Declaration of Conformity

For the following products:

308nm Excimer System
(Product Name)

KN-5000C/KN-5000D

(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+ AC:2014；EN 60601-1-2 :2015；EN ISO 15223-1:2016 ；EN 1041:2008；EN ISO 14971:2012；EN 62304:2006/AC:2008；EN 60601-2-57 :2011；EN62471:2008；EN 62366 :2008；EN ISO 10993-1:2009/AC:2010；EN ISO 10993-5:2009；EN 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:

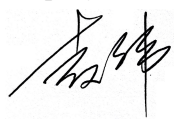
Company Name: Prolinx GmbH

Company Address: Brehmstr. 56, 40239 Duesseldorf，Germany

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



_____	General manager	2020-09-11
(Legal Signature)	(Position/title)	(Date)