EC Technical Document

Protective Cap for Connectors for Single Use

Declaration of Conformity

Document No.：QSZC03-03E-001-11

Prepared by：Wu Naiyu Date：2020-03-14

Reviewed by：Si Chunning Date：2020-03-14

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

MEDICAL DEVICE: *Protective Cap for Connectors for Single Use*

SPECIFICATIONS: M5020 TP TP-MF TP-MF-B

CLASSIFICATION - *ANNEX IX*: *CLASS* Is, *RULE 2,*
CONFORMITY ASSESSMENT ROUTE: *ANNEX* V+VII

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*

EC REP
EUROPEAN REPRESENTATIVE: *MEDNET EC-REP GMBH*
BORKSTRASSE 10,48163 MUENSTER,GERMANY

START OF CE-MARKING:20140820

PLACE, DATE OF DECLARATION: *ZIBO,SHANDONG,P.R.CHINA* Mar.14.2020
SIGNATURE:
NAME: DOU XUEFENG
POSITION: GENERAL MANAGER

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Revised Pages	Revision Form No.	Revision Status	Revised by	Verified by	Approved by	Effective Date	Brief Description of Revision
Full text	QSBG-201407-006-007	01	Wunaiyu	Niuxuefei	Sunping	Jul.30.2014	Add EC certificate number, the manufacturer information
Full text	QSBG-201411-006-002	02	XUNingNing	Niuxuefei	Sunping	Nov.14.2014	Modiify the format of the file
Full text	QSTG-201510-004-004	03	XUNingNing	Sichunning	Zhangliangli	Oct.8.2015	Modificate the version of the standard ISO11135 and the address of manufacturer.
PAGE1	QSTG-201602-004-007	D/1	XUNingNing	Sichunning	Zhangliangli	Feb.15.2016	The new (EC) CERTIFICATE(S): *G2S 15 11 88861 007.*
PAGE1	QSTG-201609-004-185	D/2	Guo Tiantian	Sichunning	Zhangliangli	sep.22.2016	Modificate the version of the standard EN ISO13485
PAGE1	QSTG-201705-004-011	D/3	Guo Tiantian	Sichunning	Zhangliangli	May.12.2017	The new (EC) CERTIFICATE(S): *G2S 17 01 88861 010*
Full tex	QSTG-201808-004-027	E/0	Wunaiyu	Sichunning	Zhangliangli	Aug.24.2018	Template change
PAGE1	QSTG-201809-004-010	E/1	Wunaiyu	Sichunning	Zhangliangli	Sep.26.2018	EC Certificate and EU Representative change

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

PAGE1	QSTG-201907-004-013	E/2	Wunaiyu	Sichunning	Zhang liangli	Jul.22. 2019	EC Certificate change
PAGE1	QSTG-202003-004-011	E/3	Wunaiyu	Sichunning	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