

USP CLASS VI - CERTIFICATE OF COMPLIANCE

Product Name	: TOYOSILICONE
Batch No.	: Hose 1
Manufacturing Date	: 28 th August 2017
Manufactured by	: Toyox ® 4371 Maezawa, Kurobe, Toyama, Japan TEL: 81-765-52-5948
Sponsor	: Medical Engineering Technologies Ltd Unit 16, Holmestone Road, Dover, Kent CT17 0UF UK

Test Parameter	Reference Study No.	Specifications	Result
Cytotoxicity	BIO-GT 943	The response to the sample extract should not greater than grade 2	Complies
Systemic Injection Test in Mice	BIO-TX 3123	None of the animals treated with the sample extract shows a significantly greater biological reactivity than the animals treated with the blank	Complies
Intracutaneous test in Rabbits	BIO-TX 3122	The difference between the sample extract and the blank mean score is 1.0 or less	Complies
Intramuscular Implantation in Rabbits	BIO-TX 3124	The difference between average scores of sample and control sites should not exceed 1.0	Complies
Subcutaneous Implantation in Rats	BIO-TX 3125	The difference between average scores of sample and control sites should not exceed 1.0	Complies

The TOYOSILICONE manufactured by Toyox ®, which has been tested for USP Class VI test, meets the requirement of U. S. Pharmacopoeia chapter <87> Biological Reactivity Tests, *In Vitro* Tests and <88> Biological Reactivity Tests, *In Vivo* test

For BIONEEDS INDIA PRIVATE LIMITED,


..... 06 February 2018

(Signature)

Dr. K. R. RAGHUNATHA REDDY, Ph.D.
Deputy Test Facility Management