

DECLARATION OF CONFORMITY



MANUFACTURER:

ZHEJIANG FERT MEDICAL DEVICE CO., LTD.
No.3618 HUANCHENG SOUTH ROAD, WUTONG DISTRICT,
TONGXIANG, ZHEJIANG, P.R.CHINA
TEL: +86-573-88106708, FAX: +86-573-88110618

MEDICAL DEVICE:

PRESSURE SURVEY CATHETER

MODEL:

LJG-C

CLASSIFICATION - ANNEX IX:

CLASS II a, RULE 2 OF ANNEX IX

CONFORMITY ASSESSMENT ROUTE:

ANNEX II EXCEPT II.4

WE, ZHEJIANG FERT MEDICAL DEVICE CO.,LTD., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC1993 CONCERNING MEDICAL DEVICES, AS AMENDED BY 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

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NOTIFIED BODY:

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

IDENTIFICATION NUMBER

 0123

(EC) CERTIFICATE(S):

G1 16 06 52267 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:

2007-08-13

PLACE, DATE OF DECLARATION:

TONGXIANG CITY, 2017-02-17

SIGNATURE:

NAME: MRS CHAI JIA YI

POSITION: MANAGING DIRECTOR

VALID FROM: 2016-08-16 VALID UNTIL: 2019-10-20

Ver:C/4 P20170217

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MEDICAL DEVICE:

SINGLE-USE RESPIRATION LOOP
LIST ATTACHED

MODEL:

HXH-A HXH-B HXH-C HXH-D

CLASSIFICATION - ANNEX IX:

CLASS II a, RULE 2 OF ANNEX IX

CONFORMITY ASSESSMENT ROUTE:

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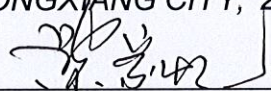
LIST OF DEVICES COVERED BY THIS DECLARATION OF CONFORMITY : ELEMENTS OF SINGLE-USE RESPIRATION LOOP

#	PRODUCT NAME	CLASS	SPECIFICATION / TYPE
1	Tubes	II a	
2	Anaesthesia face mask	II a	
3	Gas storage bursa	II a	

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MEDICAL DEVICE:

INFUSION SETS WITH PRECISION FILTERS FOR
SINGLE USE

MODEL:

SYQ-JL

CLASSIFICATION - ANNEX IX:

CLASS II a, RULE 7 OF ANNEX IX

CONFORMITY ASSESSMENT ROUTE:

ANNEX II EXCEPT II.4

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MEDICAL DEVICE:

SINGLE-USE PUNCTURE SET FOR LOCAL
ANAESTHESIA
LIST ATTACHED

MODEL:

AS-E AS-S AS-N AS-E/SII

CLASSIFICATION - ANNEX IX:

CLASS II a, RULE 7 OF ANNEX IX

CONFORMITY ASSESSMENT ROUTE:

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LIST OF DEVICES COVERED BY THIS DECLARATION OF CONFORMITY : ELEMENTS OF SINGLE-USE PUNCTURE SET FOR LOCAL ANAESTHESIA

#	PRODUCT NAME	CLASS	SPECIFICATION / TYPE
1	Peripheral nerve block puncture needle	IIa	
2	Epidural anaesthesia tube connector	I STERILE	Diam 1.0 mm
3	Sterile hypodermic syringe	I STERILE	5ml, 10ml, 20ml
4	Glass syringe	IIa	5ml
5	Sterile hypodermic needle	IIa	6#, 7#, 8#, 12#, 16#
6	Medicine Liquid filter for anaesthesia	I STERILE	GLQ-M-2
7	Air filter for anaesthesia	I STERILE	GLQ-M-1
8	Dressing towel	I STERILE	
9	Operation towel	I STERILE	
10	Latex surgical gloves	IIa	7# , 7.5#
11	Gauze	I STERILE	
12	Wound band	I STERILE	
13	Disinfectant brush	I STERILE	

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MEDICAL DEVICE:

DISPOSABLE ANAESTHESIA AIR FILTER

MODEL:

GLQ-Q

CLASSIFICATION - ANNEX IX:

CLASS II a, RULE 2 OF ANNEX IX

CONFORMITY ASSESSMENT ROUTE:

ANNEX II EXCEPT II.4

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MEDICAL DEVICE:

SINGLE-USE GENERAL ANAESTHESIA KIT
LIST ATTACHED

MODEL:

QM-2.0 QM-2.5 QM-3.0 QM-3.5 QM-4.0 QM-4.5
QM-5.0 QM-5.5 QM-6.0 QM-6.5 QM-7.0 QM-7.5 QM-8.0 QM-8.5 QM-9.0 QM-9.5 QM-10.0

CLASSIFICATION - ANNEX IX:

CLASS II a, RULE 5 OF ANNEX IX

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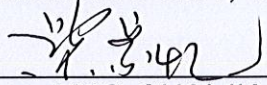
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LIST OF DEVICES COVERED BY THIS DECLARATION OF CONFORMITY : ELEMENTS OF SINGLE-USE GENERAL ANAESTHESIA KIT

#	PRODUCT NAME	CLASS	SPECIFICATION / TYPE
1	Tracheal tubes	Ila	ID2.0~ID10.0
2	Suction catheter for use in the respiratory tract	Ila	FR5~FR20
3	Gauze	I STERILE	
4	Tooth cushion	I STERILE	L/M/S
5	Sterile hypodermic syringe	I STERILE	
6	Latex surgical gloves	Ila	7.0#/7.5#
7	Guide wire	I STERILE	
8	Airway protecting device	I STERILE	
9	Laryngoscope	I STERILE	L/M/S
10	Eduction pipe	I STERILE	

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MEDICAL DEVICE:

DISPOSABLE INFUSION PUMP

MODEL:

SZB-CX SZB-CZ

CLASSIFICATION - ANNEX IX:

CLASS II b , RULE 11 OF ANNEX IX

CONFORMITY ASSESSMENT ROUTE:

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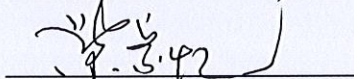
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