

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:

INSULIN NEEDLES FOR SINGLE USE
30G、31G、32G、33G、34G

CLASSIFICATION - ANNEX IX:

CLASS IIA, RULE 6

UMDNS CODES:

12745

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, 2021-09-10

SIGNATURE:

NAME: SONG XINLAN

POSITION: Quality Department Manager