

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

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.02

START OF CE-MARKING:

2001.06

Valid until:

2024-05-26

PLACE, DATE OF DECLARATION:

WENZHOU 2019.08.16

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			38	AN*1938R1
		Short	AN*1938S1			
		Regular	20G	50	AN*1950R1	
		Regular			AN*2025R1	
		Regular			38	AN*2038R1
		Regular	AN*2050R1			
		Regular	21G	16	AN*2116R1	
		Regular			25	AN*2125R1
		Regular				AN*2138R1
		Regular			50	AN*2150R1
		Regular	22G	25		AN*2225R1
		Regular			32	AN*2232R1
		Regular				38
		Regular			50	
		Regular	23G	16		AN*2316R1
		Regular			25	AN*2325R1
		Regular				32
		Regular			38	
		Regular	24G	25		AN*2425R1
		Regular			16	AN*2516R1
		Regular	25G	25		AN*2525R1
		Regular			13	AN*2613R1
		Regular	26G	23		AN*2623R1
		Regular			27G	13
		Regular	16	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.