

Department of Health and Ageing Therapeutic Goods Administration

LIMS Entry Summary

ARTG Number:

114907

ARTG Name:

Poly Implant Protheses - High Cohesive Gel Pre-Filled Breast Implant (Textured)

IMGHC-TX-S

Sponsor:

Medical Vision Australia Ptv Ltd

Batch Number:

25109

Results of the examination and analysis were as follows:

The sample was submitted by Sponsor

Results Approved By:

Jorge Garcia

rcia

Sample Staus:

VA

Approval Comments:

The sample is NOT cytotoxic

| TEST | RESULT | COMMENTS | ENTERED BY | VALIDATED BY |
|----------------------|--------|----------|------------|--------------|
| CYTOTOXICITY med dev | • | | | |
| - S1 | 100 | | wirasr | garcij |
| - S2 | >100 | | wirasr | garcij |
| - S3 | 100 | | wirasr | garcij |
| - Positive control | 13 | • | wirasr | garcij |
| - Negative control | >100 | | wirasr | garcij |
| - Blank control | >100 | | wirasr | garcij |
| - Cytotoxic titre | . 100 | | wirasr | garcij |

Sample Number:

1004001421

Printed:

03-February-2012

Page 1 of 1

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