



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 036336 0054 Rev. 03**

**Manufacturer:**

**Zhejiang Kindly Medical  
Devices Co., Ltd.**

No.758, 5th Binhai Road  
Binhai Industrial Park, Longwan District  
325025 Wenzhou, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):**

**Disposable Needles, Scalp Vein Sets, Blood-Collecting  
Needles, Huber Needles, Fistula Needles, Anaesthesia  
Needles, Dental Needles for Single Use, Sterile I.V. catheter  
for single use, Disposable Insulin Pen Needle, Sterile Biopsy  
Needles for single use, Sterile Percutaneous Vertebroplasty  
Kit for single use, Sterile Irrigation Needles for Single Use,  
Safety Needles, Safety Scalp Vein Sets, Safety Blood-  
Collecting Needles, Safety I.V. Catheter for Single Use, Safety  
Fistula Needles, Luer Adapter, Safety Blood Lancet, Syringes,  
Infusion Sets, Transfusion Sets, Burette-Type Infusion Sets,  
Sterile Intravascular Catheter Introducer for Single Use,  
Sterile Syringes for Insulin for Single Use, Sterile Disinfecting  
Cap for Single Use.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10363360054Rev.03](http://www.tuvsud.com/ps-cert?q=cert:G10363360054Rev.03)

**Report No.:** BJ20081201

**Valid from:** 2020-10-27

**Valid until:** 2024-05-26

**Date,** 2020-10-27

Christoph Dicks  
Head of Certification/Notified Body

# 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				38	AN*2138R1
		Regular					AN*2150R1
		Regular	22G	25	AN*2225R1		
		Regular			32	AN*2232R1	
		Regular				38	AN*2238R1
		Regular					AN*2250R1
		Regular	23G	16	AN*2316R1		
		Regular			25	AN*2325R1	
		Regular				32	AN*2332R1
		Regular					AN*2338R1
		Regular	24G	25	AN*2425R1		
		Regular	25G	16	AN*2516R1		
		Regular			25	AN*2525R1	
		Regular	26G	13	AN*2613R1		
		Regular			23	AN*2623R1	
		Regular	27G	13	AN*2713R1		
		Regular			16	AN*2716R1	
		Regular				19	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.**