

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING
MEDICAL DEVICES**



MANUFACTURER: SHANDONG WEIGAO GROUP MEDICAL POLYMER CO.,LTD
NO.18 XINGSHAN ROAD,HIGH-TECH INDUSTRIAL DEVELOPMENT ZONE,
264210 WEIHAI, SHANDONG PROVINCE, PEOPLE' S REPUBLIC OF CHINA

MEDICAL DEVICE: STERILE PLASTIC BLOOD BAG FOR SINGLE USE

TYPE AND SIZE: 200ML-500ML

GMDNS CODE : 10426 BLOOD DONOR SET

CLASSIFICATION - ANNEX IX: CLASS IIB , RULE 18

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 CONCERNING MEDICAL DEVICES

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER
(EC) CERTIFICATE(S):

CE 0123
G1 15 12 94273 003



EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp.
GmbH (Europe)

Eiffestrasse, 80, D-20537, Hamburg, Germany Tel: 0086-021-65951371,
0049-40-2513175, Fax: 0049-40-255726

START OF CE-MARKING:

PLACE, DATE OF DECLARATION: WEIHAI, 2016-06-07

SIGNATURE:

NAME:

POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)