

# 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 17 12 82107 013



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, 2018-06-07

SIGNATURE:

NAME: MZ SHEN YU QIN  
POSITION: quality VP