

DECLARATION OF CONFORMITY



MANUFACTURER:

ZHEJIANG RUNQIANG MEDICAL INSTRUMENTS CO., LTD.
No.618 DADE ROAD, JIAXING XIUZHOU DISTRICT JIAXING CITY,
ZHEJIANG PROVINCE, P.R. CHINA

TEL: +86-573-82287088, +86-573-82287018
FAX: +86-573-82287098

MEDICAL DEVICE:

DISPOSABLE ANAESTHESIA NEEDLE AND ANAESTHESIA KIT

CLASSIFICATION - ANNEX IX:

CLASS III, RULE 7

CONFORMITY ASSESSMENT ROUTE:

ANNEX II .3+ II .4

WE, ZHEJIANG RUNQIANG MEDICAL INSTRUMENTS CO., LTD., HEREWITH DECLARE THAT
THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE
PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES,
AS AMENDED BY 2007 /47/EEC;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
WE, AS THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE
DECLARATION OF CONFORMITY.

STANDARDS APPLIED: *RELATED APPLICABLE HARMONIZED STANDARDS (PUBLISHED IN THE OFFICIAL JOURNAL
OF THE EUROPEAN COMMUNITIES)*

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

G7 17 04 82107 009
G1 12 09 82107 003



EUROPEAN REPRESENTATIVE: *Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse, 80,
20537, Hamburg, Germany Tel: 0049-40-2513175, Fax: 0049-40-255726*

START OF CE-MARKING:

DATE OF FIRST CE MARKING(2012-12-12)

PLACE, DATE OF DECLARATION:

JIAXIANG CITY, 2018-03-07

SIGNATURE:

NAME: MZ SHEN YU QIN
POSITION: quality VP