

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-2200 I 、KN-2200B、KN-2200B I 、KN-2200 I (H)

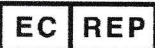
Basic-UDI DI:692879862203E

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.



European Representative:

Caretechion GmbH

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Place, Date of Declaration:

City: Xuzhou, Jiangsu / Date: 2021-12-03

Signature:

Name: Zhao wei

Position: General Manager