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.

MEDICAL DEVICE: LUER ADAPTER

CLASSIFICATION - *ANNEX IX*: *CLASS IIA, RULE 6*

CONFORMITY ASSESSMENT ROUTE: *ANNEX II.3*

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:
EN ISO13485:2012/AC2012 ISO 15223-1: 2012 EN1041:2008/A1:2013 EN ISO 14971:2012 EN ISO 11737-1:2006/AC2009 EN ISO11135-1:2007 EN ISO11607-1:2009 EN ISO11607-2:2006 EN ISO 10993-1:2009/AC:2010 EN ISO 10993-4:2009 EN ISO 10993-5:2009 EN ISO 10993-7:2008/AC:2009 EN ISO 10993-10:2013 EN ISO 10993-11:2009 MEDDEV 2.7.1 REV.3.

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

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S): G1 14 09 36336 054

START OF CE-MARKING:

PLACE, DATE OF DECLARATION: Wenzhou 2014-12-28

SIGNATURE:

POSITION: QUALITY MANAGER