



Australian Government

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 Pty Ltd
Batch Number: 25109

Approval Comments:

The sample is NOT cytotoxic

The sample was submitted by Sponsor

Results Approved By: Jorge Garcia **Sample Status:** VA

Results of the examination and analysis were as follows:

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