

# 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:

DISPOSABLE NEEDLES : 34G, 33G, 32G, 31G, 30G, 29G, 28G, 27G,  
26G, 25G, 24G, 23G, 22G, 21G, 20G, 19G, 18G,  
16G, 15G, 14G

CLASSIFICATION - ANNEX IX:

CLASS IIA, RULE 6

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 CONCERNING MEDICAL DEVICES;  
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.03

START OF CE-MARKING:

2001.06

Valid until:

2024-05-26

PLACE, DATE OF DECLARATION:

WENZHOU 2020.10.27

SIGNATURE:

POSITION: QUALITY MANAGER

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

**ATTACHMENT:**

KDL name	Brand name	Bevel	Needle gauge	Needle length (mm)	Model number
DISPOSABLE NEEDLES	TERUMO AGANI NEEDLE	Regular	18G	38	AN*1838R1
		Short			AN*1838S1
		Regular	19G	50	AN*1850R1
		Regular			AN*1925R1
		Regular	19G	38	AN*1938R1
		Short			AN*1938S1
		Regular			AN*1950R1
		Regular	20G	25	AN*2025R1
		Regular			AN*2038R1
		Regular			AN*2050R1
		Regular	21G	16	AN*2116R1
		Regular			AN*2125R1
		Regular			AN*2138R1
		Regular			AN*2150R1
		Regular	22G	25	AN*2225R1
		Regular			AN*2232R1
		Regular			AN*2238R1
		Regular			AN*2250R1
		Regular	23G	50	AN*2316R1
		Regular			AN*2325R1
		Regular			AN*2332R1
		Regular			AN*2338R1
		Regular	24G	25	AN*2425R1
		Regular	25G	16	AN*2516R1
		Regular			AN*2525R1
		Regular	26G	13	AN*2613R1
		Regular			AN*2623R1
		Regular	27G	23	AN*2713R1
		Regular			AN*2716R1
		Regular			AN*2719R1
Regular	30G	13	AN*3013R1		

**Note: The Table attached is used solely as a reference to prove the conformity of TERUMO AGANI NEEDLE products listed.**