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

MANUFACTURER: ZHEJIANG KINDLY MEDICAL DEVICES CO.LTD.
NO.758, 5TH BINHAI ROAD, BINHAI INDUSTRIAL PARK, LONGWAN DISTRICT, 325025 WENZHOU, ZHEJIANG PROVINCE, PRC.

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg GERMANY

MEDICAL DEVICE: Scalp Vein Sets : 27G、26G、25G、24G、23G、22G、21G、20G、19G、18G

CLASSIFICATION - *ANNEX IX*: *CLASS IIA, RULE 7*

CONFORMITY ASSESSMENT ROUTE: *ANNEX II.3,* Excluding(4)

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 DECLARTION OF CONFORMITY

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

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S): G1 036336 0054 Rev.02

START OF CE-MARKING: 2000.02

Valid until: 2024-05-26

PLACE, DATE OF DECLARATION: Wenzhou 2019-08-16

SIGNATURE:

POSITION: QUALITY MANAGER