

EC Technical Document

Disposable Infusion Sets without needle

Declaration of Conformity

Document No.: QSZC03-03E-001-06

Prepared by: Wu Naiyu Date: 2020-03-14

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Approved by: Zhang Liangli Date: 2020-03-14

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Zibo Qiaosend Medical Articles Co., Ltd

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

**MANUFACTURER:**

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

MEDICAL DEVICE: DISPOSABLE INFUSION SETS

SPECIFICATIONS: SEE APPENDIX

CLASSIFICATION - ANNEX IX: CLASS I_s, RULE 2,

CONFORMITY ASSESSMENT ROUTE: ANNEX V+VIII

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. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED: EN ISO13485:2016, EN ISO15223: 2016, EN ISO14971:2019, EN ISO11135:2014, EN ISO11607-1:2019, EN ISO11607-2:2019, EN ISO10993-4:2017, EN ISO10993-5:2009, EN ISO10993-7:2008/AC2009, EN ISO10993-10:2013, EN ISO10993-11:2018, 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 088861 0010 REV.03



EUROPEAN REPRESENTATIVE:

MEDNET EC-REP GMBH
BORKSTRASSE 10, 48163 MÜNSTER, GERMANY

START OF CE-MARKING: 20140812

PLACE, DATE OF DECLARATION:

ZIBO, SHANDONG, P. R. CHINA

Mar.14.2020

SIGNATURE:

NAME: DOU XUEFENG

POSITION: GENERAL MANAGER

POSITION: GENERAL MANAGER

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Appendix:

Product Specification

commodity	specification	Unit (pc/bag)
QBD	QBD004-02B, QBD004-02C, QBD004-Y (20drips) , QBD007-Y-02, QBD002-NF, QBD003-02, QBD007-A, QBD007-C, QBD018, QBD018-3, QBD018-4	1
NT	NT-82-LL, NT-82-2ELL, NT-84, NT-84-160, NT-84-, NT-85-EFA, NT-820-LL, NT-85-ERA, NT-840, NT-820- ELLA, NT-850-EFA, NT-840-AS, NT-840-E, NT-880- A, NT-840-RASL, NT-890, NT-820-LLUX, NT-820- 180LL, NT-850-EF, NT-850-EFA-, NT-840-EP, NT- 850-A, NT-810-B, NT-810-2A, NT-810-EB, NT-820- ELL180, NT-085-EA, NT-840-2F, NT-820-LLRA, NT- 840-2FR, NT-35-BOR, NT-35-P240, NT-35-P, NT-52- LLRA, NT-65-AUB, NT-81, NT-810, NT-81-B, NT-81-E, NT- 82-LLEV10, NT-820-ELLAD, NT-820-LLRAD, NT-820- UX, NT-82-3VYZ, NT-82-ELLA, NT-82-LLEV20P, NT- 82-LLEV25, NT-82-LLEV50, NT-82-LLEV75, NT-82- LLRA, NT-84/250, NT-84/2M, NT-84-3V, NT-84-AS, NT-84-EV225, NT-85, NT-850-EF210, NT-85-A, NT- 85-D, NT-85-E, NT-85-EYC, NT-85-EYF, NT-85-F, NT-85-FRA, NT-88-B, NT-89, NT-890-F, NT-89-2M, NT-89-2RA, NT-89-EFA, NT-89-F, NT-89-FEPY, NT- 89-RA, NT-82, NT-34-ND, NT-34-VND, NT-820- 180ELLP, NT-84-E160, NT-890-F180ELLP, NT-52- 180ELLP, NT-810-EB1, NT-890-EA, NT-54/2M, NT-82- LLEV20, NT-84/160, NT-84-FE160P, NT-850-FRA, NT-89-EFA2, NT-820-ELLAC, NT-820-ELL180-I, NT- 820-ELLAB, NT-820-LLRAB, NT-850-EFAGPB, NT- 820-ELL200P, NT-820-180EGP, NT-44-G, NT-55-A, NT-810-OP, NT-850-EFAB	1

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A	A34, A34-3V, A35, A35-3V, A35-D, A64, A64-23V, A64-2M, A64-3V, A64-3V100, A64-3V60, A64-3VB50, A64-3VDH, A65, A65-3R, A65-3V, A65-D, A65-TPS, A64-3V15, A65-SA, A94, A94-3V, A95, A95-3V, A64-B10, A34-3V15, A34-3V60	1
AS	AS64, AS64-, AS64-3V, AS64-3V-, AS65, AS65-, AS65-3V, AS65-3V-, AS-64-180, AS-65-3R-, AS-82-200ELLVP, AS-82-ELLA, AS-84-30C	1
B	B15, B24, B34, B35-TPS	1
IJ	IJ239, IJ1022OPACO, IJ2174OPACO	1
MK	MK-IV-200	1
RG	RG-3-CSY, RG-3-C, RG-3V25, RG-3V25-200VP, RG5(RG-5), RG-8 (RG8) , RG-15(RG15)	1
TPS	TPS-200, TPS-202	1
Other	2600, 2601, 2602	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	Sichun ning	Zhangli angli	May.12.2017	The new (EC) CERTIFICATE(S): G2S 17 01 88861 010
Full text	QSTG-201808-004-025	B/0	Wunaiyu	Sichun ning	Zhang liangli	Aug.24. 2018	Template change
PAGE1	QSTG-201809-004-008	B/1	Wunaiyu	Sichunni ng	Zhang liangli	Sep.26. 2018	EC Certificate and EU Representative change
PAGE2~3	QSTG-201902-004-030	B/2	Wunaiyu	Sichunni ng	Zhang liangli	Feb.28. 2019	Delete: NT-082-LLRA Increase: A64-B10、AS-84-30C、NT-850-EFAB
PAGE1	QSTG-201907-004-012	B/3	Wunaiyu	Sichunni ng	Zhang liangli	Jul.22. 2019	EC Certificate change
Full text	QSTG-201912-004-001	C/0	Wunaiyu	Sichunni ng	Zhang liangli	Dec.3. 2019	Add the specifications : A34-3V15, A34-3V60
PAGE1	QSTG-202003-004-009	C/1	Wunaiyu	Sichunni ng	Zhang liangli	Mar.14. 2020	1、 Change the EC Certificate and EU Representative name 2、 Delete the EU Representative TEL and FAX 3、 Change ENISO14971 ENISO 11607-1、 ENISO 11607-2 Version