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 INFUSION SETS FOR SINGLE USE VENTED AND NON-VENTED
CLASSIFICATION - *ANNEX IX*:	*CLASS IIA, RULE 7*
UMDNS CODES*:*	*12157 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.

STANDARDS APPLIED: EN ISO 13485:2016, EN ISO 14971:2007, EN ISO 11135-1:2007, EN ISO11607-1:2009, EN ISO 11607-2:2006, EN ISO 10993-1:2009, EN 556-1:2001/AC:2006, EN1041:2008, EN980:2008, ISO 8536-4:2007, ISO 8536-4:2007

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 : *2024.05.26*

PLACE, DATE OF DECLARATION: *WEIHAI，2021-10-18*

SIGNATURE: _____

NAME: WANG YI
POSITION: RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER

Digitally signed by Sarco Alexandru
Date: 2023.08.04 10:44:07 EEST
Reason: MoldSign Signature
Location: Moldova