CE-MARKING:	2011.11.05
VALID UNTIL :	2024.05.26
PLACE, DATE OF DECLARATION:	CITY, DATE（*WEIHAI，2021.03.03*）
SIGNATURE:	*NAME: Mr. YINBO-FU* *POSITION: Quality Director*

SHANDONG WEIGAO BLOOD PURIFICATION PRODUCTS CO., LTD. 血液净化制品股份有限公司 371020103957 1

PRODUCTS CO., LTD. 有限公司 01039571