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: 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, 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 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.01**

EC REP

EUROPEAN REPRESENTATIVE: ***MedNet GmbH***
Borkstrasse 10, 48163 Muenster, GERMANY.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ, REPUBLICA MOLDOVA, mun. CHIȘINĂU
S.R.L. "DITA ESTFARM"
IDNO 1002600040359

Digitally signed by Margină Veaceslav
Date: 2020.10.03 08:50:10 EEST
Reason: MoldSign Signature
Location: Moldova

Tel: +49 251 32266-0 Fax: +49 251 32266-22

START OF CE-MARKING: 2011.11.05

VALID UNTIL : 2021.11.14

PLACE, DATE OF DECLARATION: CITY, DATE（*WEIHAI，2018.11.29*）

SIGNATURE:

NAME: Mr. YINBO FU

POSITION: Quality Director