# Declaration of Conformity

**For the following products:**

UV Phototherapy
(Product Name)

KN-4003AL2 、 KN-4003BL2 、 KN-4003AL2D 、 KN-4003BL2D 、 KN-4006AL1 、 KN-4006BL1 、 KN-4006AL1D、KN-4006BL1D

KN-4003AL2S、KN-4003BL2S、KN-4003AL2DS、KN-4003BL2DS、KN-4006AL1S、KN-4006BL1S、KN-4006AL1DS、 KN-4006BL1DS
(Model Designation)

*is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)*

Applicable harmonized standards are:

EN 60601-1:2006+A1:2013 ; EN ISO 15223-1:2016 ; EN 1041:2008 ; EN ISO 14971:2012 ; EN 60601-1-2:2015; EN 62304: 2006; EN 60601-1-6 :2010; EN 62366 :2008; EN 60601-1-11:2015; EN 60601-2-57:2011; EN ISO 10993-1:2009 + AC:2010; EN ISO 10993-5:2009; ISO 10993-10:2010

**Classification: IIa**

**Conformity Assessment Route:**

Annex II excluding section 4 of Medical Device Directive

**Notified Body:**

DNV GL Presafe AS (NB No. 2460)
Veritasveien 3, 1363 Høvik, Norway

**The following European Authorized Representative is stated to the declaration:**

Company Name: Prolinx GmbH
Company Address: Brehmstr. 56, 40239, Duesseldorf

**The following manufacturer is exclusively responsible for making this declaration:**

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

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|---|---|---|
| (Legal Signature) | General manager<br>(Position/title) | 2020-05-25<br>(Date) |