

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER:

WEIFANG KAWA MEDICAL PRODUCTS CO.LTD
No.2 Xingan Road, Shouguang Beiluo Industrial Park,
Weifang, Shandong. PRC

MEDICAL DEVICE:

Sterile infusion sets for single use

CLASSIFICATION - ANNEX IX:

E.G. CLASS IIA, RULE 7

UMDNS CODE:

17825

CONFORMITY ASSESSMENT ROUTE:

E.G. ANNEX VII + V

WE, THE MANUFACTURER, 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 MUNCHEN, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

G2 057996 0014 Rev.01



EUROPEAN REPRESENTATIVE:

Prolinx GmbH
Add: Brehmstr. 56, 40239, Duesseldorf
0049 2131 4051968-0
0049 2131 4051968-9

START OF CE-MARKING: 2006-09

ISSUE DATE: 2020-02-24

PLACE, DATE OF DECLARATION:

SHOUGUANG, CHINA

SIGNATURE:

NAME: WANGWEIHUA
POSITION: BOARD CHAIRMAN