

USP CLASS VI - CERTIFICATE OF COMPLIANCE

Product Name	:	TOYOSILICONE-S HOSE
Batch No.	:	Hose 2
Manufacturing Date	:	9 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 944	The response to the sample extract should not greater than grade 2	Complies
Systemic Injection Test in Mice	BIO-TX 3127	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 3126	The difference between the sample extract and the blank mean score is 1.0 or less	Complies
Intramuscular Implantation in Rabbits	BIO-TX 3128	The difference between average scores of sample and control sites should not exceed 1.0	Complies
Subcutaneous Implantation in Rats	BIO-TX 3129	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,


 (Signature) 06 February 2018
Dr. K. R. RAGHUNATHA REDDY, Ph.D.
Deputy Test Facility Management