


**No.: ML 4029/20****Date: 20 February 2020****TO WHOMSOEVER IT MAY CONCERN**

This is to confirm that the test item, Skineasi Gel activ/Soreze Gel/Allevio Gel/ Soothy Gel/ Skifence Gel (Batch no. BS19002) obtained from Amaterasu Lifesciences LLP., was evaluated for the following tests. All three test were conducted as per ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff, FDA 2016. The results demonstrate that the product is biocompatible to skin and complies as per the ISO and US FDA requirements.


Study No.	Study Code	Study Title
BIO-GNT 362	AOA	<i>In vitro</i> Cytotoxicity Study of Skineasi Gel activ/Soreze Gel/Allevio Gel/ Soothy Gel/ Skifence Gel* by Agarose Overlay Method.
BIO-ATX 771	SSG	Skin Sensitisation Study of Skineasi Gel activ/Soreze Gel/Allevio Gel/ Soothy Gel/ Skifence Gel* in Guinea Pigs by Buehler Test Method
BIO-ATX 772	ADIN	Skin Irritation Test of Skineasi Gel activ/Soreze Gel/Allevio Gel/ Soothy Gel/ Skifence Gel* in New Zealand White rabbits

Thanking you,  
For **Bioneeds India Private Limited**,

Prepared by,

  
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Reviewed by,

  
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