EC Declaration of Conformity

Manufacturer:
Name: Zhuhai Keyu Biological Engineering Co., Ltd.
Address: 1/f, 2/f, 5/f, 6/f building 4, No.605, Yuge road, Sanzao town, Jinwan district, Zhuhai City, Guangdong Province, 519040, P.R.China
Tel: +86 - 756 -6821168;
E-mail: export@keyubio.com
SRN: CN-MF- 000023195

Whose Authorized Representative:
Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague,Netherlands.
E-mail: peter@lotusnl.com
SRN: NL-AR-000000121

Product Name: Dry Chemistry Urine Anlayzer

Model: KU-U200

Basic UDI-DI: 697473536KUA03P8

Intended Use: Used in conjunction with appropriate reagents to measure parameters such as leukocyte, nitrite, urobilinogen, bilirubin, vitamin C, protein, occult blood, potential of hydrogen, specific gravity, glucose, ketone body, microalbumin, creatinine and urinary calcium.

EMDN Code/Term: W020101020101

Classification: Class A of ANNEX VIII of IVDR EU 2017/746 Rule 5

Conformity Assessment Route: CHAPTER V SECTION 2 Article 48(10) of Regulation EU 2017/746

CE certificate No: N.A

Name and ID of the Notified Body: We, the manufacturer, herewith declare under our sole responsibility that above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Device (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Applicable Standards:

EN ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2021*	*EN 62366-1:2015*
EN ISO 18113-2:2011	*IEC 61010-1:2010*	*EN 61326-1:2013*
EN 61326-2-6:2013	*IEC 61010-2-101:2018*	*EN 62304:2006+A1:2015*

CE

Yangchang Huang

Signature:_____

Name: Yangchang Huang
Position: Registration Director
Place: Zhuhai Date: 22-May-2022