Declaration of Conformity

To CFDA:

We hereby declare that the following product conforms to *Administrative Measures for Medical Device Registration* and requirements of relevant regulations, as well as classification requirements in *Medical Device Classification Catalogue.* Meanwhile, the product also coincides with the current national standards and industry standards. The list of the standards are as follows:

Standard Number	Standard Code
GB 9706.1—2007	Medical electrical equipment Section 1: general requirements for safety
GB/T 14710—2009	Environmental requirements and test methods for medical electrical appliances
GB/T 16886.1—2011	Biological evaluation of medical devices Section 1: evaluation and testing in the process of risk management
GB/T 16886.5—2003	Biological evaluation of medical devices Section 5: toxicity test for vitro cell
GB/T 16886.10—2005	Biological evaluation of medical devices Section 10: Stimulation and delayed hypersensitivity test
YY 0901—2013	Ultraviolet treatment equipment
YY 0505—2012	Medical electrical equipment Section 1-2: general requirements for safety Collateral standard: requirements and tests for electromagnetic compatibility
YY/T 0316—2016	Medical Devices Application of risk management to medical devices
YY/T 0708—2009	Programmable medical electrical system
YY/T 0709—2009	Medical electrical equipment Section 1-8: general requirements for safety Collateral standard: general requirements, testing and guidance for alarm systems in medical electrical equipment and medical electrical systems

GB 4706.85—2008	Safety of household and similar electrical appliances Particular requirements for skin appliances with ultraviolet and infrared radiation

We hereby declare that all registration documents submitted to CFDA are true and valid, and we are willing to bear legal responsibility for any false issues.

Product name: Ultraviolet B Therapy Device

Name: Kim Misuk

Title: President

Semyeong Biotech Co.

Date: 2019. 09. 04