

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: SAFETY 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 DECLARATION 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:

Valid until:

2024-05-26

PLACE, DATE OF DECLARATION:

Wenzhou 2019-08-16

SIGNATURE:

POSITION: QUALITY MANAGER