

**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 NEEDLES : 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.03

**START OF CE-MARKING:**

**Valid until:**

2024-05-26

**PLACE, DATE OF DECLARATION:**

Wenzhou 2020-10-27

**SIGNATURE:**

浙江康德莱医疗器械股份有限公司  
ZHEJIANG KINDLY MEDICAL DEVICES CO., LTD  
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
SAFETY NEEDLES	TERUMO AGANI SAFETY HYPODERMIC NEEDLE	REGULAR	18G	25mm	SAN1825R1
		REGULAR	18G	38mm	SAN1838R1
		REGULAR	19G	25mm	SAN1925R1
		REGULAR	19G	38mm	SAN1938R1
		REGULAR	20G	25mm	SAN2025R1
		REGULAR	20G	38mm	SAN2038R1
		REGULAR	21G	25mm	SAN2125R1
		REGULAR	21G	38mm	SAN2138R1
		REGULAR	22G	25mm	SAN2225R1
		REGULAR	22G	38mm	SAN2238R1
		REGULAR	23G	25mm	SAN2325R1
		REGULAR	23G	38mm	SAN2338R1
		REGULAR	25G	16mm	SAN2516R1
		REGULAR	25G	25mm	SAN2525R1
		REGULAR	25G	38mm	SAN2538R1
		REGULAR	26G	13mm	SAN2613R1
		REGULAR	27G	13mm	SAN2713R1
		REGULAR	30G	13mm	SAN3013R1

浙江康德莱医疗器械股份有限公司  
ZHEJIANG KANDLAI MEDICAL DEVICES CO., LTD.

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