

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:

Extracorporeal Blood Circuit for Blood Purification Equipment

MODEL: JRHLL-040, JRHLL-041, JRHLL-010, JRHLL-011, JRHLL-020,
JRHLL-021, JRHLL-022, JRHLL-023, JRHLL-024, JRHLL-025, JRHLS-001, JRXL-A1, JRXL-A2, JRXL-A3, JRXL-
A4, JRXL-A5, JRXL-A6, JRXL-A7, JRXL-B1, JRXL-B2, JRXL-B3, JRXL-B4, JRXL-B5, JRXL-B6, JRXL-B7, JRXL-
C1, JRXL-C2, JRXL-C3, JRXL-C4, JRXL-A1, JRXL-A2, JRXL-A3, JRXL-A4, JRXL-A5, JRXL-A6, JRXL-A
7, JRXL-A8, JRXL-A9, JRXL-A10, JRXL-A11, JRXL-A12, JRXL-A13, JRXL-A14, JRXL-A15, JRXL-A
16, JRXL-A17, JRXL-B1, JRXL-B2, JRXL-B3, JRXL-B4, JRXL-B5, JRXL-B6, JRXL-B7, JRXL-B8,
JRXL-B9, JRXL-B10, JRXL-B11, JRXL-B12, JRXL-B13, JRXL-B14, JRXL-B15, JRXL-B16, JRXL-
B17, JRXL-B18, JRXL-B19, JRXL-B20, JRXL-B21, JRXL-B22, JRXL-B23, JRXL-B24, JRXL-B25,
JRXL-B26, JRXL-B27, JRXL-B28, JRXL-B29, JRXL-B30, JRXL-B31, JRXL-B32, JRXL-B33, JRXL-
B34, JRXL-B35, JRXL-B36, JRXL-B37, JRXL-C1, JRXL-C2, JRXL-C3, JRXL-C4, JRXL-C5, JRXL-C6,
JRXL-C7, JRXL-C8, JRXL-C9, JRXL-C10, JRXL-C11

CLASSIFICATION - ANNEX IX:

CLASS IIA, RULE 2

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.

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

