

**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 HIGH-TECH SCIENCE PARK, 264210 WEIHAI,  
SHANDONG PROVINCE, PEOPLE' S REPUBLIC OF CHINA

**MEDICAL DEVICE:** STERILE PLASTIC BLOOD BAG FOR SINGLE USE

**TYPE AND SIZE:** S-250ML, S-350ML, S-450ML, D-250ML ,D-350ML, D-450ML ,T-250ML ,T-350ML ,T-450ML, Q-250ML, Q-350ML, Q-450ML

**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 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, 2021-03-20*

**SIGNATURE:**

**NAME:** WANG YI

**POSITION:** (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)