

Declaration of Conformity

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER: SHANDONG WEIGAO GROUP MEDICAL POLYMER CO., LTD.
No.18 Xingshan Road, Torch Hi-tech Science Park,
264210 Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: STERILE TRANSFUSION SETS FOR SINGLE USE
WITH NEEDLE, WITHOUT NEEDLE

CLASSIFICATION - ANNEX IX: CLASS IIA, RULE 7

UMDNS CODES: 10421 12748

CONFORMITY ASSESSMENT ROUTE: ANNEX II.3

WE, SHANDONG WEIGAO GROUP MEDICAL POLYMER 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 094273 0003 REV.03



EUROPEAN REPRESENTATIVE: MEDNET EC-REP GMBH
BORKSTRASSE 10, 48163 MUENSTER, GERMANY

VALID UNTIL : 2024-05-26

PLACE, DATE OF DECLARATION: WEIHAI, 2022-01-18

SIGNATURE:

NAME: MR ZHAO.HENGKUN
POSITION: (MANAGEMENT REPRESENTATIVE)