EC Technical Document

Disposable Infusion Sets without needle

Declaration of Conformity

Document No.：QSZC03-03E-001-06

Prepared by：Guo Tiantian Date：2017-08-01

Reviewed by：Si Chunning Date：2017-08-01

Approved by：Zhang Liangli Date：2017-08-01

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Zibo Qiaosend Medical Articles Co., Ltd

DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES

MANUFACTURER:
ZIBO QIAOSEND MEDICAL ARTICLES CO., LTD, NO.2, GAOYUAN EAST ROAD,256300 GAOQING COUNTY,SHANDONG PROVINCE,PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: DISPOSABLE INFUSION SETS
CLASSIFICATION - *ANNEX IX*: *E.G. CLASS* Is*, RULE 2,* *SPECIFICATIONS:SEE APPENDIX*

CONFORMITY ASSESSMENT ROUTE: *E.G. 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（AMENDED BY 2007/47/EC） CONCERNING MEDICAL DEVICES;
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN ISO13485:2016,EN ISO15223：2012,EN ISO14971:2012,EN ISO11135:2014,EN ISO11607-1:2009,EN ISO11607-2:2006,EN ISO10993-4:2009, EN ISO10993-5:2009, EN ISO10993-7:2008/AC2009, EN ISO10993-10:2010, EN ISO10993-11:2009, EN ISO8536-4:2010(AMD1 2013)

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

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S): *G2S 17 01 88861 010*

EC REP
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START OF CE-MARKING:20140812

PLACE, DATE OF DECLARATION: *ZIBO,SHANDONG,P.R.CHINA* AUG.1.2017

SIGNATURE:

NAME: DOU XUEFENG
POSITION: *GENERAL MANAGER*

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Appendix:

Product Specification

commodity	specification	Unit (pc/bag)
A	A34，A34-3V，A35，A35-3V，A35-D，A64，A64-2M，A64-23V， A64-3V，A64-3V100，A64-3V60，A64-3V15，A64-3VDH，A65，A65-3R，A65-3V，A65-D	1
AS	AS-84-30C	1
NT	NT-34-ND，NT-34-VND,NT-35-P,NT-35-P240，NT-44-G,NT-52-180ELLP,NT-52-LLRA,NT-54/2M,NT-55-A,NT-65-AUB,NT-810-EB1，NT-810-OP,NT-81-B,NT-820-180EGP,NT-820-180ELLP,NT-820-180LL,NT-820-ELL180，NT-820-ELLA,NT-820-ELLAB,NT-820-ELLAC,NT-820-ELLAD,NT-820-LL,NT-820-LLRAD,NT-82-2ELL,NT-82-3VYZ,NT-82-LLEV20，NT-840，NT-840-2F,NT-840-2FR,NT-840-AS,NT-840-RASL,NT-84-FE160P,NT-850-A,NT-850-EFAGPB,NT-850-EFA-,NT-850-FRA,NT-85-D,NT-85-E,NT-85-EYF,NT-890，NT-890-F,NT-890-F180ELLP,NT-89-2RA,NT-89-EFA,NT-89-FEPY	1

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Revised Pages	Revision Form No.	Revision Status	Revised by	Verified by	Approved by	Effective Date	Brief Description of Revision
PAGE1	QSTG-201705-004-007	A/1	Guo Tiantian	Sichunning	Zhangliangli	May.12.2017	The new (EC) CERTIFICATE(S): *G2S 17 01 88861 010*
PAGE2	QSTG-201708-004-001	A/2	GUO TIAN TIAN	SI CHUN NING	ZHANG LIANG LI	AUG.1.2017	CHANGE *SPECIFICATIONS*