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 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

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

VALID UNTIL : *2024-09-26*

PLACE, DATE OF DECLARATION: *WEIHAI, 2022-01-20*

SIGNATURE:

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

Digitally signed by Şarco Alexandru
Date: 2024.09.05 11:13:29 EEST
Reason: MoldSign Signature
Location: Moldova