

# Declaration of Conformity

## TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER:

WEIGAO MEDICAL INTERNATIONAL CO., LTD.

No.1 Weigao Road, High-tech Industrial Development Zone, 264210 Weihai, Shandong Province,  
PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE:

STERILE HIGH PRESSURE ANGIOGRAPHIC SYRINGES FOR SINGLE USE  
50ML – 200ML

CLASSIFICATION - ANNEX IX:

CLASS IIA, RULE 2

UMDNS CODES:

15286

CONFORMITY ASSESSMENT ROUTE:

ANNEX II.3

WE, WEIGAO MEDICAL INTERNATIONAL 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 087117 0013 REV. 01

**EC REP**

MEDNET EC-REP GMBH

BORKSTRASSE 10, 48163 MUENSTER, GERMANY

VALID UNTIL : 2024.04.16

PLACE, DATE OF DECLARATION:

WEIHAI, 2020-07-20

SIGNATURE:

NAME: SONG XINLAN

POSITION: Quality Department Manager