DECLARATION OF CONFORMITY
TO REGULATION (EU) 2017/745 OF 5 April 2017
CONCERNING MEDICAL DEVICES

Xuzhou Kernel Medical Equipment Co., Ltd.
Kernel Mansion, Economic Development District, Xuzhou City, Jiangsu Province, China.

Medical Device: Colposcope System
Model: KN-2200、KN-2200A、KN-2200Ⅰ、KN-2200B、KN-2200BⅠ、KN-2200Ⅰ(H)
Basic-UDI DI:692879862203E
Classification: class I, rule 13
Conformity assessment Route: Chapters I and III of Annex IX of MDR

WE, XUZHOU KERNEL MEDICAL EQUIPMENT CO., LTD. HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY

Standards applied: EN ISO14971:2019,EN ISO15223-1:2016, EN1041:2008，EN 60601-1:2006+A1:2013, EN 60601-1-6 :2010, EN60601-1-2:2015 , EN 62304:2006, EN 62366-1:2015.

CE

EC REP
European Representative: Caretechion GmbH
Niederrheinstr 71, 40474 Duesseldorf, Germany
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Place, Date of Declaration: City: Xuzhou, Jiangsu/ Date: 2021-12-03

Signature:

Name: Zhao wei

Position: General Manager