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Declaration of Conformity

TO COUNCIL DIRECTIVE 93/42/EEC

CONCERNING MEDICAL DEVICES

MANUFACTURER: Weihai 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, Weihai 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 CONCERNING MEDICAL DEVICES;

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

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH

ZERTIFIZIERSTELLE RIDLERSTR. 65·80339 MÜNCHEN,GERMANY

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S): **G1 076229 0004 REV.01**

EC REP

EUROPEAN REPRESENTATIVE: ***MedNet GmbH***

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SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, mun. CHIȘINĂU, S.R.L. "DITA ESTFARM" IDNO 1002600046359

START OF CE-MARKING:	2018.11.29
VALID UNTIL :	2021.11.14

PLACE, DATE OF DECLARATION:	CITY, DATE（*WEIHAI，2018.11.29*）
SIGNATURE:	*NAME: Mr. YINBO FU* *POSITION: Vice Quality Director*

SOCIETATEA CU RASPUNDERE LIMITATĂ, REPUBLICA MOLDOVA mun. CHIȘINĂU
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