

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

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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 | | | 25 | AN*1925R1 |
| | | Regular | | | 38 | AN*1938R1 |
| | | Short | AN*1938S1 | | | |
| | | Regular | 20G | 50 | AN*1950R1 | |
| | | Regular | | | 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 |
| | | Regular | 22G | 25 | AN*2225R1 | |
| | | Regular | | | 32 | AN*2232R1 |
| | | Regular | | | | 38 |
| | | Regular | | | 50 | AN*2250R1 |
| | | Regular | 23G | 16 | AN*2316R1 | |
| | | Regular | | | 25 | AN*2325R1 |
| | | Regular | | | | 32 |
| | | Regular | | | 38 | AN*2338R1 |
| | | Regular | 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 |
| 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.