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*: *CLASS IIA, RULE 7*

CONFORMITY ASSESSMENT ROUTE: *ANNEX VII + V*

WE, WEIFANG KAWA MEDICAL PRODUCTS CO.LTD,NO.117 XINGAN ROAD,SHOUGUANG DEVELOPMENT ZONE,26270 WEIFANG CHINA HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:*EN ISO 13485:2012, EN ISO 14971:2012, EN ISO 11135:2014, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 10993-1:2009, EN 556-1:2001, EN1041:2008, EN 980:2008,KW/JS-03-011 based on ISO8536-4:2010*

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 M NCHEN, GERMANY

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S): G2 057996 0014 REV.01

EC REP

EUROPEAN REPRESENTATIVE:*PROLINX GMBH*
Brehmstr. 56
40239 Duesseldorf, Germany.

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PLACE, DATE OF DECLARATION: *SHOUGUANG,CHINA*
2020-02-28

SIGNATURE:

NAME:WANGWEIHUA
POSITION: BOARD CHAIRMAN