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 DECLARTION 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:	王劍光
	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		50	AN*1850R1
		Regular	19G	25	AN*1925R1
		Regular		38	AN*1938R1
		Short			AN*1938S1
		Regular		50	AN*1950R1
		Regular	20G	25	AN*2025R1
		Regular		38	AN*2038R1
		Regular		50	AN*2050R1
		Regular	21G	16	AN*2116R1
		Regular		25	AN*2125R1
		Regular		38	AN*2138R1
		Regular		50	AN*2150R1
		Regular	22G	25	AN*2225R1
		Regular		32	AN*2232R1
		Regular		38	AN*2238R1
		Regular		50	AN*2250R1
		Regular	23G	16	AN*2316R1
		Regular		25	AN*2325R1
		Regular		32	AN*2332R1
		Regular		38	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.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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:G1 036336 0054 Rev. 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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 036336 0056 Rev. 02

Holder of Certificate: **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

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate:

Design, Development, Production, Sales and Distribution of Disposable Needles, Scalp Vein Sets, Syringes, Infusion Sets, Transfusion Sets, Burette-Type Infusion Sets, Blood-Collecting Needles, Dental Needles, Anaesthesia Needles, Stopcock, Heparin Cap/Stopper, Extension Sets, Huber Needles, Fistula Needles, Dental Operation Instruments (Odontotenaculum, Odontoscope), Disposable Vacuum Venous Blood Specimen Collection Containers (tube), Sterile Infusion Sets for Single Use, Sterile Dual-purposed Connector for Single Use, Sterile Injection Site for Single Use, Sterile Drip Chamber for Single Use, Sterile Piercing Device for Single Use, Sterile Syringes for Single Use, Sterile Irrigation Needles for Single Use, Sterile I.V. catheter for single use, Disposable Insulin Pen Needle, Sterile Intravascular Catheter Introducer for Single Use, Sterile Biopsy Needles for Single Use, Sterile Percutaneous Vertebroplasty Kit for Single Use, Sterile Dispensing 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, Blood Collection Assembly, Irrigation Syringes, Sterile Syringes for Insulin for Single Use, Sterile Disinfecting Cap for Single Use, Blood Collection Sampling Holder.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 036336 0056 Rev. 02

Report No.: BJ20081201
Valid from: 2020-11-01
Valid until: 2023-10-31

Date, 2020-10-27

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 036336 0056 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®