

Declaration of Conformity
TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING
MEDICAL DEVICES

MANUFACTURER: Shandong Weigao Group Medical Ploymer Co., Ltd.
MANUFACTURER ADDRESS: No.1 Weigao Road, Torch Hi-tech Science Park, 264210
Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA
FACILITY ADDRESS: No.10 Junshan Road, Torch Hi-tech Science Park, 264210
Weihai, Shandong Province, PEOPLE'S REPUBLIC OF CHINA
SRN: CN-MF-000011129
MEDICAL DEVICE: Sterile Plastic Blood Bag For Single Use
S-250ml S-350ml S-450ml D-250ml D-350ml D-450ml
T-250ml T-350ml T-450ml Q-250ml Q-350ml Q-450ml
GMDN CODE: Blood Donor Set 10426
CLASSIFICATION: Class IIb, according to rule 18 in Annex IX
CONFORMITY ASSESSMENT ROUTE: Annex II (excluding section 4)
HARMONIZED STANDARDS
OF CONFORMANCE: See the attachment for further information

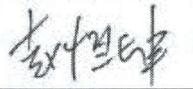
WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE MEDICAL DEVICES STATED MEET THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES.

WE, AS THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY: TÜV SÜD Product service GmbH
Ridlerstraße 65, 80339 Munich, Germany
IDENTIFICATION NUMBER **CE** 0123
(EC) CERTIFICATE(S): CL 094273 0023 Rev. 01
EUROPEAN REPRESENTATIVE: MedNet EC-REP C IIb GmbH
Borkstrasse 10, 48163 Münster, Germany

PLACE, DATE OF DECLARATION: WEIHAI, 2024.12.30

SIGNATURE:



NAME: MR. ZHAO HENKUN

POSITION: MANAGEMENT REPRESENTATIVE, PRRC