

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 INFUSION PUMP

CLASSIFICATION - ANNEX IX:

CLASS II b, RULE 11

CONFORMITY ASSESSMENT ROUTE:

ANNEX II EXCEPT 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 2007/47/EC OF 93/42/EEC CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: *EN ISO 13485:2012/AC 2012, EN ISO 14971:2012, EN ISO 11135-1:2007, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 10993-1:2009/AC2010, EN 556-1:2001/AC2006, EN1041:2008, EN 980:2008, YY0451:2010*

NOTIFIED BODY:

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

IDENTIFICATION NUMBER

 0123

(EC) CERTIFICATE(S):

G1 14 09 82107 006



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 (2013-05-28)

PLACE, DATE OF DECLARATION:

JIAXIANG CITY, 2015-04-08

SIGNATURE:


NAME: MRS CAI JIA-YI
POSITION: CAIJIA-YI DIRECTOR