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

MANUFACTURER:

ZIBO QIAOSEND MEDICAL ARTICLES CO., LTD.

No.88, Tianheng Road, Gaoqing County, 256300 Zibo ,Shandong Province,PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: *Protective Cap for Connectors for Single Use*
SPECIFICATIONS: M5020、TP 、TP-MF 、TP-MF-B、TP-MF-O、TP-MF-C、IN061040、TP-P-B、TP-P-Y
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/AC2018, EN ISO15223-1：2021,EN ISO14971:2019,EN ISO11135:2014/A12019,EN ISO11607-1:2020,EN ISO11607-2:2020,EN ISO10993-4:2017, EN ISO10993-5:2009, EN ISO10993-7:2008/AC2009, EN ISO10993-10:2013, EN ISO10993-11:2018, EN ISO8536-4:2020

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*
GCQ 114010 0003 REV.00

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* *APR*.3.2023

SIGNATURE:

NAME:DOU XUEFENG
POSITION:GENERAL MANAGER