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:	A.V. Fistula Needle Sets
MODEL:	1.4×25GD, 1.4×25XD, 1.4×32GD, 1.4×32XD, 1.6×25GD, 1.6×25XD, 1.6×32GD, 1.6×32XD, 1.8×25GD, 1.8×25XD, 1.8×32GD, 1.8×32XD, 1.4×25GS, 1.4×25XS, 1.4×32GS, 1.4×32XS, 1.6×25GS, 1.6×25XS, 1.6×32GS, 1.6×32XS, 1.8×25GS, 1.8×25XS, 1.8×32GS, 1.8×32XS
CLASSIFICATION - *ANNEX IX*:	. *CLASS IIA, RULE 7*
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**

Digitally signed by Șarco Alexandru
Date: 2022.02.17 08:25:14 EET
Reason: MoldSign Signature
Location: Moldova

EC REP

EUROPEAN REPRESENTATIVE:	***MedNet EC-REP GmbH*** ***Borkstrasse 10, 48163 Muenster, GERMANY.*** ***Tel: +49 251 32266-0 Fax: +49 251 32266-22***
START OF CE-MARKING:	2018.11.29

VALID UNTIL : 2024.05.26

PLACE, DATE OF DECLARATION:	CITY, DATE（*WEIHAI，2021.03.03*）
SIGNATURE:	*NAME: MR. YINBO FU* *POSITION: Quality Director*