

DECLARATION OF CONFORMITY To COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

FILE NO: YX/TECH-DOC/12
EDITION: B/3



MANUFACTURER:

SHANGHAI KINDLY MEDICAL INSTRUMENTS Co., LTD.
No.925 JINYUAN YI ROAD, 201803, SHANGHAI, PEOPLE'S
REPUBLIC OF CHINA.

EUROPEAN REPRESENTATIVE:

SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE)
EIFFESTRAÙE 80, 20537 HAMBURG GERMANY

MEDICAL DEVICE:

ANGIOGRAPHY SYRINGE: 1ML, 3ML, 6ML, 10ML, 20ML
SPECIFICATION: SEE ANNEX

CLASSIFICATION - ANNEX IX:

CLASS I * RULE 2

CONFORMITY ASSESSMENT ROUTE: ANNEX V

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

STANDARDS APPLIED:

MEDDEV.2.7.1 REV.4:2016, EN 556-1:2001/AC2006, EN ISO 15223-1:2016, EN 1041:2008, EN
20594-1:1993, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-4:2009, EN ISO 10993-5:2009, EN
ISO 10993-7:2008/AC2009, EN ISO 10993-10:2010, EN ISO 10993-11:2009, EN ISO 11135:2014
EN ISO 11607-1:2009, EN ISO 13485:2012, ISO 14644-1:2015, ISO 14698-1:2003, EN ISO
14971:2012, YZB/STATE 8170-2014, EN ISO 14155:2011

NOTIFIED BODY:

TÜV SÜD Product Service GmbH
Ridlerstraße 65 · 80339 München · Germany

IDENTIFICATION NUMBER:

 0123

(EC) CERTIFICATE(S):

G2S 081681 0017 REV.02

START OF CE-MARKING:

2012.12

PLACE, DATE OF DECLARATION:

SHANGHAI 2022-03-01

SIGNATURE:



POSITION: QUALITY MANAGER

Angiography Syringe	
REF.NO.	Description
ZSQ1R	1 ml. Red plunger
ZSQ1B	1 ml. Blue plunger
ZSQ1W	1 ml. White plunger
ZSQ1P	1 ml. Purple plunger
ZSQ1Y	1 ml. Yellow plunger
ZSQ1LG	1 ml. Light green plunger
ZSQ1DG	1 ml. Dark green plunger
ZSQ3R	3 ml. Red plunger
ZSQ3B	3 ml. Blue plunger
ZSQ3W	3 ml. White plunger
ZSQ3P	3 ml. Purple plunger
ZSQ3Y	3 ml. Yellow plunger
ZSQ3LG	3 ml. Light green plunger
ZSQ3DG	3 ml. Dark green plunger
ZSQ6R	6 ml. Red plunger
ZSQ6B	6 ml. Blue plunger
ZSQ6W	6 ml. White plunger
ZSQ6P	6 ml. Purple plunger
ZSQ6Y	6 ml. Yellow plunger
ZSQ6LG	6 ml. Light green plunger
ZSQ6DG	6 ml. Dark green plunger
ZSQ10R	10 ml. Red plunger
ZSQ10B	10 ml. Blue plunger
ZSQ10W	10 ml. White plunger
ZSQ10P	10 ml. Purple plunger
ZSQ10Y	10 ml. Yellow plunger
ZSQ10LG	10 ml. Light green plunger
ZSQ10DG	10 ml. Dark green plunger
ZSQ20R	20 ml. Red plunger
ZSQ20B	20 ml. Blue plunger
ZSQ20W	20 ml. White plunger
ZSQ20P	20 ml. Purple plunger
ZSQ20Y	20 ml. Yellow plunger
ZSQ20LG	20 ml. Light green plunger
ZSQ20DG	20 ml. Dark green plunger